Medical and Health Risks in Exploration Missions An Approach for Priority Setting and Resource Allocation

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Spaceflight Retrospective (as of 07/2006)

- NASA Missions
  - Representative of the US demographics
  - Cumulative 17.93 years
  - 407 individuals from 20 countries
  - Total of 319 (757) on 146 missions
  - 20 individuals flown > 3 weeks (3 for 27 d., 3 for 1.3m., 3 for 2m., 10 for 5m., 6 for 6m.)*
  - ≠108 EVAs

No mission cancellation due to medical problems

includes ISS

Spaceflight Retrospective

- Soviet/Russian Missions
  - Cumulative 44years and 239 days
  - Max. duration 437days and 17 hours
  - Max. duration cum. 747 d. 16 hrs.
  - 35 individuals > 180 days cumulative
  - 15 individuals > 365 days cumulative
  - 29 individuals with one flight > 180 days
  - 4 individuals with one flight > 365 days
  - Cumulative EVA's 174 (one cosmonaut 16 EVA's)

Three medical evacuations

Cause of Death expressed as a % of the cosmonaut and astronaut population	Soviet/Russian* Cosmonauts (N=91)(2003)	US Astronauts (N=295)(2006)
Space flight Related Accidents	4.4	4.4
Training Accidents	1.1	2.4
Accidents Unrelated to Space Flight or Training	1.0	2.7
Cardiovascular Disease	7.7	1.0
Cancers	2.2	1.7
Other/Unknown (no autopsy available)	0	0.3

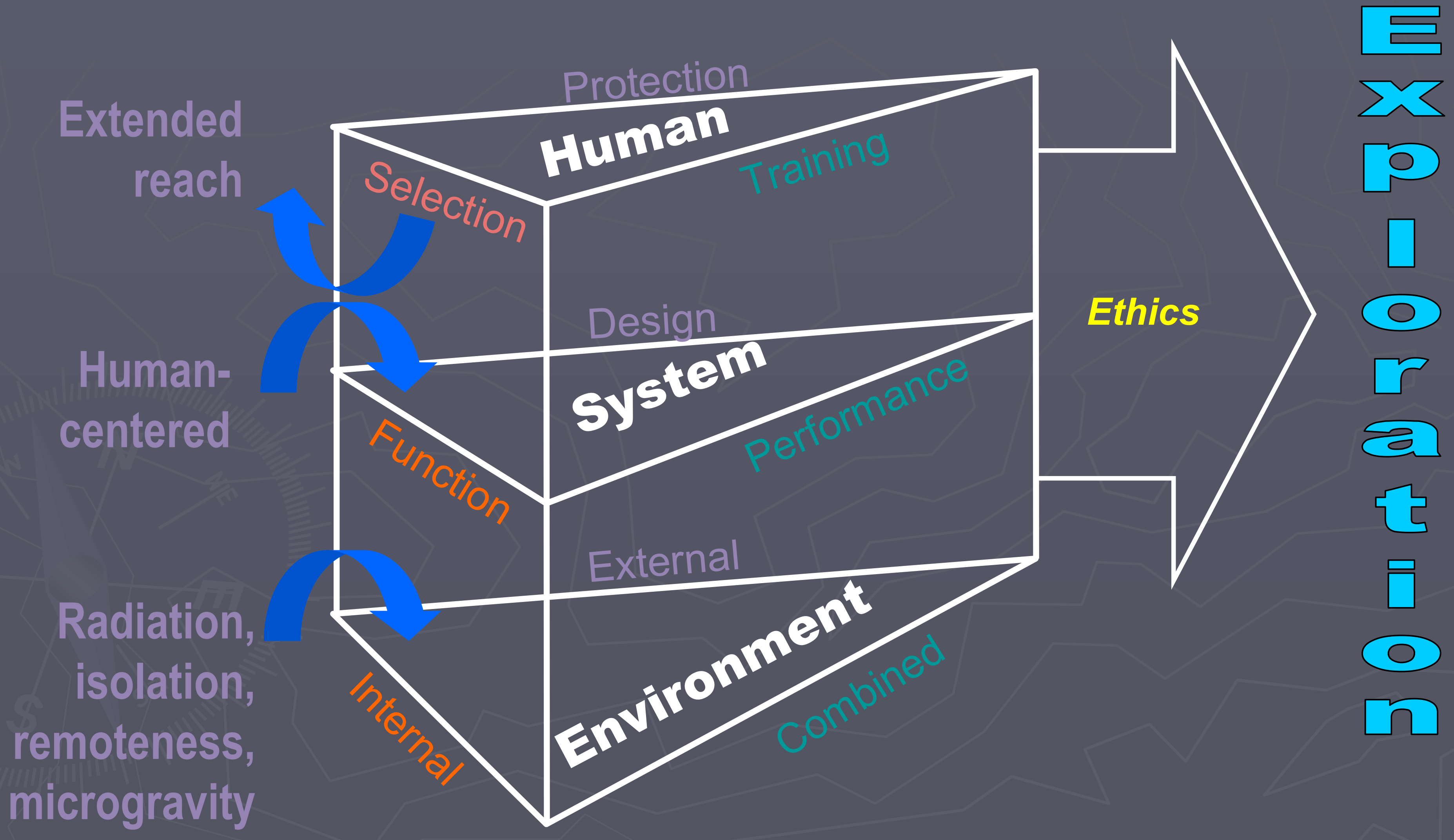
*Courtesy Academician Anatoly Grigoriev, Director Institute of Medical Problems, Moscow, Russian Federation

Lifetime Prevalence of Chronic Disorders

- Compared to the general population*
  - Astronauts are at higher risk for premature cataracts
  - Cosmonauts are at higher risk for CAD
- Do the Astronauts and Cosmonauts enjoy a better quality of life?
- What are the health consequences of permanent habitation in space?

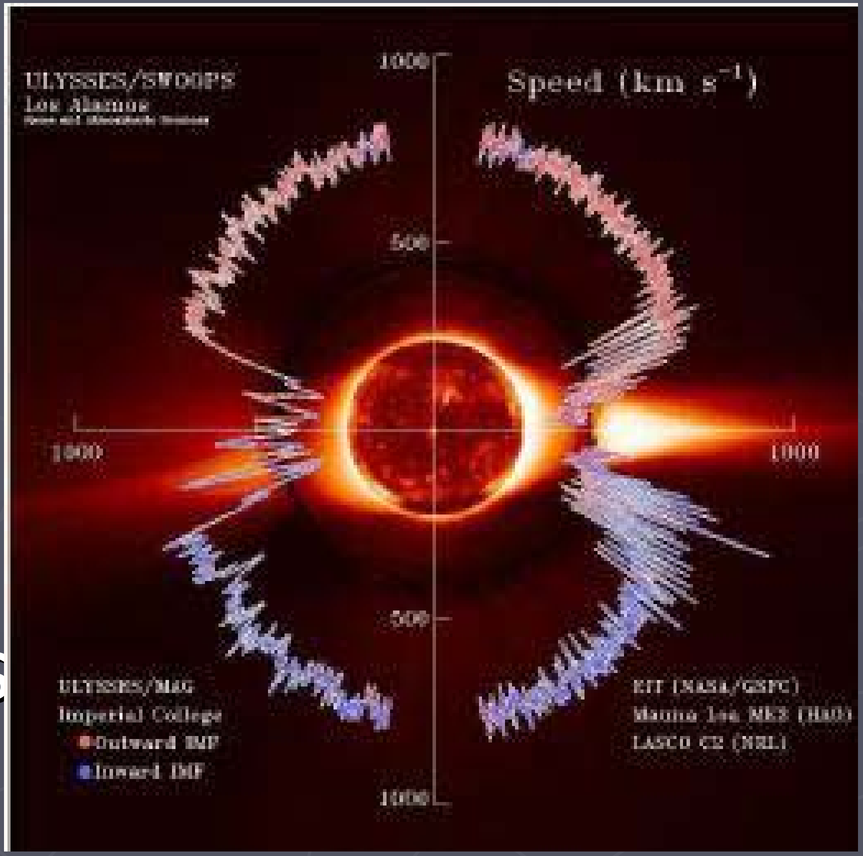
** Data for women astronauts will be compiled over time*

Human Space Mission Design: A Model



Space Environments

- Interplanetary
- Planetary
- Satellites (moons)
- Comets
- Meteorites
- Cosmic Dust/particles
- Solar Winds
- Cosmic Radiation
- Other



Courtesy NASA MSFC

Protection for the human traveler might require a multifaceted approach

Essentials for safe and productive exploration:

- Bringing together 3 elements
  - Life support
  - Transportation and habitat
  - Human beings
- Essential challenges
  - Variable gravity
  - Constant radiation
  - Extremes in temperature and pressure
  - Novel environments and ecosystems
- Loss of “real time” communications

Spacecraft\habitat essentials:

- Must provide environmental control and life support
- Provide a "portable biosphere"---home away from home
  - Atmospheric pressure and gas composition correct O^2 & N
  - Proper humidity, temperature, and pressure
- Systems capable of adapting to different atmospheres, surfaces, gravities
- Radiation held to a minimum
- Designed for work and personal space
- Recycling of resources and waste

Spacecraft/habitat essentials (2):

- Major reliance on engineered tools and systems to prevent "*mal adaptation to space flight*"
  - Exposure to toxicological and environmental conditions
- Limited emergency medical intervention
- Constraints:
  - Power and mass
  - Communications delay
  - Inability to return quickly to Earth
- Sustenance
- Sustain long term useful performance
  - Systems to counter de-conditioning

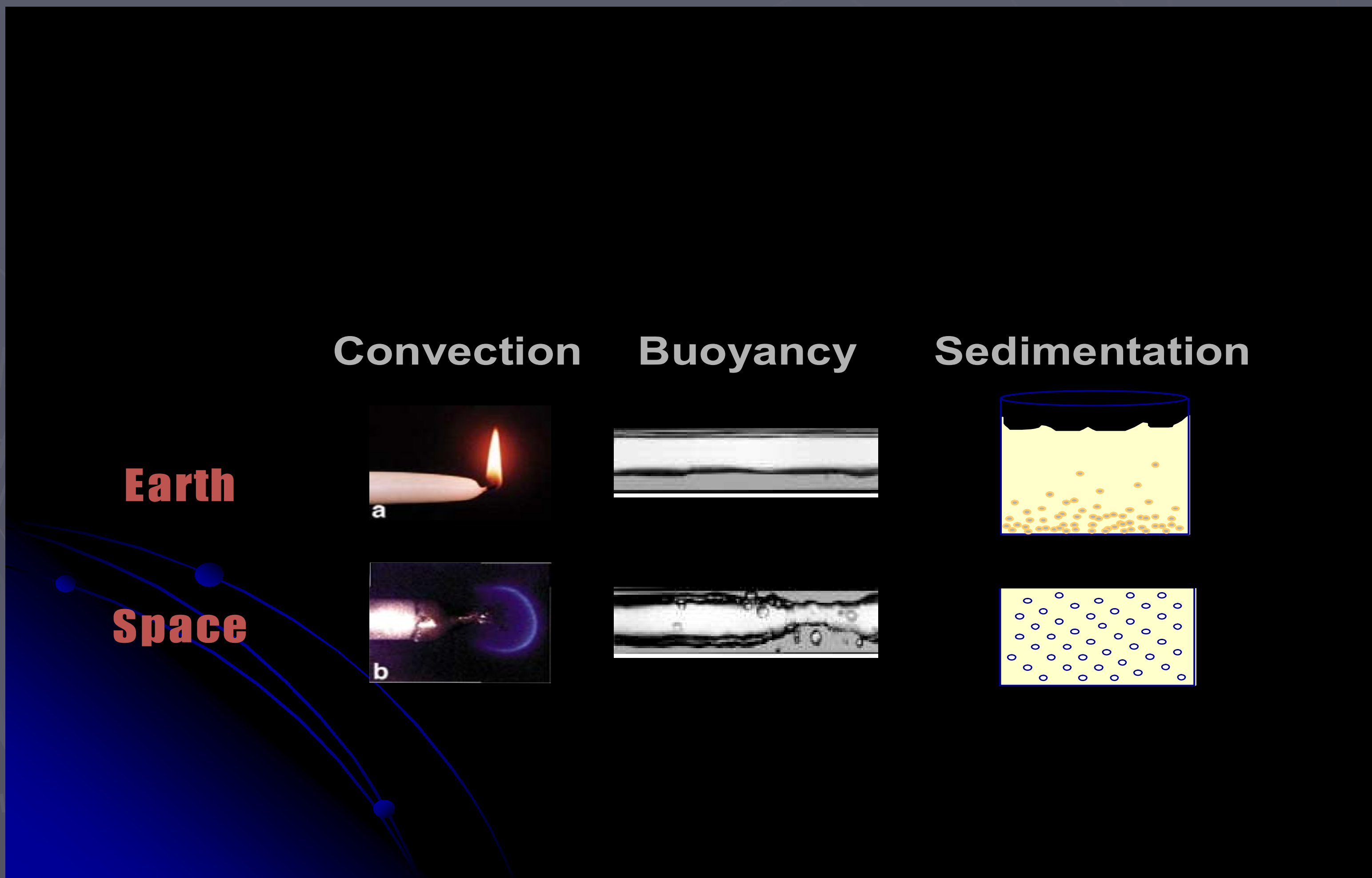
Human life beyond Earth's biosphere

- Reliance on technology
- Extended stay in microgravity presents health risks
  - Impact on genetic regulation---loss of "on/off" cues
  - "Use it or lose it" biological scenarios
  - Need to search for strategies to over ride regulation
- Need to develop ways to limit or prevent pathological changes
  - Entering gravity of another planet
  - Return to Earth---to acceleration force fields
- Must have a measure of self-sufficiency

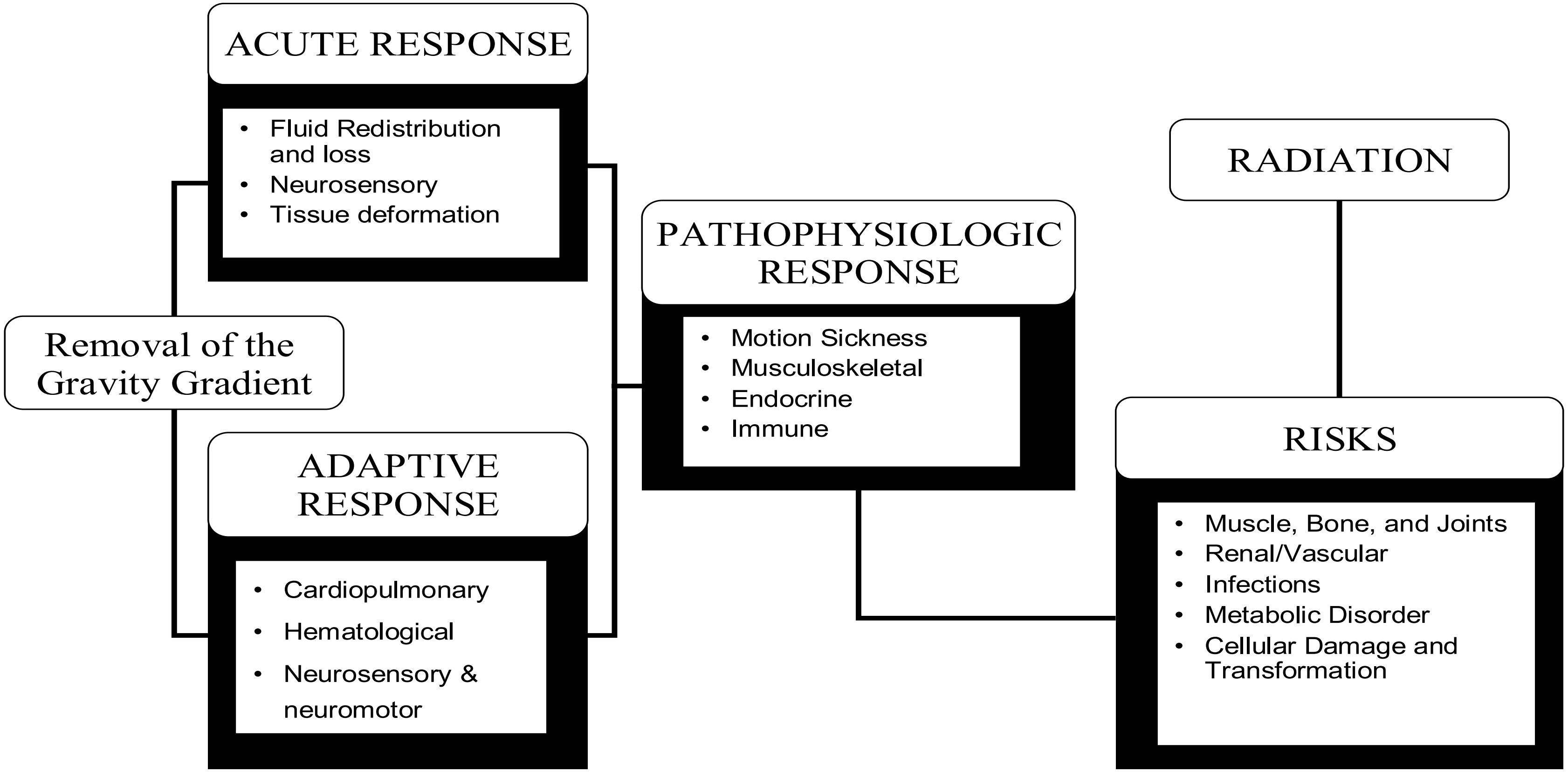
Destinations millions of miles from home:

- Communications not instantaneous
  - Example: 22 minutes for signal to travel one way from Mars to Earth
  - Communication lag increases with distance
  - Crews “on their own” for real time decisions
- Require provisions to treat accident and illness
- Scope and extent of medical support an unsettled question for continuing study—nationally and internationally
- Long duration experience is limited---to date (7/2006) 444 (996)   individuals on 249) missions

Physical Consequences og Removal of Gravity



Biological effects of the removal of the Earth's Gravity grasient



Exposure to space flight

(μg)

Acute Acclimatization

- **Losses**
  - Red blood cell mass
  - Total body fluids
- **Cardiovascular adjustments**
  - Baroreceptors response
  - Leg vessels capacitance
  - Heart Rate and Rhythm
- **Changes**
  - Pulmonary regional ventilation/perfusion
  - Neural sensory and motor control
  - Vestibulo – Ocular reflex
  - Neural Plasticity

Hypovolemic syndrome

Pathophysiological Responses

- **Bone & muscle mass loss**
- **Radiation biological effects**
  - **Stochastic (random)**
  - **Deterministic**
- **Additive responses to closed & confined environments**
  - Psycho/ socio-cultural
  - Performance
  - Immunological
  - Endocrine
  - Nutrition and metabolism

Chronic metabolic disorder

P0tential Countermeasures

Exposure to space flight

(µg)

Acute Acclimatization

Hypovolemic syndrome

Hydration
Tailored Diet
Physical condit. + αφγ
Low Fe diet
Prevention of neural plasticity changes:
- ***mechanical***
- ***pharmaceutical?***

Pathophysiological Responses

Chronic metabolic disorder

- ***Radiation protectants***
- ***Shielding***
- ***Physical condit. + αφγ***
- ***Anti osteo.+ anabolic medications?***

Return to Earth's gravity

- Neurosensory motor control dysfunction
- Diminished cardiovascular reserve
- Dehydration

Cardiovascular & neurological compromise

- **Regional osteopenia**
- **Decreased muscle endurance & strength**
- **Increased risks for**
  - **Radiation induced "bystander effect"**
  - **Kidney stone (s)**
  - **Immune compromise**

Latent asthenia and debilitation

American Society of Anesthesiologists Physical Status Classification Scale

Class 1	Healthy patient, no medical problems
Class 2	Mild systemic disease
Class 3	Severe systemic disease, but not incapacitating
Class 4	Severe systemic disease that is a constant threat to life
Class 5	Moribund, not expected to live 24 hours irrespective of operation

After Return to Earth

Cardiovascular & Neurological Compromise

Latent asthenia & debilitation

Rehabilitation and Supporting Rx (psychosocial readaptation)

Countermeasures

- **Soviet/Russian**
  - Hydration
  - Seat lining
  - Karkas
  - Penguin Suits
  - Chibis
  - Bracelet
  - Cuban Boot (Cuba)
  - Physical conditioning
  - Electromyostimulation

  PHYSICAL

  - Herbal Teas (Vietnam)
  - Biofeedback+ Relaxation
  - Nutrition

- **NASA**
  - Hydration+Salt
  - Anti-g Suit
  - Prometazine
  - Nutrition
  - Isometric+Isotonic* +aerobic conditioning
  - Potential new Rx
    - Midodrine
    - Diphosphonate class
    - Radioprotectants

IOM Risk Identification Process

- Hazard identification
- Dose response estimation
- Exposure level
- Risk characterization

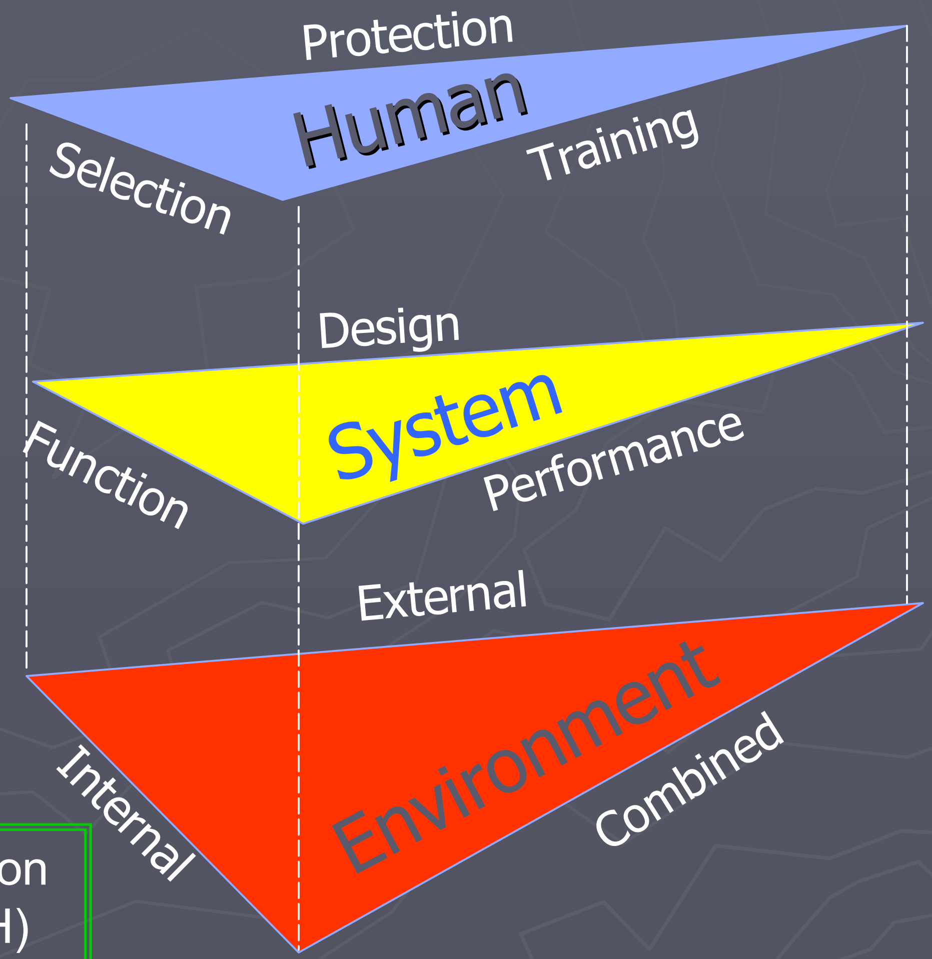
Proposed Risk Assessment Algorithm

- Given:
  - Human risk (**RH**);
  - Exploration System risk (**RT**);
  - Exploration Environ. occupational risk (**RE**)*
  - Combined risk **(RA)**

The risk to humans can be represented by

RA = (RE + RT) x (UF)**

*RH = Susceptibility/Control Population
RE= Exposure x Duration x S/P (RH)
RT = Threat x Vulnerability x Criticality



**UF = Uncertainty Factor

Types of Risks and Quantification

- **Managed**: a risk which is continuously monitored with the intent to intervene with administrative, financial, or technical actions if the risk exceeds the set limits
- **Acceptable**: a risk which cannot be eliminated, politically and budgetary driven, and subject to either efficiency (Type II reliability) or effectiveness (Type I reliability) (36)
- **Tolerable**: a risk which can be eliminated, but at a significant cost, and is subject to political opinions and decisions
- **ALARA:** as low as reasonably achievable means whatever is technologically or scientifically feasible to reduce the risk at the time of implementation.

- **None**: no known risks
- **Low**: small probability of life threatening events
- **Medium**: probability of injury or disease which can be life threatening
- **High**: significant probability of death, injury, or disease
- **Catastrophic**: loss of life or significant impairment
- **Unknown**: unquantifiable risk which can range from 0 to ∞**None** (0)

  - **Low** (1)
  - **Moderate** (2)
  - **High** (3)
  - **Catastrophic** (4)
  - **Unknown** (5)

Risks

- Risks presented by limited skills and/or resources
  - Consumables provision, logistics and availability
  - Scientific- and experience-based knowledge
  - Limitations of the expedition capabilities (people, technology and systems) and self imposed mission constraints

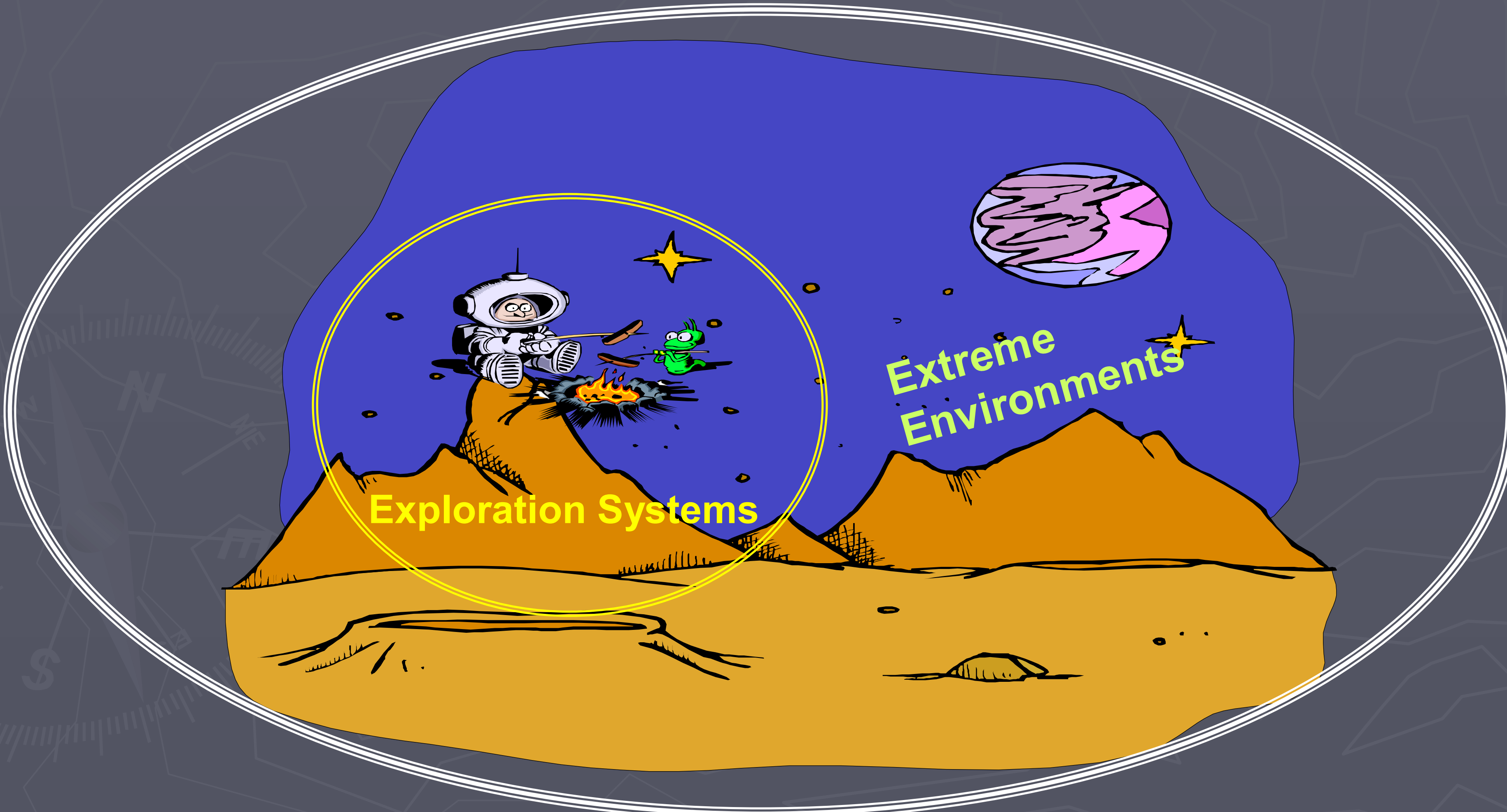
Technological Adaptation: Assumptions

- "Technological Adaptation" is a substitute for physiological adaptation for rapid human insertion and operation in extreme environments
- Properly engineered environments protect crews and assure successful achievement of mission goals
- Technology should
  - Extend the human reach
  - Be human centered
  - User friendly
  - Have high reliability, redundancy and require minimal maintenance (self diagnosing, self repairing, protective)
- Humans should be managers of technology and not the other way around

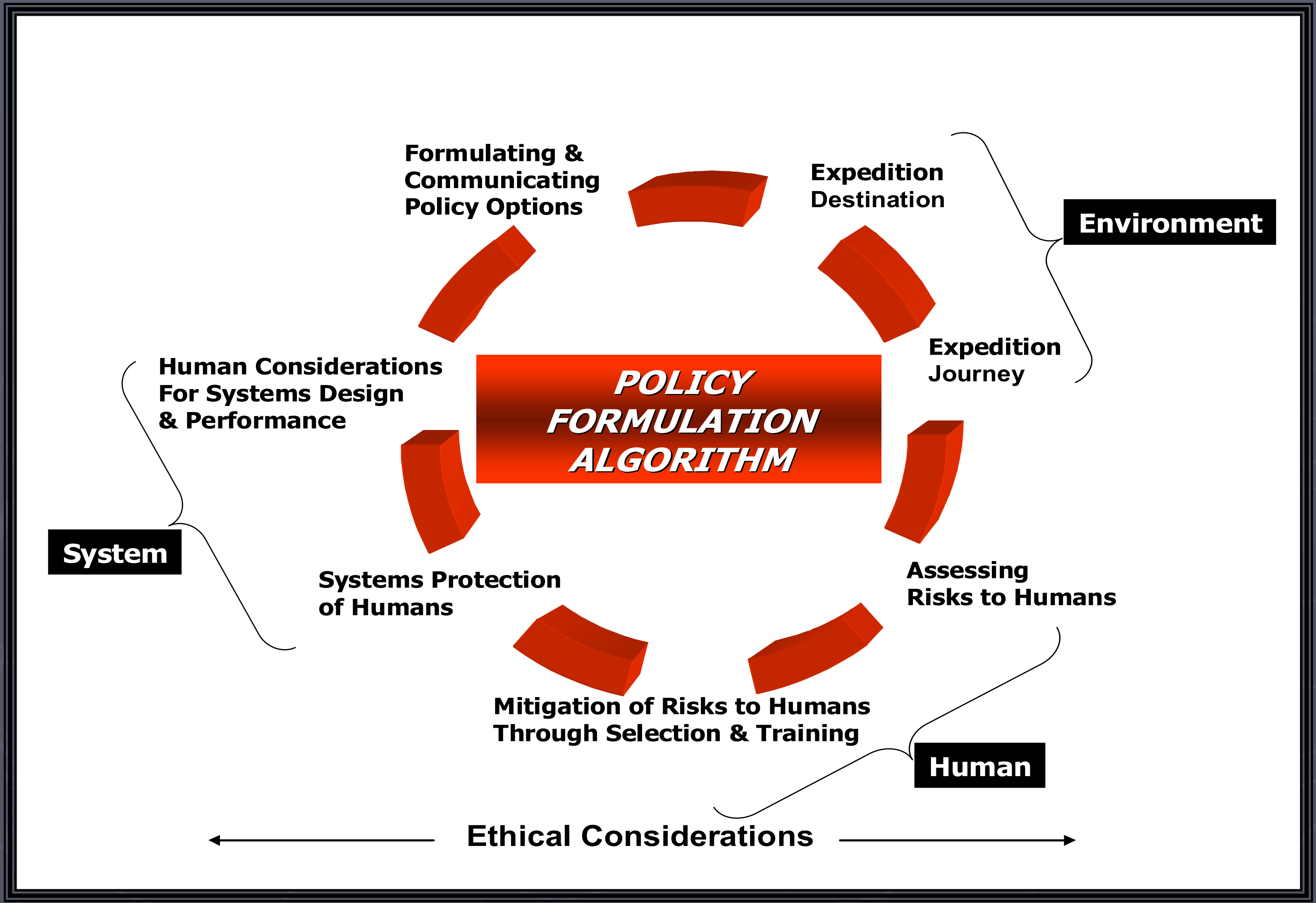
Human Exploration Systems should incorporate Human Factors and "Space Ergonomics"

Technology Role in Human Exploration

Noble Principle: **Human Exploration Systems will Protect and Enable**



Policy Formulation Process



Economic Implications in Recommending Health Policy Options

- **Approach**
  - Health maintenance
  - Prevention
  - Medical Care
- **Impacts**
  - **Long timeframe + cost effective**
  - **Moderate timeframe+ affordability**
  - **Near term + costly**

Medical Policy Recommendation

Management Decision	Medical Policy Recommendation: "Yes"	Medical Policy Recommendation: "No"
"No"	**Type II Error** **Resources Wasted Increased Health and/or Safety Risk**	***Converging Decisions*** *Illness & Injury Avoided*
"Yes"	***Converging Decisions*** *Health Risk Mitigated*	**Type I Error** **Increased Probability for Injury and/or Illness**

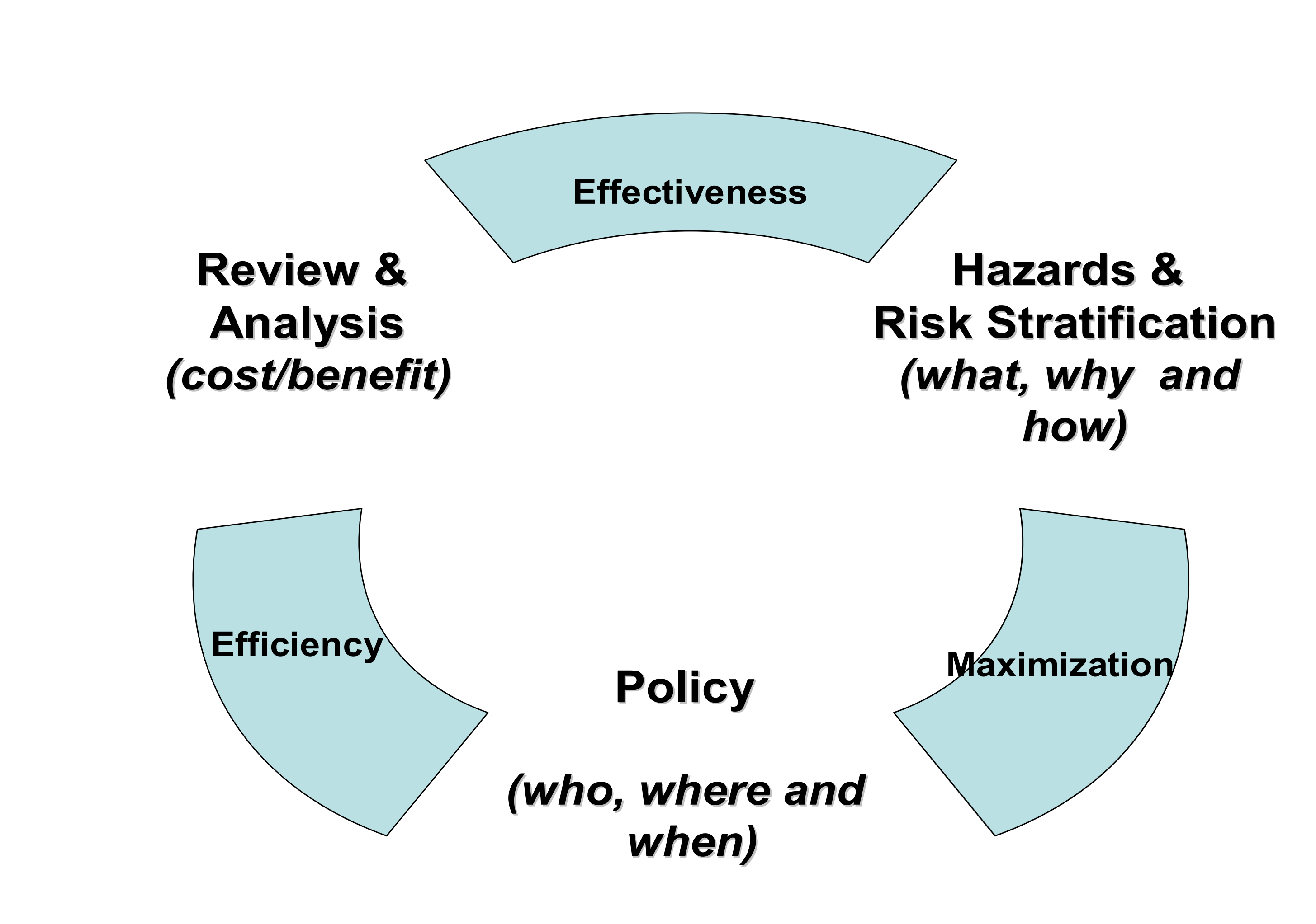
Type I Error impacts Reliability
Type II Error relates to Efficiency

Bioethical Principles in Scarce Resource Allocation

- **General**
  - ***Justice***
  - ***Priority to the worst off***
  - ***Fair Shares***
  - ***Equity***
  - ***Maximization***

- **Space Exploration**
  - ***Maximization***
  - ***Equity***

Ethical Considerations



Conclusions

- *A dialogue with the stakeholders and the public should be continued in a proactive fashion to educate and inform about the risks and benefits of the space exploration with humans.*
- *Potential scenarios and evidence-based outcomes should be researched, catalogued and disseminated to assess the level of expectations and risk acceptability by the stakeholders and the public.*
- *Transparency and accountability to the public should be enhanced to continue garner public support*
- *The determination and clarification of regulations governing NASA health and safety programs on Earth i.e. FDA rules for use of medications or OSHA workplace health and safety practices, should also be addressed and applied to the space exploration as appropriate*

Conclusions (Ethics)

- *Developing medical policies addressing loss of life*
- *Triage and amelioration of suffering in a situation of constrained medical resources*
- *Integrating engineering and medical ethics during the planning and design phases of space exploration missions*
- *Allocating resources to ensure preservation of health and wellbeing of the explorers*
- *Developing clear understanding of medical lines of authority and inclusion of medical personnel as crew members for exploration missions*
- *Regular briefings of the crews and families about mission risks*
- *Recognition that exploration missions medical care will be limited and some injuries and illnesses will not be treatable.*