



Risk Assessment and Integration Team (RAIT) Portfolio Risk Analysis Strategy

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Objective

- Describe the NASA Human Research Program Risk Assessment and Integration Team's approach to utilizing Probabilistic Risk Assessment techniques in providing risk management information to its customers.



Outline

- Section 1
 - Approach in utilizing a qualitative risk assessment to provide risk management information.
- Section 2
 - Future utilization of quantitative risk assessment towards the development of risk mitigation strategies.



Human Research Program Goal

- From Section 1.1 of Human Research Program's Program Plan dated June 1, 2006
 - “The Human Research Program (HRP) was formed in September 2005 at the Johnson Space Center (JSC) in response to NASA's decision to move human research program management from Headquarters Exploration Systems Mission Directorate (ESMD) to JSC and to **focus its research investment** on **investigating and mitigating the highest risks** to astronaut health and performance in support of exploration missions.”



Section 1

UTILIZING A QUALITATIVE RISK ASSESSMENT TO PROVIDE RISK MANAGEMENT INFORMATION



Focusing Research Investment

- Presumably, HRP will decide how to “focus research investment” based on the following criteria:
 - Risk Criticality*
 - Risk Priority*

*Human Research Program Integrated Research Plan, Revision A, January 2009 (IRP)



Criticality

- “Programmatic” Criticality
 - WHAT tasks are necessary to fill knowledge gaps
 - WHEN those tasks will be accomplished
 - WHERE the tasks will be accomplished
 - WHO will accomplish these tasks
 - WHAT results are being produced by task accomplishment



Criticality

- “Operational Criticality”*
 - “The degree to which the risk would cause a vote of ‘no-go’ for undertaking a mission.” (Kundrot)
 - Three levels of Operational Criticality
 - **Critical** to quantify or reduce prior to the Lunar Outpost or Mars Missions
 - **Important** to quantify and reduce prior to the Lunar Outpost or Mars Missions
 - **Desirable** to quantify and reduce prior to the Lunar Outpost or Mars Missions

*NOTE: “Operational” Criticality is not an industry standard term. It only has relevance within the context of RAIT’s analyses.



Criticality

- Operational Criticality and Programmatic Criticality work together.
 - “Ultimately, assessment of the criticality is based on
 - the likelihood and consequence of the risks,
 - the gaps, and
 - the tasks,
 - coupled with the uncertainty in risk projections.
 - Assessment involves integration and comparison of risk factors and the impact each task may have on the reduction of the overall risk to the mission or the crew, given different mission scenarios, research approaches, and outcomes.” (IRP, Jan. 2009)



Priority

- “The criticality of a risk for either a Lunar or a Mars mission alone is not sufficient to determine the optimum level of activity (or budget) or timing for research investments.
- Other factors combine to determine the research approach, such as
 - limited availability (of certain necessary resources like the Space Shuttle and the ISS),
 - exceptionally long lead times (needed to improve understanding and mitigation of radiation risks), or
 - the amount of risk reduction that can be obtained with a specific set of resources.” (IRP, Jan. 2009)



Priority

- The Risk Management and Assessment Tool (RMAT) is [eventually] intended “...to categorize and document the assessment of the risks and to document [risk] priority.” (IRP, Jan. 2009)
- NOTE: Priority assessment not addressed in this presentation.



Assessing Criticality

- RAIT's current focus is to provide HRP with risk management information utilizing Operational Criticality as a cornerstone.
 - Programmatic Criticality not currently being addressed by RAIT.



Assessing Criticality

Operational Criticality Domains*

*Excerpt from HRP Program Plan, Risk Management Plan Section

HRP-47051
Baseline

Table E-1. Consequence Criteria Matrix for Assessment of HRP Risks

| Classification | | Consequence Criteria | | | |
|----------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| | | Safety | Schedule | Cost | Technical |
| 5 | Very High | Condition may lead to death or permanent disabling injury, facility destruction, or loss of crew, major systems or vehicle | Slip in delivery to the flight program, slip in delivery of major system or subsystem beyond 6 months of milestone schedule | ≥10% increase to HRP budget allocation | Loss of mission |
| 4 | High | Condition may cause severe injury or occupational illness, or major property damage to facilities, systems, equipment or flight hardware. | Delay of > 5 month ≤ 6 month for deliverables from milestone schedules | ≥ 8% but < 10% increase to budget allocation | Loss of critical function or major science objective |
| 3 | Moderate | Condition may cause minor injury or occupational illness, or minor property damage to facilities, systems, equipment or flight hardware. | Delay of > 3 months < 5 months for deliverables from milestone schedules | >5% but <8% increase to budget allocation | Inability to meet power, weight, size and/or performance requirements; major science objectives not fully met |
| 2 | Low | Condition may result in minor first aid though would not adversely affect personal safety or health. Subjects facilities, equipment or flight | Delay of > 1 month ≤ 3 month for deliverables from milestone schedules | < 5% increase to budget allocation | Loss of design margins, some desired science objectives not met; some desired technical performance not completely met |
| | | or facilities | for deliverables from milestone schedules | Small impact to budget allocations | Small impact to design margins |

Assessment of Operational Criticality is dependent the impact of Safety Risk and Technical Risk



Assessing Criticality

- Operational Criticality (Safety and Technical Risk) concerns:
 - Astronaut health and safety during a mission (Short Term Health (STH))
 - Accomplishing mission objectives (In Mission Performance (IMP))
 - Astronaut health and safety after a mission (Long Term Health (LTH))



Assessing Criticality

Safety and Technical Risk – Consequence Definitions

| Classification | | Consequence Criteria | | |
|----------------|-----------|----------------------------------------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| | | Short Term Health | In-Mission Performance | Long Term Health |
| 5 | Very High | Death (LOC) or in-mission disabling injury | Contingency Abort (LOM) | Permanently disabling injury or illness, unable to correct or compensate; premature death |
| 4 | High | Injury, illness, incapacitation or impairment, could be serious enough to lead to evacuation | Failure to achieve major mission objectives | Disability or occupational illness, partially corrected, partially compensate |
| 3 | Moderate | Injury, illness or incapacitation, may affect personal safety or health | Moderate impact to operations, workarounds available | Disability or occupational illness, partially corrected, able to compensate |
| 2 | Low | Injury requiring treatment, does not affect personal safety or health | Minor impact to operations, workarounds available | Disability or occupational illness, can be corrected with terrestrial advances in treatment and/or surgery to approximate pre-flight condition |
| 1 | Very Low | Injury not requiring treatment | Negligible impact to mission operations/objectives | Disability is short term |



Assessing Criticality

- Question 1:
 - How can we provide a qualitative assessment of a risk topic's safety and technical risk profile?
- Question 2:
 - What decision rules will be used to correlate the qualitative assessment with the three Operational Criticality categories (Critical, Important, Desirable)?
- Question 3:
 - How do we display the Operational Criticality status of all HRP risks at once?



Assessing Criticality – Question 1

- In order to determine a risk topic's safety and technical risk profile, HRP must include the following considerations
 - *Consequence* that the risk may cause,
 - *Likelihood* that the risk may cause the corresponding Consequence, **and**
 - *Severity* of the risk
- A 5x5 matrix can be used to qualitatively provide this information.



Assessing Criticality – Question 1

- LxC Mapping Guidelines
 - Identify the adverse outcome from the risk topic's risk statement given the currently available mitigation strategies.
 - In all risk statements, the adverse outcome should be the reasonable and immediate outcome(s) of the risk event (i.e. the event we would like to prevent).
 - Determine what the adverse outcome's consequence level (i.e. level 5, 4, 3, 2, 1) is for each consequence category (STH, IMP, LTH)
 - *At present, we are asking for the most reasonable and immediate consequence that their adverse outcome represents. In general however, a set of rules and assumptions needs to be developed and clearly stated in order to enable discipline area scientists to map their risk's adverse outcome to a particular consequence level.*
 - Estimate the likelihood range (i.e. range 5, 4, 3, 2, 1) for each risk topic's adverse outcome
 - Provide this mapping for each mission profile (Lunar, and Mars)₁₈



Assessing Criticality – Question 1

- LxC Mapping Guidelines
 - Example Risk Statements
 - *Risk of Adverse Behavioral Conditions*
 - Given the extended duration of future missions and the isolated, extreme and confined environments, there is a possibility that *adverse behavioral conditions will occur.*
 - *Risk of Bone Fracture*
 - Given that crewmembers may experience high impact forces and/or decrease in bone strength, there is the possibility that *fracture may occur.*
 - *Risk of Radiation Carcinogenesis*
 - Given that crewmembers are exposed to radiation from the space environment, there is a possibility for *increased cancer morbidity or mortality.*



Assessing Criticality – Question 1

- LxC Mapping Guidelines
 - Example Risk Statements
 - *Risk of Crew Adverse Health Event Due To Altered Immune Response*
 - Given that the spaceflight environment results in an alteration of the immune system there is a possibility that the *crew will have an increased susceptibility to certain disease states.*
 - *Risk of Cardiac Rhythm Problems*
 - Given the condition of microgravity, there is a possibility that *cardiac rhythm disturbances may occur.*
 - *Risk of Reduced Safety and Efficiency Due to Inadequately Designed Vehicle, Environment, Tools or Equipment*
 - Given the condition of poor human factors design of physical and cognitive work environments, there is a possibility of *ineffective or inefficient crew performance.*



Assessing Criticality – Question 1

- LxC Mapping Examples
 - Bone Fracture Risk Topic
 - The adverse event, as stated in the risk statement is “fracture”.
 - Assume this fits in consequence level 4 (for the currently available mitigation strategies).
 - “Injury, illness, incapacitation or impairment, could be serious enough to lead to evacuation”
 - Assume the estimate for the likelihood of “fracture” for a Lunar mission is in the **Very Low** likelihood range.



Assessing Criticality – Question 1

Lunar Mission STH LxC Mapping for Fracture

| Likelihood | Range | | | | | |
|----------------|--------------------|---------------|----------|---------------|-----------|----------------|
| 5 Very High | >10% | | | | | |
| 4 High | 1%-10% | | | | | |
| 3 Moderate | 0.1%-1% | | | | | |
| 2 Low | 0.01%-0.1% | | | | | |
| 1 Very Low | <0.01% | | | | ✘ | |
| | Consequence | 1 Very Low | 2 Low | 3 Moderate | 4 High | 5 Very High |



•**Example of Bone Fracture Mapping**

- Consequence Level: 4**
- Likelihood Range: 1**



Assessing Criticality – Question 1

- LxC Mapping Examples
 - Cardiac Rhythm Problems
 - The adverse event as stated in the risk statement is “cardiac rhythm disturbances”.
 - Assume this fits in consequence level 5 (for the currently available mitigation strategies)
 - “Death (LOC) or in-mission disabling injury”
 - » Although not explicitly stated as such, we assume that “cardiac rhythm disturbances” means a heart attack. If simply means rhythm fluctuations rather, the consequence would not be level 5; perhaps level 3.
 - Assume the estimate for the likelihood of “cardiac rhythm disturbances” for a Lunar mission is in the **Moderate** likelihood range.



Assessing Criticality – Question 1

Lunar Mission STH LxC Mapping for Disrhythmia

| Likelihood | Range | | | | | |
|----------------|-------------|---------------|----------|---------------|-----------|----------------|
| 5 Very High | >10% | Green | Yellow | Red | Red | Red |
| 4 High | 1%-10% | Green | Yellow | Yellow | Red | Red |
| 3 Moderate | 0.1%-1% | Green | Green | Yellow | Yellow | Red with X |
| 2 Low | 0.01%-0.1% | Green | Green | Yellow | Yellow | Yellow |
| 1 Very Low | <0.01% | Green | Green | Green | Green | Yellow |
| | Consequence | 1 Very Low | 2 Low | 3 Moderate | 4 High | 5 Very High |



- Example of Cardiac Rhythm Problems Mapping
- Consequence Level: 5
- Likelihood Range: 3



Assessing Criticality – Key Points

- In order to utilize LxC mapping on a 5x5 matrix in a tenable manner, the following needs to occur
 - Explicit identification of the adverse outcome described in each risk statement
 - Confirmation by discipline area scientists on which consequence level (for each of STHH, IMP, & LTH) their adverse outcome represents
 - Requires a clearly stated set of rules and assumptions
 - Decision on what likelihood range represents a reasonable probability of occurrence of their adverse outcome for each mission profile (Lunar, Mars)



Assessing Criticality – Incorporating Severity

- Severity – “*intensity or sharpness, as of cold or pain*” (www.dictionary.com)
- Severity is a subjective measure of the overall level of detriment posed by a risk.
- Severity is inherently depicted in a 5x5 matrix.
 - See explanation of derivation of 5x5 matrix in Appendix B of [APR 8000.4](#)



Assessing Criticality – Incorporating Severity

| Likelihood | Range | | | | | |
|----------------|-------------|---------------|----------|---------------|-----------|----------------|
| 5 Very High | >10% | | | | | H |
| 4 High | 1%-10% | | | | | H |
| 3 Moderate | 0.1%-1% | | | | | |
| 2 Low | 0.01%-0.1% | L | | | | |
| 1 Very Low | <0.01% | | | | | |
| | Consequence | 1 Very Low | 2 Low | 3 Moderate | 4 High | 5 Very High |

•The Severity level of a risk is determined by resultant mapping it's LxC scoring produces.

•Severity Classification:

- High – Red
- Medium – Yellow
- Low – Green



Assessing Criticality – Question 2

- Decision Rules on Operational Criticality Scoring
 - Map Severity ranking directly to Operational Criticality ranking
 - Critical = High Severity
 - Important = Medium Severity
 - Desireable = Low Severity



Assessing Criticality – Question 2

- Decision Rules on Operational Criticality Scoring
 - If a risk’s LxC scoring identifies it’s potential impact as “High Severity”, then
 - it is “Critical to quantify or reduce [the risk] prior to the Lunar Outpost or Mars Missions”.
 - If a risk’s LxC scoring identifies it’s potential impact as “Medium Severity”, then
 - it is “Important to quantify and reduce [the risk] prior to the Lunar Outpost or Mars Missions”.
 - If a risk’s LxC scoring identifies it’s potential impact as “Low Severity”, then
 - it is “Desirable to quantify and reduce [the risk] prior to the Lunar Outpost or Mars Missions”.



Assessing Criticality – Question 2

| Likelihood | Range | | | | | |
|----------------|-------------|---------------|----------|---------------|-----------|----------------|
| 5 Very High | >10% | | | | | C |
| 4 High | 1%-10% | | | | | |
| 3 Moderate | 0.1%-1% | | | | | I |
| 2 Low | 0.01%-0.1% | | | | | |
| 1 Very Low | <0.01% | | | | | |
| | Consequence | 1 Very Low | 2 Low | 3 Moderate | 4 High | 5 Very High |

•Operational Criticality now linked to outcome of qualitative assessment of risks using 5x5 matrix.



Assessing Criticality – Question 3

- Displaying the result of qualitative assessment of Operational Criticality
 - HRP has a “portfolio” of 27 risks.
 - All risks have a research team hoping to receive funding.
 - HRP customers (NASA Space and Life Sciences Directorate and Office of the Chief Medical Officer (OCHMO)) needs a “snapshot” of Operational Criticality in order to help with program management decisions.



Assessing Criticality – Question 3

- Operational Criticality Display Development
 1. Aggregate all 5x5 matrices into an Operational Criticality Table (OCT).
 2. Prepare a weighted Operational Criticality Score (OCS) for each risk.
 3. Plot all OCS scores.



Assessing Criticality – Question 3

1. Operational Criticality Table*

| Risk/Risk Factor of: | Lunar Consequences | | | Martian Consequences | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----|-----|----------------------|------|------|
| | STH | IMP | LTH | STH2 | IMP2 | LTH2 |
| Acute or Late Central Nervous System Effects from Radiation Exposure | I | I | I | C | C | C |
| Inability to Adequately Treat an Ill or Injured Crew Member | I | I | D | C | C | D |
| Behavioral and Psychiatric Conditions | D | D | D | C | C | D |
| Inadequate Nutrition | D | D | D | C | C | D |
| Inadequate Food System | D | D | D | C | C | D |
| Radiation Carcinogenesis | D | D | C | D | D | C |
| Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity | D | I | D | D | C | D |
| Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance | D | I | D | D | C | D |
| Degenerative Tissue or other Health Effects from Radiation Exposure | D | D | I | D | D | C |
| Acute Radiation Syndromes Due to Solar Particle Events | I | I | D | I | I | D |
| Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems | D | I | D | I | I | D |
| Intervertebral Disc Damage | D | D | D | I | I | D |
| Cardiac Rhythm Problems | D | D | D | I | I | D |
| Orthostatic Intolerance During Re-Exposure to Gravity | D | D | D | I | I | D |
| Crew Adverse Health Event Due To Altered Immune Response | D | D | D | I | I | D |
| Therapeutic Failure Due to Ineffectiveness of Medication | D | D | D | I | I | D |
| Adverse Health Effects Due to Alterations in Host-Microorganism Interactions | D | D | D | I | I | D |
| Performance Errors Due to Poor team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation | D | D | D | D | I | D |
| Accelerated Osteoporosis | D | D | D | D | D | I |
| Impaired Ability to Maintain Control of Vehicles and Other Complex Systems | D | D | D | D | I | D |
| Reduced Safety and Efficiency Due to Poor Human Factors Design | D | D | D | D | I | D |
| Associated with Poor Task Design | D | D | D | D | I | D |
| Error Due to Inadequate Information | D | D | D | D | I | D |
| Adverse Health Effects from Lunar Dust Exposure | D | D | I | | | |
| Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload | D | D | D | D | D | D |
| Bone Fracture | D | D | D | D | D | D |
| Renal Stone Formation | D | D | D | D | D | D |

*NOTE: Scoring is illustrative only and does not represent official NASA Operational Criticality scoring.



Assessing Criticality – Question 3

2. Operational Criticality Weighting

| | Weighting | | | | | |
|------------------|-----------|------|------|---------|------|------|
| | Lunar | | | Martian | | |
| | STH | IMP | LTH | STH | IMP | LTH |
| Critical | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| Important | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| Desirable | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |

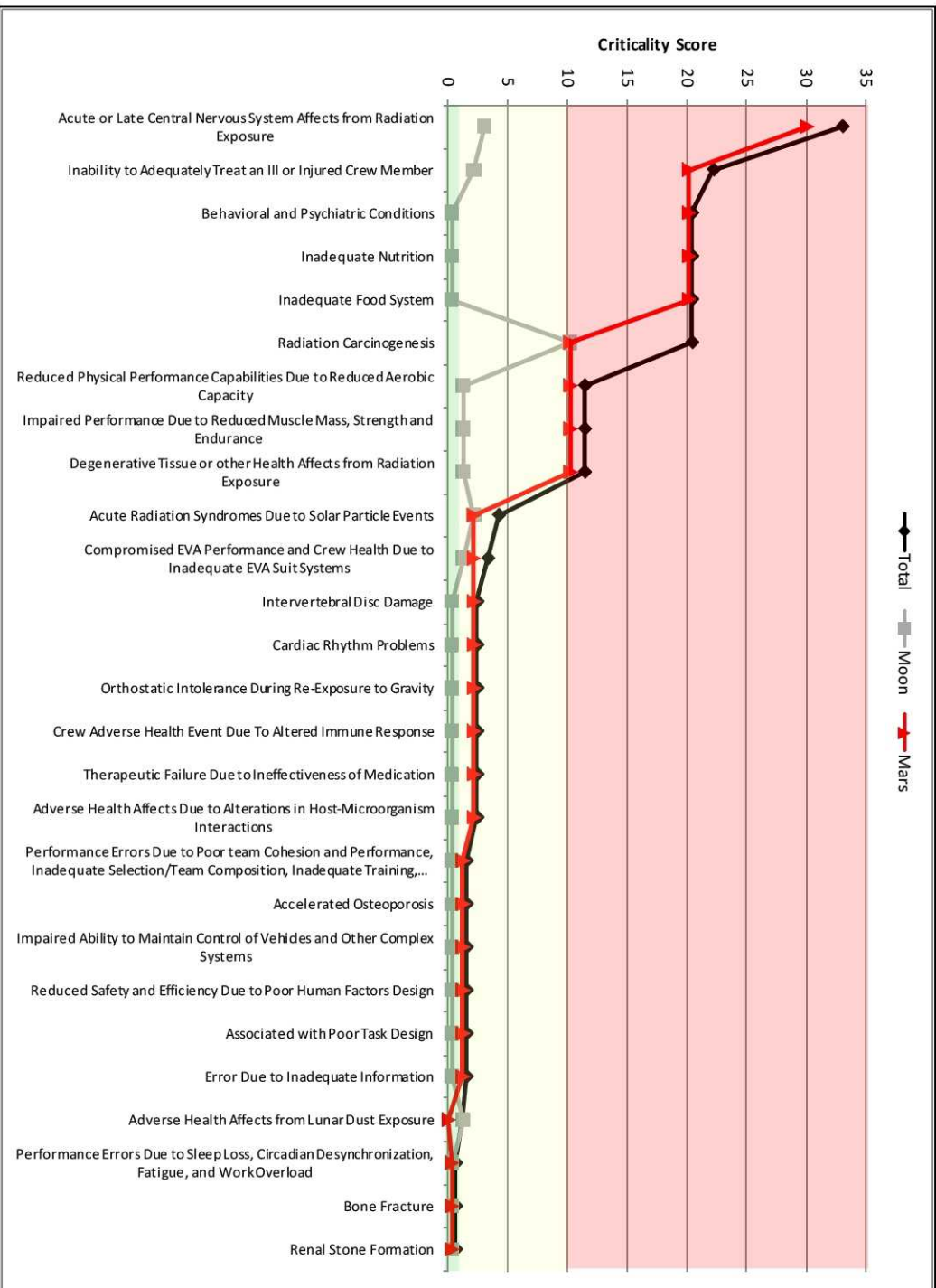
- The OCS, for each risk is the sum of weights over each mission type (Lunar and Martian) and consequence type (STH, IMP, and LTH).
- For example, the OCS of the risk of inability to treat an ill or injured crew member is $1 + 1 + 0.1 + 10 + 10 + 0.1 = 22.2$



Assessing Criticality –

Question 3

3. Operational Criticality Chart





Assessing Criticality – Question 3

- The OCS allows risks to be rank ordered based on:
 - Their relative importance to the missions (Lunar or Martian)
 - Their level of imposed safety and technical risk (STH, IMP, LTH).
 - NOTE: Arithmetic operations on the OCS (e.g., addition, multiplication) to calculate quantities such as averages are not meaningful.



"The Qualitative Big Picture"

Lunar – STH Matrix

Lunar – LTH Matrix

Martian – IMP Matrix

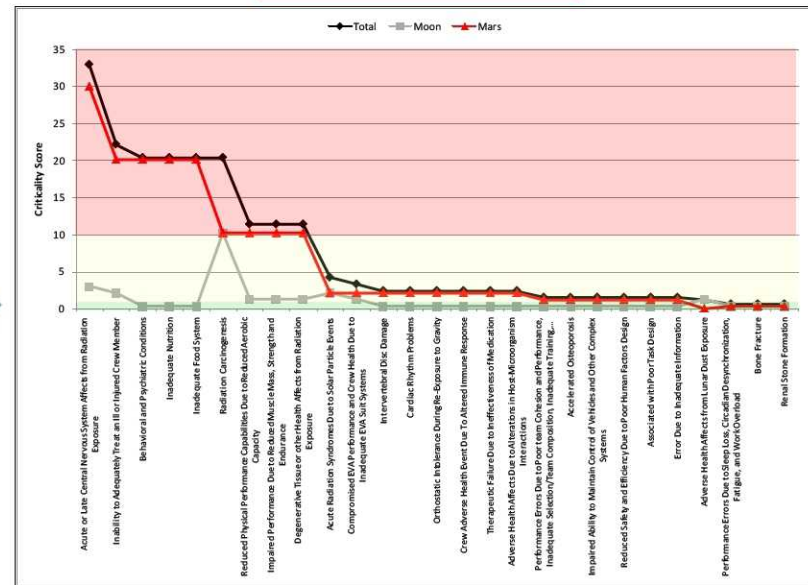
5x5 Matrices for Each Risk Per Consequence

Criticality Keyed to Severity

OCS Chart

Operational Criticality Table

| Risk/Risk Factor of: | Lunar Consequences | | | Martian Consequences | | |
|-----------------------------------------------------------------------------------------------|--------------------|-----|-----|----------------------|------|------|
| | STH | IMP | LTH | STH2 | IMP2 | LTH2 |
| Acute or Late Central Nervous System Effects from Radiation Exposure | I | I | I | C | C | C |
| Inability to Adequately Treat an Ill or Injured Crew Member | D | D | D | C | C | D |
| Behavioral and Psychiatric Conditions | D | D | D | C | C | D |
| Inadequate Nutrition | D | D | D | C | C | D |
| Inadequate Food System | D | D | D | C | C | D |
| Radiation Carcinogenesis | D | D | C | D | D | C |
| Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity | D | I | D | D | C | D |
| Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance | D | I | D | D | C | D |
| Degenerative Tissue or other Health Effects from Radiation Exposure | D | D | I | D | D | C |
| Acute Radiation Syndromes Due to Solar Particle Events | I | I | D | I | I | D |
| Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems | D | I | D | I | I | D |
| Intervertebral Disc Damage | D | D | D | I | I | D |
| Cardiac Rhythm Problems | D | D | D | I | I | D |
| Orthostatic Intolerance During Re-Exposure to Gravity | D | D | D | I | I | D |
| Crew Adverse Health Event Due to Altered Immune Response | D | D | D | I | I | D |
| Therapeutic Failure Due to Ineffectiveness of Medication | D | D | D | I | I | D |
| Accelerated Osteoporosis | D | D | D | I | I | D |
| 35% Bone Loss Due to Inadequate Training and Poor Psychological Adaptation | D | D | D | I | I | D |
| Impaired Ability to Maintain Control of Vehicles and Other Complex Systems | D | D | D | I | I | D |
| Reduced Safety and Efficiency Due to Poor Human Factors Design | D | D | D | I | I | D |
| Associated with Poor Task Design | D | D | D | I | I | D |
| Error Due to Inadequate Information | D | D | D | I | I | D |
| Adverse Health Effects from Lunar Dust Exposure | D | D | I | D | D | D |
| Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload | D | D | D | D | D | D |
| Bone Fracture | D | D | D | D | D | D |
| Renal Stone Formation | D | D | D | D | D | D |





Summary – Section 1

- Qualitative assessment approach provides useful risk management information.
- Risk manager can:
 - view a “snapshot” assessment of the entire portfolio of risks and
 - use OCS Chart as a touch-stone in guiding the allocation of resources for the management safety and technical risks.
- The OCS alone cannot dictate funding priorities.
 - The cost per unit risk reduction and the timeframe in which the risk must be addressed are among the other factors that must be considered for funding priorities.



Section 2

PLANNED USE OF QUANTITATIVE RISK ASSESSMENT TOWARDS THE DEVELOPMENT OF RISK MITIGATION STRATEGIES



Objective

- Provide guidance to customers in utilizing quantitative risk assessment for development of risk mitigation strategies.



Assessment Context

- Section 1 allowed us to help risk managers develop the “investment policy” regarding a portfolio of risks.
 - “Investment policy” based on LxC mapping and Operational Criticality.



Assessment Context

- However, LxC mapping is based on the conditional probability of a worst-case/level 5 consequence and is independent of a risk's inherent probability of occurrence.
- We also seek to determine the inherent probability of occurrence of the adverse event(s) stated in each risk topic's risk statement.
- This information will assist discipline area researchers with the development of risk mitigation strategies.



Assessment Guidance

- Managers should identify the level of risk it is willing to tolerate for the probability of occurrence of each risk topic.
- For example:
 - The probability of traumatic bone fracture shall not exceed 1E-1 at the 95th percentile for any given mission.
 - The number disrhythmias shall not exceed 2 at the 95th percentile for any given mission.
 - The prevalence of human factors driven human error shall not exceed 1 in 30 at the 95th percentile for any given mission.
- The statement describing the level of risk tolerance is often called a Performance Measure (PM).
 - (often these PMs are set as program/project/design requirements)



Assessment Guidance

- The probability of occurrence per mission of each risk topic should be determined in order to identify how the risk topic stands relative to its PM.
- If the probability of occurrence of the risk topic is beyond its PM, researchers should develop mitigation strategies in an effort to achieve the PM requirement.



Section 2 Case Study

NOTIONAL QUANTITATIVE ASSESSMENT OF RENAL STONE RISK



Risk Statement

- “Given changes in urinary biochemistry during space flight, there is a possibility that symptomatic renal stones may form, resulting in urinary calculi or urolithiasis, renal colic (pain), nausea, vomiting, hematuria, infection, and hydronephrosis.”



Motivations for Simulation

- Traditional PRA approaches represent systems statically or at best quasi-dynamically even though many systems are continually evolving temporally.
- The state of human physiological systems change with time.
- In order to represent human systems using traditional PRA methods, we would need to string multiple models together.
- This cascade of multiple models pushes beyond the reasonable limits of current RAIT labor resources and computing power.



Simulation Model

- Scope Limitation
 - Assessment identifies an astronaut's propensity to form clinically relevant renal stones, rather than focusing on symptomatic renal stones.
 - Definition: a clinically relevant stone is one that grows to a size such that it blocks fluid flow in any section of the renal system.



Simulation Model

- Temporal Constraint: 1000 day mission
 - Captures a time frame similar to NASA's longest planned mission to date (Martian transit and return).
 - Likely to provide a worst-case scenario estimate of the risk since at this point RAIT assumes the longer the exposure to spaceflight conditions, the higher the likelihood of stone formation.



Simulation Model

- Assessment Metric
 - The probability that a clinically relevant renal stone exists during a 1000 day space mission.



Simulation Model

- Groundrule:
 - There are three main contributors to the formation of clinically relevant stones:
 1. Supersaturation of calcium in the renal system
 2. Presence of a nidus size (2 – 3 micron radius) uric acid crystal
 3. Growth rate of a nidus while transiting through the renal system



Simulation Model

- Key Features:
 - Once calcium supersaturation is reached, a generic countermeasure is applied.
 - The countermeasure reduces calcium concentration by 50% over 10 days.
 - The model is sensitive to whether an astronaut is a “stone-former”.



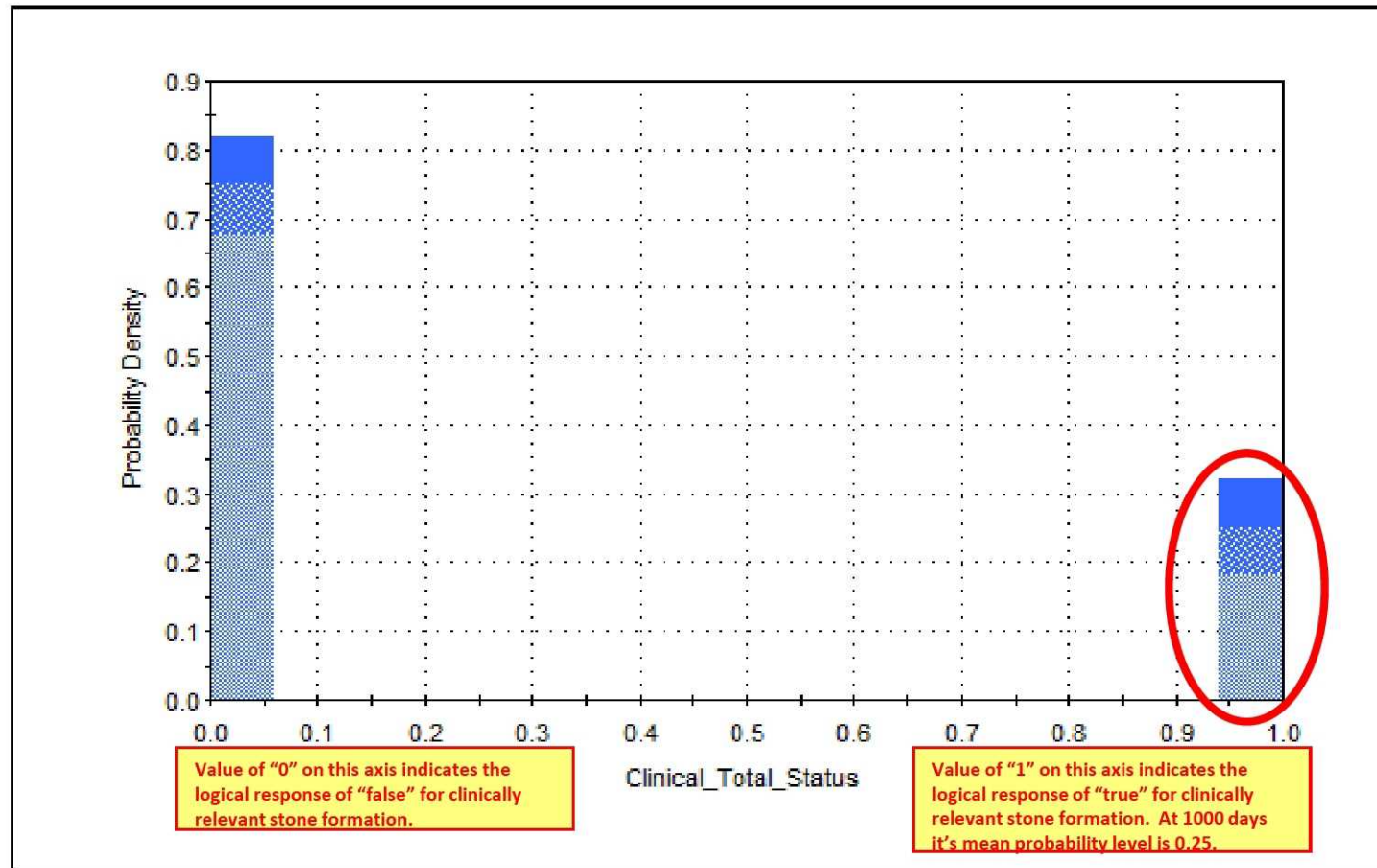
Simulation Model

- Simulation Milestone
 - If nidii reach clinically relevant size while travelling the length of the renal system, the model records the event as well as the number of times the event occurred.



Preliminary Results

Probability of Clinically Relevant Stone at 1000 Days

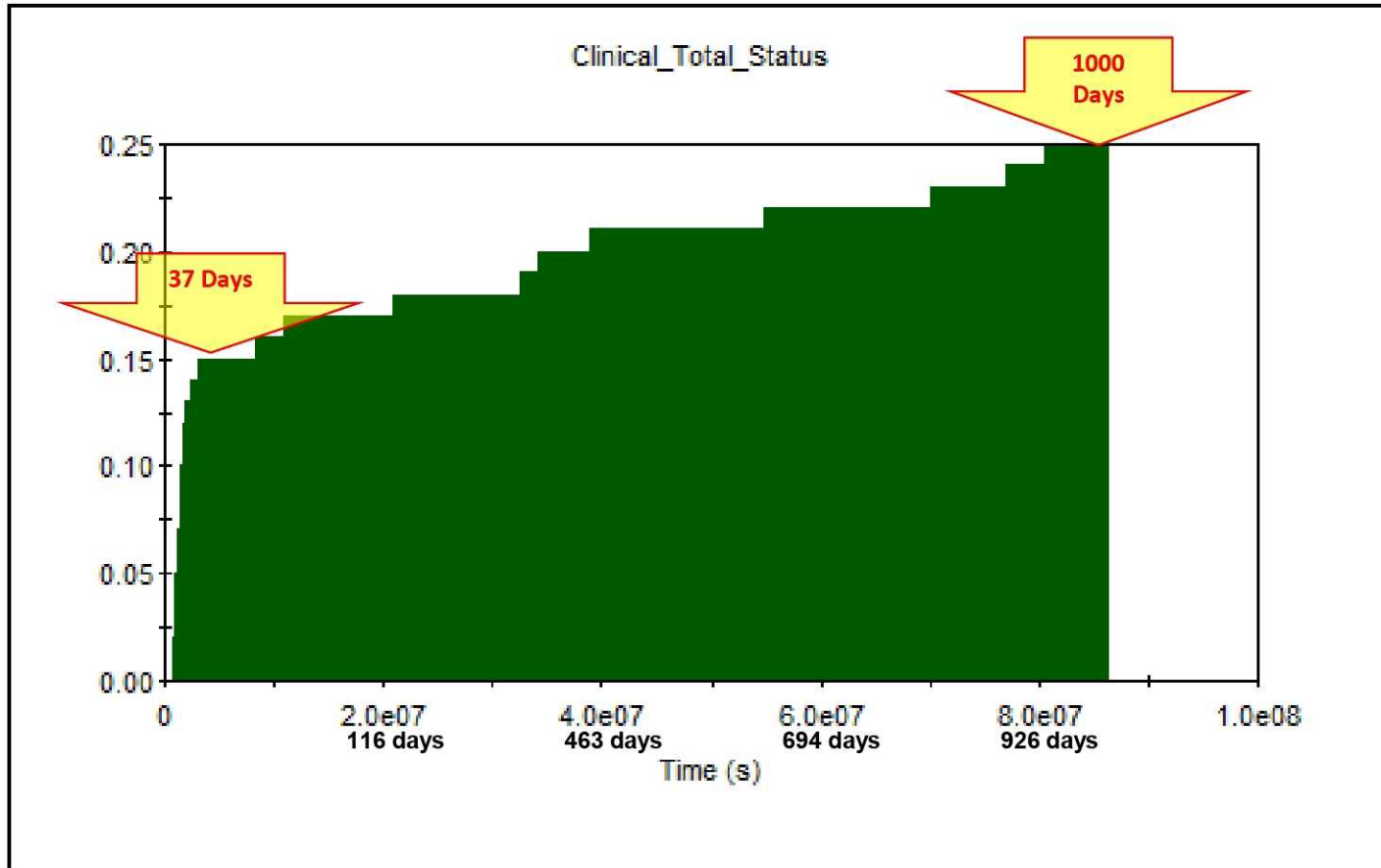


- By day 1000 of a mission, the mean probability that an astronaut will experience a clinically relevant renal stone is 0.25.
 - Ninety percent of the estimates for this probability value (i.e. the 5th to 95th percentile confidence interval) fall between the values of 0.18 and 0.32.



Preliminary Results

Time History of Clinically Relevant Stone



- **15% probability of clinically relevant stone by about day 37. Probability steadily increases to 25% by day 1000.**



Development of Mitigation Strategies

- Assumed PM:
 - *“Probability of clinically relevant stone shall not exceed 20% at any time during a 1000 day mission.”*
- Example Mitigation Options:
 - Develop better screening in order to only approve “non-stone formers” for flight.
 - Increase countermeasure effectiveness by:
 - Improving reduction in calcium concentration
 - Decreasing time delay for countermeasure to affect change
 - Change tolerance to risk by changing PM requirement.



Summary – Section 2

- Quantitative assessment approach provides useful risk mitigation information.
- Researchers and risk managers can:
 - Utilize quantification results in developing multiple strategies to achieving risk tolerance goals
- NOTE: it is vital to define PMs/requirements in order to capture tolerance for each risk being assessed.



Summary – Overall

- Impact at management level
 - Qualitative assessment of risk criticality in conjunction with risk consequence, likelihood, and severity enable development of an “investment policy” towards managing a portfolio of risks.
- Impact at research level
 - Quantitative risk assessments enable researchers to develop risk mitigation strategies with meaningful risk reduction results.