Commercial Space Medical Certification

Bonus: The Rosetta Stone Project

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Fit to Fly
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U.S. Aeromedical Certification Systems
U.S. Aeromedical Certification Systems

- **FAA**
  - AME based medical certification
  - BasicMed

- **Military**
  - Medical recommendation for flying duties
  - Provides comprehensive health care for aviators

- **NASA**
  - Elements of both
  - Certifies for flight and space flight like FAA medical certification system
  - Provides comprehensive health care for astronauts
NASA’s Aeromedical Certification System

• Medical certification standards
  – Aviation standards
    • High performance aircraft standards
  – Short duration space flight standards
  – Long duration space flight standards
  – Space flight participant standards
  – Standards are similar to FAA, military
  – NASA standards include extensive examination and testing requirements
NASA’s Aeromedical Certification System

• Medical Policy Board (MPB – NASA HQ)
  – Chaired by NASA Chief Health and Medical Officer
  – Advises on medical policy for space medicine, atmospheric flight, and occupational health
  – Permanent waiver authority for astronauts – Chief Health and Medical Officer
  – Reviews/approves health and medical standards
  – Review of space medicine issues with advice to Chief Health and Medical Officer as appropriate
  – Analogous to Federal Air Surgeon, Surgeons General (USAF, USA, USN)

• Aerospace Medicine Board (AMB – NASA JSC)
  – Clinical board, chaired by JSC Chief Medical Officer
  – NASA flight certification
  – Temporary medical waiver authority for astronauts (6 months)
  – Permanent medical waiver authority for flight controllers, etc.
  – Medical certification standards development
  – Analogous to CAMI, USAF consult service, etc.
International Space Station Medical Certification

• Multilateral Space Medicine Board (MSMB)
  – Medical certification authority for ISS crewmembers and space flight participants
    • All crew and SFP must meet and pass respective international partner medical boards first
  – Established by international agreement, operates under supervision of the Multilateral Medical Policy Board (MMPB)
  – Mandatory for all ISS crew and space flight participants to be MSMB certified
Minimal Medical Evaluations for ISS Spaceflight Certification for Short Duration Commercial Crewmembers

• Preflight IP Agency Aeromedical Board and MSMB
• Within 12/6 months of Flight the following must be completed as a minimum by a qualified AME/Commercial Crew Surgeon (CS) and IP-Assigned CS:
  – Medical History and Physical Exam (1st class FAA or Equivalent)
  – Dental: clinical evaluation and full orthopantomogram or full mouth x-ray series
  – Audiometry, Tympanogram
  – Optometry per Med C (uncorrected and corrected visual acuity, refractive error, tonometry, fundoscopy, visual fields, color vision)
  – Psychiatric Exam/Screen by ISS partner psychiatrist
  – Cardiopulmonary: EKG, EST/VO2max, CACs (males >40, females >50), PFT, 24-Holter and Echo on record
Minimal Medical Evaluations for ISS Spaceflight Certification for Short Duration Commercial Crewmembers

- Imaging: CXR, AP ultrasound, and mammography (females) within the last 1 year, MRI/MRA brain on record
- Others As Clinically Indicated (ACI)
- Laboratory
  - CBC, PT, PTT
  - Chemistry Profile same as Med C including HbA1C and pregnancy test
  - ID Profile (HIV, Hep B, & C, PPD, and Vaccine Immune Status)
  - Urinalysis
- Physiologic Training
- High Performance or Vehicle specific G-Training
Minimal Medical Evaluations for ISS Spaceflight Certification for Short Duration Commercial Crewmembers

- **Preflight**
  - L- 90/30 - MRSA, GABHS, H Pylori and Other ACI
  - L- 14 - Quarantine
  - L-14/10 - Medical Evaluation by Crew Surgeon
  - L-2/1 - Prelaunch Medical Evaluation
- **Inflight**
  - PMC daily to L+3, weekly, ACI, daily R-3/0
- **Postflight**
  - R+0 and 3/7 PEX
  - ACI - Labs and PEX
  - ID Swabs
Commercial Space Flight Medical Certification

- FAA is responsible for commercial space flight medical certification
- Currently a 2\textsuperscript{nd} class medical certificate is required to pilot a spacecraft
- No medical evaluation or certification is required of spacecraft passengers or space flight participants
- Passenger safety and medical fitness to fly is the responsibility of the commercial provider
- Illness/incapacitation of a crewmember or passenger is a risk to the entire crew
Diagnoses in Active Astronauts That were Discovered, Repaired, & Returned to Flight

- Cervical disc herniation with impingement on spinal cord
- Kidney stone x 14
- Clostridium deficile infection
- Gastroenteritis/ colitis
- Inguinal hernia x 4
- Olecranon bursitis r/o septic joint
- Hand bacterial tenosynovitis
- Pneumonia x 2
- Corneal ulcer
- Severe epistaxis
- Right ovarian cyst
- Dysmenorrhea
- Sudden hearing loss x 2
  - V-tach, exercise induced
  - Angina
  - A-fib
  - Allergic reaction - severe
  - Retinal detachment x 2
  - Appendicitis x 2
  - Diverticulitis
- Prostate Cancer x 5
- Stroke with Patent Foramen Ovale
- Stroke from A. Fib
- Bladder Outlet Obstruction
- Ulcerative Colitis
- Flexor Digitorum Synovitis
- Bowel Resection
- Fatty Liver Disease
- Bulging Disc with Radiculopathy
- Hypercholesterolemia
- Hypertension (essential)
- Atrial Fibrillation with ablation x 5
- Brain (Pituitary) Tumor x 2
- Choledocholithiasis x 4
- Pancreatitis x 2
- Hemorrhagic cyst
- Lower GI bleeding
- Duodenal ulcer with upper GI bleeding
- Malignant Melanoma
- Total Hip Replacement
- Hip Fracture with Rod and Screw
Commercial Space Flight Medical Certification

• To visit ISS, medical certification by the MSMB is required
• To dock with and ingress ISS, commercial space flight pilots and passengers must be MSMB certified
• Some medical experience with “space tourists” from Soyuz/ISS flights has been published
Space Flight Participants

- Dennis Tito: April 28 - May 6, 2001
- Mark Shuttleworth: April 25 - May 5, 2002
- Gregory Olsen: October 1–11, 2005
- Anousheh Ansari: September 18–29, 2006
- Charles Simonyi: April 7–21, 2007, 26 March - 8 April 2009
- Richard Garriott: 12 - 23 October 2008
- Guy Laliberté: 30 September - 11 October 2009
Gregory Olsen

Commercial Space Flight Medical Certification

- 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
- Credit: Dr. Melchor Antunano
Commercial Space Flight Medical Certification

- International Association for the Advancement of Space Safety (IAASS), Suborbital Space Safety Technical Committee
  - Operations Working Group produced a report on recommended best practices on Flight Crew and Spaceflight Participant Medical and Training Requirements. 2013
• Flight Crew Medical Standards and Spaceflight Participant Medical Acceptance Guidelines for Commercial Space Flight, June 30, 2012
• Investigation team
  – Principal Investigator: Richard Jennings, M.D., M.S. UTMB
  – Co-investigators: James Vanderploeg, M.D., M.P.H. UTMB, Melchor Antunano, M.D., M.S. FAA-CAMI, Jeffrey Davis, M.D., M.S. NASA-JSC

• Outcome
  – A consolidated set of recommendations for crew medical standards that will be useful to the FAA in its regulatory responsibility for crew medical standards and safety.
  – A consensus set of passenger acceptance guidelines that can serve as advice to commercial operators as they develop their own medical programs.
Challenges to Commercial Spaceflight Medical Certification

- Best practices and the experience base demonstrate the need for space medical certification of space flight crewmembers
  - Environmental stresses
  - Altered physiology
  - Isolation/confine ment
  - Safety Implications of illness/injury
- Aeromedical screening (and possibly certification) of passengers also might reflect best practice from a safety perspective
- Regulatory environment will preclude codification of space medical certification standards
  - Basic Med
Commercial Space Flight Medical Certification

• Meetings underway between HQ NASA and HQ FAA medical personnel
• NASA is the US caretaker of most of the evidence and experience base relevant to human space flight
• FAA needs ready access to the NASA experience and evidence base as commercial space flight operations commence
• Memorandum of Understanding between the Federal Air Surgeon’s office and the NASA Office of the Chief Health and Medical Officer is in work
• Exciting times are ahead!
The “Rosetta Stone” Project

Rich Williams
Senior Advisor for Health and Medical Policy
The Rosetta Stone
“So, what is the latest dog and pony floor show from Life Sciences today? I always enjoy hearing about these things, go ahead and entertain me.”
Risks from Inadequate Human Factors Integration

STS-93 Collateral damage to wiring

“Lack of Consideration for Human Factors Led to In-Flight Breakup of SpaceShip Two” NTSB

“Lack of sufficient human-systems integration (HSI) testing before operational deployment of the F-22 [life support system]” NESC

Littoral Combat Ship Fleet Stand down
# Life science differs from engineering

<table>
<thead>
<tr>
<th>Engineers...</th>
<th>Life Scientists...</th>
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<tbody>
<tr>
<td>...design their systems</td>
<td>...reverse engineer Nature to understand the system</td>
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<tr>
<td>...use quality controlled components</td>
<td>...study diverse individuals with diverse components</td>
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<tr>
<td>...use established frameworks to employ physical laws</td>
<td>...discover concepts and qualitative relationships before developing quantitative understanding</td>
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<tr>
<td>...design PID controllers</td>
<td>...discover biased walks in chemotaxis</td>
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![Diagram of PID controller and chemotaxis process](image-url)
Aeromedical vs. Clinical Relationships
Cystic Artery and Cystic Duct Variations
What these features really look like
NASA Human Health and Performance
Goal: Enable Successful Space Exploration by Minimizing the Risks of Spaceflight Hazards

**Mitigations**
- Deliverables: Technologies, Countermeasures, Preventions, Treatments

**Standards**
- Requirements

**Evidence**
- Risks

**Spaceflight Hazards**
- Hostile Spaceflight Environment
- Altered Gravity, Radiation, Isolation, Closed Environment, Distance from Earth

**Human Risks**
- Bone & Muscle loss, Radiation Exposure, Toxic Exposure, etc

**Medical Ops**
- Occupational Surveillance, Environmental Research
Integrated Human System Risk Mitigation Framework

Policy, Operations, and Research are integrated through a Human Health Risk Framework

- **Office of the Chief Health and Medical Officer (OCHMO)** – Level I
  - NASA HQ
    - Develops Medical Policy, Health and Performance Standards, and Bioethics
    - Risk Assessment and Mitigation - Implemented via the Health and Medical Authority (HMTA) – Level II – JSC

- **Crew Health and Safety (CHS)**
  - Medical Operations and Occupational Health (career health care/post career monitoring)

- **NASA Human Research Program (HRP)**
  - Human health & performance research in support of space exploration
    - Perform research necessary to understand & reduce health & performance risks

- **AES & STMD** – Technology/Protocol Development

- **International Space Station (ISS), Orion, Commercial Crew Programs**
  - Implementation of Medical Operations
    - Medical Requirements, Tests and hardware
    - Engineering Requirements
“Rosetta Stone” Manuscript
Multidisciplinary Team: Science, Engineering, Medicine

Aerospace Human Systems Integration: Challenges and Opportunities (Table of Contents)

- The perennial challenge of human systems integration: failures, compromises, and the effectiveness of lessons learned
  - The impact of sex/gender in human systems integration
- Technical authority in NASA
- The complexities, risks, and rewards of Human / Machine interdependent space systems and missions
- Engineering and medical/life sciences culture, training, practice and ethics
- Risk analysis and acceptance: a model ethical framework
- Humans in complex systems
- The HHP Human System Risk Mitigation Cycle: Standards to Requirements to Deliverables
  - Human System Risk Board activities
  - HRP Risk matrix and research schedule
- The Integrated Medical Model: a case study in communication
- Building cross cultural bridges for crew health and mission success
Emerging Thoughts

• Roles and relationships to the project and mission generates dynamic tension
  – Program/project management
  – Technical authorities
• Engineering and medicine have large cultural differences
  – Substrate we work on
  – Problem solving
  – Analytic methods
  – Methods of communication/lexicon
  – Training
• “Communities of practice do not understand each other at a visceral level”
• Aeromedical relationship
• Being human imparts expertise
• Developers vs. operators: Accountability
• Commonality with other disciplines (Safety and Mission Assurance, Planetary Protection)
Thoughts on Recommendations

- There are deep cultural differences between communities of practice that pose a risk to effective human rated systems development and operations – these must be addressed.
- Effective communication is imperative: develop common lexicon, common means of communication, methods and practices recognizable and understandable by all.
- Cross cultural understanding and tolerance is imperative – best initiated in early training.
- Mutual respect between communities of practice is imperative – facilitated by understanding.
- Inclusion is imperative – all applicable expertise should be brought to bear early in any project.
- Inclusion and integration between communities of practice is clearly a leadership responsibility, must be implemented as a core value.
Progress/Forward Work

- Authors and review teams established
- Chapters completed
- Draft complete manuscript is being edited
- Manuscript will be finalized by Dec 2017
- Publication options pursued in 2018
  - NASA technical report
  - Peer reviewed literature
THE FLIGHT SURGEON

- Main function was to first develop and then apply physical qualifications for flight duty
- Driven by high losses of life due to physically unqualified pilots