The Integrated Medical Model
A Risk Assessment and Decision Support Tool for Human Space Flight Missions

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Wyle Integrated Science and Engineering Group

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Integrated Medical Model (IMM)

A Risk Assessment and Decision Support Tool for Human Space Flight Missions

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Outline

• IMM Overview

• International Space Station Probabilistic Risk Assessment Update

• Validation

• Optimization
IMM Project Goals

• To develop an integrated, quantified, evidence-based decision support tool useful to NASA crew health and mission planners.

• To help align science, technology, and operational activities intended to optimize crew health, safety, and mission success.
What is IMM?

- A software-based decision support tool
  - Forecasts the impact of medical events on space flight missions
  - Optimizes the medical system within the constraints of the space flight environment during simulations.
Scope and Approach

IMM addresses in-flight risk using ISS data as a stepping stone

• Scope
  • Forecast medical outcomes for in-flight operations only
  • Forecast medical impacts to mission
  • Does not assess long-term or chronic post-mission medical consequences

• Approach
  • Use ISS data as stepping stone to Exploration Program
  • Employ best-evidence clinical research methods
  • Employ Probability Risk Assessment (PRA) techniques
  • Collaborate with other NASA Centers and Organizations
“What if…?” Questions

IMM is designed to help answer specific in-flight questions

Questions

• Is the current ISS medical kit adequate for a crew of 6 on a 6-month mission?
• Does a 33-day lunar sortie mission require a different Level of Care than a 24-day lunar sortie mission?
• Are we carrying enough Ibuprofen for a crew of six on a 12-month mission?
• How does risk change if the ventilator fails at the start of a 3-year mission?

Questions

• What is the probability of a bone fracture occurring 10 years after a 6-month mission?
• What is the probability of renal stone formation after a 12-month mission?
“Risk” is what is left over after you have accounted for likelihood, outcome, and the mitigation associated with the threat.

5 x 5 Risk Matrix

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

**Risk Score (2x1) for a single “risk”**

- **Likelihood (Score 1-5)**
  - Medical Condition Incidence
- **Mitigation?**
  - In-flight Medical Capabilities
- **Outcome (Score 1-5)**
  - Crew Functional Impairment
- **Impact to mission due to all medical conditions for the crew compliment**
Comparison – 5x5 Risk Matrix vs. IMM

**5x5 Matrix**
- Qualitative
- Categorical
- Subjective
- Single Risk
- No Uncertainty
- No Confidence Interval
- Limited context

**IMM**
- Quantitative
- Probabilistic, Stochastic
- Evidence-based
- Integrated Risks
- Uncertainty
- Confidence Interval
- In context

- Medical Conditions & Incidence Data
- Crew Profile
- Mission Profile & Constraints
- Crew Functional Impairments
- In-flight Medical Resources

- Medical Condition Occurrences
- Crew Impairment
- Clinical/Mission End States
- Resource Utilization
- Optimization of Vehicle Constraints and Medical System Capabilities
IMM Conceptual Model

**INPUTS**

- Medical Conditions & Incidence Data
- Crew Profile
- Mission Profile & Constraints
- Potential Crew Impairments
- Potential Mission End states
- In-flight Medical Resources

**OUTPUTS**

- Medical Condition Occurrences
- Crew Impairments
- Clinical End States
- Mission End States
- Resource Utilization
- Optimized Medical System

`Integrated Medical Model`
Best-case resources available?

Yes

Treated case: Decrement medical resources

Yes

Calculate End States:
• Evacuation (EVAC)
• Loss of Crew Life (LOCL)
• Crew Functional Impairment
• Type and Quantity of Medical Events (organized by Medical, Injury, or Environmental categories)
• Resource Utilization and Depletion

No

Untreated Best Case

No

Untreated Worst Case

Yes

Treated case: Decrement medical resources

No

Worst-case Scenario

Worst-case resources available?

Medical Event

Best-case Scenario
IMM Logic

For each comparative assessment, the identical questions are asked 10,000+ times to develop outcome distributions

- Did the medical condition happen?
- How many times?
- Best- or worst-case scenario?
- Were resources available?
- What was the outcome?
Clinical Findings Form (CliFF)

Standardized Format for IMM Clinical Inputs

• The likelihood of occurrence of the medical condition
  • Incidence proportion or incidence rate

• The clinical outcomes of the medical condition
  • Considers ISS-based best-case, worst-case, and untreated case scenarios
  • Specifies functional impairments and duration times
  • Specifies potential end states (evacuation, loss of crew life)
  • Specifies levels of evidence for input data
  • References sources of data

• Medical Resource Tables
  • Specifies the resources required to diagnose and treat best- and worst-case scenarios
The resource tables specify the required in-flight medical resources

- Specify resources required for diagnosis and treatment
- Consider the best-case and worst-case scenarios
## Best and Worst Cases

### Best-Case Scenario

<table>
<thead>
<tr>
<th>Consumable</th>
<th>Disorder: Musculoskeletal</th>
<th>Description</th>
<th>Quantity</th>
<th>Mass (Kg)</th>
<th>Gm</th>
<th>Volume (cc³)</th>
<th>mm³</th>
<th>Power (W)</th>
<th>Cost Estimates</th>
<th>COTS</th>
<th>Flight Certify</th>
<th>Sustaining Eng</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sprain/Strain Extremities</td>
<td>Ace Bandage</td>
<td>1</td>
<td>0.03875</td>
<td>38.75</td>
<td>442.5</td>
<td>442500</td>
<td></td>
<td></td>
<td>$</td>
<td>3.08</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>SAM splint</td>
<td>1</td>
<td>0.1134</td>
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</tr>
<tr>
<td>1</td>
<td>Acetaminophen</td>
<td>Carpuject</td>
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<td>0.00036</td>
<td>0.36</td>
<td>0.02632</td>
<td>26.32</td>
<td></td>
<td></td>
<td>$</td>
<td>0.10</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Ibuprofen</td>
<td></td>
<td>1-9</td>
<td>0.00066</td>
<td>0.66</td>
<td>0.04202</td>
<td>42.02</td>
<td></td>
<td></td>
<td>$</td>
<td>0.14</td>
<td></td>
</tr>
</tbody>
</table>

### Worst-Case Scenario

<table>
<thead>
<tr>
<th>Consumable</th>
<th>Disorder</th>
<th>Description</th>
<th>Quantity</th>
<th>Mass (Kg)</th>
<th>Gm</th>
<th>Volume (cc³)</th>
<th>mm³</th>
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<th>Cost Estimates</th>
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<td>442500</td>
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<td>26.32</td>
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<td>0.10</td>
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<td>42.02</td>
<td>$</td>
<td>0.14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Crew Health Index (CHI)

- Quality-Adjusted Mission Time
- Modification of quality-adjusted life years (QALY)
  - Standard epidemiologic measure
- Single, weighted measure of the net change in quality time
Example of QALY

- Consider the following individual:
  - 35 years old
  - 75-year life expectancy

- Medical event results in 30% functional impairment
  - Below knee amputation

- What is the QALY?
  
  \[
  QALY = 40 - 40 \cdot 0.3 = 40 - 12 = 28 \text{ yrs}
  \]
  
  \[
  PQALY = \frac{28}{40} \cdot 100\% = 70\%
  \]

- With respect to IMM, “life years” is mission time
Crew Health Index (CHI)

Measure of crew health based on functional impairment

- Ranges from 0 to 100%
- 0% - completely impaired due to medical conditions for duration of mission
- 100% - no impairment due to medical conditions
Summary

• IMM is an evidence-based decision support tool that can be used for risk assessment and mission planning.

• IMM forecasts the impact of in-flight medical events on space flight missions.

• IMM inputs include 83 medical conditions, incidence values, functional impairments, potential end-states (EVAC, LOCL) and required medical resources.

• IMM outputs include EVAC, LOCL, CHI, and resource utilization.

• IMM can be used to optimize the medical system within the constraints of the space flight environment.
ISS PRA Update using IMM

• **Purpose**
  - To update medical risk forecasts of evacuation (EVAC) and loss of crew life (LOCL) for ISS

• **Justification**
  - Current medical risk data and approach were developed over 12 years ago, use broad assumptions, and only address a subset of medical conditions relevant to the current mission profile
  - Risk of EVAC and LOC due to medical events will be underreported
  - Updated crew health risk estimates help prioritize medical system capabilities
Background - ISS Risk Model

• Probability Risk Assessment (PRA) methods required by ISS Program (per NPR 8705.5)

• Current Approach for Medical Risk
  • Based on pre-ISS operations evidence (1997)
  • Medical conditions organized by 9 categories
  • Only ‘severe’ medical conditions addressed
  • Assumes medical resources available > 98%
  • Assumes positive clinical outcomes > 75%
IMM Evidence Base

- Astronaut Health Database
- ISS Expeditions 1 thru 13 (2006)
- STS-01 thru STS-114 (2005)
- Apollo, Skylab, Mir (U.S. crew only)
- Analog, terrestrial data
- Review of crew medical charts
- Flight Surgeon Subject Matter Expertise
- Russian medical data not used
ISS PRA Update - Methods

- Reference Mission (as defined by ISS PRA Group)
  - 6-person crew (1 female, 5 males)
  - 6-month mission
  - 3 EVAs total for mission
- 83 medical conditions
- Industry standard statistical software, SAS 9.1
- SQL Database manages all clinical inputs
- Monte Carlo Simulations
- Fully treated medical with ISS medical system
- In-flight ISS Resource Utilization
# Results

## ISS Reference Mission - Fully Treated

<table>
<thead>
<tr>
<th>Category</th>
<th>EVAC</th>
<th>EVAC (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Illness</td>
<td>1 in 32</td>
<td>3.14</td>
<td>2.97-3.32</td>
</tr>
<tr>
<td>Injury/Trauma</td>
<td>1 in 169</td>
<td>0.59</td>
<td>0.52-0.67</td>
</tr>
<tr>
<td>Environmental</td>
<td>1 in 135</td>
<td>0.74</td>
<td>0.65-0.81</td>
</tr>
<tr>
<td><strong>All Conditions</strong></td>
<td>1 in 23</td>
<td>4.43</td>
<td>4.25-4.61</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>LOC</th>
<th>LOC (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Illness</td>
<td>1 in 270</td>
<td>0.37</td>
<td>0.31-0.43</td>
</tr>
<tr>
<td>Injury/Trauma</td>
<td>1 in 769</td>
<td>0.13</td>
<td>0.10-0.16</td>
</tr>
<tr>
<td>Environmental</td>
<td>1 in 172</td>
<td>0.58</td>
<td>0.49-0.65</td>
</tr>
<tr>
<td><strong>All Conditions</strong></td>
<td>1 in 94</td>
<td>1.06</td>
<td>0.97-1.16</td>
</tr>
</tbody>
</table>
Conversion of % EVAC to events/person-yr

- IMM forecasts a **4.43%** probability of EVAC for a 6-crew/6-month ISS mission
  - 6 crew x 0.5 years (6 months) = 3 person-yrs
  - 0.0443 events/3 person-yrs = **0.015 events/person-yr**

- IMM forecasts a **1.06%** probability of LOCL for a 6-crew/6-month ISS mission
  - 6 crew x 0.5 years (6 months) = 3 person-yrs
  - 0.0106 events/3 person-yrs = **0.0035 events/person-yr**
## Comparison of Risk of EVAC Rates

IMM forecasted *Risk of EVAC* rates compare favorably with literature review EVAC rates (0.010 to 0.072)

<table>
<thead>
<tr>
<th>Source</th>
<th>Low (events/person-yr)</th>
<th>Max (events/person-yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMM (mean)</td>
<td>0.015</td>
<td>-</td>
</tr>
<tr>
<td>ISS PRA (mean)</td>
<td>0.001</td>
<td>-</td>
</tr>
<tr>
<td><strong>ISS Independent Safety Task Force (February 2007)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISS Independent Safety Task Force (February 2007)</td>
<td>0.028</td>
<td>0.042</td>
</tr>
<tr>
<td>Terrestrial General Population</td>
<td>0.060</td>
<td>-</td>
</tr>
<tr>
<td>Antarctic Population</td>
<td>0.036</td>
<td>-</td>
</tr>
<tr>
<td>U.S. Submarine Population</td>
<td>0.023</td>
<td>0.028</td>
</tr>
<tr>
<td>Russian Historical Space Flight Data</td>
<td>0.032</td>
<td>0.072</td>
</tr>
<tr>
<td>LSAH (Astronaut Health) Data</td>
<td>0.010</td>
<td>0.020</td>
</tr>
<tr>
<td>SSF Clinical Experts Seminar Proceedings (1990)</td>
<td>0.010</td>
<td>0.030</td>
</tr>
</tbody>
</table>
Validation - Risk of EVAC

<table>
<thead>
<tr>
<th>IMM Simulation Data</th>
<th>Actual Russian Flight Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical illness (71%)</strong></td>
<td><strong>Three EVACs</strong></td>
</tr>
<tr>
<td>1. Dental Abscess</td>
<td>1. Urosepsis</td>
</tr>
<tr>
<td>2. Sepsis</td>
<td>2. Cardiac Arrhythmia</td>
</tr>
<tr>
<td>4. Stroke</td>
<td><strong>Three Close Call EVACs</strong></td>
</tr>
<tr>
<td>5. Atrial Fibrillation</td>
<td>1. Kidney Stone</td>
</tr>
<tr>
<td>6. Acute Chest Pain/Angina</td>
<td>2. Dental Abscess</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Injury/Trauma (13%)</strong></th>
<th><strong>Environmental (16%)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hypovolemic Shock</td>
<td>1. Smoke Inhalation</td>
</tr>
<tr>
<td>2. Wrist Fracture</td>
<td>2. Toxic Exposure</td>
</tr>
</tbody>
</table>

**NOTE:** No Russian data are in the IMM
Validation – *Risk of LOCL* forecast

IMM forecasted *Risk of LOC* rates compare favorably with literature review results for LOC rates (0.0028 to 0.0081)

<table>
<thead>
<tr>
<th>Source</th>
<th>LOC (events/person-yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMM (6-crew/6-month mission)</td>
<td>0.0035</td>
</tr>
<tr>
<td>ISS PRA (3-crew/6-month mission)</td>
<td>0.0006</td>
</tr>
<tr>
<td>Terrestrial Mortality Rate</td>
<td>0.0081 (2006)</td>
</tr>
<tr>
<td>48-year old male</td>
<td>0.0047 (2006)</td>
</tr>
<tr>
<td>48-year old female</td>
<td>0.0028 (2006)</td>
</tr>
<tr>
<td>Antarctic</td>
<td>0.0054 (1904-1964)</td>
</tr>
<tr>
<td>LSAH Data</td>
<td>0.0054 (1959-1991)</td>
</tr>
</tbody>
</table>
## Summary of Validation

### Risk of Evacuation (EVAC) Estimates

<table>
<thead>
<tr>
<th>Source</th>
<th>Low (events/person-year)</th>
<th>Max (events/person-year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMM (mean)</td>
<td>0.015</td>
<td>-</td>
</tr>
<tr>
<td>ISS PRA (mean)</td>
<td>0.001</td>
<td>-</td>
</tr>
<tr>
<td>Evidence-based Literature</td>
<td>0.010</td>
<td>0.072</td>
</tr>
</tbody>
</table>

### Risk of Loss of Crew Life (LOCL) Estimates

<table>
<thead>
<tr>
<th>Source</th>
<th>Low (events/person-year)</th>
<th>Max (events/person-year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMM (mean)</td>
<td>0.0035</td>
<td>-</td>
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<tr>
<td>ISS PRA (mean)</td>
<td>0.0006</td>
<td>-</td>
</tr>
<tr>
<td>Evidence-based Literature</td>
<td>0.0028</td>
<td>0.0081</td>
</tr>
</tbody>
</table>
## Comparison of Data – IMM vs. ISS PRA

<table>
<thead>
<tr>
<th>Source Model</th>
<th>Risk of EVAC*</th>
<th>Risk of LOC*</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMM (mean)</td>
<td>0.015 (4.43%)</td>
<td>0.0035 (1.06%)</td>
</tr>
<tr>
<td>ISS PRA (mean)</td>
<td>0.001 (0.35%)</td>
<td>0.0006 (0.17%)</td>
</tr>
<tr>
<td>Difference</td>
<td>x15 factor</td>
<td>x5.8 factor</td>
</tr>
</tbody>
</table>

* Shown as events/person-year, and percent during mission
Summary of ISS PRA Update

- Medical events will be lead contributor to “Risk of EVAC/LOC”, surpassing ISS PRA estimates of “Risk of EVAC/LOC” from MMOD
- A comprehensive evidence review forms the basis for updating the ISS PRA Risk Model
- Presented to and accepted by the ISS Program Office in December, 2010
IMM Validation - Background

• The IMM is expected to be a significant contributor to medical decision making in operational and planning processes for space flight missions.

• NASA Standard 7009 requires that real world events be accurately represented by the model results to reach sufficient levels of validation.

• For the IMM, this requirement is partially fulfilled by comparing the model’s predicted outcomes with observed mission data that have not been included in the model.
Validation

• Model Validation
  • “Substantiation that a computerized model within its domain of applicability possesses a satisfactory range of accuracy consistent with the intended application of the model”

• Historical Data Validation
  • “If historical data exist, part of the data is used to build the model and the remaining data are used to determine (test) whether the model behaves as the system does”
    • Sargent. Verification and Validation of Simulation Models. *Proceedings of the 2007 Winter Simulation Conference*
Data Analysis

• Data on historical space flight missions were collected from mission medical records

• Data available for comparison included
  • Total number of medical events
  • The number of occurrences of each medical event
  • Medical resource utilization
Validation Approach

- Qualitative and quantitative approaches were used to compare historical data to model output
  - Qualitative Approach
    - Plots were created to visualize the differences between the model and historical data
  - Quantitative Approach
    - Goodness of Fit (GoF) testing was chosen to test the null hypothesis that the predicted outcomes are statistically equivalent to the observed data
Methods

Simulation

• Model was run for seven ISS missions and fourteen Shuttle missions *

• Mission and crew profile were matched to historical mission data [# of crew, sex, mission length, and number of extravehicular activities (EVAs)]

• Each simulation was executed for 20,000 trials

* Data from these missions have not been used as inputs for the model
## Results

### Total Medical Events - ISS Missions

<table>
<thead>
<tr>
<th>Mission</th>
<th>Expected</th>
<th>Observed</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>18</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>18</td>
<td>13</td>
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<td>4</td>
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<td>5</td>
<td>15</td>
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</tr>
<tr>
<td>6</td>
<td>17</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>19</td>
<td>23</td>
<td>-4</td>
</tr>
<tr>
<td>Average</td>
<td>16</td>
<td>14</td>
<td>2</td>
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</tbody>
</table>
Results

Spider Plot for ISS Missions

Total Number of Medical Events by Crewmember

\[ p = 0.36 \]
Results – Total Medical Events – Shuttle Missions

<table>
<thead>
<tr>
<th>Mission</th>
<th># of Crew</th>
<th>Expected</th>
<th>Observed</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>24</td>
<td>26</td>
<td>-2</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>24</td>
<td>25</td>
<td>-1</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
<td>24</td>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
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Results

Spider Plot for Shuttle Missions
Total Number of Medical Events by Mission

Expected

Observed

p = 0.83
Summary of Results

• Total Medical Events

  • There was no significant difference between the total number of medical events forecasted by IMM and the total number of medical events observed on missions
Optimization

• Optimize medical kit using IMM results
  • Specific mission and crew profile

• Approaches
  1) Maximize outcome given resource constraints
  2) Minimize resources given desired outcome(s)

Approaches

1) Maximize (or Minimize) outcomes
   • What can we fit in the box?
   • Resource constraints must be satisfied

2) Minimize resources
   • How big of a box do you need?
   • Outcome constraints must be satisfied
Resource Constraints

- Multiple constraints on medical resources
  - Mass
  - Volume
  - Cost
  - Packaging
  - Bandwidth
  - Power
  - Etc.
Define Constraints and Outcomes

• Define resource constraints
  • Maximum mass
  • Maximum volume

• Decide which outcome(s) are of interest
  • Maximize CHI
  • Minimize Pr(EVAC)

• Fill medical kit with the most efficient set of medical resources
Example

- Number of crew members
  - 4 (2M, 2F)
- Mission Length
  - 24 days
- Maximize CHI
- Resource constraints
  - 4.3 kg
  - 6421.7 cm³
Results (24 days, 4 crew)

- **Resource constraints**
  - 4.3 kg
  - 6421.7 cm³

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<td>Mass (kg)</td>
<td>4.11</td>
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<td>Volume (cm³)</td>
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Minimizing Resources

• Define outcome(s), constraints
  • Pr(EVAC) ≤ 2%
  • Mean CHI ≥ 90%

• Identify sets of conditions that should be treated to satisfy the constraints

• Identify the minimum such set
Example

• Number of crew members
  • 4 (2M, 2F)

• Mission Length
  • 24 days

• Minimize Mass and Volume

• Evacuation constraints
  • Pr(EVAC) < 2%
  • Mean CHI > 90%
Results (24 days, 4 crew)

- **Constraints**
  - $\Pr (EVAC) < 2\%$
  - Mean CHI > 90\%

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Two alternative optimization modules
  • Answer different questions
  • Multi-objectives
  • Multiple constrains

Results provide suggestions

Compromises must be made

Results demonstrate effectiveness of these optimization routines
Conclusions

- IMM provides an evidence-based analysis of likely medical events and outcomes during space flight missions
- IMM provides the capability to assess risk
- IMM provides the capability to optimize medical systems
- IMM is a tool to assist in the decision making process
  - It does not make decisions
Questions?