THE INTEGRATED MEDICAL MODEL: OUTCOMES FROM INDEPENDENT REVIEW

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Providing a tool to help informed decision making

Mission Specific Inputs
- Crew Member Attributes
- Crew Composition
- Mission Duration and Profile

Monte Carlo Simulations
Integrated Medical Model

Quantified Outputs
- Type and Quantity of All Medical Events
- Risk of EVAC
- Risk of Loss of Crew
- Medical Resources Used
- Optimized Medical System within Vehicle Constraints

Informed Analysis
Flight Surgeon

ISS Medical System Resources
- Diagnosis and Treatment of Medical Conditions
- Medical Condition Incidence Data
- Risks due to EVAs

IMM Relational Database

13,500+ data elements
IMM in a Nutshell

• Platform to assess mission medical risk using proven risk assessment techniques.

• Platform for exploration of the medical kit trade space effects on risk.

• Gives decision-makers a means to balance medical risk with limited resources.

• Provides engineering teams with quantitative medical information to characterize risk.

This is fundamentally about how the NASA Medical and Engineering communities communicate.
Validation Against Real World Observations

• Model validation utilized real world system (RWS) observations from International Space Station (ISS) Expedition (Exp) 14 through 39/40
• IMM simulation for each expedition
  – Assuming ISS med capabilities, crew specific parameters and duration
  – Using data obtained from ISS missions and STS missions prior to referent
• Total number, type and outcomes compared to RWS

Snapshot of results for RWS ISS missions: IMM generally over-predicts by 3-4 medical events as indicated by regression intercept estimates and slope generally less than 1 (considering IMM Condition List events only).
Monte Carlo Simulation: Typically ~100,000 trial simulations

Model and External Review

Medicine
Epidemiology
Biostatistics
Software

Biostatistics
Modeling
Probability
Theory
Software

Aerospace
Medicine
Engineering
Software

Model Inputs:

- Medical Condition Incidence Data
- Medical Condition Impairment, Duration and Outcome Data
- Medical Condition Treatment Data
- ISS Health Maintenance System Resources
- Crew Composition and Attributes
- Mission Duration and Profile

Model Outputs:

- Integrated Medical Model (IMM)
- Type and Quantity of all Medical Events
  - Risk of EVAC
  - Risk of Loss of Crew
  - Medical Resources Used
  - Crew Health Index

Monte Carlo Simulation: Typically ~100,000 trial simulations

Review Expertise Needed in Red

- Project
- Management
- Software
ExMC convened an external review panel through the GSFC Systems Review Branch

- Chair: Dr. Bryant Cramer (GSFC – Retired)
- Review Manager: Mr. Neil Martin (GSFC)
- Aerospace Medical: Dr. Jan Stepanek (Mayo Clinic)
- Epidemiologist: Dr. Guohua LI (Columbia University)
- Chief Engineer /Software: Mr. Steve Scott (GSFC)
- Software: Mr. Robert Schweiss (GSFC)
- Biostatistics/Probability Theory: Dr. Nancy Lindsey (GSFC)
- Software/ Project Management: Mr. Dick Kauffman (Criterion systems)
- Computational Modeling: Dr. Gary Pradhan (Mayo Clinic)
From Nov 2015 to May 2016

- 2 Pre-Meeting Summaries: “Introduction to IMM” and “IMM Validation Strategies”
- Board formally convened three times Dec 2015, Jan 2016, March/April 2016

External Review Topics

- Model Concepts and Software and code standards (i.e. JPR-7150.2B compliance)
- Input pedigree of incidence and outcomes information (NASA-STD-7009: Input Pedigree Credibility Factor)
- Model performance (NASA-STD-7009 Verification, Validation, Sensitivity, Operations, Use History)
Ensure internal processes for identifying, ranking quality, and including medical data with evidence-based rationale are appropriate to capture medical risk likelihood, medical information, and outcome uncertainty for the model application.

- Presented evidence related to data process and data capture
  - A selection of 10 Clinical Findings Forms (CliFFs) summarizing the types of data and conditions used to inform IMM simulations

  - Atrial Fibrillation
  - Burns Secondary to Fire
  - Decompression Sickness Secondary to EVA
  - Dental Abscess
  - Headache (Space Adaptation)
  - Hip-Proximal Femur Fracture
  - Eye Chemical Burn
  - Stroke
  - Sepsis
  - Urinary Retention (Space Adaptation)
Board identified strengths:

• The concept of the IMM is scientifically sound and it works.

• The IMM represents a necessary, comprehensive approach to identifying medical and environmental risks facing astronauts in long duration missions.

• Because it integrates with the Exploration Probabilistic Risk Assessment (ExPRAT), the IMM has become an excellent tool through which engineers and physicians can better communicate with each other by speaking a common risk assessment language.

• The validation approach is sound and the use of actual space medical data is logical and compelling.

• IMM statistical methods for processing and analyzing the input data, performing simulations, and generating and presenting quantitative outputs are scientifically sound.

• The IMM validation approach is sound and the match between the IMM and the real world system is good.
Board identified issues:

• Need for stronger software engineering involvement particularly in terms of quality assurance.

• Accuracy concerns regarding the CliFFs; the Board found a number of errors necessitating a robust review of all remaining CliFFs.

• Need for a sustainable approach to augment, peer review, and maintain the CliFFs.

• Organizational issues:
  – Physical separation of Project Management from Development Team presents a challenge.
  – Evolutionary path for IMM insufficiently defined.
  – Need for a well-developed Operations Concept.
• Total of 28 RFAs and 6 advisories submitted
• Project combined 8 of the RFAs for consolidated responses
  – New total: 24 RFAs
• RFA closure summary
  – All submitted for closure as of 11/15/2016
    • 23 – Evidence or plan to secure evidence supplied as a response
    • 1 – Element and project decision not to pursue a response at this time
  – Closure acceptance received 12/2016
Summary of Significant RFA Closure Activities

• Code modifications were performed to reduce run times by 70%.

• Adjustments to reviewed condition information
  – Minor typographical updates to DCS and Stroke CLIFF.
  – Updated data after addressing board suggestions and source data from the primary references.
    • Dental Abscess CLIFF – reevaluation of source data categorization of medical condition.
    • Space Adaptation headache leading to evacuation reduced from 1.5% max to 0% max.
    • Eye Chemical Burn – updated rationale.
    • Sepsis – updated rationale.

• Developed survey document guidelines for improved configuration management of clinical data identification.

• Performed a calibration of CHI using the RWS and iMED data information (Accepted for Closure RFA 3.02).
IMM Project Planned Pre-Delivery Activities

• Updated NASA-7009 Credibility Thresholds per accepted RFA plan (12/1/2016 – 3/7/2017)

• Complete STS RWS validation activity (12/1/2016 – 6/1/2017)

• Complete iMED 6.5 (12/5/2016 – 2/10/2017)

• Add RWS data to iMED 6.5 (3/31/2017 – 4/21/2017)
Conclusions

• IMM is a tool intended to help mission planners make decisions regarding medical risk and supplies.

• It is intended to pull in data and experience to provide the best current information to inform medical resource planning.

• Outcomes of the IMM 4.0 review
  – Definite need for the model of this type - validation testing illustrates its utility
  – Concerns expressed that the medical condition information requires further review

• Forward work plan toward transition to customer baselined
  – Final negotiation of ConOps plan with CHS
  – RWS validation for STS and RWS data integrated into iMED
  – Completion planned NLT 5/30/2017