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<td>D. Butler</td>
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<td>Clinical Methods</td>
<td>E. Kerstman</td>
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<td>C. Minard</td>
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The Integrated Medical Model
A Decision Support Tool for In-flight Crew Health Care

Presenter: Doug Butler
dbutler@wylehou.com
(281) 212 -1380

Presentation to the Human Systems Integration Knowledge Broadcast Series
NASA Johnson Space Center/SD4
Wyle Integrated Science and Engineering Group
Houston, TX
26 May 2009
IMM Project Goals

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

• To help align science, technology, and operational activities intended to optimize crew health, safety, and mission success.
Scope and Approach

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

IMM addresses in-flight risk only, and uses ISS data as stepping stone
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.
Software Technology

Software is used across a wide range of industries to represent stochastic, probabilistic processes and uncertainty

- Crystal Ball Software (Oracle Corp.)
  - Commercially available software application
  - Microsoft Excel user interface
  - Stochastic forecasting and optimization

- SAS (Statistical Analysis Software)
  - IMM 1.0 currently transitioning to SAS due to large number of variables in the model
How does a decision support tool like IMM aid a Program that’s just forming?

- Knowledge Management
- Objectivity
- Prioritization
- Rationalization
- Optimization
- Communication
Who can benefit from IMM capabilities?

• Flight Surgeons
  • What in-flight medical threats are greatest for reference mission A?

• Risk Managers
  • What is the risk of evacuation - due to a medical event - for a 6-person, 180 day mission assuming the current in-flight medical capability?

• Vehicle Designers
  • What’s the optimum medical mass allocation for given level of risk?

• Health Care System Designers
  • What medical items do we fly for a given mass/volume allocation?

• Trainers
  • How do I prioritize limited crew training hours?

• Requirement Managers
  • What’s the rationale for this crew health requirement?
“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?
When does IMM prove useful?

IMM supports decisions at all program phases
IMM Usage History

• IMM Inputs
  • Rationale for ISS Medical Kit Redesign
  • List of Prioritized Medical Conditions by Reference Mission
  • Requirements rationale for vomitus and diarrhea

• IMM Outputs
  • ISS Risk Model Medical Updates - Pending
## Risk Vocabulary

### Common Risk Management Terms vs. IMM

<table>
<thead>
<tr>
<th>Common Risk Management Terms</th>
<th>IMM</th>
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<tbody>
<tr>
<td>Hazard</td>
<td>Medical condition experienced by the crew in flight</td>
</tr>
<tr>
<td>Threat</td>
<td>Probability of a medical event</td>
</tr>
<tr>
<td>Initiating event</td>
<td>Evacuation</td>
</tr>
<tr>
<td>Likelihood</td>
<td>Loss of Crew Life</td>
</tr>
<tr>
<td>Consequence</td>
<td>Crew Health Index (CHI)</td>
</tr>
<tr>
<td>Outcome</td>
<td>In-flight capability to diagnose and treat the medical event</td>
</tr>
<tr>
<td>End State</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Mitigation</td>
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</table>
“Risk” is what’s left over after you’ve accounted for likelihood, outcome, and the mitigation associated with the threat.

### 5x5 Matrix for Threat Z

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<th>Outcome</th>
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<table>
<thead>
<tr>
<th>Mitigation A</th>
<th>Mitigation B</th>
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<tbody>
<tr>
<td>Risk</td>
<td>Risk</td>
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</table>

### 5x5 Matrix IMM

<table>
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<th>IMM</th>
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<tbody>
<tr>
<td>Likelihood (Score 1-5)</td>
<td>Medical Condition Incidence</td>
</tr>
<tr>
<td>Mitigation?</td>
<td>In-flight Medical Capabilities</td>
</tr>
<tr>
<td>Outcome (Score 1-5)</td>
<td>Crew Functional Impairment</td>
</tr>
<tr>
<td>Risk Score (2x1) for a single “risk”</td>
<td>Impact to mission due to all medical conditions for the crew compliment</td>
</tr>
</tbody>
</table>
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
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

Integrated Medical Model

- Medical Condition Occurrences
- Crew Impairment & Clinical End States
- Resource Utilization
- Optimization of Vehicle Constraints and Medical System Capabilities
IMM Logic

INPUTS

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

OUTPUT of Distributions

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

A simulation set may include 5-25,000 trial missions.
For each comparative assessment, the identical questions are asked 5,000+ times to develop outcome distributions.

1. Did the medical condition happen?
2. How many times?
3. Best or worst-case scenario?
4. Were resources available?
5. What was the outcome?
Key Development Steps

Each step is in the critical path

• Develop a Conceptual Model
• Create initial list of relevant medical conditions
• Characterize incidence data
• Quantify crew impairment and clinical end states
• Quantify resources needed to diagnose and treat
• Develop a quantified Crew Health Index
• Understand implications of assumptions
• Verify & Validate
• Refine & Maintain Data
Development Status

• Current Status of Model
  • First version of IMM 1.0 completed (Sept 2008)
  • IMM 1.0 supports assessments of 1-6 crew members
  • 83 medical conditions represented
  • 47 of 83 medical conditions have been recorded to occur in flight
  • Medical Resources (type, quantity, mass, volume) per condition

• Capabilities
  • Forecasts medical condition occurrences
  • Identifies medical conditions that most influence crew impairment and mission impact
  • Identifies key contributors to crew impairment and clinical outcomes (e.g. depleted or lack of in-flight medical resources)
  • Compares crew health risk between different missions
IMM Development vs. Constellation Program Schedule
PMR ’08 Rev 1 – As of 03/31/09

Flight Plan
Ares I / Orion Launches

Program Integration

Orion

Altair

IMM

IMM Transition to Operations
Next Steps

• Work in Progress
  • Transition to SAS software platform
  • Optimization Algorithm Implementation
  • Database Development & Integration
  • Internal Verification & Validation

• Next 12 Months – Key Milestones
  • Develop database user interfaces
  • Develop IMM 2.0
  • Initiate external Verification & Validation
  • Communication to stakeholders
  • Prepare for transition to operations
Closing

IMM addresses the observations documented by the RTF Task Group

...experience and instinct are poor substitutes for careful analysis of uncertainty...

...This requires that analytical models be used appropriately to inform decisions...

(Source: NASA Return to Flight Task Group Final Report: Annex A.2 Individual Member Observations by Dr. Dan L. Crippen, Dr. Charles C. Daniel, Dr. Amy K. Donahue, Col. Susan J. Helms, Ms. Susan Morrisey Livingstone, Dr. Rosemary O'Leary, and Mr. William Wegner.)
IMM Clinical Methods and Inputs

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IMM Clinical Inputs

Outline

• Development of the Medical Condition List (MCL)
• Overview of Incidence Determinations
• Functional Impairments
• Clinical Findings Form (CliFF)
Medical Clinical Inputs

Purpose
• To provide a list of medical conditions relevant to in-flight operations

Relevant Medical Condition
• Has occurred in flight or has the potential to occur in flight
• Requires mitigation and/or results in functional impairment

Current Status
• Consists of 83 medical conditions (47 have occurred in flight)
Development of the Medical Condition List

- **MCL Phase I**
  - ISS Medical Checklist (70 conditions)

- **MCL Phase II**
  - STS Medical Checklist (+1)

- **MCL Phase III**
  - Longitudinal Study of Astronaut Health (LSAH)
  - In-flight Medical Condition Occurrences (+6)

- **MCL Phase IV**
  - Flight Surgeon Delphi Study (+6)
LSAH

In flight Medical Condition Occurrences

- Includes Apollo, Skylab, Mir, Shuttle, and ISS
- STS-1 through STS-114 in 2005
- Expedition 1 through Expedition 13 in 2006
- 47 relevant medical conditions
The Use of Incidence

• Incidence is a measure of the likelihood of developing a medical condition

• IMM uses incidence to quantify the likelihood of occurrence of medical conditions in flight
Incidence Definitions

The number of new medical events that occur within a specified time period

**Incidence Proportion** (Cumulative Incidence)
- The proportion of a population who develop a medical condition within a specified period of time (events/person)

**Incidence Rate** (Incidence Density)
- The number of new medical events that occur within a population divided by the total time the population was at risk (events/person-year)
- Accounts for the different times that each individual was at risk
Space Adaptation Syndrome (SAS)

Non-Space Adaptation Syndrome
SAS Medical Conditions

1) Back Pain
2) Constipation
3) Headache
4) Insomnia
5) Nasal Congestion
6) Nosebleed
7) Space Motion Sickness
8) Urinary Incontinence
9) Urinary Retention
Space Adaptation Syndrome Medical Conditions

- Likelihood of occurrence is **not** related to mission duration
- Condition does not recur
- **Incidence proportions** (events/person) are determined from LSAH in flight occurrence data

**Example: Nasal Congestion**

405 events among 660 persons = 0.614 events/person
Non-SAS Medical Conditions

- The likelihood of occurrence is related to mission duration
- Condition may recur
- **Incidence rates** (events/person-year) are determined from LSAH in flight occurrence data or other sources

**Example: Skin Rash**
90 events within 27.34 person-years = 3.29 events/person-year
Incidence Rate Determinations

Conditions that have occurred in flight
- LSAH in flight occurrence data

Conditions that have not occurred in flight
- External models (fractures)
- Environmental engineering data (altitude sickness)
- Terrestrial general/analog population data (appendicitis)
- Bayesian statistics for rare events (kidney stones)
IMM uses the concept of functional impairments to quantify the severity of medical condition outcomes.

**Impairment**
- A loss or loss of use of a body part, organ system, or organ function
- Considers both anatomic and functional loss
- Can develop from an illness or injury
Impairments

- Percentages that reflect the severity of the medical condition
- No impairment = 0 percent
- Fully dependant/approaching death = 100 percent

Examples

Skin Infection = 10 to 24 percent impairment
Shoulder Dislocation = 36 to 74 percent impairment
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
Summary

- Relevant list of medical conditions established
- Incidence data established for each medical condition
- Crew functional impairments and end states (evacuation and loss of crew life) used to characterize impact due to medical events
- Standardized tool (CliFF) established for clinical inputs of likelihood and outcomes for each medical condition
In-flight Diagnosis & Treatment Resources

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Resource Tables

The resource tables (RT) define the in-flight medical resources

- Specifies the necessary resources for diagnosis
- Considers the treatment of best and worst case scenarios
- Provides input into IMM
### Best and Worst Cases

#### Best Case Scenario

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<th>Volume (cc³)</th>
<th>Power (W)</th>
<th>Cost Estimates</th>
<th>COTS</th>
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</tbody>
</table>
Resource Table Assumptions

- The resource tables reflect the current ISS medical equipment, supplies, drugs, etc.
- Conditions go “untreated” when an “essential” item is not available (due to depletion or omission from the health care system)
- Cost information only includes Commercial-off-the-shelf (COTS)
- Spacecraft resources (e.g. oxygen, water, power, bandwidth) are not constrained
In-flight Mitigation

- Medical resources can be optimized for specific missions and crew profiles
- Resource tables identify the necessary supplies to mitigate risk by improving medical outcomes
Integrated Medical Model

Outputs and Simulated Mission Scenarios

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“Essentially, all models are wrong, but some are useful.”

George Box (1987)
Professor Emeritus of Statistics at the University of Wisconsin
Statistical Methods

- IMM uses Monte Carlo simulation
  - Crystal Ball software
  - Microsoft Excel
  - Distribution of outcomes

- Probability distributions
  - Beta, Beta-PERT, Poisson, Bernoulli, Binomial, Lognormal, Uniform, Discrete uniform

- Crew Health Index (CHI)
  - Quality-adjusted mission time
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?
  \[ QALY = 40 - 40(0.3) = 40 - 12 = 28 \text{ yrs} \]
  \[ PQALY = \frac{28}{40} \cdot 100\% = 70\% \]

- With respect to IMM, “Life” is mission time

Crew Health Index (CHI)
Crew Health Index (CHI)

• Measure of crew performance

  • Ranges from 0 to 100%
  
  • 0% - completely impaired due to medical conditions for duration of mission

  • 100% - no impairment due to medical conditions
Key Model Assumptions

- 83 medical conditions
- ISS Health Maintenance System (HMS)
- Conservative estimate of Crew Health Index (CHI)
  - Medical events assumed to occur on the first day of the mission
6 Month Mission

• Is the current HMS adequate for a 6 member crew?

• Consider two alternative 6 month missions
  • 3 crew members (2M, 1F)
  • 6 crew members (5M, 1F)

• 2 EVAs per crew member

• Identical medical resources (ISS)
Total Medical Events (3 Crew)
Total Medical Events

- Expect about twice as many medical events
- Expect greater variation in the number of events

<table>
<thead>
<tr>
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<th>3 Crew</th>
<th>6 Crew</th>
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<tbody>
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<tr>
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<td>91.0</td>
</tr>
<tr>
<td>SD</td>
<td>6.6</td>
<td>9.3</td>
</tr>
<tr>
<td>95% Inf.</td>
<td>34-59</td>
<td>73-110</td>
</tr>
</tbody>
</table>
Sensitivity Analysis

• What are the most influential factors?
  • Which variables describe the greatest variation in the distribution of the outcome?
  • Which variables are most highly correlated with the outcome of interest?
Sensitivity Analysis – Total Events

3 Crew Members

6 Crew Members
Sensitivity Analysis – Total Events

3 Crew Members
1) Late insomnia
2) Skin rash
3) Skin abrasion/laceration
4) Corneal abrasion

6 Crew Members
1) Late insomnia
2) Skin rash
3) Skin abrasion/laceration
4) Corneal abrasion
Crew Health Index (3 Crew)
Crew Health Index (6 Crew)
Crew Health Index

<table>
<thead>
<tr>
<th>Statistic</th>
<th>3 Crew</th>
<th>6 Crew</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>84.8</td>
<td>65.3</td>
</tr>
<tr>
<td>Median</td>
<td>89.5</td>
<td>67.0</td>
</tr>
<tr>
<td>SD</td>
<td>13.0</td>
<td>17.6</td>
</tr>
<tr>
<td>95% Inference</td>
<td>51-98</td>
<td>28-93</td>
</tr>
</tbody>
</table>

- Expect decreased CHI with 6 crew members
- Expect greater variation
CHI Sensitivity Analysis

<table>
<thead>
<tr>
<th>3 Crew Members</th>
<th>6 Crew Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Skin rash</td>
<td>1) Skin rash</td>
</tr>
<tr>
<td>2) Cough</td>
<td>2) Paresthesia</td>
</tr>
</tbody>
</table>

Why was the CHI decreased for 6 crew members?

• Consider medical resources for skin rash
Skin Rash Resources (6 Crew)
Lotramin AF

3 Crew Members
Insufficient for 13.3% of the trials

6 Crew Members
Insufficient for 76.0% of the trials
Summary

• Is the current ISS HMS adequate for a 6 member crew?
  • Substantial decrease in CHI with three additional crew members

• What conditions had the greatest impact?
  • Skin rash
  • Paresthesia
  • Corneal abrasions

• Why did skin rash impact the CHI?
  • Insufficient medical resources
Alternative Analyses

• Examine specific medical resources
  • Ibuprofen

• Alternative resource allocation
  • Increase supply for 6 crew, 6 month mission

• Shorter missions
  • 24 versus 33 day missions

• Vary number of crew members
  • 3 crew versus 4 crew
Alternative Outcomes

- Probability of evacuation
- Probability of loss of crew life
- Summary measures that combines CHI, EVAC, and LOCL?
Probability of EVAC

Information has not been validated.
Summary

- IMM is a tool to assist in the decision making process
  - It does not make decisions

- IMM provides an objective analysis of likely medical events and outcomes during space flight

- IMM provides comparative analyses
Questions?
Skin Abrasion/Laceration Resources (3 Crew: Best Case only)
Skin Abrasion/Laceration Resources
(6 Crew: Best Case only)
Gauze Pads

3 Crew Members
Insufficient for 0.6% of the trials

6 Crew Members
Insufficient for 41.9% of the trials
Povidone Iodine Swabs

3 Crew Members
Insufficient for 4.8% of the trials

6 Crew Members
Insufficient for 59.5% of the trials
Ibuprofen

- Compare Ibuprofen use
  - 3 crew, 6 months
  - 6 crew, 6 months

- What medical conditions explain the Ibuprofen usage?
Ibuprofen (6 Month Mission)

3 Crew Members
Insufficient for 2.0% of the trials

6 Crew Members
Insufficient for 45.0% of the trials
Ibuprofen Sensitivity Analysis

3 Crew Members
1) Back injury
2) Sprain/Strain - Shoulder
3) Paresthesia
4) Back pain (SAS)
5) Sprain/Strain – Elbow

6 Crew Members
1) Back injury
2) Sprain/Strain - Shoulder
3) Paresthesia
4) Back pain (SAS)
5) Sprain/Strain – Elbow
Increase Medical Resource Supply

• Will increasing the medical supplies increase the Crew Health Index?

• Double these resources for 6 crew member mission
  • Gauze pads
  • Povidone iodine swabs
  • Benadryl capsules
  • Ibuprofen

• Increases HMS requirement
  • 0.42 kg
  • 833.1 cm³
  • $47.60
Crew Health Index

Current ISS Resources
Mean = 48.8%
Median = 49.2%
95% Inference: (15 – 81%)

Additional Resources
Mean = 59.4%
Median = 60.6%
95% Inference: (26 – 86%)
Does a 33 day lunar mission require a different level of care than a 24 day lunar mission?

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mission 1</th>
<th>Mission 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mission length</td>
<td>24 Days</td>
<td>33 Days</td>
</tr>
<tr>
<td># Crew</td>
<td>4 (3M, 1F)</td>
<td>4 (3M, 1F)</td>
</tr>
<tr>
<td># EVAs/Person</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Resources</td>
<td>ISS</td>
<td>ISS</td>
</tr>
</tbody>
</table>
Total Medical Events

24 Days
- Mean: 18.3
- Median: 18.0
- St. Dev.: 3.6
- Minimum: 4.0
- Maximum: 33.0
- 95% Inference: 12 - 26

33 Days
- Mean: 21.0
- Median: 21.0
- St. Dev.: 4.0
- Minimum: 5.0
- Maximum: 38.0
- 95% Inference: 13 - 29
Sensitivity Analysis

24 Day Mission
• Headache (SAS)
• Nasal congestion (SAS)
• Space motion sickness (SAS)
• Insomnia (SAS)
• Back pain (SAS)

33 Day Mission
• Headache (SAS)
• Nasal congestion (SAS)
• Space motion sickness (SAS)
• Skin rash
• Late insomnia
Crew Health Index

24 Days

• Mean: 89.6%
• Median: 92.0%
• St. Dev.: 7.9%
• Minimum: 50.0%
• Maximum: 99.6%
• 95% Inference: 69.0-98.2%

33 Days

• Mean: 89.0%
• Median: 91.6%
• St. Dev.: 8.4%
• Minimum: 26.8%
• Maximum: 99.7%
• 95% Inference: 66.9-98.1%

Mission Outcome Crew Health Index

[Graphs showing distribution of health index values over time]