Enabling Space Exploration Medical System Development Using a Tool Ecosystem

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The NASA Human Research Program's (HRP) Exploration Medical Capability (ExMC) Element is utilizing a Model Based Systems Engineering (MBSE) approach to enhance the development of systems engineering products that will be used to advance medical system designs for exploration missions beyond Low Earth Orbit. In support of future missions, the team is capturing content such as system behaviors, functional decompositions, architecture, system requirements and interfaces, and recommendations for clinical capabilities and resources in Systems Modeling Language (SysML) models. As these products mature, SysML models provide a way for ExMC to capture relationships among the various products, which includes supporting more integrated and multi-faceted views of future medical systems. In addition to using SysML models, HRP and ExMC are developing supplementary tools to support two key functions: 1) prioritizing current and future research activities for exploration missions in an objective manner; and 2) enabling risk-informed and evidence-based trade space analysis for future space vehicles, missions, and systems. This paper will discuss the long-term HRP and ExMC vision for the larger ecosystem of tools, which include dynamic Probabilistic Risk Assessment (PRA) capabilities, additional SysML models, a database of system component options, and data visualizations. It also includes a review of an initial Pilot Project focused on enabling medical system trade studies utilizing data that is coordinated across tools for consistent outputs (e.g., mission risk metrics that are associated with medical system mass values and medical conditions addressed). This first Pilot Project demonstrated successful operating procedures and integration across tools. Finally, the paper will also cover a second Pilot Project that utilizes tool enhancements such as medical system optimization capabilities, post-processing, and visualization of generated data for subject matter expert review, and increased integration amongst the tools themselves.

TABLE OF CONTENTS

1. INTRODUCTION

NASA is committed to successfully extending human exploration beyond Low Earth Orbit. The Human Research Program's (HRP) Exploration Medical Capability (ExMC) Element is utilizing a Model-Based Systems Engineering (MBSE) approach to ensure timely input for the development of a broadly-scoped, integrated human health and performance system for deep space exploration. NASA's future deep space exploration missions mandate a significant paradigm change for mission planning, spacecraft design, human systems integration, and in-flight medical care due to constraints on mass, volume, power, resupply missions, and medical evacuation capabilities. These constraints require further development of a human health and performance system (which includes medical, health and wellness, and human systems). The human health and performance system will be tightly integrated with mission and habitat design to provide a sufficient human health and performance infrastructure to enable mission success. ExMC and HRP are developing and utilizing a tool suite ecosystem to enhance the MBSE approach to support this integration effort.

2. BACKGROUND

The scope of spaceflight medical systems has historically been limited to kits with additional devices manifested as needs have arisen. Current medical operations on the International Space Station (ISS) are largely reliant on Earth for support and decision-making. To extend beyond Low Earth Orbit, key changes in the mission characteristics, such as reduced mass, power, volume, and data, along with real-time communication time delays, force a shift to a more

sophisticated medical system. This means reduced initial resource allocations, limited or no resupply or augmented capabilities using later manifests, increased time/difficulty required for removal to definitive medical care, and limited real-time operational support [1].

Recently, ExMC has been addressing how to inform the design of a sophisticated exploration medical system using a systems engineering approach [5]. The ExMC Systems Engineering team is applying an MBSE application of a largely traditional systems "Vee" model, progressing from stakeholder engagement, development of a concept of operations, defining functions, developing an architecture, and writing requirements. Mindock et al discuss those high-level system engineering efforts in additional detail [4].

Current work of the ExMC Systems Engineering team includes converging medical system level systems engineering products, such as the existing concept of operations document, requirements and in process interfaces definitions, into a cohesive medical system foundation. This foundation is similar to a conceptual baseline, with the important distinction that it is based on assumptions for exploration missions, and is not a programmatic baseline. It is, however, a powerfully solid, defensible, and traceable system foundation due to the MBSE approach described further in this paper. This foundation can be adjusted by future programs as details and plans solidify for specific missions.

The high-level medical system foundation work is not sufficient to determine the exact contents and devices to be included in a medical system. It shapes and guides the system from a "black box" perspective, but key decisions impacting the risk accepted by a program due to a specific implementation of a medical system will also occur at the "white box" level to define what aspects such as medications, devices, supplies, and even crew skills, need to be "inside."

3. APPROACH

ExMC has chosen to take a quantitative approach to inform the detailed definition of a medical system. This allows for evidence based, data-informed decisions when selecting what to include in any medical system. To execute a quantitative approach, tools are required. The ExMC Systems Engineering team has viewed the set of tools as a system itself, as the "black box" equivalent of various tools acting together to produce cohesive quantitative, analytical outputs. This "black box" is referred to as the tool suite, and is further discussed in this paper.

The approach to the tool suite development to date has been somewhat non-traditional from the perspective of systems engineering practice. In Fiscal Year (FY) 2016, which runs from September to September, the initial concepts for integrating medical system evaluations were developed [2]. In FY2017, work was underway on some of the individual tools envisioned as part of the tool suite, but no effort had yet been established to integrate development activities across the various tools. FY2018 was the first time such an effort was undertaken in an initial Pilot Project to help the ExMC Systems Engineering team familiarize themselves with the desired technical outputs and capabilities of the various tools. The technical and organizational value of the initial Pilot Project was apparent, and in FY2019 a second Pilot Project was initiated to build upon the first and help shape stakeholder needs and expectations. At the time of this paper writing, parallel work developing more traditional systems engineering products has begun in order to focus stakeholder convergence on the long-term needs for the tool ecosystem. This paper discusses the current tools (as of the end of FY2019) and provides an overview of the analytical capabilities as exercised in the Pilot Projects.

4. TOOL ECOSYSTEM OVERVIEW

The tool suite ecosystem discussed in this paper provides a means for the HRP's ExMC Element's interests to be represented during deep space mission development. The long-term goal of the tool suite is to characterize the exploration medical system architecture trade space to inform mission development, vehicle and habitat development, and research planning. It allows the stakeholders to quantify engineering impacts and risks that a potential human health and performance capability could have on crew and mission outcomes. This assessment is done in the context of human health and performance missions with a specified information flow. The tool suite will follow the flow shown in Figure 1.

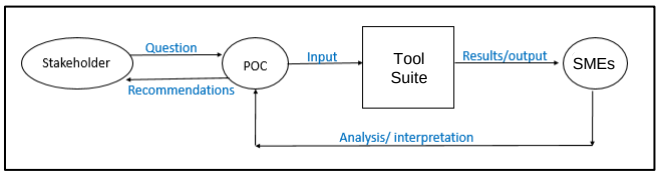

Figure 1: Tool Suite Information Flow

In brief, stakeholders will pose a question about a human health and performance capability to a tool suite point of contact (POC), who will then collect and/or generate the information necessary as inputs into the tool suite. The results generated by the tool suite will be presented to subject matter experts (SMEs), who will then analyze and validate the output and provide an interpretation of the results to the POC. The POC will then provide the recommendations to the relevant stakeholders. Iterations on system options, inputs, and outputs may be required. Currently, the tool suite provides users with information on risk parameters, resources used such as medications, supplies, or devices, health state of the crew, and whether relevant metrics are within acceptable limits or constraints.

Within the "Tool Suite" box shown in Figure 1, the current tool suite consists of five tools: the Medical Evidence Library; the Medical Extensible Dynamic Probabilistic Risk Assessment Tool (MEDPRAT); the Medical Item Database (MedID); the Exploration Medical System Model (EMSM)

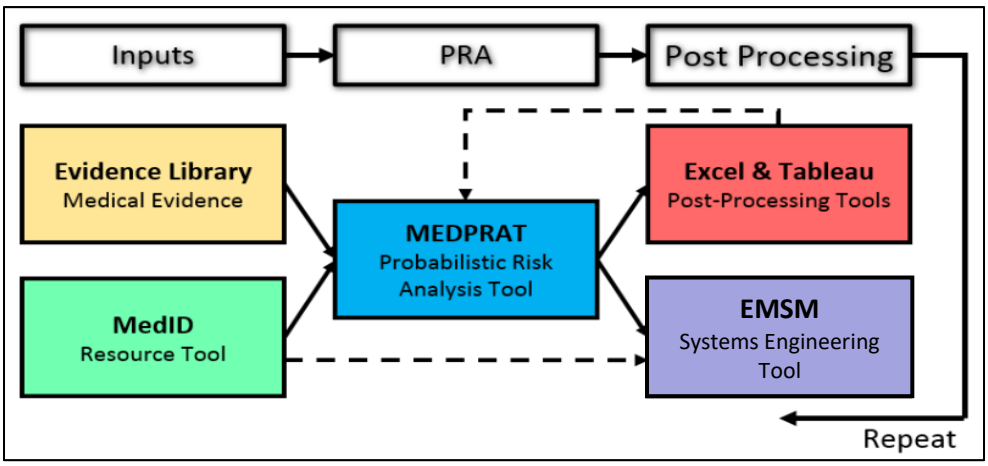

Figure 2: Tool Suite Interactions

written in the Systems Modeling Language (SysML); and post-processing data visualizations created with Excel and Tableau. The current block diagram for this tool suite is in Figure 2, and a more detailed view of the tool interactions is shown in Figure 4. Each tool will be discussed in detail to provide a broader overview of this tool suite in development for exploration spaceflight missions.

Evidence Library

The Evidence Library is a proposed clinical database of spaceflight and terrestrial medical evidence. As of the end of FY2019, it is still under development. It will include intervention options and resources required for each medical condition, references for each medical condition, incidence of occurrence of medical conditions, and other supporting data. The database will be a single library of evidence for exploration spaceflight medical condition and health outcome data. The ExMC Clinical and Science Team will maintain the Evidence Library.

The inputs to Evidence Library come from a variety of sources, including clinical evidence from literature reviews by the ExMC Clinical and Science Team, documentation of spaceflight medical data from the Lifetime Surveillance of Astronaut Health, and candidate resources from MedID. While the Evidence Library is still under development, the tool suite is using legacy data from the Integrated Medical Model's Medical Evidence Database (iMED). However, iMED content is outdated and does not contain the discrete data needed to inform the wider array of tools that will be utilized in future iterations of the tool suite.

Medical Item Database

MedID is a secure, curated, cloud-based database of medical items potentially available for exploration spaceflight missions. The purpose of MedID is to support and facilitate medical system-related evaluations for exploration missions. Within the tool suite, it provides the information characterizing medical resources (i.e. equipment, pharmaceutics) available in candidate medical systems to MEPDRAT and generates a Master Equipment List (MEL) after MEDPRAT is run. MedID contains mass, volume, power, quantity, storage information, and packaging information for every resource represented. A use case for MedID is shown in Figure 3.

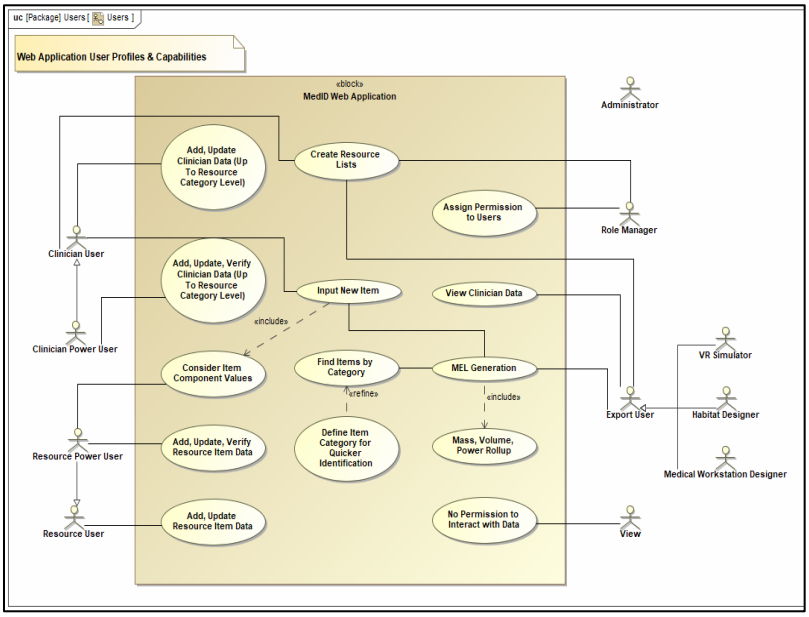

Figure 3: MedID Use Case

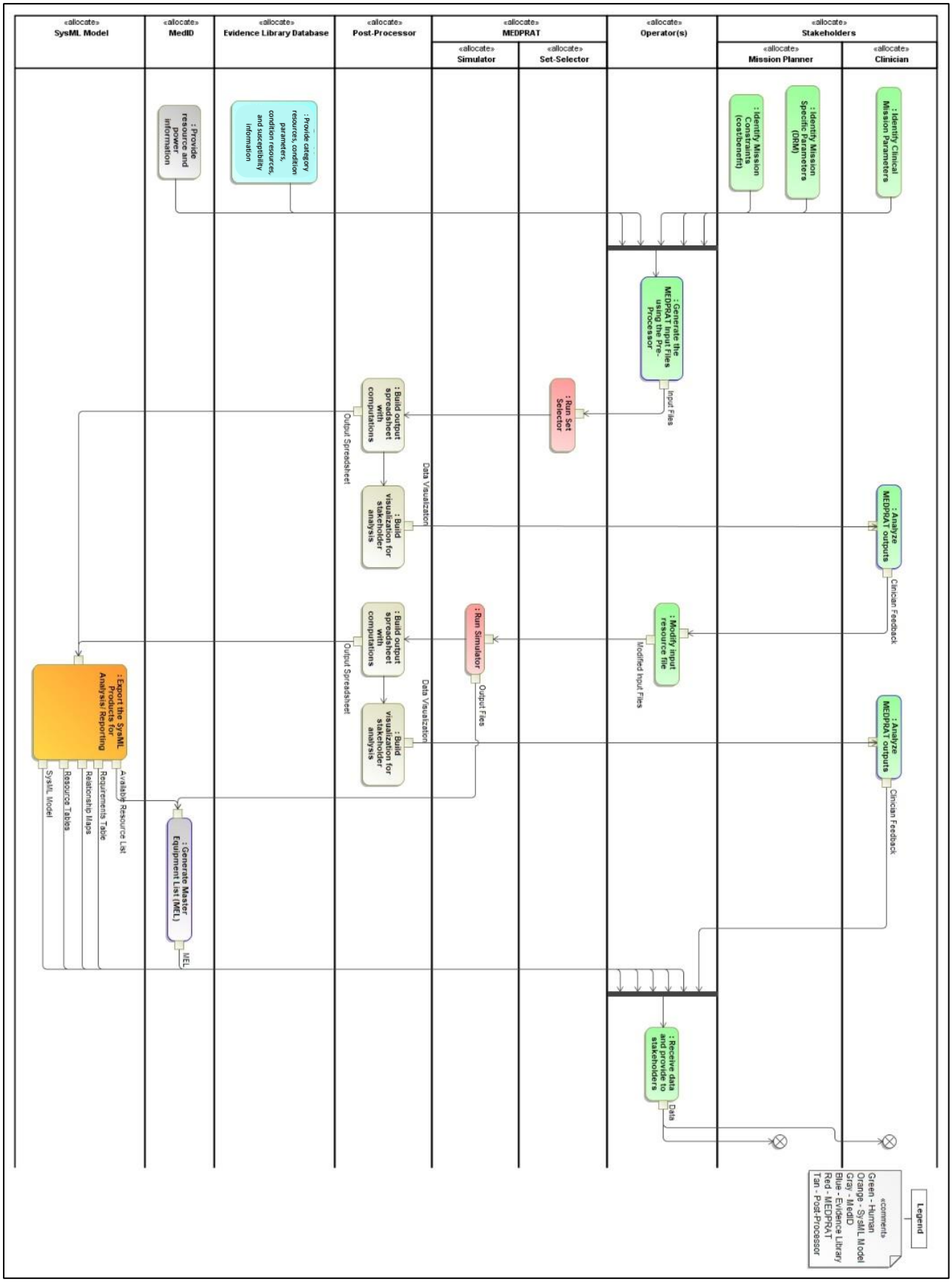

Figure 4: Activity Diagram

MEDPRAT

MEDPRAT generates probabilistic predications of human health and medical risks during spaceflight under user-specified mission conditions using historical medical evidence from both human spaceflight and terrestrial studies. MEDPRAT models discrete events in a dynamic, probabilistic simulation, accounting for the effects of cascading, unplanned events involving the crew, the vehicle, and supporting equipment. MEDPRAT also accounts for the positive effects of interventions for treating specific medical conditions and countermeasures for mitigating the effects of spaceflight. Generally, MEDPRAT assesses spaceflight health risks in a manner consistent with the assessment of other risk measures in spacecraft design, mission design, or decision-making.

MEDPRAT is extensible, allowing it to work with a wide variety of mission scenarios. It has the capability to run with an expanding base of medical evidence, with new technologies being developed for space medicine, and, eventually with domains outside of the medical system, such as the exercise system or the life-support system.

MEDPRAT has three modes of operation for medical conditions – fully treated, partially treated (with limited medical capability), and untreated – to predict the risks of loss of crew life (LOCL), removal to definitive care (RTDC), and quality time lost (QTL). These risk metrics provide important information about human health and performance. The probability of medical conditions occurring is based on a given mission scenario, for which assumptions are made on the number/gender of crew, pre-existing conditions, and number and timing of occurrence of extravehicular activities (EVAs).

MEDPRAT has two primary components known as the simulator and the set-selector. The simulator code is C++ based and performs the Monte-Carlo simulations while extensively documenting the results of the individual trials. These results include both statistical summaries and detailed reports of outcomes, which include occurrence of medical conditions, usage of medical resources, and courses of treatment.

The set-selector code is Python based and performs global optimization to determine the best set of medical resources, drawn from an available resources list, which will minimize a combination of medical risks while meeting constraints on the overall medical system footprint. These constraints are typically acceptable notional target values for mass, volume and power consumption, or a combination thereof. The set-selector invokes the simulator many times while it pares down the medical system from infinite quantities of each resource until the footprint is within user-specified acceptable targets. The resulting medical set represents a feasible, nearly optimized solution.

EMSM

An MBSE approach is being implemented with the EMSM, which is created in the Object Management Group Systems Modeling Language™ (OMG SysML®), a general-purpose graphical modeling language for specifying, analyzing, designing, and verifying complex systems that may include hardware, software, information, personnel, procedures, and facilities. The model is populated with cross-correlated medical conditions, medical resources, and medical system requirements. Based on the relationships between conditions, resources, and requirements, the EMSM depicts how inclusion or non-inclusion of medical resources translates to addressing or not addressing medical conditions and to mission medical requirements satisfaction.

As a graphical modeling language, SysML relies on a defined data structure. Within the exploration medical systems model, a data structure relevant to the tool suite is captured within "stereotypes." These stereotypes enable the user to create domain specific terminology that remains consistent throughout the model. The user can also create attributes that pertain to each stereotype. An example of a stereotype with attributes is shown in Figure 5.

Figure 5: Example of a Stereotype

In this example from the tool suite EMSM, an *IMED Resource* stereotype was assigned attributes of mass, volume, power, quantity, resource category, resource type, and consumability. Similarly, an *IMED Medical Condition* stereotype was created and assigned attributes that include medical condition name, probabilistic risk information, and incident rate. In both cases, other attributes that would make each medical resource or condition unique could be added as needed to characterize the system. The stereotypes are applied to model elements so that information for a unique medical condition is related to a unique set of medical resources, once a resource has been allocated to the medical condition. The allocation dependency matrix is shown in Figure 6.

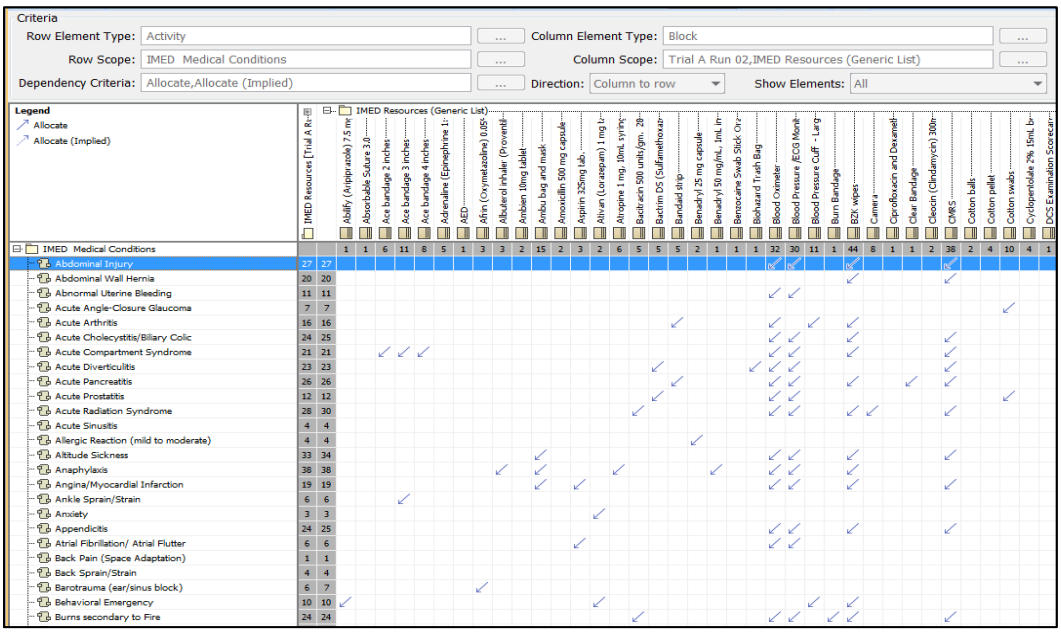

Figure 6: Dependency Matrix

The ExMC Clinical and Science Team uses a dependency matrix to map the allocations of medical resources to medical conditions. They can also utilize their knowledge and experience to create a dependency matrix to allocate medical resources to a number of other data structures such as clinical capabilities or knowledge, skills, and abilities required to address medical conditions. Using these dependency matrices, the EMSM can suggest what medical conditions will be impacted given the loss or removal of a medical resource, based on information from MEDPRAT. MEDPRAT identifies candidate medical sets containing resource removal options arising from user-imposed constraints. Results of MEDPRAT analysis are exported into an Excel spreadsheet identifying the proposed removed set of medical resources for each candidate medical set. This data is re-formatted to import the proposed removed set of medical resources into SysML and a dependency matrix is used to allocate these resources to the appropriate medical conditions for comparison.

The EMSM can then provide a comparison of the two candidate medical sets showing the conditions that are impacted by the removal of resource, which aids clinicians in identifying how the removal of those resources will impact the medical capability for addressing a set of medical conditions. A screenshot of the EMSM showing this capability is shown in Figure 7, in which Scenario 19 and Scenario 38 represent the two candidate medical sets with different resources. The EMSM additionally includes a filtering capability that allows the ExMC Clinical and Science Team to determine exceptions between two sets of consolidated medical condition lists. The examination of the differences between the two candidate medical systems can provide insight on which medical outcome is preferred. This information can also be presented in tabular form for the ExMC Clinical and Science Team review. Similarly, for a given resource change, the EMSM has the capability to explore how requirements are impacted for a specific mission.

#	Name	Scenario 19 Items	Scenario 38 Items	Medical Conditions Trace	Requirements Trace	Resource Type
1	Abilify (Aripiprazole...			Behavioral Emergency	Hab-MedSys-Resources-0001 Provide Abilify (Aripiprazole) 7.5 mg/m	Abilify (Aripiprazole) 7.5 mg/mL, 1.3 mL
2	Absorbable Suture ...		ABSORBABLE SUTURE 3.0	Skin Laceration	Hab-MedSys-Resources-0002 Provide Absorbable Suture 3.0	Absorbable Suture 3.0
3	Ace bandage 2 inches		ACE BANDAGE 2 INCHES	Acute Compartment Syndrome Shoulder Dislocation Lower Extremity (LE) Stress Fracture Elbow Dislocation Hip/Proximal Femur Fracture Shoulder Sprain/Strain	Hab-MedSys-Resources-0003 Provide Ace bandage 2 inches	Ace bandage 2 inches
4	Ace bandage 3 inches		ACE BANDAGE 3 INCHES	Elbow Dislocation Lower Extremity (LE) Stress Fracture Shoulder Dislocation Wrist Sprain/Strain Knee Sprain/Strain Wrist Fracture Hip/Proximal Femur Fracture Acute Compartment Syndrome Elbow Sprain/Strain Shoulder Sprain/Strain	Hab-MedSys-Resources-0004 Provide Ace bandage 3 inches	Ace bandage 3 inches
			ACE BANDAGE 4 INCHES	Hip/Proximal Femur Fracture Wrist Sprain/Strain	Hab-MedSys-Resources-0005 Provide Ace bandage 4 inches	Ace bandage 4 inches

Figure 7: Impacted Medical Conditions

Post-Processor

Post-processing includes the use of both Microsoft Excel and Tableau data visualization software. There are two post-processing visualizations built with Tableau, based on the outputs from the MEDPRAT set-selector and the MEDPRAT simulator runs, respectively. The post-processors present the MEDPRAT output data so that stakeholders can make expedient, informed decisions based on the results of the MEDPRAT run. Once vetted through a clinician, the results are then used as input to the EMSM.

For the MEDPRAT set-selector, the post-processing is used to help determine a best candidate medical set to meet all constraints and acceptable risk thresholds while being able to view the set contents easily. The set-selector post-processor is a Tableau workbook linked to an Excel workbook containing results from the MEDPRAT set-selector of various mission scenarios. It can be modified to be extensible to any collection of mission trades with regard to medical capability that can be analyzed and simulated by the MEDPRAT set-selector. The set-selector post-processor allows the ExMC Clinical and Science Team to analyze the selected medical system's mass, volume, contents, and descriptions.

For the MEDPRAT simulator, the post processing is used to provide information about condition occurrence, resource utilization, and overall medical risks. The simulator post-processor is a Tableau workbook linked to an Excel workbook containing results from the MEDPRAT simulator of various mission scenarios. One example of the post-processing capability for the simulator post-processor is shown in Figure 8.

5. PILOT PROJECT OVERVIEW

In developing the tool suite, the ExMC Element is conducting a multi-phase Pilot Project to demonstrate incremental advancement in capability and integration among the various tools each fiscal year, beginning in FY2018. Because the tools are being developed at multiple NASA Centers under different design philosophies, the Pilot Project has adopted objectives that relate to integrating the tools into a more cohesive whole.

The ongoing Pilot Project has completed its first and second phases. Table 1 lists the goals of the first two phases, while Table 2 contains the status of each tool in the tool suite during each phase. Table 3 lists the notional target allocation values and acceptable risk thresholds assumptions for Phase II, which are representative and not programmatic values. In Phase I the goals were modest and were intended to demonstrate that a user could interact with the tools to produce outcomes. The Phase II goals focused on medical system optimization, tool and team integration, and more substantive trade analysis with the tools. For both phases of the Pilot Project it is important to emphasize that developing the process is currently valued over results, because the input information is notional and incomplete, particularly the medical evidence and resource packaging data, which are still being gathered.

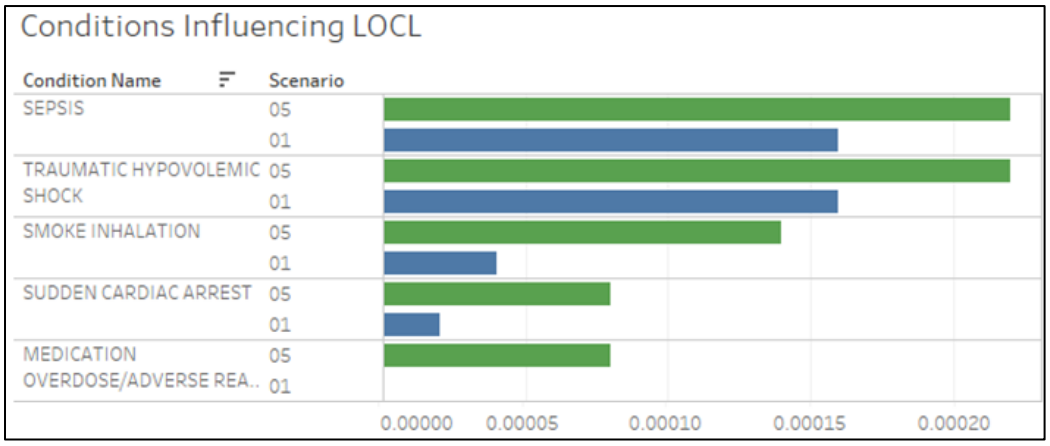

Figure 8: Top 5 Conditions Influencing LOCL

Table 1: Goals of the Phase I and II Pilot Projects

Category	Phase I Goal	Phase II Goal
Trade studies	Remove equipment items from a baseline medical set and determine outcomes	• Perform trades on mission scenarios (length, activities, crew histories) • Produce an optimal medical set to meet risk target(s) while meeting footprint constraint(s) • Determine the effect of reducing footprint of heavier items through technology development on overall risk • Demonstrate that optimization can produce a medical set that simultaneously meets two cost targets (mass, volume) while also meeting two acceptable risk thresholds (LOCL, QTL)
Outcomes	Produce relevant outputs: • Risk metrics (LOCL, QTL, RTDC) • Master equipment list • Requirements met/unmet by medical system • Conditions addressed/not addressed by medical system	• Refine outcome fidelity and reporting • Fully exercise the MEDPRAT optimization capability • Visualization of MEDPRAT outcomes in Excel/Tableau to assist with decision- making • Produce detailed reports from SysML model regarding impacts of reduced medical sets
Formatting	Ensure consistent data products across teams	Standardize formats and interfaces among the tools
Process	Demonstrate manual process flow	Identify the interfaces between tools and identify opportunities for automation
Time to results	Weeks	Days
Continuous improvement	Document lessons learned going forward	Adopt a systems engineering approach to the tool suite, including a concept of operations
# of scenarios	2	38

Table 2: Tool Development Status

Tool	Phase I Pilot Status	Phase II Pilot Status
Evidence Library	Legacy iMED information	Legacy iMED information
MedID	ISS medical resources with legacy iMED mass and volume information	Expanded medical resources with updates to legacy iMED mass and volume information
MEDPRAT	Simulator only	Simulator and set-selector optimizer in place
EMSM	Basic reporting of impacted conditions and requirements met/not met	Phase I capability plus the ability to directly compare two or more trials
Post-Processing	Basic Excel/Tableau visualizations constructed ad hoc	Substantial development in Excel/Tableau to enhance visual interpretation of data and to directly facilitate decision making

Table 3: Notional Optimization Targets & Risk Thresholds

Parameter	Phase II Pilot Project
Target Mass Allocation	≤ 12.09 kg
Target Volume Allocation	≤ 18721 mL
Acceptable LOCL	≤ 0.001
Acceptable QTL	≤ 8.4 days
Acceptable RTDC	≤ 0.05

To meet these goals, the tool suite supported nine different trials (A – I) whose Design Reference Mission (DRM), medical capability, trade scenarios and qualitative outcomes are summarized in Table 4. These trials were selected to be representative of a variety of possible trade space scenarios. For Phase I the DRM for Trial A was a 42 day mission with 4 crewmembers, and the DRM for Trial B was a 180-day Mars fly-by with 6 crew members, and the baseline medical capability was the medical kit for the ISS using data from the iMED database for resources. For Phase II trials (C – I) the DRM was a 42-day mission to a cis-lunar habitat, and the baseline medical capability was similar to the ISS medical kit, but with updated capabilities and values for mass and volume from MedID.

Table 4: Description and Outcomes of Pilot Project Scenarios

	Trial	DRM	Medical Capability	Trade Scenarios	Outcomes
Phase I	A	42 days 4 crew 1 female EVAs	ISS medical kit from iMED	Remove space motion sickness medications from a baseline medical set and determine outcomes	• Removing meds resulted in increases in LOCL, QTL, and RTDC
	B	365 days 6 crew 1 female EVAs	ISS medical kit from iMED	Remove a significant portion of mass/volume by eliminating defibrillator and oxygenation hardware	• Removing equipment resulted in non-significant increases in LOCL, QTL, and RTDC • 32 conditions no longer addressed
Phase II	C	42 days 4 crew 1 female EVAs	Updated medical set from MedID	Investigate effects of: • Extend mission to 90 days • With/without EVAs • With/without RTDC option • With/without pre-existing conditions among crew members	• Mission duration increase from 42 days to 90 days contributed significantly to increased risk • Other effects did not significantly affect risk factors for a 42 day mission • High variance in outcomes, especially LOCL
	D	42 days 4 crew 1 female No EVAs	Optimized version of Trial C	• Optimize to meet a mass target only. Reduce baseline mass target by 12.5% and 25%. • Optimize each combination within acceptable LOCL only, then within acceptable QTL only	• Optimizing to meet a mass target for LOCL only resulted in unacceptably high QTL • Optimizing for QTL only still resulted in acceptable LOCL
	E	42 days 4 crew 1 female No EVAs	Optimized version of Trial C	• Optimize to meet a volume target only. Reduce baseline volume target by 12.5% and 25%. • Optimize each combination within acceptable LOCL only, then within acceptable QTL only	• Optimizing to meet a volume target for LOCL only resulted in unacceptably high QTL • Optimizing for QTL only still resulted in acceptable LOCL
	F	42 days 4 crew 1 female No EVAs	Optimized version of Trial C	• Optimize to meet a weighted combination of mass and volume targets. • Optimize each combination within acceptable LOCL only, then within acceptable QTL only	• Optimizing to meet a combined mass and volume target for LOCL only resulted in unacceptably high QTL • Optimizing to meet a combined mass and volume target for QTL only still resulted in acceptable LOCL • Better overall solution when volume weighting was higher relative to mass
	G	42 days 4 crew 1 female No EVAs	Optimized version of Trial C	Optimize to meet mass target or a weighted combination of mass and volume targets and a weighted combination of acceptable risk thresholds.	• A weighted combination of risk thresholds resulted in the ability to meet both simultaneously • Better overall solution when volume weighting was higher relative to mass
	H	42 days 4 crew 1 female No EVAs	Optimized version of Trial C	Optimize to meet a mass target with the two heaviest items reduced in mass and volume by 80% each through technology development	• An 80% reduction in mass of two bulky items permits their inclusion in the medical system and enables medical requirements to be met that were previously not being met, while maintaining acceptable risk
	I	42 days 4 crew 1 female No EVAs	Optimized version of Trial C	Determine the weighting coefficients required to meet mass and volume targets as well as acceptable thresholds for LOCL and QTL simultaneously.	• It was possible to meet mass and volume targets within acceptable risk thresholds for LOCL and QTL • The target for volume requires a higher weighting because it constrains the medical system more than the target for mass

Results of selected scenarios

Loss of resource trades (Trials A and B) – The scenarios examined in Phase I dealt specifically with the elimination of specific resources and the resulting effects on mission risks. The DRM parameters for these trials appear in Table 4. Trial A determined that eliminating space adaptation sickness medications on a 42-day mission would result in increases in risk for LOCL (8.5%), QTL (11.4%), and RTDC (20.3%), although only the latter two were statistically significant. Trial B found that removing heavier equipment (AED, oxygenation hardware) resulted in non-significant increases in LOCL (8.5%), QTL (0.4%), and RTDC (1.1%), despite a 7.4% decrease in mass, and 32 medical conditions that were no longer fully treatable.

Mission trades (Trial C) – Figures 9 and 10 show the effects of the binary mission-specific factors (pre-existing conditions, extravehicular activities, long duration, and no return to definitive care option) on LOCL and QTL. Of the four factors, only the long duration factor had a significant effect on LOCL (+180%) or on QTL (+263%). All other factors produced non-significant differences. LOCL demonstrated much higher variance (25% of mean vs. 0.5% of mean value, respectively) than QTL throughout all of the simulations.

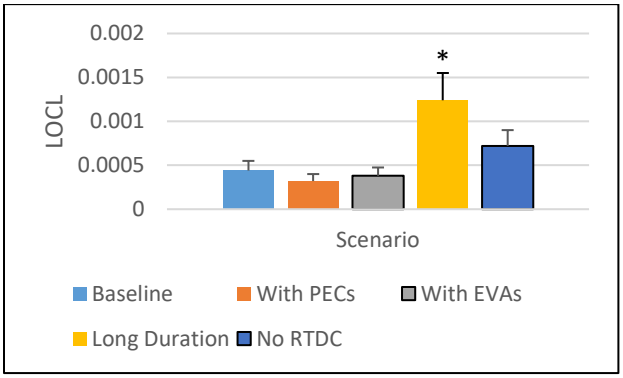

Figure 9: Effects of Binary Mission Trades on LOCL

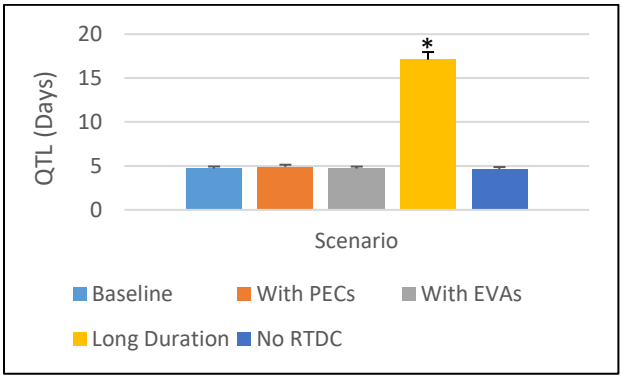

Figure 6: Effects of Binary Mission Trades on QTL

Optimized trade scenarios (Trials D through I) – The quantitative results of the optimization scenarios (17 – 38) are summarized in Table 5. In this table, the red numbers do not comply with the notional target values. Each of the trade scenarios in Trials D through I may be represented as a unique combination of either weighting coefficients on either cost factors (mass, volume) or risk factors (LOCL, QTL), or notional target values for cost factors. RTDC is always computed, but it was not used in the Phase II Pilot Project weightings. In general, the notional mass and volume targets were challenging to meet simultaneously while maintaining acceptable risk using the current set of available medical resource information, unless the proper combinations of weighting factors were employed for the set-selector. Trial D focused on mass reduction scenarios whereby the nominal baseline mass allocation was reduced from 100% (12.09 kg) to 87.5% (10.58 kg) and 75% (9.07 kg). Scenarios 17 through 19 considered LOCL only as a risk factor, while scenarios 20 through 22 considered QTL only.

Trial E focused on volume reduction scenarios whereby the nominal baseline volume allocation was reduced from 100% (18.3 L) to 87.5% (16.0 L) and 75% (13.7 L). Scenarios 23 through 25 considered LOCL only as a risk factor, while scenarios 26 through 28 considered QTL only. Reducing the allocations generally resulted in higher risk factors, with LOCL being more sensitive to the reductions than QTL, especially when LOCL was not part of the weighted cost function. A significant finding is that while optimizing for LOCL only, the QTL tends to remain unacceptably high (i.e., > 8.4 days). However, the reverse is not true when optimizing for QTL only; in this case the LOCL can be brought within acceptable thresholds (i.e., < 0.001).

Weighted combinations of cost factors only in Trial F, scenarios 29 through 32, allowed for significant reductions in volume but not improved risk performance for the weights chosen. Similarly, for weighted combinations of risk factors in Trial G, scenarios 33 through 36, the risk performance was better, but did not illustrate the tool suite's ability to meet notional cost targets.

Reducing the mass of two heavy items and forcing their inclusion in Trial H resulted in much improved performance in meeting all factors, although the notional target volume was slightly exceeded.

The best performance was obtained in Trial I, by intuitively changing the weights on the factors until all notional targets and acceptable thresholds were met successfully. For this particular mission and this set of notional target values, it was possible to determine a nearly optimal medical set that met all of the constraints.

Table 5: Outcomes of Optimized Runs

Trial	Scenario	Selected Set ID	Cost Factors		Risk Factors		
			Total Mass (kg) [Mass weight]	Total Volume (mL) [Volume weight]	RTDC [RTDC weight]	LOCL [LOCL weight]	QTL (days) [QTL weight]
D	17	14	12.00	**90323**	**0.132**	0.00064	**16.6**
			1	0	0	1	0
	18	64	10.57	**85893**	**0.132**	0.00044	**16.2**
			1	0	0	1	0
	19	66	6.56	**70144**	**0.119**	0.0006	**16.2**
			1	0	0	1	0
	20	49	11.47	**93171**	0.008	**0.0014**	4.8
			1	0	0	0	1
	21	56	9.68	**83318**	0.008	**0.00102**	4.9
			1	0	0	0	1
	22	60	8.56	**82169**	0.009	**0.00114**	4.9
			1	0	0	0	1
E	23	110	4.46	18032	**0.132**	0.00076	**16.5**
			0	1	0	1	0
	24	110	4.15	13197	**0.128**	0.00074	**16.5**
			0	1	0	1	0
	25	139	4.21	**13489**	**0.129**	0.00076	**16.5**
			0	1	0	1	0
	26	96	6.59	18271	**0.086**	**0.00172**	8.3
			0	1	0	0	1
	27	17	6.01	15702	0.029	**0.00122**	5.8
			0	1	0	0	1
	28	51	3.46	11024	0.038	**0.00132**	5.9
			0	1	0	0	1
F	29	49	9.97	**24427**	**0.131**	0.001	**17.0**
			2	1	0	1	0
	30	59	8.54	**23959**	**0.134**	**0.00108**	**16.6**
			1	1	0	1	0
	31	54	6.74	**34099**	0.012	**0.00132**	5.0
			2	1	0	0	1
	32	17	11.22	**96130**	0.040	0.00072	6.2
			1	1	0	0	1
G	33	31	12.05	**104901**	0.024	0.00068	5.4
			1	0	0	2	1
	34	83	12.05	**105029**	0.023	0.00064	5.3
			1	0	0	1	1
	35	40	8.45	**26429**	**0.052**	0.00076	6.5
			2	1	0	2	1
	36	55	5.45	**42333**	0.036	0.00062	5.7
			2	1	0	1	1
H	37	59	6.79	**21656**	0.039	0.00062	6.1
			2	1	0	2	1
I	38	41	4.88	15709	0.041	0.00068	6.1
			1	4	0	1	1

Further analysis of the tool suite

Post-processing tools developed for the tool suite have enabled more sophisticated analyses to occur. Figures 11 and 12 show the LOCL and QTL effects of reducing mass and volume while focusing optimization on LOCL, respectively (Trials D and E). The LOCL metric is shown by the blue line and the QTL metric is represented in orange. These figures show that when mass and volume allocations are reduced, LOCL is more sensitive to these reductions than QTL due to its higher slope.

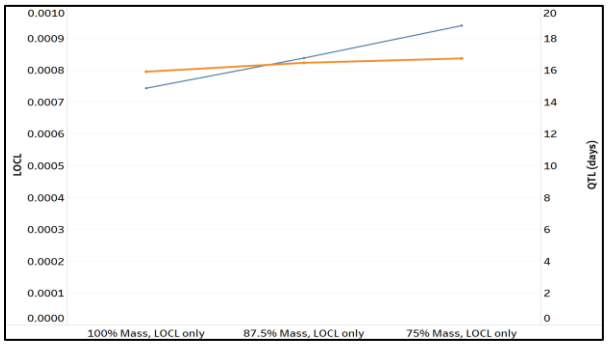

Figure 7: Effects of Reducing Mass

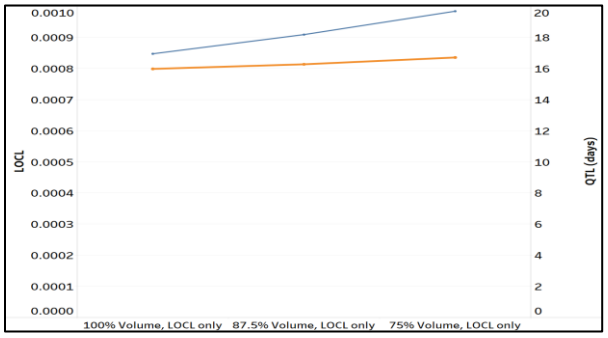

Figure 8: Effects of Reducing Volume

Additionally, it is possible to determine the most influential medical conditions affecting the risk factors, as shown in Figures 13 and 14. These figures illustrate the top five conditions of influence for each risk factor, though many more influencing conditions exist. It is apparent that the lists of conditions influencing each risk factor are very different from one another with very little overlap. Optimizing the medical system for one factor only will likely be accomplished in part at the expense of the other.

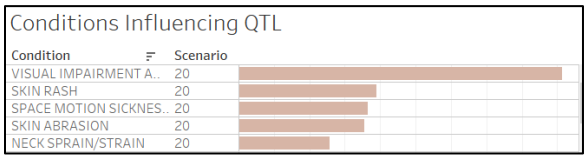

Figure 9: Top 5 Conditions Influencing QTL

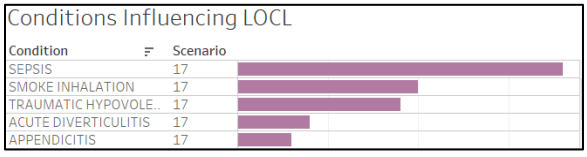

Figure 10: Top 5 Conditions Influencing LOCL

A more sophisticated use of the MEDPRAT set-selector involves changing the weighting coefficients on cost and benefit by guided trial and error until all of the notional cost targets and acceptable risk thresholds are met simultaneously (Trial I, informed by Trials F and G). The coefficients that are ultimately used will be very highly mission-dependent. For the DRM used in the Phase II Pilot Project, the cost function that produced the desired result was

$$Cost = C_{mass}\, Mass + C_{volume}\, Volume \qquad (1)$$

where $C_{mass} = 1$ and $C_{volume} = 4$ and the benefit function was

$$Benefit = C_{LOCL}\, LOCL + C_{QTL}\, QTL + C_{RTDC}\, RTDC \qquad (2)$$

where $C_{LOCL} = 1$, $C_{QTL} = 1$, and $C_{RTDC} = 0$.

The resulting feasible medical set produced the outcomes shown in the last row of Table 5. These values may be compared to the notional target values in Table 3.

Another useful application of the tools requested by the stakeholders is a technology development trades to aid in the decision making process for the prioritization of research by the ExMC Element and HRP. In this scenario, heavy items that would normally be left out by the MEDPRAT set-selector are considered at a fraction of their original footprint for possible re-inclusion to the nearly optimal medical set. However, it is not guaranteed that the MEDPRAT set-selector will still retain the item, even at its reduced footprint, unless it is specifically instructed to do so by a user-selected parameter. This necessitates a four-part simulation approach for performing this analysis.

1. The item(s) under consideration are left at 100% footprint, and the set-selector is permitted to include/exclude the items based on their cost/benefit merit.
2. A simulation is run with the items set to their original benefit, but at zero mass and zero volume. In this case, the set-selector retains the items and the resulting outcomes define a maximum achievable benefit possible with any technology development to reduce the item's (or items') footprint.
3. The set-selector is run with the footprint reduced to a user-specified target amount and the items are forced to be included in the medical set.
4. The previous simulation is repeated with the set-selector given the option to include/exclude based on merit.

By comparing the outcomes of all four simulations, one can determine the worth of pursuing a technology development to reduce the footprint of heavier items.

In the case of the Phase II Pilot Project, the two items selected were the blood pressure/electrocardiogram monitor and the

ultrasound machine, and the chosen reduction factor was 75%. The mass and volume properties of these items are shown in Table 6. The notional results of the four-part simulation approach for the Phase II Pilot Project are shown in Table 7.

Table 6: Mass and Volume of Heavy Items

Item	Mass/Reduced Mass (kg)	Volume/Reduced Volume (mL)
Blood Pressure/ECG	7.9/1.6	28998/7250
Ultrasound Machine	6.0/1.5	17340/4335

Table 7: Results of Technology Development Trades

Run	Mass/Vol of Heavy Items (%)	Forced Inclusion?	Were they Included?	Total Mass (kg)	Total Volume (mL)	RTDC	LOCL	QTL (days)
1	100	No	No	5.12	17645	0.038	0.00094	6.04
2	0	Yes	Yes	5.10	17113	0.034	0.00068	5.90
3	25	Yes	Yes	6.55	16836	0.050	0.0009	6.39
4	25	No	No	5.10	17273	0.039	0.0006	6.02

From the notional evidence in Tables 6 and 7, it is apparent that given the Phase II Pilot Project's DRM, available resources, medical evidence, and acceptable cost/risk targets, there seems little justification for pursuing a 75% reduction in mass and volume for the two heavy items. While a more drastic reduction may produce a small benefit, it seems unlikely that the gain in risk reduction would justify the effort in pursuing the technology development. Much of this result may be attributed to the relatively short duration of this deep space mission, 42 days in length. Perhaps a much longer Martian transit mission would produce a result more conducive to justifying the technology development, and such an analysis is suggested for future work.

6. CONCLUSIONS

Summary of Results

Over the two phases of the Pilot Project, the tool suite has demonstrated that for a given DRM, a list of available medical resources, and a set of target values for allocation and acceptable risk, it can identify a nearly optimal set of medical resources that meets all of the notional targets if such a solution exists. Additionally, the tool suite can identify system requirements and medical conditions and capabilities that will be met/unmet by such a medical resource set. This capability is important for mission planning, because the very worthwhile objective of maintaining crew health and safety must be balanced against the realities of limited resource capabilities during long duration spaceflight.

Significance of Work

The Pilot Project work supports the advancement of a tool suite intended to both enable systematic trade study evaluations and to inform research priorities.

The tool suite will assist the ExMC Element to identify which medical capabilities have the potential to provide the greatest possible risk reduction benefit, leading to an increased likelihood of their inclusion in exploration medical systems. It can additionally inform NASA mission developers regarding the prioritization of research and technology development for deep space medical capability, provided that the input evidence is of sufficient pedigree to draw conclusions regarding the efficacy and applicability of future capabilities. Perhaps most importantly, the tool suite enables human health and performance to be considered as early as possible in the mission planning and vehicle design process, allowing for full integration into architectures as they are conceptualized, developed, and adopted.

Limitations

Key limitations of the current work involve the data and model content used in the Pilot Projects. As discussed previously, the integration process was prioritized over content development for these early efforts in part to help identify what the content development needs will be. Limitations of each tool are shown in Table 8.

Table 8: Limitations of Tools

Tool	Limitations
Evidence Library	Updates to condition incidence rates used by MEDPRAT, updates to conditions to consider, and updates to treatment and resource capabilities are in process.
MedID	The ServiceNow platform used in Phase II was not as configurable as previously expected for an operating platform. The team is moving towards using an SQL database.
MEDPRAT	A Susceptibility Inference Network (SIN), a capability to capture interdependencies among medical conditions, is in development to capture condition dependencies.
EMSM	Incomplete tracing among all applicable requirements as the requirements set is still in development
Post-Processing	Need for stakeholders to have appropriate software to view results

After the conclusion of the Phase II Pilot Project work for the tool suite, there were many lessons learned about the processes and the tools. A significant limiting factor to the work was that data formatting and automation requirements

were not captured. Formatting details of .csv files and naming conventions should be consistent amongst the tools in the tool suite, and they were not consistent at first implementation of the data flow process. Additionally, automation capabilities were minimal between tools. All inter-tool interfaces are candidates for improved automation capabilities.

A minor limiting factor is that there was not a standardized folder structure while compiling data across NASA centers or tools in the tool suite. With the team scattered across multiple locations, it was difficult for team members to find and understand the work that others were doing, the rationale behind the work, and how the work would be integrated with other elements.

Additionally, there is a non-trivial learning curve associated with each of the tools that should be budgeted and planned for by stakeholders. This is a limiting factor for users of the tool suite who are outside of the development team. Key topics for training new users are shown in Table 9.

Table 9: Training for Each Tool

Tool	Training
Evidence Library	Platform is in development, so training needs are still to be determined
MedID	SQL, import/export functionality
MEDPRAT	Input/output interfaces, computing in a cluster environment running UNIX, optimizer theory/practice, operation details
EMSM	Model content, SysML and MagicDraw basics, generating reports, import/export functionality
Post-Processing	Tableau (or equivalent), data unions and joins, Excel functionalities

Future Work

In terms of the tool ecosystem capabilities, technology assessments of candidate components (Technology Readiness Levels – TRL) are yet to be included in Pilot Project analyses and are future work to enable informing HRP programmatic research priorities. This would allow the ExMC element to identify specific items for improvement through technology development, which could lead to an overall mass/volume footprint reduction and improved efficacy. It is the desire that implementing the research prioritization capability would eventually lead to the reduction of incidence rates through the development of preventive countermeasure and improved resources in the treatment of medical conditions.

Automation of the data exchange and operation of tool suite runs is also future work, and the team is investigating EMSM as one option for the orchestrator. Automation should also be included in the MEDPRAT set-selector to choose only one or two feasible optimized sets. The ExMC Clinical and Science Team is currently involved in this step of the process; however, it would only act in the capacity of validating sets selected by the tool, if automation is an implemented capability. Integration scripts could be written for the Evidence Library and MedID tools to MEDPRAT, MEDPRAT to the post-processor, and MEDPRAT to EMSM. This automation would decrease the overall run time of the tool suite and add a decreased dependency on human resources.

Another element of future work is the development of the evidence base and models supporting the PRA capabilities. The MEDPRAT Susceptibility Inference Network (SIN) that is currently in development could be implemented as a capability for the tool suite. The SIN defines dependent relationships among conditions, which would lead to more accurate output data.

The capability to bundle resources together using resource dependencies should also be considered in the future. These bundles would allow for resources used for the same medical treatment to be tied together, such as the ultrasound machine and ultrasound gel. For example, the ultrasound machine is frequently left out during set selection, but the ultrasound gel is still often retained. These bundles should reside somewhere in the tool suite to provide more detailed and accurate output data, increasing the fidelity of the trade space analyses

Additionally, the tool suite can be used to exercise the capabilities of the tools further and to assess research and development priorities for ExMC and HRP. This could be implemented by more extensive simulations of longer duration missions, adding potential new capabilities to the available resources and evidence library, implementing full traceability of requirements in the EMSM and incorporating simulations, and expanding the capability of the tools beyond just the medical system to include other human health and performance system components. These possible expansions would build on the work done in the Phase II Pilot Project.

Planned efforts to create key systems engineering products regarding the development of the tool suite will be beneficial. These products will help clarify stakeholder needs, the vision of the needed system, and key and driving requirements for the integrated tool suite ecosystem. Various development approaches could be applied to the ecosystem and each of the tools, but the ecosystem itself will benefit from additional systems engineering efforts to manage the technical and organizational interfaces.

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