The Integrated Medical Model

Statistical Forecasting of Risks to Crew Health and Mission Success

M.A. Fitts[1], E. Kerstman[2], D.J. Butler[3], M.E. Walton[4], C.G. Minard[5], L.G. Saile[6], S. Toy[7], J. Myers[8]

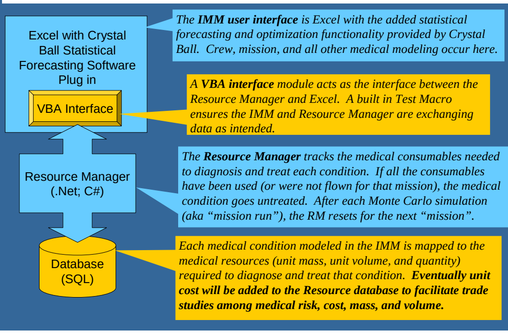
[1]NASA Johnson Space Center, [2]University of Texas Medical Branch - Galveston, [3,4,5,6]Wyle, [7]Muniz, [8]NASA Glen Research Center

Overview

The Integrated Medical Model (IMM) helps capture and use organizational knowledge across the space medicine, training, operations, engineering, and research domains. The IMM uses this domain knowledge in the context of a mission and crew profile to forecast crew health and mission success risks. The IMM is most helpful in *comparing* the risk of two or more mission profiles, not as a tool for predicting absolute risk. The process of building the IMM adheres to Probability Risk Assessment (PRA) techniques described in NASA Procedural Requirement (NPR) 8705.5, and uses current evidence-based information to establish a defensible position for making decisions that help ensure crew health and mission success. The IMM quantitatively describes the following input parameters:

- medical conditions and likelihood,
- mission duration,
- vehicle environment,
- crew attributes (e.g. age, sex)
- crew activities (e.g. EVA's, Lunar excursions),
- diagnosis and treatment protocols (e.g. medical equipment, consumables pharmaceuticals), and
- Crew Medical Officer (CMO) training effectiveness.

It is worth reiterating that the IMM uses the data sets above as *inputs*. Many other risk management efforts stop at determining only likelihood. **The IMM is unique in that it models not only likelihood, but *risk mitigations*, as well as subsequent clinical *outcomes* based on those mitigations.** Once the mathematical relationships among the above parameters are established, the IMM uses a Monte Carlo simulation technique (a random sampling of the inputs as described by their statistical distribution) to determine the probable outcomes. Because the IMM is a stochastic model (i.e. the input parameters are represented by various statistical distributions depending on the data type), when the "mission" is simulated 10-50,000 times with a given set of medical capabilities (risk mitigations), a prediction of the most probable outcomes can be generated. For each "mission", the IMM tracks which conditions occurred and decrements the pharmaceuticals and supplies required to diagnose and treat these medical conditions. If supplies are depleted, then the medical condition goes untreated, and crew and mission risk increase. The IMM currently models approximately 30 medical conditions. By the end of FY2008, the IMM will be modeling over 100 medical conditions, approximately 60 of which have been recorded to have occurred during short and long space missions.



*The **IMM user interface** is Excel with the added statistical forecasting and optimization functionality provided by Crystal Ball. Crew, mission, and all other medical modeling occur here.*

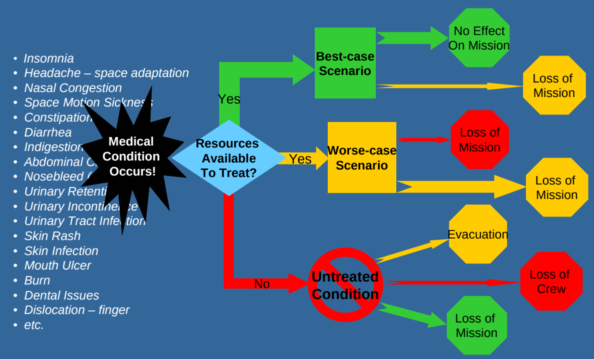
*A **VBA interface** module acts as the interface between the Resource Manager and Excel. A built in Test Macro ensures the IMM and Resource Manager are exchanging data as intended.*

*The **Resource Manager** tracks the medical consumables needed to diagnosis and treat each condition. If all the consumables have been used (or were not flown for that mission), the medical condition goes untreated. After each Monte Carlo simulation (aka "mission run"), the RM resets for the next "mission".*

*Each medical condition modeled in the IMM is mapped to the medical resources (unit mass, unit volume, and quantity) required to diagnose and treat that condition. **Eventually unit cost will be added to the Resource database to facilitate trade studies among medical risk, cost, mass, and volume.***

IMM Capabilities

- Simultaneously assesses ALL parameters that influence medical risk in the context of a mission and crew profile. Other risk efforts typically examine one medical condition at a time (e.g. by using the 5x5 risk matrix),.
- Evaluates mission risk by modeling all three risk components (likelihood, available mitigation strategy, and consequence). Many risk efforts stop once an estimation of likelihood is characterized,
- Uses Monte Carlo simulation to forecast the most likely outcomes for a mission and crew profile
- Offers optional optimization of the contents of a crew health care system
- Aids operational and research decisions based on risk, mission or crew attributes, or medical system mass and volume
- Provides various analysis capabilities (e.g. sensitivity analyses, spider charts, and tornado charts) to identify key contributors that influence clinical outcomes, mission success, and enterprise budgets. By identifying contributors that are most influential to risk, organizational resources can be focused on the efforts that matter most
- Accounts for *uncertainty* in both the model inputs and outputs, and
- Characterizes the level and duration of impairment of a crew member by using a utility measure (i.e. % whole body impairment; also termed "functional impairment) currently used by the American Medical Association (AMA) and the medical insurance industry



Methods

- **Establishing a List of Relevant Medical Conditions** – A baseline list of medical conditions serves as the IMM clinical modelling roadmap and is required to manage the scope of the project. The current Baseline List of Medical Conditions (BLMC) – derived from the ISS Medical Checklist - covers approximately 75 conditions, most of which have occurred during past space flights. The ISS Checklist was used as a starting point; the BLMC will be supplemented with new data from the Longitudinal Study of Astronaut Health (LSAH) Database, Delphi Study, and space medicine peer reviews.
- **Establishing incidence rates** – The IMM incidence rate (defined as events/person-year) for each condition on the BLMC was initially established from reviewing historical medical event records from the Apollo, Skylab, Shuttle, Mir, and ISS Programs. Additional incidence data was derived by conducting brief literature reviews and queries to the LSAH Database. The in-flight incidence data will be updated with terrestrial surrogate population data as applicable; a collaboration with the United States Army Aeromedical Research Laboratory is underway.
  - To gain greater insight of operations or risk factors, some medical conditions such as bone fracture, renal stone formation, behavioural health have stochastic predictive models developed to forecast incidence rates. These forecasted distributions are then used in the IMM as inputs.
- **Clinical Findings Form (CliFF); Quantifying clinical information for each condition** - The CliFF serves as both a clinical requirements document (for the development of the IMM) and reference document for each medical condition modeled in the IMM. The CliFF provides a framework for the clinician to capture clinical and operational data in a quantified form needed by the IMM. The quantified data (either deterministic or stochastic), assumptions, and sourced references provide a defensible position for accepting risk and making financial investments in areas where little information exists. The table below is an excerpt from the CliFF for corneal abrasion:

Table of Treatments and Outcomes

TREATMENT OPTIONS	Diagnosis & Initial Treatment		Treatment/ Convalescence		Recovered/ Mission End State	
	FI* (%)	Duration (hrs)	FI (%)	Duration (hrs)	FI (%)	Mission End state results**
ISS-based Treatment (best case scenario): A1=90-99%	100	0.5-0.75	16-24[2]	24-48	0	N/A
ISS-based Treatment (worst case scenario): A2=1-10%	100	0.75-1.5	16-24[2]	336	23.3-24.5[2]	EVAC (0-2%)
Untreated Case	N/A	N/A	10.8-35[3]	>336	10.8-35[3]	EVAC (0-100%)

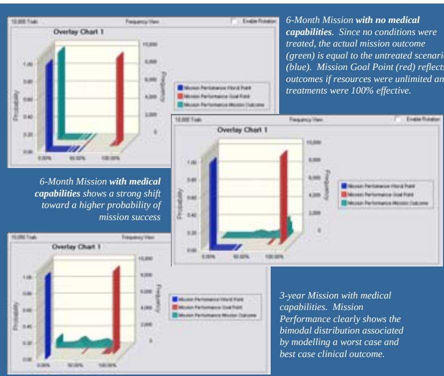
- **Resource Table; Quantifying the items needed to diagnose and treat each condition –** For each medical condition, the tasks and items needed to diagnose and treat the disorder are recorded. For each medical item, the quantity required, unit mass, and unit volume are tracked for both a best-case and worse-case treatment scenario. Eventually, tasks and items required to provide the best urban care will be included in the IMM to enable comparisons with terrestrial standards and establish a metric for clinical effectiveness.
- **Establishing Metrics for Crew Health Risk –** Adopted from AMA guidelines, the Quality Adjusted Life Years (QALY) *lost* metric accounts for the final functional impairment of the individual based on available mitigation strategies and life expectancy. All things equal, health risks (a.k.a. QALY lost) will be greater for younger individuals since they have more quality years to lose due to their longer life expectancy.
- **Establishing Metrics for Mission Risk resulting from crew health disorders –** Mission risk is done by scaling the lost QALY's to the duration of the mission instead of expected life span.

Validation

- **Clinical** – Clinical validation is a multi-tiered, continuous effort. Data is initially vetted by the IMM Clinical Lead, then reviewed by Space Medicine Subject Matter Advisors, and finally Independent Clinical Reviewers. This validation process would also assess the accuracy of the tasks and resources required to diagnose and treat each condition.
- **Statistical** – Statistical validation is currently a three-phased effort. Phase I ensures the correct distributions have been assigned to all model assumptions. Phase II tests the model with extreme values. And Phase III compares predicted forecasts with empirical data if available.
- **Architecture/Design** – To ensure the IMM is operating properly, the IMM is tested after medical conditions are modelled per the CliFF. The Clinical Lead reviews IMM forecasts and sensitivity analyses to identify and resolve inconsistencies early.

IMM Output - Examples

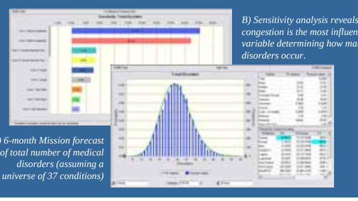
The IMM currently models 37 disorders, however only a few conditions have assigned diagnosis and treatment protocols so the following forecasts are offered as examples only. Each forecast represents 10,000 mission simulations, with one male and one female crew member (two crew total).



*6-Month Mission **with no medical capabilities**. Since no conditions were treated, the actual mission outcome (green) is equal to the untreated scenario (blue). Mission Goal Point (red) reflects outcomes if resources were unlimited and treatments were 100% effective.*

*6-Month Mission **with medical capabilities** shows a strong shift toward a higher probability of mission success*

3-year Mission with medical capabilities. Mission Performance clearly shows the bimodal distribution associated by modelling a worst case and best case clinical outcome.



B) Sensitivity analysis reveals nasal congestion is the most influential variable determining how many disorders occur.

A) 6-month Mission forecast of total number of medical disorders (assuming a universe of 37 conditions)

Key Assumptions, Inaccuracies

- The IMM views the mission from the point of view of the mission debrief. This means the mission is viewed as if it was already completed. What happened on which day is not tracked. We experimented with tracking each day and building a mission log, but it turned out to be very complex and not very helpful at the time. This choice leads to additional limitations.
- All medical events are completely separate. The only exception are recurrent disorders that depend on an index case. All outcomes are calculated as if they were the only impact on the mission, then summed together. This causes a higher QALY lost.

Summary

The IMM will continue to add conditions and refine the clinical evidence base, and is on track to help support risk-based decisions for medical systems and operational concepts for the Constellation Program. The IMM Project coordinates data mining and modeling activities with other Risk Management efforts such as the Exploration Medicine Element, Risk Assessment and Integration Team (RAIT), SD2/Delphi Study, and Longitudinal Study of Astronaut Health (LSAH) Office.

The Integrated Medical Model (IMM) Project

- Overview – Statistical decision support tool for forecasting crew health and related mission risks, and optimizing the medical logistics “footprint” of in-flight crew medical systems

- Progress to Date
  - Established Baseline list of approximately 75 conditions
  - 37 medical conditions modeled
  - Defined Risk Metrics for crew and mission
  - Established Clinical Finding Form Template
  - Developed Resource Manager Software to track medical consumables
  - Compiled historical Review of Medical Events
  - Populating Resource Tables with unit quantity, mass, and volume Collaborating with USAARL to refine incident data with surrogate population data
  - Developing Clinical and Statistical Validations Plans

IMM Key Milestones

FY2008	FY2009	FY2010	Capabilities
Δ Baseline Medical Conditions List Δ Complete CLIFF's (72+ conditions) Δ Model 72+ Conditions Δ Integrate Resource Table (72+ conditions x2) Δ Establish Statistical/Clincal Validation Plans Δ Assess/Integrate USAARL data			✓ Initial roadmap established ✓ Outcomes mapped to conditions and treatments ✓ Initial assessments capable ✓ Logistics mapped to risks ✓ Baseline conditions list expanded via surrogate population data
	Δ Incorporate Delphi Data (when available) Δ Develop Database Integration Requirements Δ Refine Loss of Mission (LOM) metric Δ Initiate Statistical/Clinical Validation Plans Δ Migrate CliFF's to database Δ 100+ conditions modeled (est.)		✓ Baseline conditions list + ✓ Ensure knowledge capture ✓ Refined comparative mission risk assessments ✓ Efficient, current modeling ✓ Prep. for database integration ✓ Increased confidence levels
		Δ Complete Initial Validation Δ Expand Risk Factors Δ Database Integration Δ 120+ conditions modeled	✓ Validated planning tool ✓ Increased crew/mission modeling fidelity ✓ Efficient, current modeling with HITT/PCDB ✓ Increased confidence levels