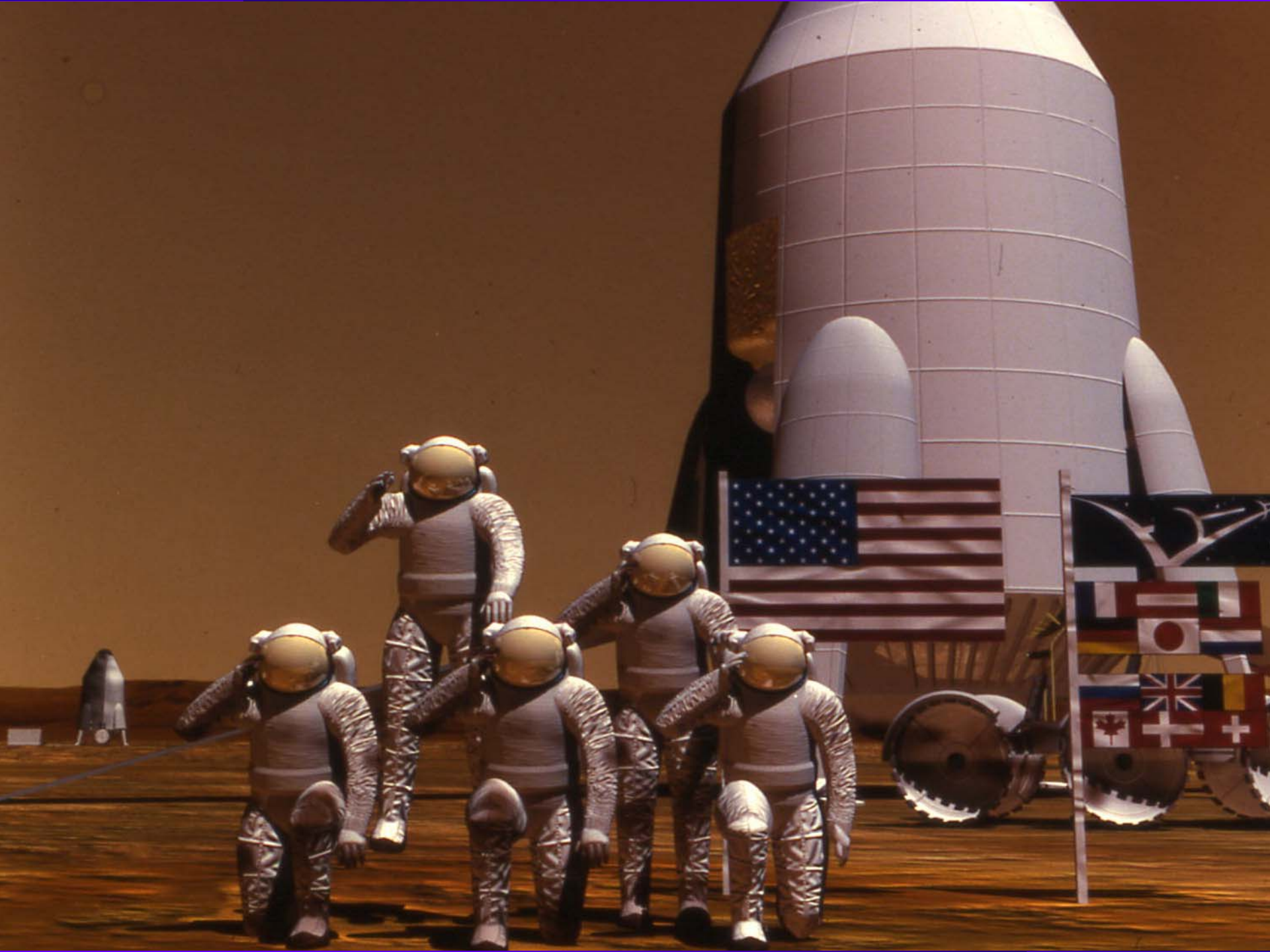




*Medical Policy Formulation for Space
Flight and Aviation
An International Perspective*

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Evolution of Space Medicine

- **Initial approach based upon application of terrestrial clinical judgment to predict medical problems in space**
- **Early American and Russian short duration missions documented medical events that occurred in space providing first clinical experience to form the basis for clinical practice of space medicine**
- **The first Space Station missions enhanced scientific knowledge of long duration human adaptation to space**

Evolution of Space Medicine (cont'd)

- **Space exploration in the last two decades has been associated with significant advances in understanding human physiological and behavioral adaptation to space with accumulation of broader range of clinical experiences in space**
- **Long duration missions have provided a number of significant clinical challenges and have illustrated the benefits of MD astronauts assisted by flight surgeons in provision of on orbit care**

Evolution of Space Medicine (cont'd)

- **ISS era marks beginning of transition from primarily experience based practice to the evidence based practice of space medicine**
- **Experience-based practice has served the program well; augmentation by the expansion and incorporation of clinical trials, risk analysis, decision analysis and evaluation of cost effectiveness as well as cost benefit analysis will be critical in optimizing the evidence-based practice of space medicine**

- 1. International variability in delivery of health care**
- 2. Different diagnostic and therapeutic approaches**
- 3. Cultural issues**
- 4. Acceptance of risk in exploration of extreme environment**
- 5. Different perspectives on role of evidence-based practice**
- 6. Protocols for delegated medical acts**
- 7. Certification/Licensing/Credentials for Space Physicians**

"The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."¹

1. Sackett D.L., Rosenberg W M C, Gray J A M, Haynes R B, Richardson W S. Evidence based medicine: what it is and what it isn't BMJ 1996; 312:71-2

Guidelines for Establishing the Levels of Evidence

Evidence from:

Ia. Meta-analysis of randomized trials

Ib. At least one randomized trial

IIa. At least one well designed controlled study without randomization

IIb. At least one other type of well designed quasi-experimental study

III. Well-designed, non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV. Expert committee reports or opinions or clinical experiences of respected authorities

Source: "Evidence Based Practice in Primary Care," Edited by Chris Silagy and Andrew Haines, BMJ Books, 1998.

System for Establishing the Grade of Guideline Recommendation

- A.** Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B.** Based on well conducted clinical studies but without randomized clinical trials on the topic of the recommendation
- C.** Made despite the absence of directly applicable clinical studies of good quality

Source: "Evidence Based Practice in Primary Care," Edited by Chris Silagy and Andrew Haines, BMJ Books 1998.

Implementation of Space Medicine

Illness and Injury in Space:

Acute, sub-acute or chronic pathophysiological process manifest in healthy individuals who have physiologically adapted to a challenging hostile environment.

Diagnostic Dilemma:

Differentiation between pathophysiology and physiological adaptation in manifestation of illness or injury.

Therapeutic Dilemma:

Assessing therapeutic impact of physiological adaptation.

What we thought before + Test information = **What we think after**



Pre-test probability + Likelihood ratios = **Post-test probability**

Pre-test Probabilities in Space Medicine:

Personal Experience

- **Console flight surgeons have greatest personal experience**
- **MD astronauts have mission specific personal experience**
- **CMOs have variable personal experience**
- **On-orbit diagnosis and console diagnosis may be affected by sampling and saliency bias**
- **Suggests possible the benefit of weighting of clinical characteristics as diagnostic adjunct – smart medical systems**

Published Data

- **Prevalence data from longitudinal study of astronaut health**

Likelihood Ratios in Space Medicine:

Diagnostic History

- Weighting of clinical characteristics as diagnostic adjunct – smart medical systems
- Defining likelihood ratios of key historical information

Diagnostic Tests

- Volume and weight constraints preclude having wide range of diagnostic tests
- Range of non-invasive, non-radiologic diagnostic tests is limited
- CMO skills either alter ability to collect specimen or perform test
- Telemedicine should support transmission of diagnostic data that has a high likelihood of refining the probability of disease
- Likelihood ratios of diagnostic tests in “0”-G largely unknown

Decision Analysis in Space Medicine

Selection and Retention Medical Certification:

- Risk mitigation through selection

Formulation of Flight Rules:

- Generic and flight specific aero-medical flight rules created pre-flight to reduce probability of medical event and facilitate medical decision making during the mission.
- Strength of recommendation for flight rules is C usually on the basis of grade IV medical evidence
- Clinical research required to strengthen the level of evidence for implementation of flight rules and therapeutic guidelines.

Therapeutic Guidelines:

- “Long form malfunction” procedure format amenable to creation of evidence based utilization of therapeutic interventions

ALARA – As low as reasonably achievable

Perception of reasonably achievable has strong cultural influence

Perception of acceptable risk has strong cultural influence

Relative importance of probability of event and outcome

Acceptance of risk influenced by political will

Certification/Licensing/Credentials

Certification

- Transition from experience to evidence based – body of clinical knowledge emerging
- Training programs limited – Console certification
- Research opportunities limited
- Publications in medical literature
- ISS partner publications/experience

Licensing

- Jurisdiction
- Terrestrial license
- Delegation of medical acts

Credentials:

- Verification

Maintenance of Competency:

- CME

- 1. Space medicine in ISS era will evolve from experience-based to evidence-based – International Practice Guidelines**
- 2. Establishment of licensing policies for Flight Surgeons and Space Physicians**
- 3. Certification of Competency will be required for International Practice of Space Medicine**
- 4. International Policy of Acceptable Risk**
- 5. Implementation of Occupational Health model for health protection of astronauts**
- 6. Provision of long term health care for space explorers**