Considerations Toward Defining Medical "Levels of Care" for Commercial Spaceflight

Stefan M. Neis and David M. Klaus

Aerospace Engineering Sciences Department, University of Colorado–Boulder, Boulder, Colorado.

ABSTRACT

While all modes of human transportation introduce some degree of risk to life and health, the rigors of spaceflight present particularly challenging physiological and environmental factors that occur under very unforgiving operational circumstances. Commercial spaceflight will face issues similar to those experienced on prior traditional space missions, as well as encounter other health concerns more common to civil aviation. Consequently, in addition to vehicle design safety considerations, some form of medical care equipment is likely to be made available as good practice. Lessons learned from past experiences in space along with existing commercial aviation standards offer valuable insight into defining appropriate medical care needs for the commercial space industry. This article outlines current practices and rationale from these related applications, and offers considerations for establishing effective medical level of care provisions for future commercial spaceflight operations.

INTRODUCTION

While all modes of human transportation introduce some degree of risk to life and health, the rigors of spaceflight present particularly challenging environmental factors and very unforgiving operational circumstances. Risks ranging from unforeseen vehicle failure modes to personal illness or injury can arise throughout the various phases of a mission. Standard spacecraft design methods include incorporating methods to systematically identify and subsequently mitigate these risks to the extent practical through approaches such as added redundancy and increased factors of safety. In addition to these hardware-centered design strategies, operational competency and training also both play roles in ensuring safety and mission success.

Career astronauts are selected from an exceptionally fit and well-trained subset of individuals capable of handling harsh conditions and dealing with emergency scenarios that might arise. In contrast to the historical astronaut selection process, the onset of commercial spaceflight opens up opportunities for people with a variety of health issues found in the general public to participate. Medical evaluations can be performed to ensure some standard of acceptable health and fitness is met and, similarly, vehicle design accommodations can be implemented to adequately protect passengers as well as the flight crew. Therefore, not only are space vehicle designs generally well thought out in terms of safety and reliability, but also the professional crewmembers and commercial passengers (or spaceflight participants) flying in them are unlikely to become sick or injured under normal operational scenarios. Even with these precautions in place, however, some form of emergency medical care equipment is likely to be available as good practice, and as such, the crew must also be adequately trained to be proficient in their use. Therefore, while general passenger health concerns and medical qualifications can be assessed preflight to evaluate a given individual's risk factors[1] and ground teams will likely be on standby for possible spaceport emergency situations,[2] the ability to deal with inflight concerns in real time can also be considered by incorporating appropriate "levels of care" into the vehicle design and outfitting plans. Level of care refers to the amount and type of care rendered based on perceived need and the ability of the provider.[3] This includes provision of medical equipment and diagnostic tools, as well as consumables (dressing material, patches, medications, *etc*.).

In the medical community, the terminology "level of care" is typically categorized by terms such as primary, secondary, ambulatory, tertiary, and quaternary. Primary care covers generalized treatment for minor, acute injuries or illnesses. Secondary care follows with more specialized services on specific body systems or for specific diseases or chronic health conditions. Ambulatory care typically refers to outpatient treatment. Tertiary care involves highly specialized equipment and expertise for complex treatments such as surgeries or other procedures associated with hospitalization. And quaternary care is an extension into even more specialized and highly unusual treatment options, up to and including experimental medicine.[4,5] As such, determining an appropriate "level of care" to provide for commercial spaceflights should take into account the unique risks posed by each phase of suborbital and orbital missions, as well as consider the potential for effectively accommodating safety and medical concerns as they relate to the vehicle design and operations and the onboard crew's degree of training.

National Aeronautics and Space Administration (NASA) has established detailed sets of safety requirements for space missions derived from over 50 years of human spaceflight experience, but these are not addressed from a regulatory perspective. The aviation industry, on the other hand, offers examples of regulated commercial approaches, but these do not take into account the specific concerns that might arise during a spaceflight. The goal of this

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analysis was to examine existing practices from both of these fields in order to provide considerations toward defining appropriate onboard levels of medical care for the commercial space transportation (CST) industry as applicable to different types and phases of flight.

BACKGROUND

Medical care standards and/or regulations exist for most air, water, and land transportation industries. The up and coming CST era will likely follow suit. In the U.S. government spaceflight sector, detailed health, human performance, and medical standards are established by the NASA Office of the Chief Health and Medical Officer and address factors such as "appropriate levels of medical care, permissible exposure limits, fitness-for-duty criteria, and permissible outcome limits as a means of defining successful operating criteria for the human system."[3,6] Through this approach, overall risks to personnel, vehicle systems, and operations are mitigated to the extent practical, while crew health and performance are optimized, thus contributing to overall mission success and also helping to prevent incurring negative long-term health consequences due to spaceflight.

Similarly, medical standards and regulations for civil aviation are overseen by the Civil Aviation Authorities. In the United States, this is the Federal Aviation Administration (FAA). Since 1995, the FAA has also been responsible for CST and thus is the current regulatory body and standard-setting agency for this industry. The FAA is primarily concerned with the "protection of the public, property, and the national security and foreign policy interests of the United States during commercial launch or reentry activities"[7] (cf. 51 U.S.C. Ch. 509 §50901). Following the Commercial Space Launch Amendments Act of 2004, the FAA has been working to establish key safety requirements for human spaceflight aimed at providing an acceptable level of safety to the general public and ensuring individuals on board are aware of the risks associated with a launch or reentry (Federal Register: December 15, 2006, Volume 71, Number 241, Rules and Regulations, pp. 75615–75645).

OVERVIEW OF RELATED PRACTICES

NASA Standards

"Level of care," which refers to the amount and type of care rendered based on perceived need and the ability of the provider,[3] is defined and described in NASA Standard 3001, Volume 1 (Crew Health). Level of care can be extended beyond the medical focus to include other factors such as acceleration and vibration, acoustics, and atmosphere constituents as addressed in NASA Standard 3001, Volume 2 (Human Factors, Habitability, and Environmental Health). This study suggests a few items beyond medical concerns, but is not intended to provide a systematic framework for all issues that might be addressed in this regard. Volume 2 states that "a medical system shall be provided to the crew to meet the medical standards of NASA-STD-3001, Volume 1, in accordance with Table 13, Medical Care Capabilities."[8]

NASA-defined levels of care depend on various operational and mission scenarios. The mission duration, trajectory (*i.e.,* low Earth orbit, lunar, Mars), and environment are key considerations for determining the type of medical diagnosis and treatment capabilities to be used on a spacecraft. The likelihood of specific injuries occurring, the level of risk involved, and the feasibility of treatment needs to be defined to understand the medical capability that will be needed on a given mission. Developing concepts of operations for specific mission profiles will help to determine the capabilities needed to support expected illness and injuries.[9] NASA-STD-3001, Volume 1,[3] lists the following factors associated with establishing proper level of care, which should similarly be considered in the context of commercial spaceflight applications.

1. The level of training of the medical provider.
2. The technology and advances in medicine that allow such care to be rendered in austere environments.
3. The distance from the platform to more definitive care.
4. The duration of the mission.
5. The health and performance of the crew upon embarking on the mission.
6. The type of mission, to include vehicle, mass, length of stay, extravehicular activities (EVAs), and mission objectives.
7. Mission/Programmatic philosophy of accepted medical risk (Crew Health Concept of Operations and MORD).
8. Medical risk of illness or injury.
9. Time required for return to Earth or other fallback location for more definitive medical treatment.
10. Terrestrial medical standards

Six different levels of care (0–V) as defined in NASA-STD-3001, Volume 1, are summarized in *Table 1*. Since ground facilities used in preparation for spaceflight missions (vacuum chambers, diving operations, flying operations, survival training, *etc.*) also carry some inherent risk themselves, the levels of care used by NASA apply to the training environment as well.

Relevant Aviation Standards and Regulations

The International Civil Aviation Organization (ICAO), a specialized agency of the United Nations, effectively sets aviation standards. Member states are required to transform these into national law, though national law sometimes deviates from ICAO recommendations. National Civil Aviation Authorities oversee and regulate civil aviation in states. In the United States, the FAA fulfills this task. Furthermore, national states may delegate tasks and functions to regional organizations such as the European Aviation Safety Agency (EASA). Other international organizations, including the International Air Transport Association (IATA) and the Aerospace Medical Association, offer recommendations as well. The focus is primarily on medical equipment and services. Finally, commercial aviation's standards regarding passenger health (fitness to fly) as well as other important legal, economic, and operational aspects can also be reviewed for relevancy to commercial space travel.

Table 1. Summary of the NASA Levels of Care (NASA-STD-3001)

Level of Care	Applicable Missions	Perceived Level of Threat to Health or Life	Planned Medical Support	Specified Preventative Strategies[a]
0	Training	Low	None specified, opportunistic treatment employed	None; injuries are unplanned/ unforeseen.
I	LEO <8 days, *e.g.*, transfer, suborbital	Little	Basic life support first aid capability, *e.g.*, space motion sickness, private audio, anaphylaxis response	Risk of medical maladies has been mitigated by preventive medicine.
II	LEO <30days	Moderate risk for medical problems	Clinical diagnostics, ambulatory care, private video, private telemedicine	Screening used to reduce risk, most major illnesses mitigated
III	Beyond LEO <30 days, *e.g.*, lunar missions	Moderate to high for medical problems	Medications, equipment. Limited advanced life support, trauma, limited dental. Ability to sustain critically ill or injured limited by consumables, training or vehicle constraints	Used to a greater degree to reduce overall risk
IV	Lunar/planetary surface missions >30 days, LEO >30 days, *e.g.*, ISS	Moderate to high level of risk for medical problems.Risk to mission is greater for medical issues beyond ambulatory medicine.	Includes medications, equipment, training, consumables. Medical care limited or triaged due to availability of supplies, consumables or mission risk. Limited chronic illness support. Medical imaging, sustainable advanced life support, limited surgical, dental care. AED available	Used to a greater degree to reduce overall risk
V	Lunar/planetary missions >210 days, *e.g.*, Mars expedition	High level of potential risk for medical problems	Autonomous medical care. Training and caliber of caregiver shall be at physician level. Medical care limited or triaged due to availability of supplies, consumables or mission risk. Limited chronic illness support. Basic surgical care. Ability to sustain critically ill or injured limited by consumables, training or vehicle constraints. Medical care system dependent on means and availability of return to Earth	Used to a greater degree to reduce overall risk

[a]NASA-STD-3001, Volume 1, Appendix E contains detailed descriptions of medical prevention and implementation strategies.
AED, automated external defibrillator; LEO, low Earth orbit.

Since the early days of commercial air transportation, demographics and flight profiles have changed significantly.[10] More and more people travel by air, flights tend to be longer, and the population is aging. At the same time, the in-flight environment is considered to be one of the worst for suffering serious medical events, for example, cardiac events (cf. Refs.[11–14]). Commercial airlines are expected to provide care for their passengers, and so must balance immediate risks, implied risks, and implementation costs of doing so. In addition to direct costs (*e.g.*, associated with a diversion due to a medical event), inconvenience to other passengers and increases to overall risk must be considered.[15] Passenger care also is an economic necessity where public perception and social media play important roles. The handling of both minor and major medical events is therefore important for airlines to address in an adequate manner. Flight crew medical standards are motivated by the continuous ensuring of flight safety, economics (*e.g.*, health problems of employees might have a significant financial impact for an airline related to the large investment in selection and training of flight crews), and occupational healthcare (airlines are responsible for occupational health and safety of their employees).[10] Moreover, crew medical standards serve to protect the crew, passengers, and the general public.

International Standards: ICAO's Recommendations

ICAO's recommendations regarding medical services can be found in Annex 6 to the Chicago Convention.[16] They are different for different types of flight: Part 1 (Operation of Aircraft—International Commercial Air Transport—Aeroplanes), section 6.2.2, specifies recommendations for international commercial air transport[17]: "An aircraft operation involving the transport of passengers, cargo or mail for remuneration or hire."; Part 2 (Operation of Aircraft—International General Aviation—Aeroplanes), section 6.1.3, provides recommendations for international general aviation[17]: "An aircraft operation other than a commercial air transport operation or an aerial work operation."

For commercial aviation, ICAO recommends: "An aeroplane shall be equipped with: a) accessible and adequate medical supplies appropriate to the number of passengers the aeroplane is authorized to carry; Recommendation—Medical supplies should comprise: 1) one or more first-aid kits; and 2) a medical kit, for the use of medical doctors or other qualified persons in treating in-flight medical emergencies for aeroplanes authorized to carry more than 250 passengers."[17] Recommendations for general aviation are less stringent: "All aeroplanes on all flights shall be equipped with: a) an accessible first aid kit."[18] ICAO Annex 6 also states that "the prescribed instruments and equipment, including their installation, shall be approved or accepted by the State of Registry."[17,18] ICAO Annex 6 also gives guidance on the types, number, location, and contents of the medical supplies, which are detailed in Attachment B of ICAO Annex 6, Part 1.

ICAO divides medical services into first aid kits and emergency medical kits. First aid kits can essentially be used by anyone with no specific training required. These typically contain a handbook on first aid, materials for treating minor injuries, water-miscible antiseptic/skin cleanser, materials for treatment of extensive burns, ophthalmic ointment, a decongestant nasal spray, insect repellant, emollient eye drops, sunburn cream, and oral drugs as follows: analgesic, antispasmodic, central nervous system stimulant, circulatory stimulant, coronary vasodilator, antidiarrhoeics, and motion sickness medications. Emergency medical kits, on the other hand, are intended for the use of medical doctors or other qualified persons. They usually contain sterile surgical gloves, stethoscope, sterile scissors, sterile equipment for suturing wounds, disposable syringes and needles, disposable scalpel handle and blade, and drugs such as coronary vasodilators, analgesics, diuretics, anti-allergics, steroids, sedatives, and ergometrine (cf. Refs.[17,19]).

This equipment, however, is not mandated by any international aviation body, although the IATA, the Aerospace Medical Association, and ICAO have agreed upon standardized recommendations.[19] As noted above, ICAO may only recommend standards and practices, but they have to be transformed into national law. Exemplary, the next sections look at U.S. civil aviation law as well as European civil aviation regulations.

U.S. Regulations: FAA

FAA's medical equipment regulations are detailed in the Federal Aviation Regulations (FARs) that are part of Title 14 of the Code of Federal Regulations (14 CFR). The relevant information is included in 14 CFR part 121 (Operating Requirements), §121.309 and §121.803. The latter specifies required equipment as follows:

> (c) For treatment of injuries, medical events, or minor accidents that might occur during flight time each airplane must have the following equipment that meets the specifications and requirements of appendix A of this part: (1) Approved first-aid kits.…(3) In airplanes for which a flight attendant is required [usually if an airplane has a seating capacity of 19 seats or more (cf. FAR 14 CFR §121.391)], an approved emergency medical kit as modified effective April 12, 2004. (4) In airplanes for which a flight attendant is required and with a maximum payload capacity of more than 7,500 pounds, an approved automated external defibrillator as of April 12, 2004. (FAR 14 CFR §121.803)

These items are all listed in the Minimum Equipment List, meaning that an aircraft must have all the listed items on board in operational state to be allowed to fly. Furthermore, flight attendants must be trained to be familiar with the contents of the kits and in the use of an automated external defibrillator (AED).[19]

In addition to these kits, 14 CFR §91.211 and §121.333 regulate supplemental oxygen for certain flight profiles: "No person may operate a civil aircraft of U.S. registry—[…] At cabin pressure altitudes above 15,000 feet (MSL) unless each occupant of the aircraft is provided with supplemental oxygen." (14 CFR §91.211) and "For first-aid treatment of occupants who for physiological reasons might require undiluted oxygen following descent from cabin pressure altitudes above flight level 250, a supply of oxygen in accordance with the requirements of §25.1443(d) must be provided for two percent of the occupants for the entire flight after cabin depressurization at cabin pressure altitudes above 8,000 feet, but in no case to less than one person." (14 CFR §121.333). In addition to supplemental oxygen, other preventative safety measures include seatbelts and harnesses. The FAA details requirements for seats and safety belts in 14 CFR §91.107, $121.311, and §121.317. These requirements are different for general and commercial aviation. In summary, the binding FAA regulations are more stringent than ICAO recommendations; for example, in terms of equipment, a commercially operated aircraft with a flight attendant must have an AED.

Overview of IATA Medical Care

The IATA medical manual[10] gives an overview of on-board medical emergency services usually provided by commercial airlines. These may include first aid and medical response kits, trained cabin personnel, air–to-ground communication between the cockpit and ground physicians, an AED, and telemedicine capability. Yet, this is only a summary of the most common services, since the IATA has no regulatory authority.

European Civil Aviation Regulations: EASA

Although regulation of aviation is the responsibility of national states, some European states have delegated safety-relevant regulatory and executive functions to the EASA in order to harmonize safety standards and regulations. The EASA follows the Joint Aviation Authorities (JAA), which, however, did not have a regulatory function; regulation had to be achieved through the member authorities. The JAA framed the Joint Aviation Regulations (JAR), including Airworthiness, Operations (JAR-OPS), Flight Crew Licensing (JAR-FCL), and Maintenance regulations.

European regulations on medical equipment can be found in JAR-OPS 1 (Commercial Air Transportation), Section 1 (Requirements), Subsection K. JAR-OPS 1.745 specifies that "an operator shall not operate an aeroplane unless it is equipped with first-aid kits, readily accessible for use […]." JAR-OPS 1.755 specifies regulations regarding Emergency Medical Kits: "(a) An operator shall not operate an aeroplane with a maximum approved passenger seating configuration of more than 30 seats unless it is equipped with an emergency medical kit if any point on the planned route is more than 60 minutes flying time (at normal cruising speed) from an aerodrome at which qualified medical assistance could be expected to be available. (b) The commander shall ensure that drugs are not administered except by qualified doctors, nurses or similarly qualified personnel."

Airline Policies

Not all relevant or standardized equipment or procedures regarding medical emergencies are regulated. Often the exact implementation of more general regulations (*e.g.,* the composition of first aid and emergency medical kits beyond the regulated must-have items) underlies airline policies. The same is true for the so-called "passenger restraint kits." Items in these kits may include handcuffs, ties, and so on. Not all airlines carry them, however, and the exact composition underlies not only airline policy but also national regulations of state of registry. The same applies for the application and use of items in the passenger restraint kits, which follows strict guidelines as a last resort.[20] Applications are primarily to restrain "unruly and disturbing" passengers, but may also include "panicking" passengers.

Passenger and Crew Health Considerations

Unlike with NASA's spaceflight participants (SFPs), the commercial aviation industry distinguishes between passengers and flight crew, defined as a "licensed crew member charged with duties essential to the operation of an aircraft during a flight duty period."[21] Both categories are addressed in the following sections.

Passenger "Fitness to Fly"

Commercial aviation is a means of mass transportation. Therefore, it is not feasible that airlines screen every single passenger to determine if he or she is "fit to fly" as it is done with astronauts. Legal citizens even have the right to travel as stated in federal U.S. law: "A citizen of the United States has a public right of transit through the navigable airspace" (49 USC 40103). The right to move freely can also be found in the U.S. Constitution as well as in international treaties (*e.g.,* the International Covenant on Civil and Political Rights, Article 12).

Yet, airlines do have the right to refuse to carry passengers under certain circumstances, usually if there are safety concerns (49 USC 44902(b): "Permissive Refusal.—Subject to regulations of the Under Secretary, an air carrier, intrastate air carrier, or foreign air carrier may refuse to transport a passenger or property the carrier decides is, or might be, inimical to safety") or if FAA regulations are violated. These decisions will be made by the captain of the aircraft who is "in command of the aircraft and crew and is responsible for the safety of the passengers, crewmembers, cargo, and airplane" (14 CFR §121.533(d)).

There are no current regulations on the necessary level of fitness for a person to fly on a commercial airliner, but each airline usually has its own policies and procedures (often within the "Contract of Carriage"). Airlines may require medical clearance from their medical department or adviser if there is an indication that a passenger could be suffering from any disease or physical or mental condition that:

- may be considered a potential hazard to the safety of the aircraft;
- adversely affects the welfare and comfort of the other passengers and/or crew members;
- requires medical attention and/or special equipment during the flight;
- may be aggravated by the flight.[22]

Conditions that generally may require medical clearance in advance include, for example, advanced pregnancy, infants younger than 7 days, recent surgeries, and diseases that are actively contagious and communicable. A full list and detailed information can be found in IATA.[10] Whenever there is a medically supported concern that the flight will not be able to reach its destination without needing to divert for a medical emergency, airlines cannot accept the passenger. Decisions to refuse to transport a passenger are not made arbitrarily. Besides the above-mentioned civil rights, there are laws to protect disabled passengers from refusal of transportation, for example, the Air Carrier Access Act and its implementing regulation, Part 382, cf. Ref.[13]

Regulations by National and Civil Aviation Authorities require that passengers sitting in exit rows must be able and willing to assist the crew during an evacuation of the aircraft (cf. 14 §CFR 121.585). Exact requirements vary by country and airline, but usually they include a minimum age, having no physical or mental impairment (including visual and auditive functions) that would hinder quickly reaching and operating the emergency exit or understanding instructions, not using seatbelt extensions, speaking and reading the national language of the airline's home countries, and not be traveling with anyone requiring special assistance in an emergency (*e.g.,* an infant or person with a disability). 14 CFR §121.585 details all FAA requirements in this regard.

Flight Crew Medical Certificates

Unlike passengers, the flight crew of a commercial airliner is required to be screened and obtain a medical certificate that acts as "acceptable evidence of physical fitness on a form prescribed by the Administrator" (14 CFR Part 1). "The primary goal of the airman medical certification program is to protect not only those who would exercise the privileges of a pilot certificate but also air travelers and the general public."[23]

There are three different classes (I, II, and III) of medical certificates with different requirements and purposes for each. A class I medical certificate, the most stringent, is usually required when exercising the pilot-in-command privileges of an airline transport pilot certificate, a class II medical certificate when exercising privileges of a commercial pilot certificate, and a class III medical certificate when exercising the privileges of a private pilot certificate. Details and all conditions can be found in 14 CFR §121.61.

Legal, Economic, and Operational Aspects

Commercial airliners are not usually required to carry medical personnel onboard their aircraft, even for extended overwater operations. Instead, they rely on having medical physicians among their passengers, which is the case in about half of all commercial flights,[24] with various other medical personnel present in about 75%. Others report doctors present in about 70–80% of flights.[25] However, national laws differ in the legal obligations for physicians to help in inflight medical emergencies. The United Kingdom, Australia (with exceptions), the United States of America, Asia (with exceptions), and Canada (with exceptions) have no legal duty to aid or rescue a person in distress or in an emergency (unless this person is one of the doctor's patients or has a family or other dependent relationship with the doctor).[25,26] "There are, however, moral and professional obligations for all doctors to act as Good Samaritans." The Hippocratic Oath states that a doctor has a special obligation to all fellow human beings and, in addition to the personal application of that broad principle, the General Medical Council enforces adherence to the "Good Medical Practice" guidelines. In particular, paragraph 9 states that: "in an emergency, wherever it may arise, you must offer anyone at risk the assistance you could reasonably be expected to provide."[19,26]

In other national laws, such as Germany, France, Russia, as well in Quebec (Canada), the failure to provide assistance is an offense (*e.g.,* Germany: section 323c of the Criminal Code, France: Article 223-6 of the Criminal Code). Although not legally obliged to help in some countries, the so-called "Law of the Good Samaritan," which offers legal protection to people who, unless they give reasonable help to the injured or ill, are guilty of gross negligence or willful misconduct, applies in most countries, even in those who do not have a "duty to rescue" law. An exception to that is the United Kingdom, which does not have a Good Samaritan Law. The United States of America "adopted legislation in 1998 in the form of the Aviation Medical Assistance Act, which includes a Good Samaritan provision."[26] The Good Samaritan Law, as well as the duty to rescue law in commercial aviation, is based on the nationality of the aircraft irrespective of current airspace.

In every case, it is not medical personnel on board of a flight, but the pilot in command of the aircraft who decides whether to divert for specific medical treatment of an ill passenger. With this decision, an "airline faces a dilemma in reaching a good balance between the immediate risk and cost of a diversion, versus the implied risk—or even liability—when deciding to continue a flight with an ill or injured passenger. Duty of care to a passenger is expected even when the event is not a result of an airline's fault."[13,15] Also, "diversion of a commercial airliner to an unscheduled destination for an ill passenger requires consideration of both medical and operational issues. The potential medical benefit should be assessed on the basis of the condition and its time sensitivity, the ability to stabilize the patient's condition with available supplies, and the likely time savings with consideration of the time needed to land and the proximity of medical resources to specific airports. Immediate operational factors that may contribute to variability in airline practices include weather, fuel load and the potential need to drop fuel before landing, the availability of specific aircraft services at airports, and air-traffic control."[13,24]

Summary

Recommendations by the ICAO must be transformed into national law. If any state deviates from ICAO's recommendations in their national regulations, ICAO must be notified. The transformation to national regulations implies that national regulations are slightly different from each other. The baseline rules, however, are the same; often it is only the detailed conditions, number, or contents of equipment that differ. The baseline equipment usually includes first aid kits, emergency medical kits, and AEDs. Commercial aviation crew must have a medical certificate to operate. Passengers are not screened to fly; however, airline personnel and crew are usually trained to recognize and handle the most common illnesses.[12] If there are indications that a passenger might not be fit to fly, medical clearances may be required (*e.g.,* on the IATA MEDIF form).

COMPARISON OF NASA MEDICAL STANDARDS AND RELATED U.S. CIVIL AVIATION REGULATIONS

While NASA spaceflight standards and FAA aviation regulations do not directly support the needs of the CST industry entirely, these existing practices can serve to help create a baseline for future CST levels of care. *Table 2* gives a high-level summary of the medical standards of civil aviation and NASA that were introduced above.

FAA Approach to Levels of Care

In general, existing space and aviation medical standards and practices are not directly applicable to commercial human spaceflight. Not only must the necessary levels of care be adjusted to different flight profiles and scenarios, FAA-AST has acknowledged that the "wide variety of commercial human spaceflight activities likely to take place in the near future makes a single level of safety impractical and inappropriate."[27] In 2013, the FAA released a draft document titled "Established Practices for Human Space Flight Occupant Safety."[27] The goal is to "gain the consensus of government, industry, and academia on established practices as part of our mandate to encourage, facilitate, and promote the continuous improvement of the safety of launch and reentry vehicles designed to carry humans". In addition, this may also "serve as a starting point for a future rulemaking project." FAA-AST articulates two levels of care.[27] An overview of medical guidelines and levels of care as stated in the FAA Established Practices document is summarized as follows:

1. The occupants of commercial human spacecraft should not experience an environment during flight that would cause death or serious injury. This is a low bar, below the level of comfort that most SFPs would want to experience.
2. The level of care for flight crew when performing safety critical operations is increased to the level necessary to perform those operations.

Table 2. Comparison of Aviation Regulations and NASA Medical Care Standards

	Commercial Aviation	NASA Human Spaceflight
Rationale	Medical equipment: Duty of care to passengers is expected, airlines must balance immediate risk and costs; demographics: aging population, inflight environment among worst for suffering serious medical events. Crew medical standards: flight safety, occupational healthcare and economics, cf. IATA[10]	Reduce the risk that exploration missions are impacted by crew medical issues and that long-term astronaut health risks are managed within acceptable limits. As mission duration and complexity increase, the capability required to prevent and manage medical contingencies correspondingly increases.
Flight crew requirements	FAA class I/II medical certificate, annual evaluations	Extensive prescreening, annual and mission-specific evaluations
Passenger requirements	None (with exceptions, *e.g.*, exit rows), when indications present: medical clearance, final decision made by captain	
Medical equipment and consumables	First aid kit, emergency medical kit (to only be used by trained individuals), AED	Dependent on mission scenario (level of care): first aid capability, medications, ambulatory care, surgery care, advanced life support, *etc.*
Prevention strategies	Airline policies, medical clearances	Dependent on mission scenario (level of care): preventive medicine, screening
Intervention strategies	Doctors on board, MedLink (inflight medical support), diversions	Dependent on mission scenario (level of care) including telemedicine (private video + audio), advanced care, possible return to Earth
Mission termination	No definitive criteria; medical and operational aspects (including cost, implied risks, operational issues, availability of and time to more definitive care, etc.) must always be considered to decide on mission termination.	

In addition, FAA-AST assumes the following:

1. If a failure occurs that leaves the system in a state where another failure may lead to a catastrophic situation, the operator will terminate the flight, providing the occupants the same level of care through the end of flight.
2. In an emergency, the same level of care is not expected to be maintained. The expectation in emergencies is only a reasonable chance of survival.

Medical Equipment

It can be expected that medical injuries will potentially be incurred during commercial spaceflights. Having first aid and medical equipment on board, consistent with the mission profile and number of occupants, could help mitigate illnesses and injuries.[27] Therefore, CST vehicles should have some form of medical capabilities: "The vehicle should provide first aid and medical equipment for treatment of injuries or medical emergencies that might occur during flight, consistent with the design reference mission and the number of occupants" (AST-2205, cf. Established Practices document). An FAA Center of Excellence for Commercial Space Transportation (COE CST) report from the University of Texas Medical Branch[28] lists a selection of the most common risks to humans in spaceflight, which may also serve as a starting point to determine necessary levels of care.

Medical Certificates, Screening, and Training for Flight Crews and SFPs

FAA-AST includes medical considerations for both flight crew and passengers in the Established Practices. In this regard, FAA-AST follows FAA civil aviation regulations that distinguish between crew and passengers (or SFPs), while NASA guidelines do not. SFPs are defined as noncrewmembers who participate in suborbital or orbital spaceflight. They are not physically separated from the crew, and may be flying for pleasure or could be scientists conducting microgravity research or providing medical care/monitoring for other SFPs.[28]

To be able to perform safety critical tasks necessary for operating a vehicle, flight crew for suborbital flights should possess a valid FAA Class II Medical Certificate, and flight crew for orbital flights should possess a valid FAA Class I Medical Certificate (AST-1880). A medical screening can help identify unacceptable medical conditions. Similar to current civil aviation and NASA guidelines, flight crews should be trained in the use of on-board medical equipment and in the recognition of "when an occupant requires medical attention that exceeds the capability of the flight crew and on-board equipment" (AST-1908). The rationale for this is that the "inability to locate or improper use of medical equipment can lead to further incapacitation or the inability to perform safety critical tasks."[27]

The practices regarding SFPs are different. To determine medical requirements for SFPs, one could look at astronauts. However, from a medical fitness point of view, astronauts who have been subject to very thorough medical selection should not be considered as a representative sample of the general population. And even among astronauts, more than 2200 separate medical events or symptoms have been reported during 106 Space Shuttle missions.[29] Unlike NASA guidelines and like civil aviation regulations, the FAA Established Practices document "does not include any medical criteria that would limit who should fly in space due to medical conditions" since there is little clear statistical evidence on the actual impact of spaceflight on the health of an occupant with preexisting conditions. Thus, SFPs do not need a medical certificate. However, it is suggested that they consult with an aviation medical examiner to ascertain their medical risks of spaceflight within 6 months of a flight (AST-2216) and complete a medical questionnaire (*e.g.,* FAA,[27] FAA COE CST UTMB,[28] IAA,[29] and Antuñano *et al.*[30]). This can help determine their medical fitness to withstand the stresses of spaceflight so that they do not pose a hazard to themselves or to other occupants. Preexisting medical conditions can be aggravated or exacerbated by exposure to environmental and operational stressors such as acceleration, microgravity, and solar/cosmic radiation, among others.[30]

The FAA Established Practices document further specifies that a medical examination is meant to raise awareness in order for SFPs to make an informed decision about their own health and implications of spaceflight.[27] In addition, "SFPs should indicate to the examining physician and operator if they know or have reason to know of a medical condition that would impair their ability to 1) safely perform a sub-orbital/orbital flight without compromising the safety of other occupants and 2) safely perform an emergency egress without assistance" (self-certification[28]; see also IAA[29]).

In the early days of commercial spaceflight, these medical assessments (questionnaires, examinations) might prove helpful to refine and adjust levels of care needs and onboard medical equipment expectations. As experience grows and suborbital point-to-point travel becomes available, the necessity to have a medical certificate as well as any early requirements for passenger medical examinations and certificates might be relaxed. And due to practical constraints, only a limited quantity and quality of medical equipment can be accommodated onboard a spacecraft.

"SFPs can become a source of a hazard as well as a resource to respond to off nominal events. Providing pre-flight instruction to spaceflight participants on identifying hazards that result from human interactions, how their bodies will react to the space environment, and their expected roles in emergency situations, will provide the operational knowledge required to recognize, avoid, and respond to potential on-board hazards." Therefore, operators should instruct SFPs prior to flights on identified hazards of human interactions, aerospace physiology, and how to respond to emergency situations (AST-1931)[27] depending on the specifics of a given flight.

Summary

The FAA Established Practices document does not attempt to establish a single, prescribed level of safety for the industry as a whole. Therefore, the levels of care and safety are generically stated and intentionally set low. For each commercial human spaceflight profile, specific levels of care must be developed, just as NASA guidelines include unique medical provisioning for different mission scenarios. The necessary medical equipment and capabilities are dependent on many variables, including the flight profile and duration, number of occupants, and training of onboard personnel. Level of care for commercial human spaceflight transportation will differ from civil aviation regulations and NASA practice; therefore, their implementation process will likely vary as well. While the FAA "certifies" commercial aircraft, it currently "licenses" spaceflight vehicles (cf. Messier[31]). Certification generally implies that an authorized agency assesses and verifies defined attributes of an entity, while licensing usually refers to formal permission being provided to conduct an activity. Permits and waivers can also be used in this context. The ultimate process for defining and overseeing commercial spaceflight level of care has not yet been established, but will likely utilize some form of the above practices.

LEVELS OF CARE CONSIDERATIONS FOR COMMERCIAL HUMAN SPACEFLIGHT TRANSPORTATION

Considering existing space and aviation guidelines and regulations, a baseline level of care can be developed for the commercial human spaceflight industry. These thoughts may be seen as a potential extension of FAA-AST's Established Practices document. To determine what makes sense for the complex and multifactorial commercial space industry, different commercial reference mission scenarios will be introduced. *Table 3* lists a representative selection of different mission scenarios that were considered for this study.

Dependencies

As derived from NASA's definition of the levels of care, two dependencies of the levels of care stick out: the "perceived need" and the "ability of the provider." These two factors form the basis for the following considerations on level of care dependencies. *Table 4* identifies general variables and factors that influence level of care decision for any specific mission (mission scenario, environment, occupants, technology & knowledge, corporate philosophy and design, and other aspects). These are based on levels of care dependencies defined by NASA[3] as well as from Barratt and Pool.[32] They also include aspects from civil aviation regulations. The factors listed are very general and introduce many uncertainties (*e.g.,* perceived level of risk during mission), which make defining specific levels of care for commercial spaceflight challenging, but are nonetheless relevant considerations that should be taken into account in the design process.

Early Termination

Early termination due to medical emergencies is generally a last resort, similar to making inflight landing diversions due to medical emergencies in commercial aviation. Diversions entail high cost, interrupted operations, and new risks—therefore the "diversion of a commercial airliner to an unscheduled destination for an ill passenger requires consideration of both medical and operational issues."[24] This decision differs from abort scenarios that might arise due to vehicle anomalies in which case safe return to Earth becomes an unquestioned priority. Normalized operational costs for commercial spaceflights will be considerably higher than in the aviation industry, and so minimizing the likelihood of having to terminate a mission due to medical emergencies becomes increasingly cost effective. This, along with the factors and unique characteristics of

Table 3. Overview of Representative Commercial Human Spaceflight Mission Scenarios

Category	Scenarios	Typical Mission Characteristics
Suborbital	Tourist/research flights	Parabolic flight, microgravity exposure on the order of minutes, return to the origin. Total flight duration: minutes to hours. Number of passengers <10
	Point-to-point transportation	Parabolic flight, microgravity exposure on the order of minutes, multiple rocket engine burns in space possible. Total flight duration: minutes to hours.
Orbital	Tourist/research flights (space hotels, space stations)	May include docking, undocking, and transfer to another space vehicle/habitat. Total flight duration in the order of days to months.
	Flights to ISS (*e.g.*, resupply mission)	Includes docking/undocking and transfer to and from ISS. Total flight duration in the order of days to months.
Planetary	Moon, planetary, and asteroid encounters	Includes additional engine burns during the mission (target injection burns). May include docking, undocking, and transfer to another space vehicle/habitat. Total flight duration in the order of months to years.
	Landing on other planets/moons/asteroids	Includes additional engine burns during the mission (target injection burns). May include docking, undocking, and transfer to another space vehicle/habitat. Includes orbit insertion and landing, as well as lift-off from distant surface body. Total flight duration in the order of months to years.

spaceflight listed in *Table 4*, is why the level of care in space might generally needs to be greater than for commercial aviation. It may, however, be lowered for very short flights due to impracticality of providing treatment within the timeframe. Similar to the NASA and commercial aviation approach, definitive criteria for mission termination of a commercial spaceflight cannot readily be established. Mission (or flight) early termination decisions are ultimately dependent on a consideration of many different aspects, including medical, operational, feasibility, economic, legal, and moral aspects.

THOUGHTS ON LEVELS OF CARE FOR DIFFERENT COMMERCIAL SPACEFLIGHT SCENARIOS

The following factors summarize thoughts on the level of care for suborbital tourist flights:

1. Mission: Because of the short duration, enhanced medical care is not necessary. Medical risk is relatively low, and platforms of more definitive care on Earth can be reached within hours. Due to the dynamics of suborbital flight, most of the time the crew and SFPs will be strapped to their seats limiting possibilities for medical interference. Return-to-Earth capability is guaranteed throughout the mission, making a high level of care nonessential.
2. Environment: Due to the short exposure to space environment, environmental factors do not require a high level of care. Earth environment (*e.g.,* weather and high winds) might require an increased level of care.
3. Occupants: The crew, unless a flight attendant is specified, will not likely be available for intervention in medical emergencies occurring in flight and SFPs will likely have limited, if any, medical training. These operational and training constraints imply that only some low level of care will be practical. However, SFPs might have health constraints, in which case specific medication and equipment for dealing with typical illnesses or minor concerns would become necessary.
4. Technology and knowledge: Existing commercial off-the-shelf (COTS) technologies typically require modification to become space qualified.
5. Corporate philosophy and design: Launch mass and vehicle volume will most likely limit medical equipment and therefore the level of care.
6. Other aspects: Public perception might increase the need for a higher level of care. Informed consent might limit the need for a high level of care. Since suborbital flight's phases are mostly very dynamic, the intervention in case of a major medical emergency might pose the caregiver to greater risk of getting injured himself or herself, which limits the necessary level of care.

From this insight, the level of care for suborbital tourist flights might include medications to prevent (space) motion sickness and analgesics. Simple first aid kits, including patches and bandages, seem to be appropriate. Furthermore, portable oxygen masks should be included to treat possible air contamination such as smoke. Pressure suits might also be appropriate as level of care; however, they are not specified in the FAA Established Practices document (cf. Ref.[27]).

For orbital flights of increasing duration, higher levels of care will become necessary to ensure the health and well-being of passengers and crew.

Table 4. Level of Care Dependencies for Commercial Human Spaceflight

A	Mission		
	A.1	Mission type	Includes destination and purpose of mission (*e.g.,* suborbital, suborbital point-to-point, orbital, planetary)
	A.2	Mission phase	Constraints and options during different phases, including risks, response times, criticality of injury/illness
	A.3	Mission duration	Length of mission, especially time in space environment
	A.4	Distance and time from platform of more definitive care	Defines the minimum and maximum distances to more definitive care during mission. Also important are the times to get to this platform (*e.g.,* another station and Earth).
	A.5	Return-to-Earth capability	Does the mission profile include return-to-Earth capability? During which phases of the mission? How does this influence the mission?
	A.6	Medical risk during mission	What is the risk that an occupant gets injured or sick during the mission? Dependent on mission type and Design Reference Mission as well as vehicle characteristics.
	A.7	Activities during mission	What activities are performed during the mission, *e.g.,* EVAs, research tasks, and instrument operation? Do the activities implicate additional risk for medical emergencies?
B	**Environment**		
	B.1	Risks due to environment	Does the encountered space environment pose medical risks to the occupants? If yes, which risks? What are the relevant factors that increase risk? Can they be mitigated? How does the environment influence the level of care?
C	**Occupants**		
	C.1	Number of (flight) crew and SFPs	How many occupants are on board? Does this influence medical risk and how? Generally, the more people, the higher the risk?
	C.2	Roles of crew and SFPs	Are SFPs tourists or payload specialists? Who can provide medical care/treatment and when? Is there a "flight attendant" on board who is specifically trained?
	C.3	Level of medical training of (flight) crew	What level of medical training does the crew have?
	C.4	Level of medical training of SFPs	What level of medical training does the crew have? Can occupants treat other occupants or the crew in case of emergency?
	C.5	Available crew time	As per Design Reference Mission. Does crew schedule permit crew interference during medical emergencies?
	C.6	Health status of SFPs before flight	What is the health status of SFPs before the mission? Does this increase medical risk? What countermeasures might be taken to decrease risk during the mission?
D	**Technology & Knowledge**		
	D.1	Available technology	Is the technology available to use certain medical equipment in the space environment (*e.g.,* microgravity and radiation)?
E	**Corporate Philosophy and Design**		
	E.1	Vehicle constraints	Includes launch mass, volume, power, and consumables constraints
	E.2	Vehicle design	Does the design increase medical risks? This also includes the Environmental Control and Life Support System (*e.g.,* total pressure and gas composition).
	E.3	Philosophy of accepted medical risk	Includes prescreening, health rules for SFPs. What medical risk accepts the company? What is the philosophy of the company?

(*continued*)

Table 4. (Continued)

F	Other Aspects		
	F.1	Legal aspects	Do legal aspects (national and international laws, *e.g.,* legal duty to aid or rescue a person in distress or in an emergency) have an influence on the level of care or its implementation or application?
	F.2	Ethical implications	Do ethical and moral issues influence levels of care?
	F.3	Insurance	Do insurance contracts of provider, SFPs, crew, countries, or others influence the level of care? For example, informed consent
	F.4	Risks of intervention/treatment	Does the intervention for treatment pose additional threats on occupants? For example, not wearing a seatbelt during reentry
	F.5	Risks of no intervention/treatment	Does no intervention/treatment in case of an emergency pose any additional risk?
	F.6	Public perception	Does public perception influence the level of care, *e.g.,* through negative publicity resulting in economic disadvantages for the provider?

EVAs, extravehicular activities; SFPs, spaceflight participants.

1. Mission: The longer the flight duration before nominal return to Earth in case of a medical emergency as well as due to other activities (EVAs, research, maintenance) conducted during the mission, the higher the level of care will be needed. This should include treatment of typical illnesses. Stabilization of an injured occupant until return to Earth might be necessary. Return-to-Earth capability is ensured throughout the mission.
2. Environment: Space environment during orbital missions (including exposure to microgravity and radiation) might require additional medical capabilities.
3. Occupants: Available crew time and the possible higher level of medical training allows for a higher level of care. The health status of SFPs before the mission may require a higher level.
4. Technology & Knowledge: As for suborbital use, COTS devices require space qualification, and increasing knowledge of the hazards associated with orbital flight will lead to advances in technology and operations
5. Corporate Philosophy and Design: Vehicle constraints allow for a higher level of care, since there may be more usable volume for equipment and consumables. Also, there will most likely be regular resupply missions, allowing for a higher level.
6. Other aspects: The risk of intervention in case of a medical incident is low; however, the risk of no intervention cannot be ignored any more as it was for suborbital flights due to the dynamics and risks to the caregiver. Ethical implications and insurance and legal aspects might require a high level of care.

In summary, equipment and consumables may include outfitting similar to that mandated by civil aviation authorities: for example, first aid kits, emergency medical kits, AEDs, oxygen masks, and supplemental oxygen. At least one occupant should have some degree of basic medical emergency response training. Hyperbaric treatment capabilities (*e.g.,* in the spacesuits) might be necessary whenever extravehicular activities are planned and executed or to deal with potential cabin depressurization scenarios. Since relatively quick return to Earth is available, however, there is no need for advanced medical and surgical care. Clinical diagnostics (to support ground decisions on mission termination in case of a medical emergency as well as help define treatment of the injured), ambulatory care, private video, and private telemedicine are deemed suitable. In addition, over-the-counter medications for typical illnesses (including fever, diarrhea, infections, and colds) might be provided. Restraint kits may be useful since the potential for psychological problems might be increased (due to the possible longer duration and the health/psychological "fitness" of SFPs) or issues stemming from potential intoxication.

Long-term orbital missions, in particular if return to Earth is not a feasible option, will demand higher levels of care and will likely need to be automated to some degree. Similarly, planetary and lunar surface outposts require a different level of care than long-term transit orbits. Planning for these future scenarios will benefit from experiences gained during the early stages of commercial spaceflight, and are not addressed in any detail here.

Personal Preferences, Provider Policies, and Regulation

The previous sections present rationale and examples of equipment and consumables anticipated for different levels of care. Of course, these are not complete. Furthermore, the listed items vary in importance, possible impact (in effectiveness, mass & volume, service life, power requirements, etc.), cost, required crew and maintenance time, and so on, and their availability, feasibility, usefulness, and application depend on a variety of factors (such as vehicle design and constraints); therefore, it is not suggested to mandate and regulate all mentioned items. In contrast, policies as used in the commercial aviation industry (passenger fitness to fly, handcuff/restraints, optional items for emergency medical kits, *etc.*) and personal preferences (as applied in the aviation industry: doing exercise while flying to prevent thrombosis, *etc.*) may be used to establish guidelines for reducing risks without introducing regulations *per se*.

IMPLICATIONS FOR FURTHER DECISION MAKING

The purpose of this study was to explore how related medical care standards could be applied to the developing CST industry and to provide insight into what level of care might be necessary for different mission scenarios. In order to do so, we first looked at the existing medical care standards and regulations of NASA and the international commercial aviation industry, as well as the draft FAA-AST Established Practices document. While neither NASA nor civil aviation applications directly support all the needs of commercial space, relevant elements can be drawn from both. Given the complexity and variety of commercial space mission scenarios, it is not likely that a single, comprehensive level of care requirement can be defined. Rather, if an agreeable minimum standard set of guidelines can be established as a baseline of good practice, individual companies will have the opportunity to provide additional care as a discriminating feature of their business model. These accommodations might include items such as first aid up to emergency medical kits, portable oxygen masks, AEDs, seat belts or similar restraints, analgesics, (space) motion sickness medication, and pressure suits. Longer term care capabilities might be extended to include hyperbaric treatment capacity, private telemedicine and conference capabilities, unruly passenger restraints, radiation mitigation strategies, clinical diagnostics, and basic or advance surgical and dental care. Ultimately, decisions can be made as to whether these items will be regulated, standardized, recommended as policy, or left open to personal preferences as the fledgling commercial space industry evolves into an established business market.

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Address correspondence to:
David M. Klaus
Aerospace Engineering Sciences Department
1111 Engineering Drive
University of Colorado–Boulder
429 UCB
Boulder, CO 80309-0429

E-mail: klaus@colorado.edu