

Using Systems Engineering to Develop an Integrated Crew Health and Performance System to Mitigate Risk for Human Exploration Missions

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New space exploration missions are currently being designed to take humanity beyond low Earth orbit (LEO) to cis-lunar space, the lunar surface, and eventually to Mars. These missions carry increased risks due to a number of factors, including distance from Earth, exposure to deep space hazards, reduced capacity and ability to resupply and evacuate, and increased communication delays. As distance from Earth grows and mission length increases, a growing proportion of mission risk can be attributed to the

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“human system.” Almost twenty years ago, the Institute of Medicine in the United States recommended the early and complete integration of the human system into the spacecraft and mission design process to mitigate this increased risk inherent in exploration missions. Exploration missions will require increasing levels of crew self-sufficiency that will challenge the current operational paradigms established in LEO. Enabling progressive Earth independence requires management of the increasingly complex interactions among spacecraft systems and integration of all the data and functions that affect human health and performance into one coordinated system – the Crew Health and Performance (CHP) system. This system is a critical spacecraft system that is analogous to other systems such as propulsion, guidance and navigation, or avionics. Design and integration of the CHP system requires the evidence-based merger of typically disparate disciplines such as medicine, human factors, and life support system design, using systems engineering (SE) practices. SE provides traceability of spacecraft requirements and enables reliable and repeatable trade space analysis of the many competing options for hardware and software to be included in the mission architecture. The approach described here enables spacecraft and mission designers to align the scope of a CHP system with mission specific requirements, decrease risk to the crew, and increase the probability of mission success.

I. Introduction

IN 2001, the Committee on Creating a Vision for Space Medicine During Travel Beyond Low Earth Orbit released a report entitled *Safe Passage: Astronaut Care for Exploration Missions* [1]. This committee acted on authority of the Institute of Medicine to assess what is known about the health effects of space travel and provide recommendations on how to approach health care during these missions. In the years since *Safe Passage* was published, some of its recommendations have been implemented in low-Earth orbit. The recommendations from this report formed the conceptual basis for the current workings of the Human Research Program and a roadmap for biomedical research [2]. Much work remains to extend the vision to exploration missions through the merging of engineering requirements and medical priorities in the context of technology and process development. As *Safe Passage* suggests, NASA’s exploration goals will require a comprehensive Crew Health and Performance (CHP) system built on a strategic research plan while ensuring the integration of the engineering and health sciences. A systems engineering approach is required to meet the exploration crew management needs within a system of opposing constraints. The rest of this paper will provide an example of how one of the CHP subsystems, medical, is undertaking these system engineering activities [3,4].

II. Background

Exploration missions outside of low Earth orbit (LEO), and particularly those targeting Mars, present challenges outside the current experience base of human spaceflight. Just as medical care has evolved throughout the early flight programs (Mercury, Gemini, Apollo, and Sky Lab), Space Shuttle and International Space Station (ISS) eras, this next venture into expanded space travel will demand another level of sophistication in our medical system [5]. For the medical system, lack of consumable resupply, evacuation opportunities, and real-time ground support are key drivers toward greater autonomy. In addition, predicting the exact medical conditions for which to plan will not be possible. Therefore, an exploration medical system must provide flexible capabilities to support the care of crewmembers with conditions that were not considered specifically in advance. Medical technologies to be considered in exploration designs will continue to rapidly evolve for the foreseeable future, so the design framework must allow for new technologies. Limited flight resources such as mass, power, volume, and data, are constraints requiring the medical system to be viewed as an integrated part of flight system development for exploration. Medical technology will need to be incorporated into the vehicle architecture, rather than ferried on in kits and stowed. Integration of medical data with core flight software systems will be needed to enable a more autonomous CHP system design, empowering the crew to manage their own health care needs while out of direct communication with ground care personnel.

III. Systems Engineering Approach for the Medical System

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 large scope of an integrated CHP system, starting with the medical system, for exploration missions [6,7,8,9]. The mission of the ExMC Systems

Engineering (SE) team is to “Define, develop, validate, and manage the technical system design needed to implement exploration medical capabilities for Mars and test the design in a progression of proving grounds.” ExMC SE is utilizing Model-Based Systems Engineering (MBSE) to support medical system definition and analyses that will inform research activity needs and prioritization. MBSE is an engineering approach used to model the life cycle activities of a project, and provides an alternative to the more traditional document-based approach to engineering. Using a traditional document-based approach to systems engineering can result in cost increases, raise technical risk and create information silos among teams. Diverging from the document-based approach will offer significant savings through avoidance of maintaining disparate documentation that runs the risk of becoming obsolete or inconsistent with evolving project goals. The ExMC system engineering team’s use of MBSE, applying the System Modeling Language (SysML) and supporting MBSE tools, is enabling technical communication through the use of shared mental models of the medical system, consistent notation and integrated data sets. These system models will be integral for successful integration of the medical system with exploration vehicles and system verification and validation using terrestrial analogs and precursor exploration missions.

The use of MBSE tools helps to streamline communication, content, and system design across the ExMC SE team that works in different geographic locations and addresses a variety of technical disciplines. The SE team’s tools are being designed and selected to support meta-data exchange as integration points to crew health, crew performance, and other vehicle system and subsystem models are identified. MBSE is improving shared understanding of system needs and schedules between stakeholders, provides a common language for analysis, and will help to facilitate identification of risks. SysML is being utilized here to provide a controlled common model of the medical system and requirements definition activities [10,11].

IV. NASA Standard Interpretation: Level of Care Assumptions

NASA medical care standards establish requirements for providing health and medical programs for crewmembers during all phases of a mission. These requirements are intended to prevent or mitigate negative health consequences of long-duration spaceflight, thereby optimizing crew health and performance over the course of the mission. Current standards are documented in the two volumes of the NASA-STD-3001 Space Flight Human-System Standard document, established by the Office of the Chief Health and Medical Officer. Their purpose is to provide uniform technical standards for the design, selection, and application of medical hardware, software, processes, procedures, practices, and methods for human-rated systems. NASA-STD-3001 Vol. 1 [12] identifies five levels of care for human spaceflight, listed in Table 1. Each level has several components listed that illustrate the type of medical care expected. Interpretation of these components and the associated amount and type of care required at each level is dependent upon several factors, including the duration of the mission, accepted amount of medical risk, the level of training of the healthcare provider, terrestrial medical standards, technology and resources available for use in the flight environment, and the time it would take to get an ill or injured crewmember to a definitive care location.

Level of Care	Capability
I	Space Motion Sickness, Basic Life Support, First Aid, Private Audio, Anaphylaxis Response
II	Level I + Clinical Diagnostics, Ambulatory Care, Private Video, Private Telemedicine
III	Level II + Limited Advanced Life Support, Trauma Care, Limited Dental Care
IV	Level III + Medical Imaging, Sustainable Advanced Life Support, Limited Surgical, Dental Care
V	Level IV + Autonomous Advanced Life Support and Ambulatory Care, Basic Surgical Care

Table 1. Levels of Care (Reference [12], V2, Rev A, Table 13).

ExMC has expanded the context of the levels of care and components to assist the multidisciplinary ExMC team with consistent interpretation as they approach future work [13]. This supplemental information includes definitions for each component of care and example actions that describe the type of capabilities that coincide with the definition. This interpretation is necessary in order to fully and systematically define the capabilities required for each level of care in order to define the medical requirements and plan for infrastructure needed for medical systems of future exploration missions, such as one to Mars. Table 2 gives an example of a definition and capabilities associated with Limited Advanced Life Support, a component listed in Level of Care 3.

Capability	Definition	Example Actions “*” indicates augmentation of action from lower level of care
Limited Advanced Life Support (ALS)	<p>Diagnosis and initial treatment for an emergent medical event.</p> <p>Resources to support medical decision making using data obtained from telemedicine, limited physical exam, vital signs, and clinical diagnostics.</p>	<p>- Control over body positioning and workspace</p> <p>Airway:</p> <ul style="list-style-type: none"> - Reposition airway, insert airway adjuncts *and supraglottic airways - Clear obstructed airway with manual maneuvers - *Suction airway <p>Breathing:</p> <ul style="list-style-type: none"> - Provide breaths using *manual means - *Provide and titrate oxygen via noninvasive/invasive means <p>Circulation:</p> <ul style="list-style-type: none"> - Control bleeding using direct pressure - Provide chest compressions - *Defibrillate using automated device - Measure, record, and trend vital signs (heart rate & rhythm, respiratory rate, blood pressure, temperature, oxygen saturation)

Table 2. Example of an expanded component definition within a Level of Care definition

Clearly defined levels of care, and what capabilities are included in each, provides a common starting point for discussing the medical system; not just for use within the ExMC team but also for communicating with the project’s many stakeholders and to other CHP subsystems.

V. Stakeholders Needs and System Goals

A thorough understanding of stakeholders’ needs and expectations is vitally important and serves as the foundation for other systems engineering activities and products. This process provides ExMC systems engineers with a way to ensure key stakeholders are in agreement and that the realized system will meet expectations. Reaching consensus early in the project on things such as high level capabilities, system characteristics, behaviors and performance is important because it shapes customer expectations, bounds the problem/solution space and establishes criteria to determine if the right system is built and delivered.

ExMC has identified a core set of driving stakeholders that are important in understanding how the system will be used in its operational environment. Driving stakeholders include the Office of the Chief Health and Medical Officer (OCHMO) Health and Medical Technical Authority (HMTA), the HRP, the Astronaut Office, the Medical Operations community, the Human System Risk Board (HSRB) and international partner representation in coordination with the CHP System Maturation Team (SMT), under the Human Exploration and Operations Mission Directorate (HEOMD). Refer to Figure 1 to see relationships between the driving stakeholders and ExMC. Red numbered text indicates primary types of outputs from ExMC.

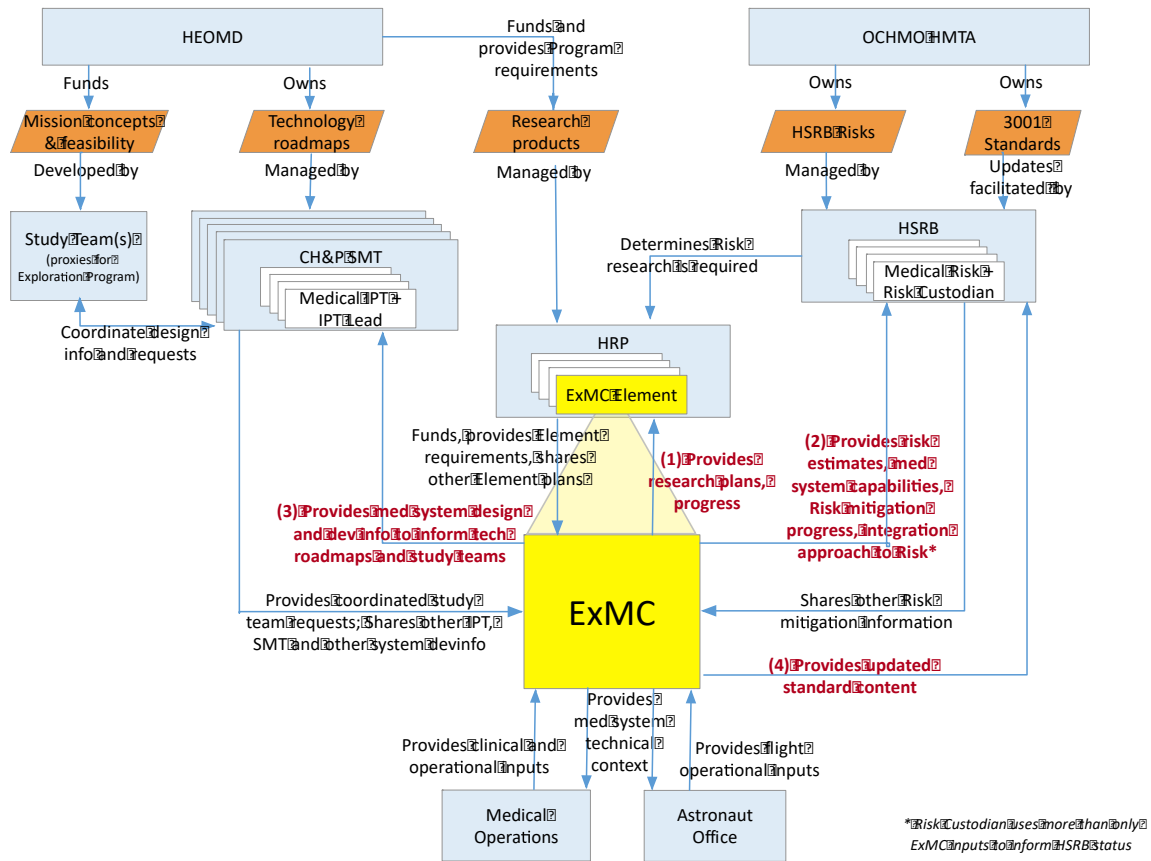


Figure 1. ExMC interactions with driving stakeholders.

A set of system goals has been developed to provide a foundation for exploration medical system development. They are based on stakeholder expectations and constraints levied or imposed on the medical system. These goals influence technical measures commonly used for insight into performance of the technical solution, and establish the basis for high-level requirements and quality attributes of the medical system.

Comprehensive Health Management

Provide comprehensive health management capabilities to enable mission task performance and mission success. Recognizing the extended duration and distance from Earth during exploration missions, in-mission care capabilities must span prevention, diagnosis, treatment, and long term management for both clinical and well-being aspects of health. These capabilities will use resources (e.g., skillsets, software, hardware, medication) to prepare for and execute planned and unplanned medical operations, pharmacy operations, personalized medicine, training, resource management, ethics considerations, data management, and risk estimation.

Crew Autonomy

Enable crew autonomy in medical task execution and decision-making. Although ground medical support will remain an important part of medical care, the autonomous care model for exploration requires flight surgeons and other support staff to fill a consultant role. The mission physician astronaut will serve as director of care during real-time medical events and will be the primary source for in-mission medical decision-making. To support the physician astronaut this medical care paradigm requires comprehensive vehicle capabilities and resources in the form of onboard medical references, smart diagnostics, and decision support systems.

Continual Information Application and Learning

Support medical system knowledge augmentation over the mission lifetime. It is desired to be able to use knowledge gained both in-mission and on the ground to update medical system elements, such as task training, decision support, and models for estimation and prediction of crew health and system status.

System Flexibility and Extensibility

Balance conflicting needs for medical system resource conservation (in design and in mission) and medical system operations. Flexibility and extensibility are needed because the in-mission resources will be constrained and because of the inability to definitively predict all medical conditions that will occur during the mission. Medical flexibility helps identify the broadest use opportunities for a limited resource set relevant for clinical needs. Extensibility addresses conditions and situations outside of the target design conditions.

Medical, Vehicle, and Mission Systems Integration

Integrate hardware, software, human, and operational aspects of the medical system with the mission and vehicle design. The in-mission medical system should be viewed as a component of the overall integrated vehicle system. When allowed and appropriate, medical data and information should be shared with other vehicle system components, and vice versa.

Crew and the Medical System Integration

Design the medical system to fit the needs, abilities, and limitations of the crew. A well-designed medical system minimizes training time and operations complexity and lowers mission medical risk. It accounts for the various modes of data entry, input devices, computing platforms, and user preferences employed on the vehicle and incorporates human system integration and human factors guidelines to reduce the cognitive and physical workload while using the medical system. A well-designed, usable medical system is easy to learn and operate, keeps the user informed on what is going on, reduces the number of errors and makes them easy to recover from, and assists in the timely completion of tasks. The expectation is that unobtrusive automated and manual processes are available to support crew activities.

Ground Awareness

Maintain ground situation awareness of crew health and medical system status as flight communication constraints permit. The ground support system will continue to be informed on the state of the crew and medical system to assess impacts to the mission goals and objectives and to provide support as needed. Defining the medical system goals enabled fruitful discussions with stakeholders at an early stage, and provided initial insight into the functions the medical system will need to provide.

VI. Concept of Operations

The development of an effective medical system model must include the identification and documentation of the problems to be solved (stakeholder concerns), the expected abilities of the system (needs), and the specific ideologies by which the system will be designed (goals). This content is documented in a Concept of Operations (ConOps) document. Each ConOps uses a set of diverse medical scenarios to explore the various types of care that may be required to prevent, diagnose, treat, and provide long-term management of medical conditions during a Mars exploration mission. By adjusting mission and system parameters, such as communication availability, biomonitoring capabilities, and the urgency of care, each scenario provides a unique use case that outlines areas of stakeholder concerns and highlights potential needs the system must fulfill. Each scenario consists of narrative text and a flow chart of expected activities. Collectively, these ConOps scenarios represent a wide range of possible medical capabilities and provide a high-level operational description of the system.

A ConOps document decomposes the overall mission into a series of mission phases (e.g., Earth-based launch and concluding with Earth entry, descent, and landing). When complete, the ConOps will illustrate the potential medical capabilities for each mission phase through sets of medical scenarios, involving the crew, onboard equipment and tools, and ground personnel. Each scenario consists of a context description (e.g. dental exam), a highlighted functionality list, assumptions, an activity flow chart (see Figure 2), and a narrative text to provide context for the flowchart. Collectively, these scenarios enable ExMC to use MBSE tools for planning, designing, and prototyping an

integrating a medical system for preventing, diagnosing, treating, and managing long-term the health and medical risks inherent to human exploration missions. The following activity flowchart represents a planned (routine) dental exam involving a patient, a caregiver, the medical system, the ground system, and the vehicle system:

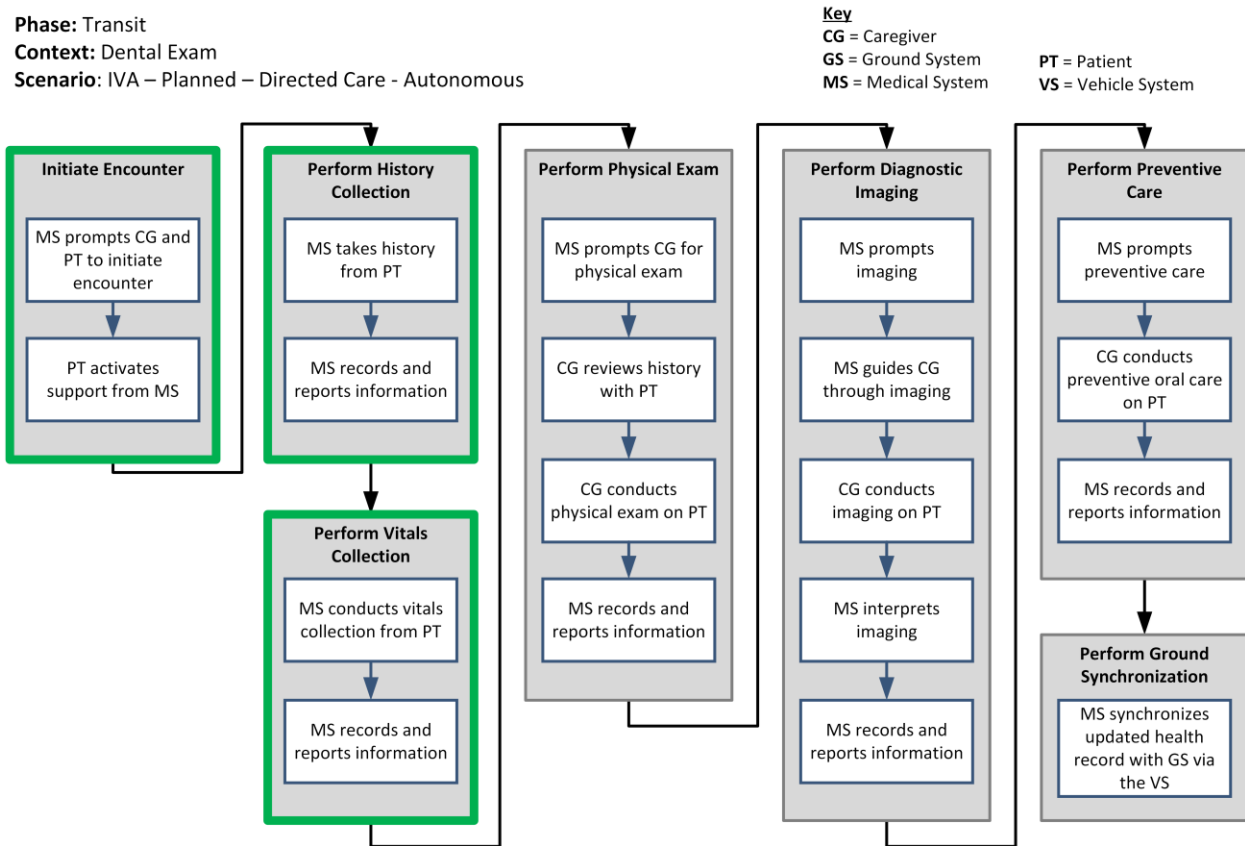


Figure 2. Flow chart of activities in the dental exam scenario.

The narrative text associated with the highlighted boxes is provided below as an example:

The medical system sends an alert to the physician astronaut and patient that a scheduled dental exam will start in ten minutes. The patient heads over to the medical bay and picks up a display, which uses biometric analysis to identify him and grants him access to his health record in the medical system.

The medical system starts the appointment by prompting him to review his health record documentation for accuracy and update if needed. Areas of review include: past medical, surgical, and dental treatment history, allergies, current medications, and then a series of questions to complete a review of systems. It then uses biosensors to collect vital signs from the patient, such as blood pressure, heart rate, oxygen saturation, temperature, and respiratory rate. These are all automatically saved to his health record and displayed back to him.

Each scenario is intended to demonstrate a set of functions. For the dental exam scenario, those functions are:

- prompt the initiation of an activity per the crewmember's schedule
- prompt the initiation of an activity based on a protocol
- retrieve information from the patient

- d) guide a crewmember during an activity
- e) interpret information gathered during an activity
- f) provide varying levels of support to a crewmember

VII. Modeling

Flow charts, such as illustrated in Figure 2, from the ConOps are analyzed and translated into Activity Diagrams in a SysML model. An example Activity Diagram of the first portion of the Dental Exam scenario is shown in Figure 3. This clarifies the activities expected to be performed by the medical system, each crewmember (whether in a patient or caregiver role), and the other flight or ground systems. Each horizontal swimlane represents actions performed by either the Patient, Caregiver, or Medical System. For example, one action “Prompts CG and PT to initiate encounter,” under the “Initiate Encounter” box defined in the ConOps flow chart (Figure 2) can now be understood to be performed by the Medical System, and the other action “Activates support from MS”, will be performed by the Patient.

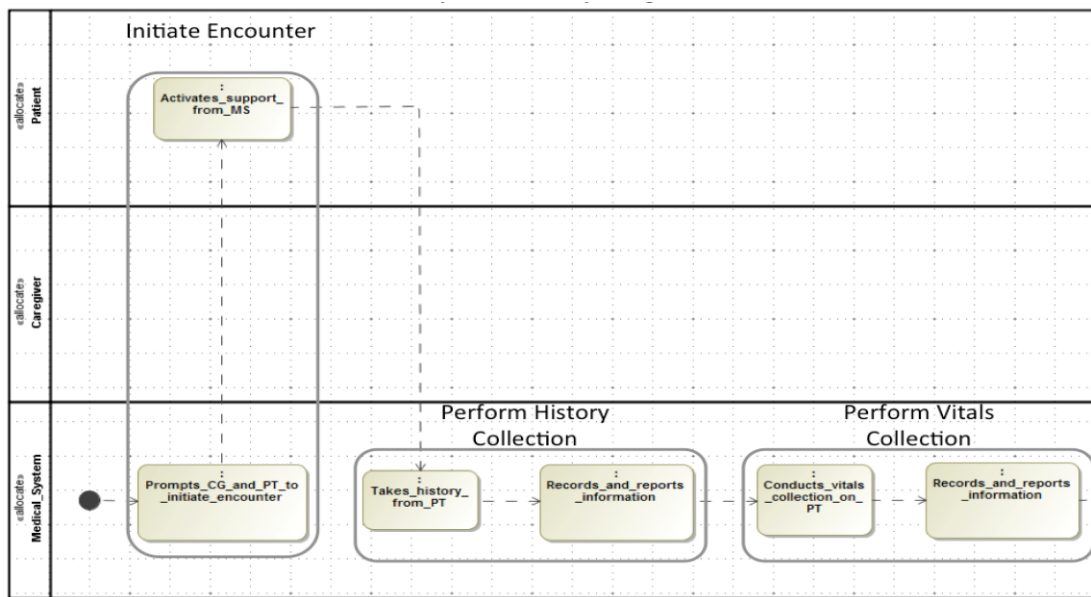


Figure 3. Portion of the dental exam scenario Activity Diagram.

A. Functional Decomposition

The system behavioral content was analyzed and grouped into functions. A function typically starts with a verb and describes what the system does. These functions were further decomposed until each activity was mapped to a function. Information in this functional decomposition provides a more complete representation of the medical system “problem space”. At the highest level, these functions aid in the development of the medical system architecture, which is the first foray into the “solution space”.

Figure 3 shows how the medical system functions are broken into 8 sub-functions. One of these sub-functions is “Inform decisions on crew health actions”.

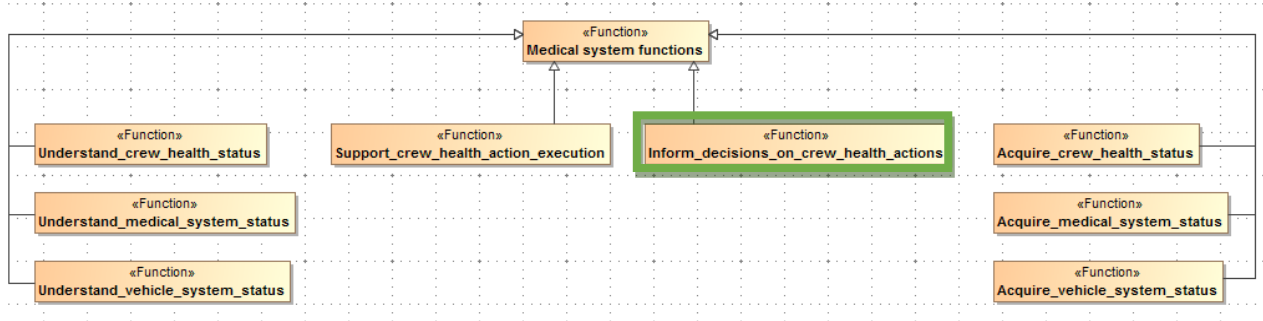


Figure 3. High-level medical system functional decomposition.

Figure 4 further breaks-down this sub-function and shows the mapping of the activities to this sub-function. The earlier mentioned activity “Prompts CG and PT to initiate encounter” maps to the function “Prompt crew” which is a sub-function of “Inform decisions on crew health actions”.

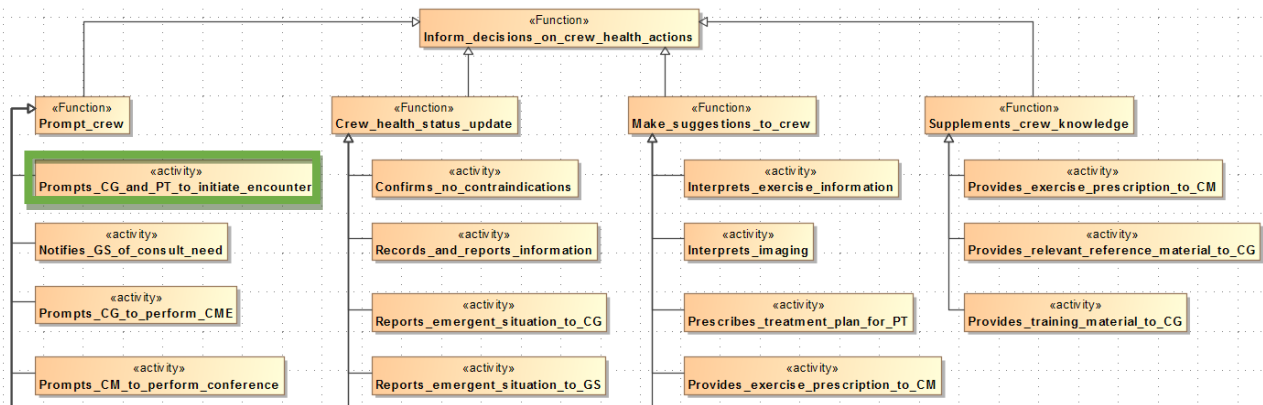


Figure 4. Sample scenario activities grouped under “Inform decisions on crew health actions”.

VIII. Medical System Architecture Description

A draft system context and architecture was developed based on the needs, goals, and behaviors of the system. As requirements are written, the architecture will be refined, including defining lower levels of detail and eventually relating to physical components. Figure 5 presents a context architectural view centered on the Medical System as part of the overall vehicle Flight System. The focus of the initial ExMC MBSE activity is on the Medical System that will support crew for Deep Space Transportation missions (refer to Figure 1). The Flight System, Ground System, Caregiver, and Patient are included as high level components of this context view because the Medical System will have important interactions with each. For example, defining the required medical skillset of the Caregiver is important for understanding the necessary Medical System support.

Within the Flight System, traditional functional flight systems such as Structures and Avionics appear as the bottom row of blocks to provide context and awareness of future interfaces with those subsystems. For example, certain vehicle consumables, such as water and oxygen, will be required for medical purposes, but are not within the scope of the Medical System; they will likely be provided by the Environmental Control and Life Support System (ECLSS).

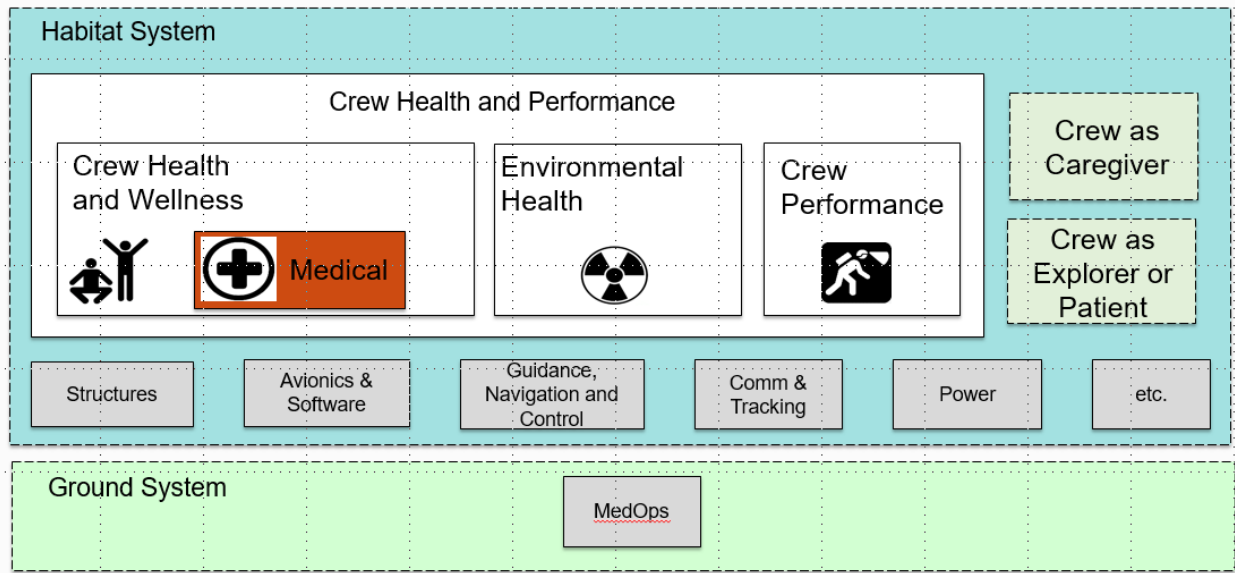


Figure 5. High-level medical system architecture and context.

Within the Crew Health and Performance (CHP) System, there are also blocks for the environmental health not covered by other vehicle subsystems (e.g., radiation monitoring or protection not incorporated in the vehicle structure), and characterization of mission task support functions, which includes in-mission training for the crew and user interfaces for each device, including any device-specific procedure guidance, and user interfaces for the CHP Data System. A Crew Health and Wellness subsystem block, which medical is a subsystem, is noted within the CHP System as it captures necessary crew support systems such as the food supply, exercise system, and behavioral health support.

IX. Requirements

Requirements were written using the functions and clinical capabilities captured in the SysML model as guidance. These requirements are imported and traced to medical activities, capabilities, conditions, and functions. As a result, space medical requirements and associated rationale are tied directly to the relevant system functions and recommended clinical capabilities. This process provides clear justification for requirements, which is vital to aid in negotiations anticipated through the space system maturation process. Visualizations of model traceability are created to aid in ongoing iterations of the requirements.

X. Data Informed Decisions

The SysML model will be used as one tool for trade space analysis of requirements, mission risk, and physical specifications of in-flight capabilities associated with the medical system [9]. 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.

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 6.

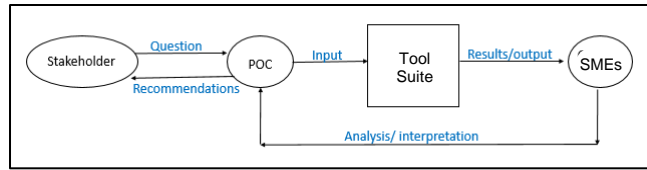


Figure 6: Tool Suite Information Flow

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 6, 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) 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 and tools interactions is in Figure 7. Each tool was discussed in detail in Amador, et al. [9]. This publication provided a broader overview of this tool suite in development for exploration spaceflight missions.

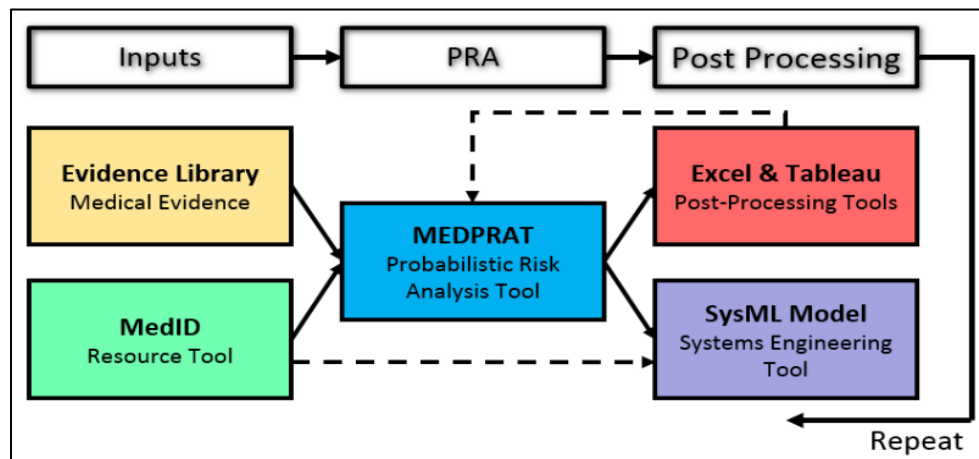


Figure 7: Tool Suite Interactions

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.

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 CHP 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.

XI. Future Work

The ExMC SE team will apply the approach outlined in this paper to additional CHP subsystems. Having an integrated CHP model will enable NASA to define, develop, validate, and manage the technical system design needed to implement exploration capabilities for future missions.

XII. Conclusion

Successful implementation of any system or subsystem in a complex project requires thoughtful and structured design from project initiation through maturation and implementation. The MBSE approach is key to ensuring consistent workflow, practices, and streamlined integration with vehicle design. Here, we describe the methods, tools, and collaborative interactions that have helped to establish a working model, infrastructure, architecture, and early model of the medical system being designed for exploration missions. Throughout the life cycle of this exploration program requirements will ebb and flow, trades and resource negotiations will be made, and mission objectives will morph. A strong systems engineering foundation will inform research activity needs and prioritization.

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