Medical System Design and Risk Assessment

January 2024



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Element Scientists

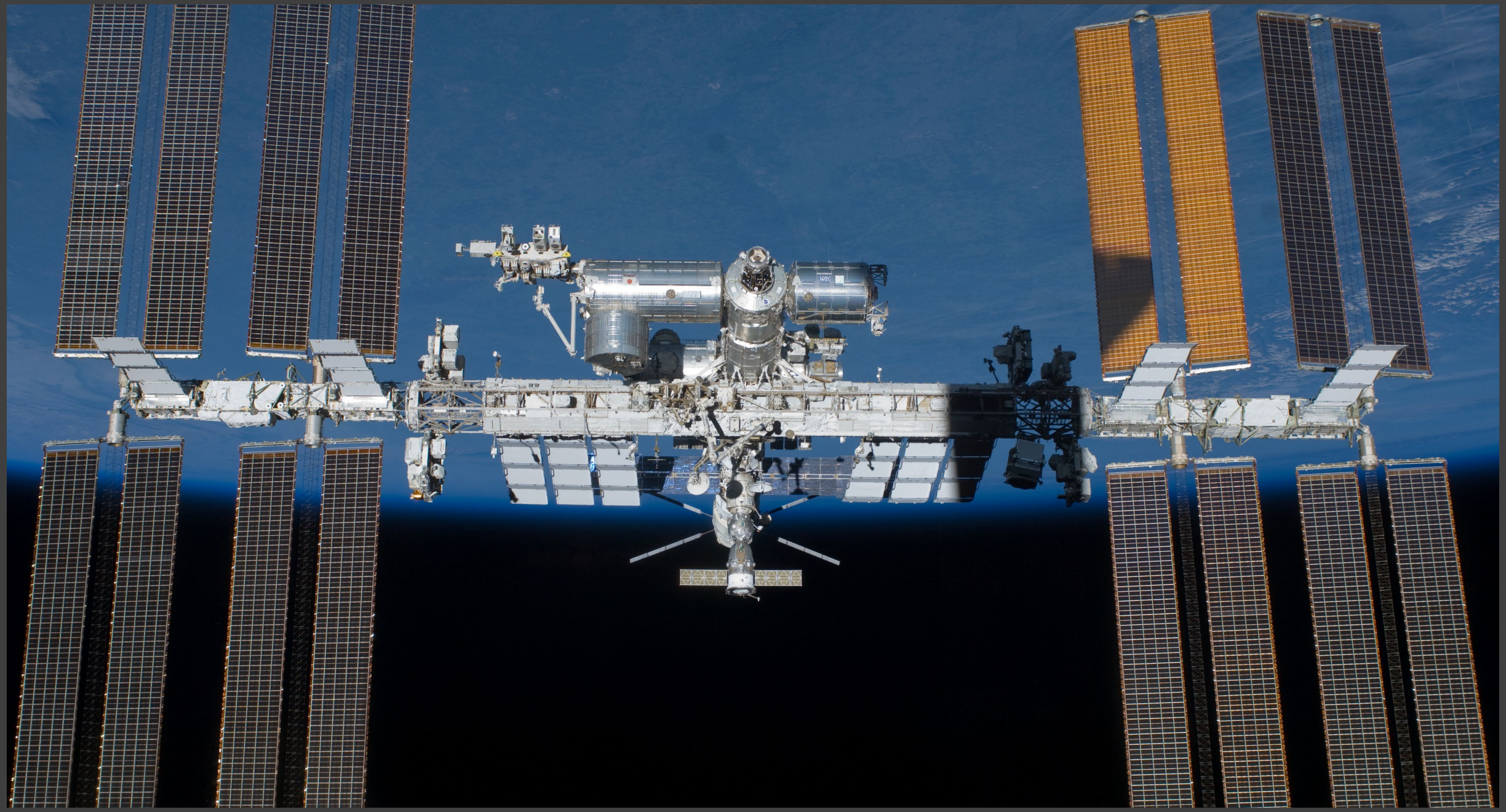
Exploration Medical Capability
NASA Human Research Program

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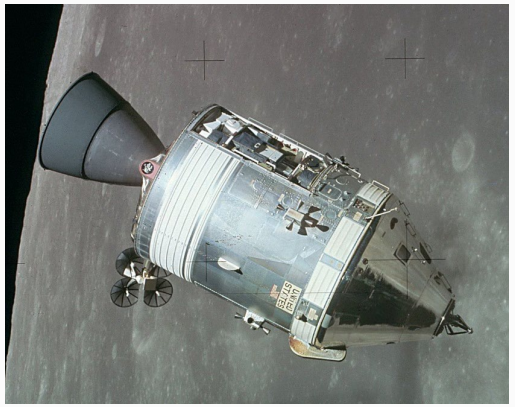


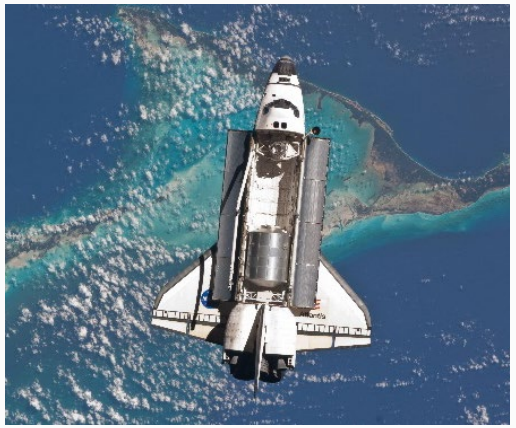
Advance medical system design and risk-informed decision-making for exploration beyond low Earth orbit to promote human health and performance in space

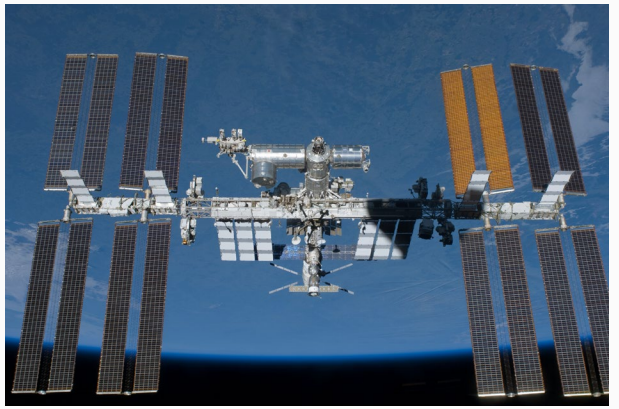

NASA



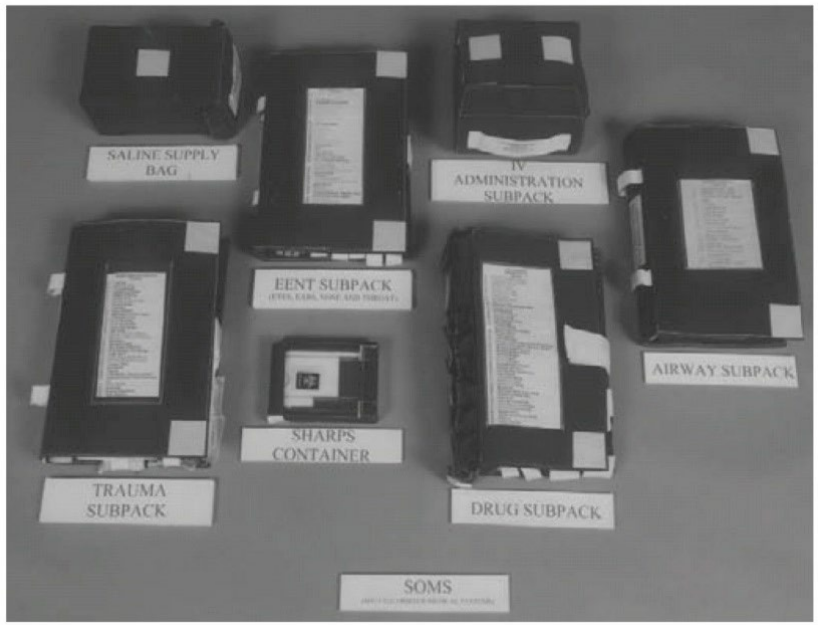
Examples of medical kits for human spaceflight











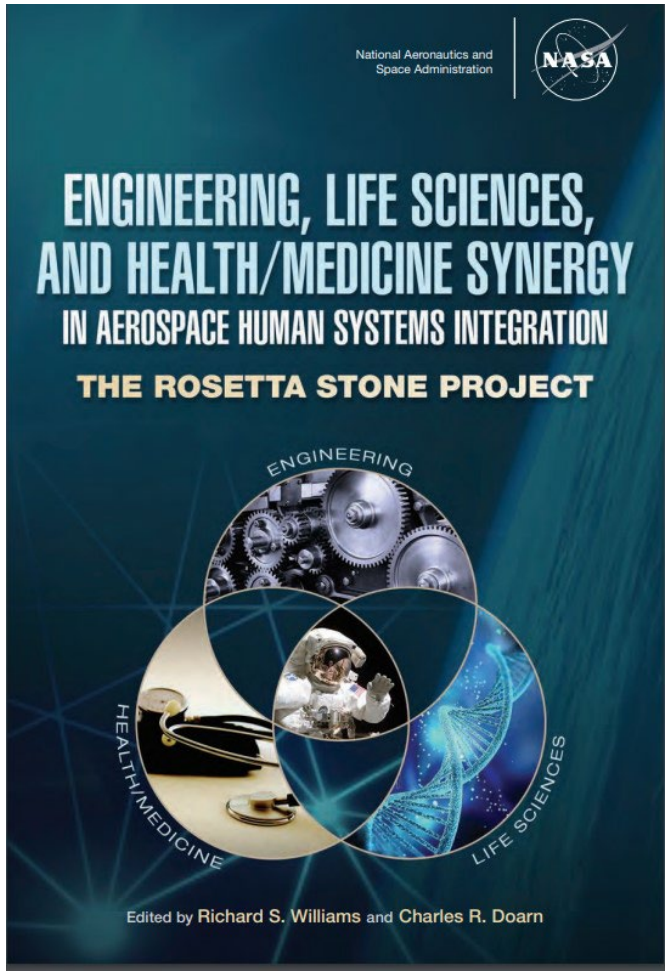


Motivation

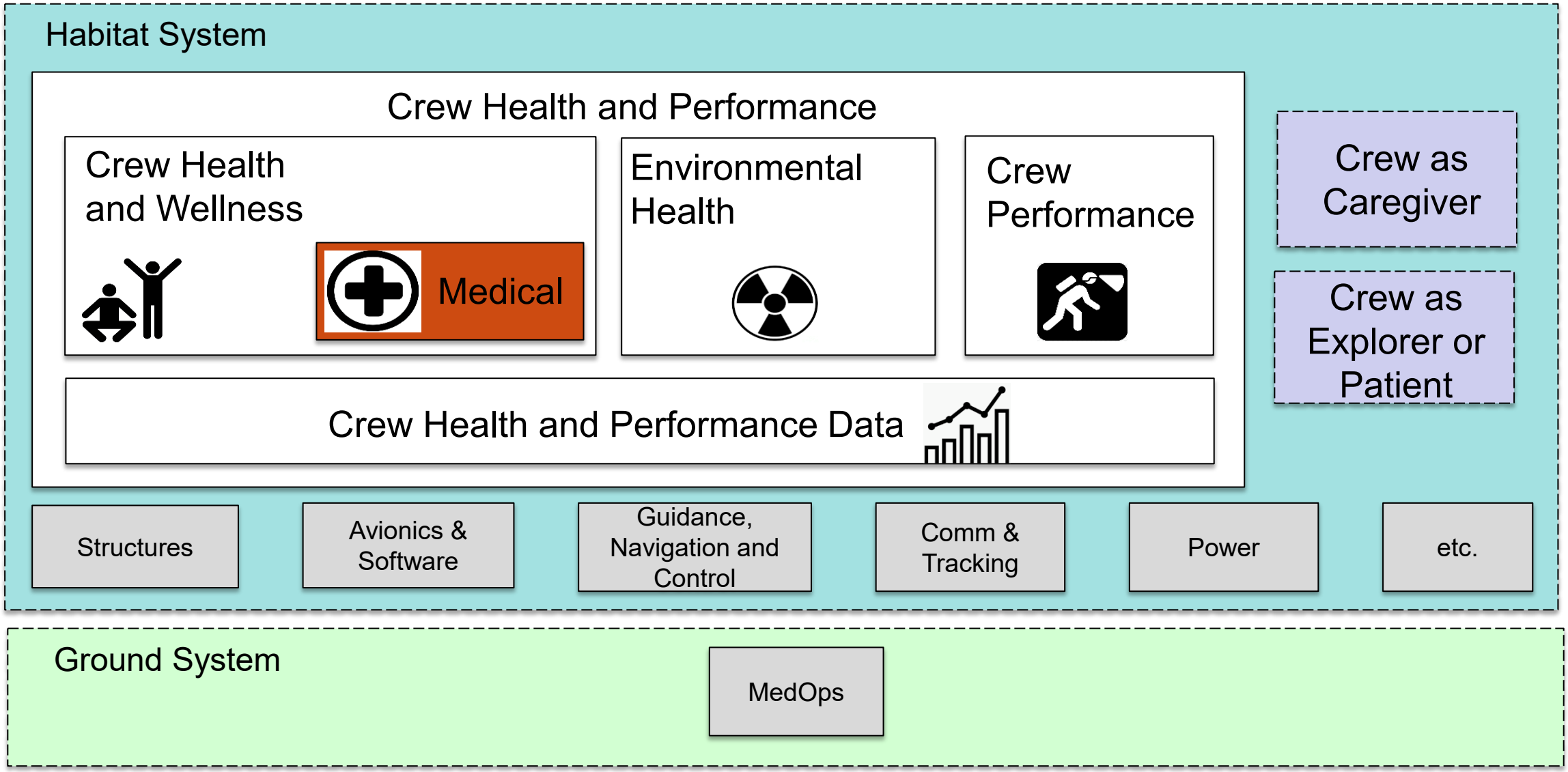
- How will the provision of medical care evolve for exploration missions?

- How can ExMC help to facilitate communication among spaceflight programs, engineers, scientists, and clinicians?

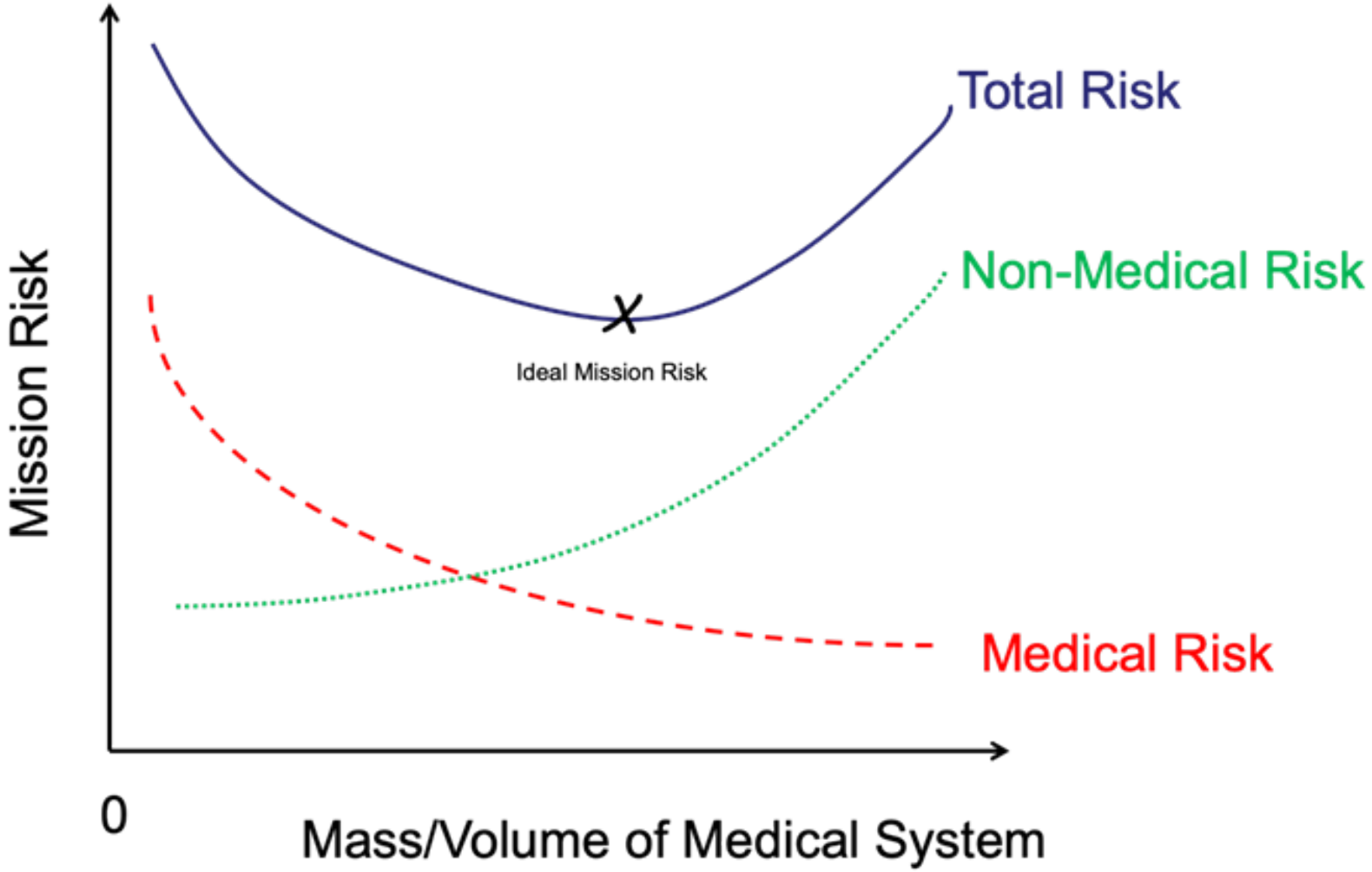
- Identified need to:
  - Employ systems engineering **principles** (just like how other vehicle systems are designed)
  - Assist in the development of evidence-based medical system **requirements** and their rationales
  - Enable **traces** between requirements, medical capabilities, medical conditions, and medical resources.
  - Advance and refine the medical **system architecture** for future mission planning.
  - Present information in an easily accessible format that is **understandable** across disciplines.



Integrating medical into a broader crew health and performance system



Medical vs. non-medical risks to a mission



Should we take an Automated External Defibrillator (AED) to Mars?

Yes?



No?

What if you had to choose?

AED



VS.

Ultrasound device



TRADE SPACE ANALYSIS






IMPACT

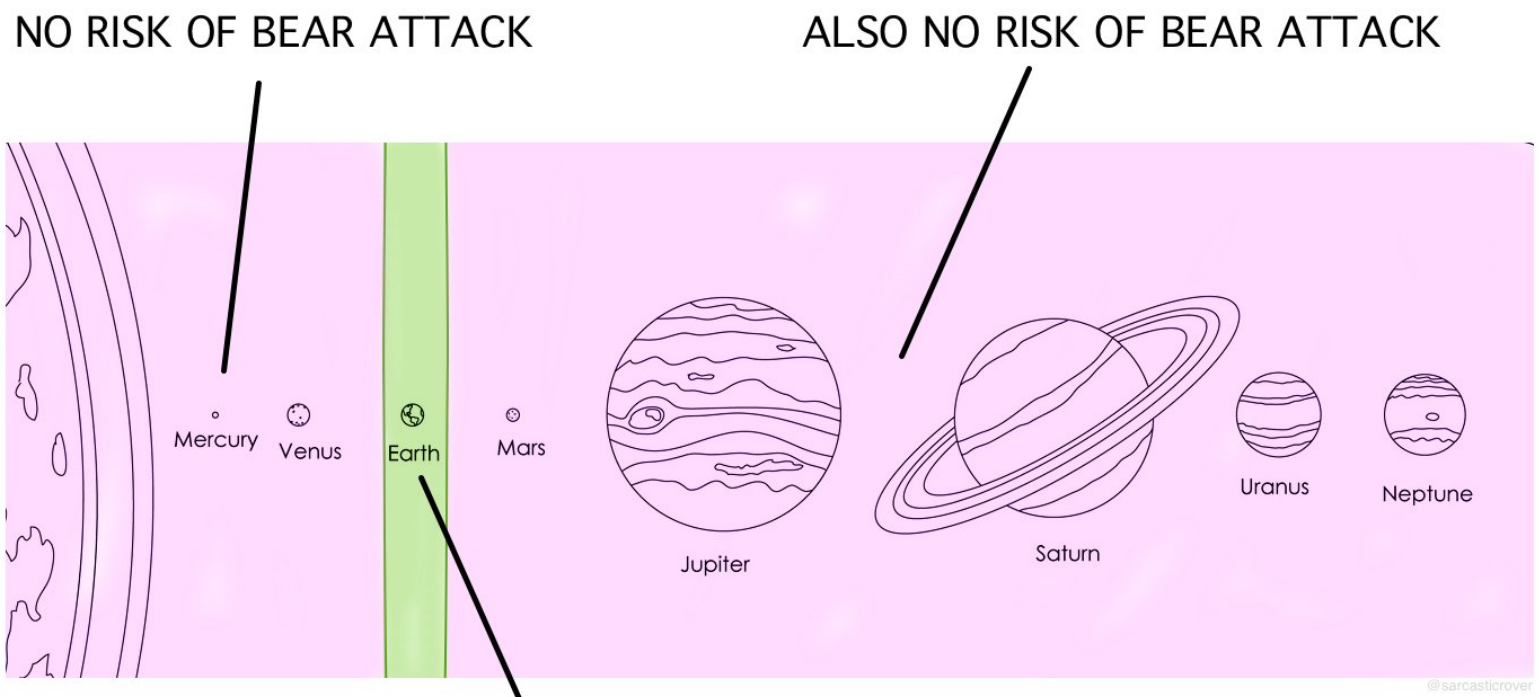
Overview

- IMPACT is a new quantitative, evidence-based medical system risk and tradespace analysis tool for exploration missions
- IMPACT = Informing Mission Planning via Analysis of Complex Tradespaces

- Tool will complete SAR in March 2024
- Presentation conveys the types of questions and data that you can expect from IMPACT
- NASA is looking for commercial partner use cases

Medical System Planning Needs

CHART TO HELP DETERMINE RISK OF BEAR ATTACK:



*And it is required by NASA STD-3001

What is Probabilistic Risk Analysis/Assessment?

- **Risk analysis for complex engineered system with many variables and complex interactions**
- **Three basic questions**
  - What can go wrong?
  - How frequently?
  - What are the consequences?
- **Probabilistic**
  - Evidence-based but intentionally incorporate randomness
  - Use historical data to inform possibility of events that have not yet occurred

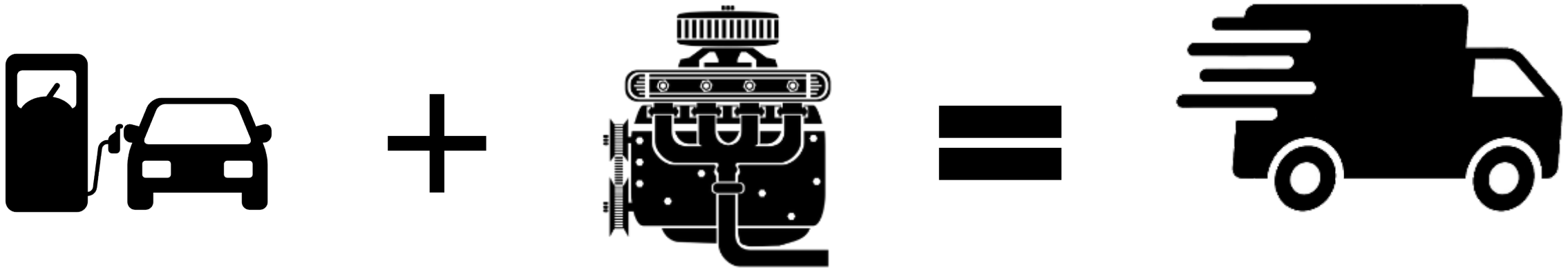
Integrated Medical Model (IMM)

- **Existing risk analysis tool**
- **Evidence and capabilities baselined to ISS**
- **100 medical conditions**
- **Limitations**
  - Considers only microgravity
  - Not specifically designed for trade space analysis
  - Heavy computational resources
  - Last comprehensive update of evidence base was in 2017

What is IMPACT?

Informing **M**ission **P**lanning via **A**nalysis of **C**omplex **T**radespaces

Evidence Base + Computational Engine (PRA) = IMPACT



- New Evidence Base
- New resource warehouse
- Expanded condition list
- Built-in tradespace capability
- Faster computational engine

Step 1 - IMPACT Medical Condition Selection

- Determine medical conditions that are in scope or out of scope for system design (i.e. which conditions to plan around)
- 119 medical conditions of greatest likelihood and consequence for lunar missions
- Nothing specific about that number – determined by schedule/resources

Reference HRP-48036, Rev A

IMPACT v1.0 Condition List

Abdominal Wall Hernia	Barotrauma (Ear/Sinus Block)	Burn - Mild, Thermal	Dental Luxation/ Avulsion (Tooth Loss)	EVA Related Hand Injury	Fracture - Cervical Spine
Abnormal Uterine Bleeding	Benzodiazepine or Opioid Overdose	Burn - Moderate To Severe, Thermal	Dislocation - Finger	EVA Related Heat Illness	Fracture - Distal Leg
Acute Coronary Syndrome	BHP - Adjustment Disorder	Cerebrovascular Accident	Dislocation - Shoulder	EVA Related Paresthesia	Fracture - Femur
Acute Radiation Syndrome	BHP - Anxiety	Cerumen Impaction	Diverticulitis, Acute	EVA Related Shoulder Injury	Fracture - Hand
Allergic Reaction (Mild To Moderate)	BHP - Depression	Choking/Obstructed Airway	Dust Exposure - Lunar	EVA Related Suit Contact Injury	Fracture - Wrist
Altitude Sickness	BHP - Grief Reaction	Cholelithiasis/Biliary Colic, Acute	Ebullism	Eye - Retinal Injury	Fracture- Thoracic/ Lumbar Spine
Anaphylaxis	BHP - Psychosis Secondary To Depression	Dental Abscess	Epistaxis	Eye Foreign Body	Gastritis/Reflux/ Esophagitis
Appendicitis	BHP - Sleep Disturbance	Dental Crown Loss	EVA Related Decompression Sickness	Eye Irritation/Corneal Abrasion/Ulceration	Gastroenteritis/ Acute Diarrhea
Arthritis, Acute	Burn - Chemical Eye	Dental Filling Loss	EVA Related Dehydration	Eyelid And Anterior Eye Infection	Glaucoma, Acute Angle-Closure
Atrial Fibrillation/ Atrial Flutter	Burn - Chemical Skin	Dental Fracture/Exposed Pulp	EVA Related Fingernail Delamination	Fracture - Arm	

IMPACT v1.0 Condition List

Gravity Well - Entry Motion Sickness	Nephrolithiasis	Respiratory Failure	Small Bowel Obstruction	Spaceflight Associated Neuro-Ocular Syndrome (SANS)	Toxic Inhalation Exposure
Gravity Well – Neurovestibular Disturbance	Neuropathy - Central, Impingement Related	Respiratory Tract Infection - Lower	Space Adaptation - Back Pain	Sprain/Strain - Back	Toxic Inhalation Exposure - Combustion Products
Gravity Well - Orthostatic Intolerance	Otitis Externa	Respiratory Tract Infection - Upper	Space Adaptation - Constipation	Sprain/Strain - Lower Extremity	Trauma - Abdominal Injury (Blunt)
Headache	Otitis Media	Seizures	Space Adaptation - Epistaxis	Sprain/Strain - Neck	Trauma - Chest Injury (Blunt)
Headache - Co2 Induced	Pancreatitis, Acute	Sepsis	Space Adaptation - Headache	Sprain/Strain - Upper Extremity	Trauma - Minor Head
Hearing Loss	Pregnancy, First Trimester	Shock - Cardiogenic	Space Adaptation - Insomnia	Streptococcal Pharyngitis	Trauma - Severe Head
Hearing Loss - Noise-Related	Pregnancy, Risk For	Skin Abrasion	Space Adaptation - Nasal Congestion	Sudden Cardiac Arrest	Traumatic Hypovolemic Shock
Hemorrhoids	Prostatitis, Acute	Skin Infection - Bacterial	Space Adaptation - Space Motion Sickness	Tendinopathy/Enthesopathy/ Bursitis/Over-Use Injuries - Lower Extremity	Urinary Tract Infection
Herpes Zoster Reactivation (Shingles)	Rash, Spaceflight Associated	Skin Infection - Viral/Fungal	Space Adaptation - Urinary Retention	Tendinopathy/Enthesopathy/ Bursitis/Over-Use Injuries - Upper Extremity	Vaginal Yeast Infection
Mouth Ulcer	Reactive Airway	Skin Laceration	Space Adaptation - Urinary Incontinence	Toxic Dermal Exposure	Venous Thromboembolism

Step 2 – Medical Condition Data

- **Data Sources**
  - Spaceflight
  - Analog
  - Modeling (e.g. ISS fire model)
  - Terrestrial Data













- **Incidence**
- **Best Case/Worst Case Definitions and probabilities**
- **Clinical Phase Durations**
  - Diagnosis
  - Treatment
  - End State

Step 2 – Risk Metrics

How does each intervention affect:

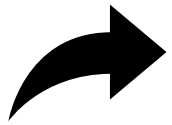
Loss of Crew Life (events/mission)

- Likelihood of a crewmember's death during the mission



Medical Evacuation (events/mission)

- Vehicle capabilities insufficient forcing consideration of evacuation to higher level of care



Task Time Affected (crewmember-days)

- Crew time affected by medical condition



Step 2 - Capability Resource Tables (CRTs)

- CRTs detail the capabilities/resources needed for prevention, diagnosis, stabilization, and management of each condition
- Adapted from evidence-based practice guidelines by space medicine SMEs
- Condition -> Capabilities -> Resources -> Mass/Volume
  - Capability - cognitive/procedural skillset or action (e.g., deliver IV antibiotics)
  - Resource - a piece of equipment, pharmaceutical, or skillset (e.g., 20g IV, interpret physical exam)
- **600+ capabilities and 800+ discrete resources in IMPACT**

Step 3 - Probabilistic Risk Analysis

- **Mission-specific inputs**
  - Mission Duration
  - Mission Destination (with segment-specific conditions; e.g., Space Adaptation Syndrome)
  - Crew Characteristics (number, sex, pre-existing medical conditions)
  - EVA number and frequency
- **Simulate 100k-300k missions**

Step 3 - Probabilistic Risk Analysis

Best-case resources available?

Yes

Treated Case: Decrement medical resources

No

Untreated Case Decrement medical resources

Best-case Scenario

Medical Event Incidence

Worst-case Scenario

No

Untreated Worst-Case Decrement medical resources

Worst-case resources available?

Yes

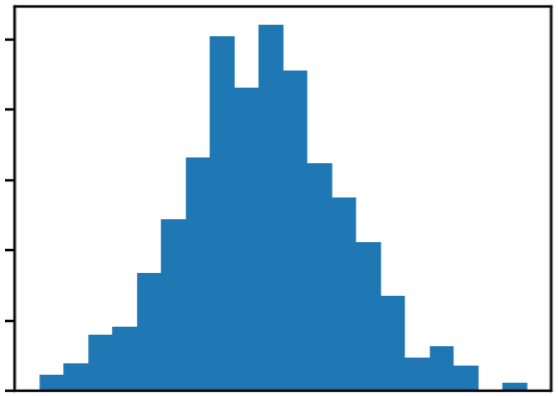
Treated case: Decrement medical resources

Calculate End States:

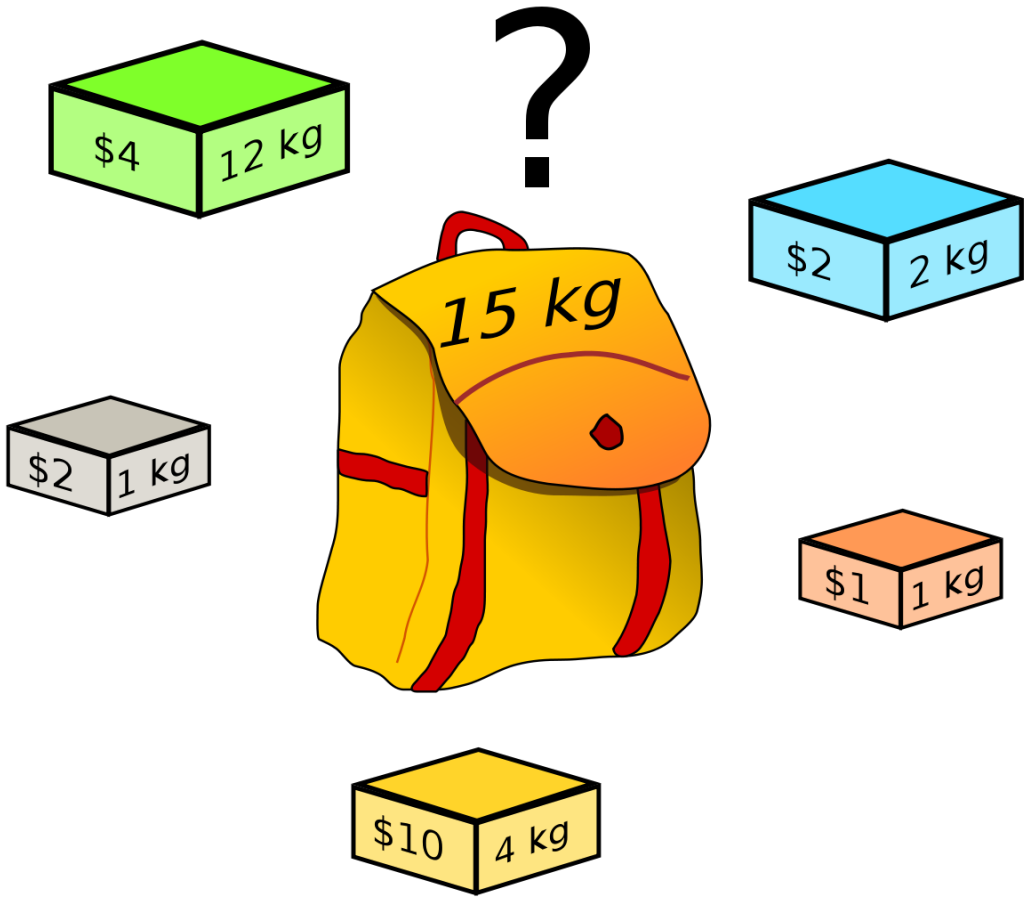
- Loss of Crew Life (LOCL)
- Medical Evacuation
- Task Time Affected
- Resource Utilization

Outputs can adjust with changes in mass/volume

100,000 simulations



Step 4- Tradespace Optimization (The Backpack Problem)



- Optimization problem
- Maximize value subject to constraints
- Question: what combination of blocks yields the most money but does not exceed the weight limit?



Mission Characteristics

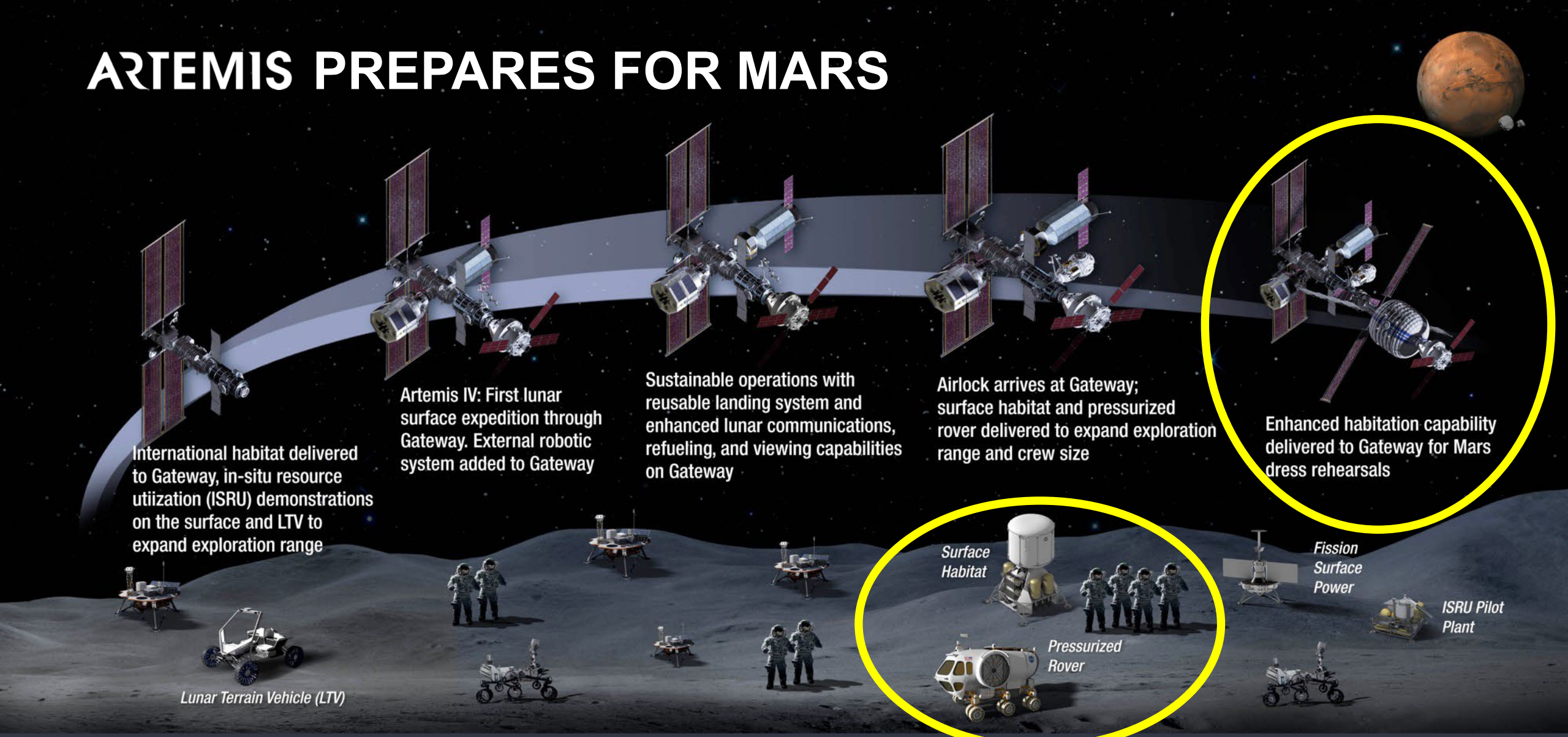
Medical system:
- Mass
- Volume

Capabilities/Resources



Risk Metrics
- Loss of Crew Life
- Medical Evacuation
- Task time affected

ARTEMIS PREPARES FOR MARS



SUSTAINABLE LUNAR ORBIT STAGING CAPABILITY AND SURFACE EXPLORATION

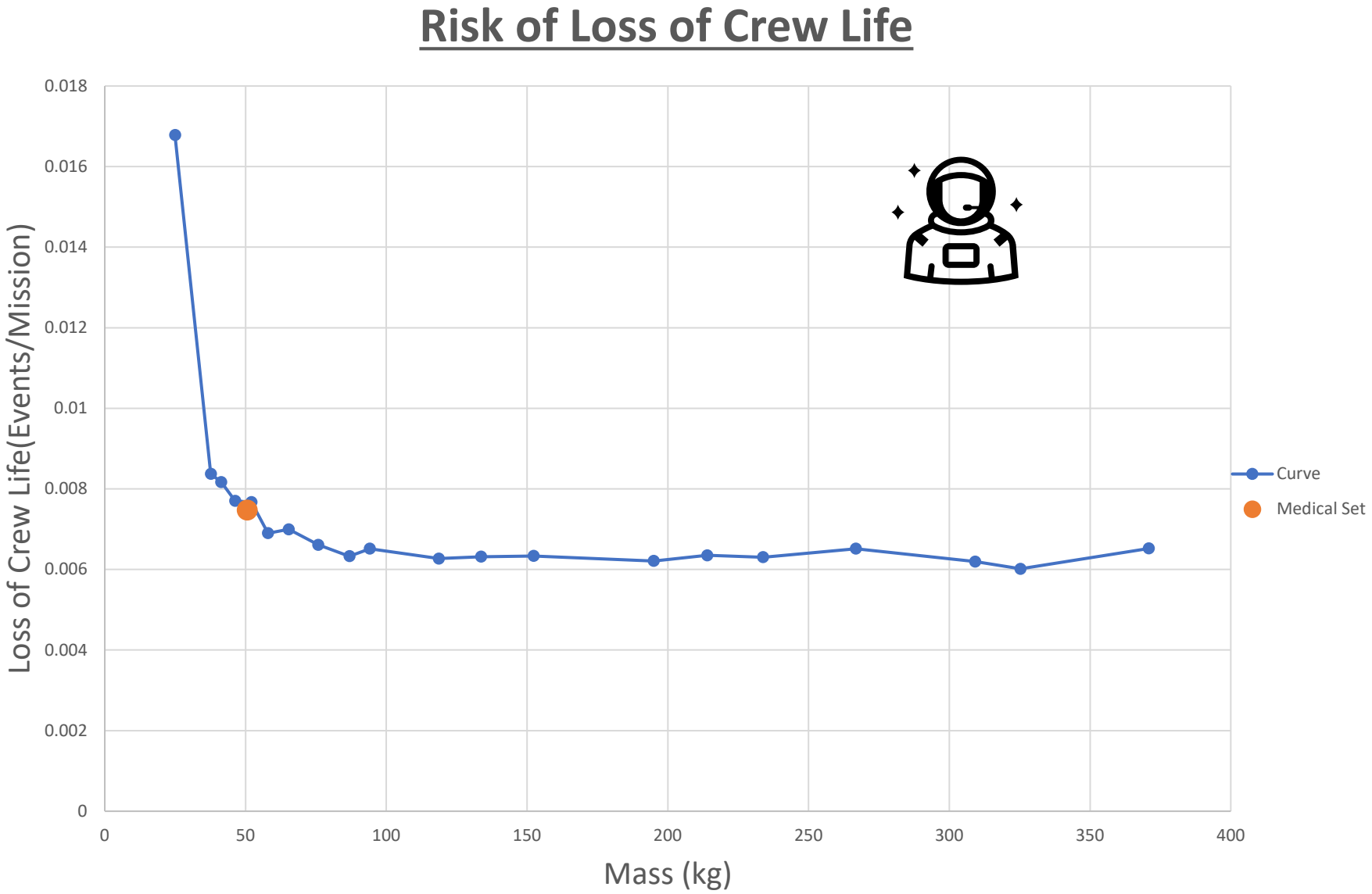
MULTIPLE SCIENCE AND CARGO PAYLOADS | U.S. GOVERNMENT, INDUSTRY, AND INTERNATIONAL PARTNERSHIP OPPORTUNITIES | TECHNOLOGY AND OPERATIONS DEMONSTRATIONS FOR MARS

All contents represent notional planning and are for discussion purposes only

Crew Members

- **Representative of NASA astronaut population**
  - Met Med A (selection) standards
- **2 Male Crew members**
- **2 Female Crew members**
- **No pre-existing medical conditions**
  - No prior surgeries
  - No prior dental work
  - Not on long term medication

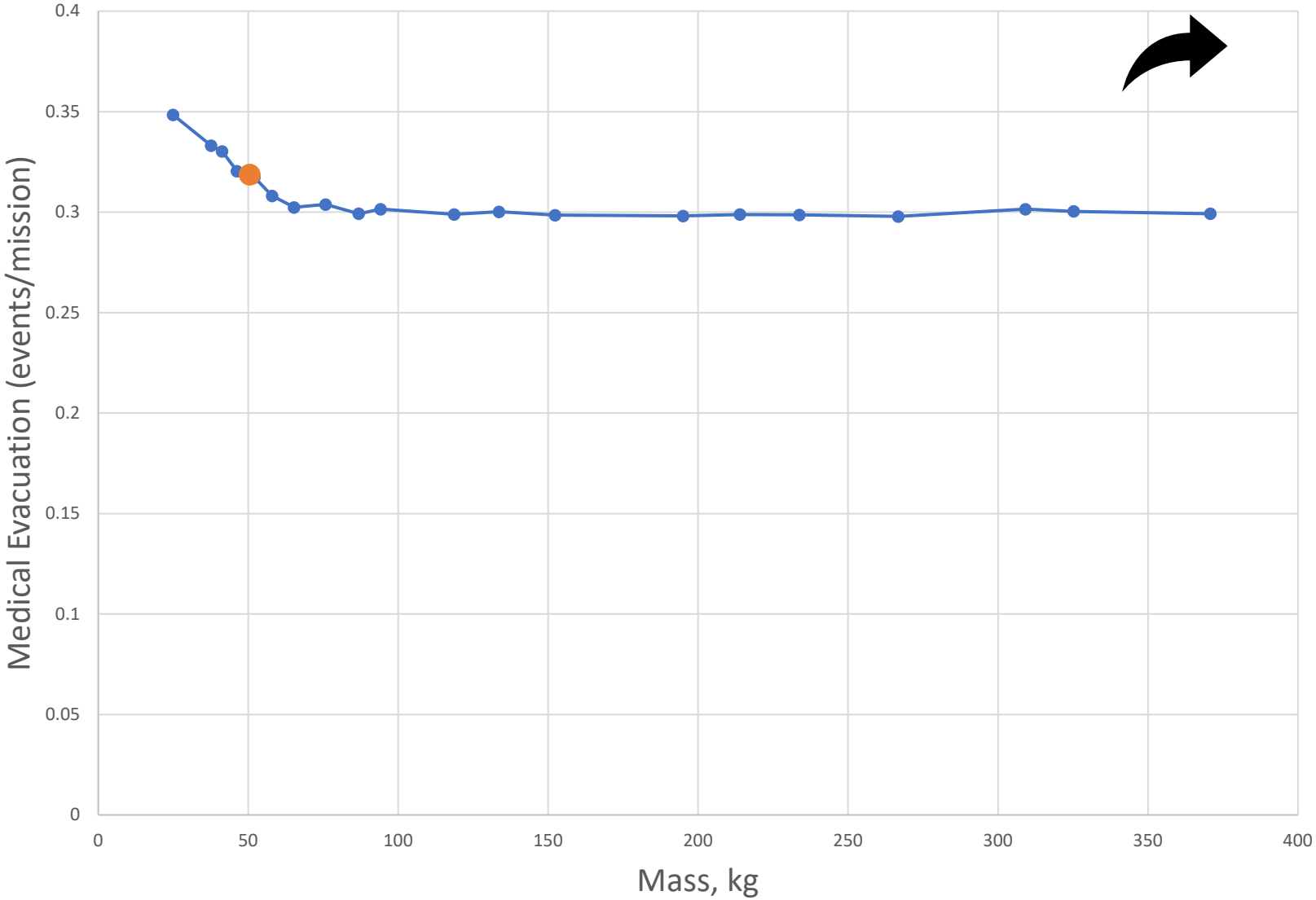
Loss of Crew Life



Notional

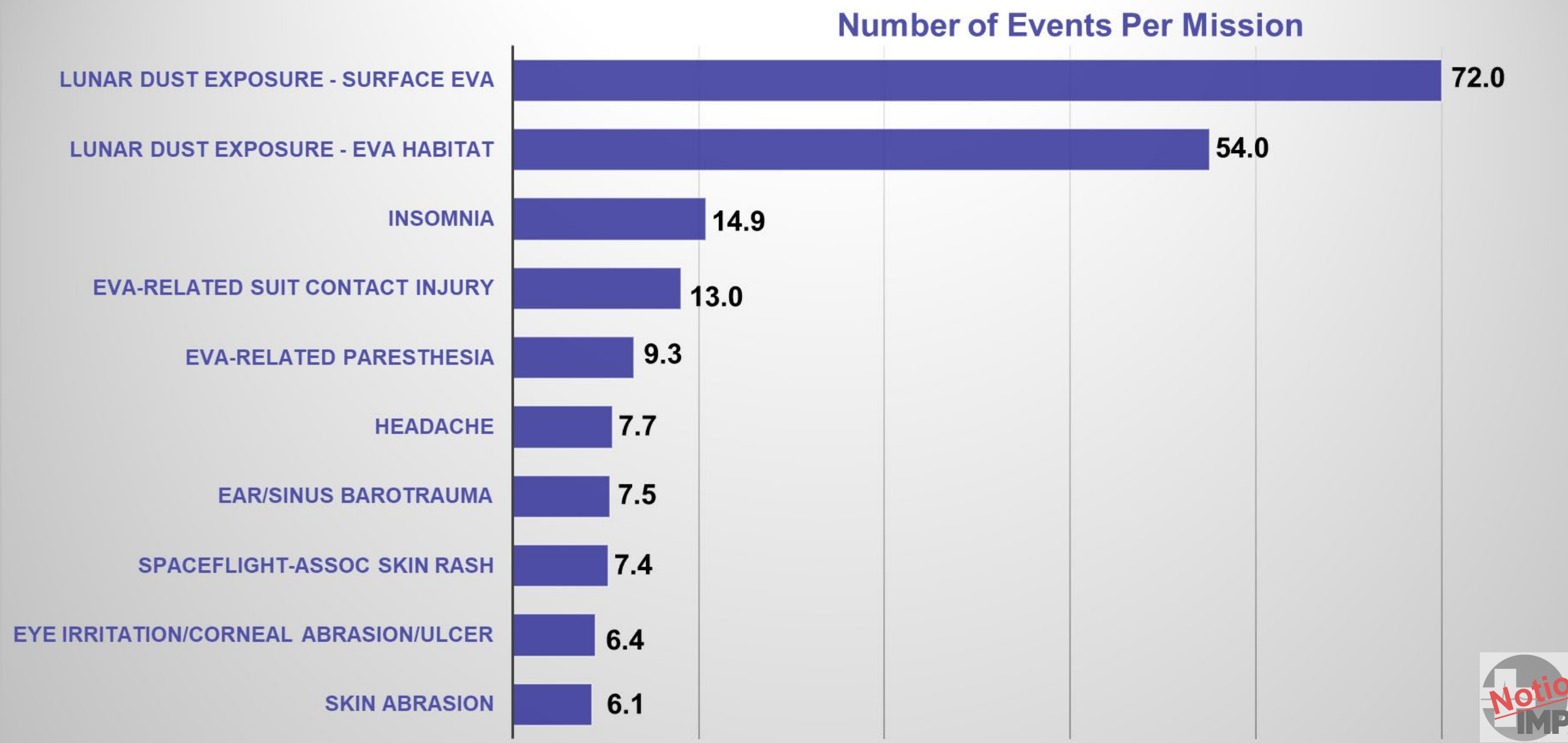
Medical Evacuation

Risk of Medical Evacuation

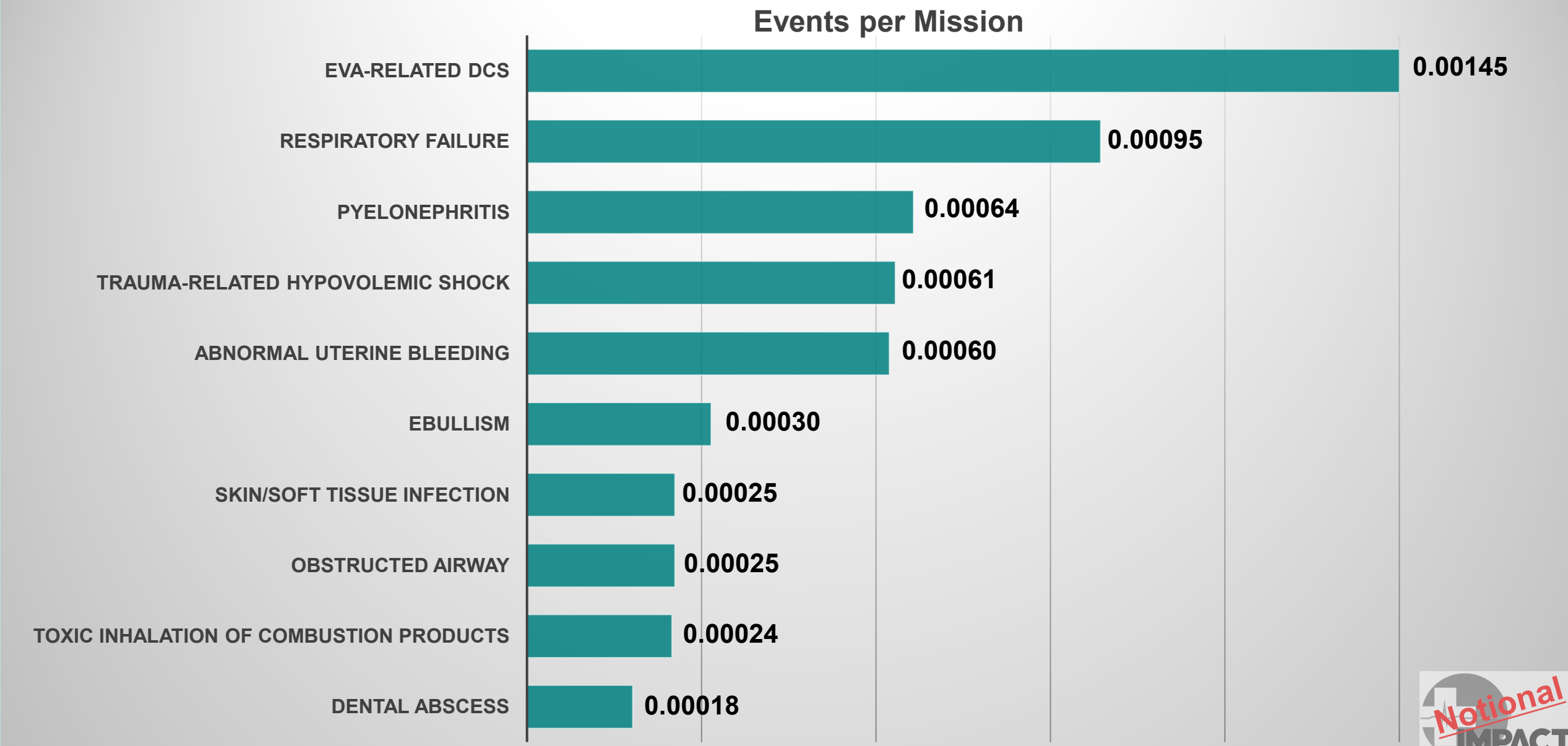


Notional

Most Frequent Conditions



LOCL – Events Per Mission

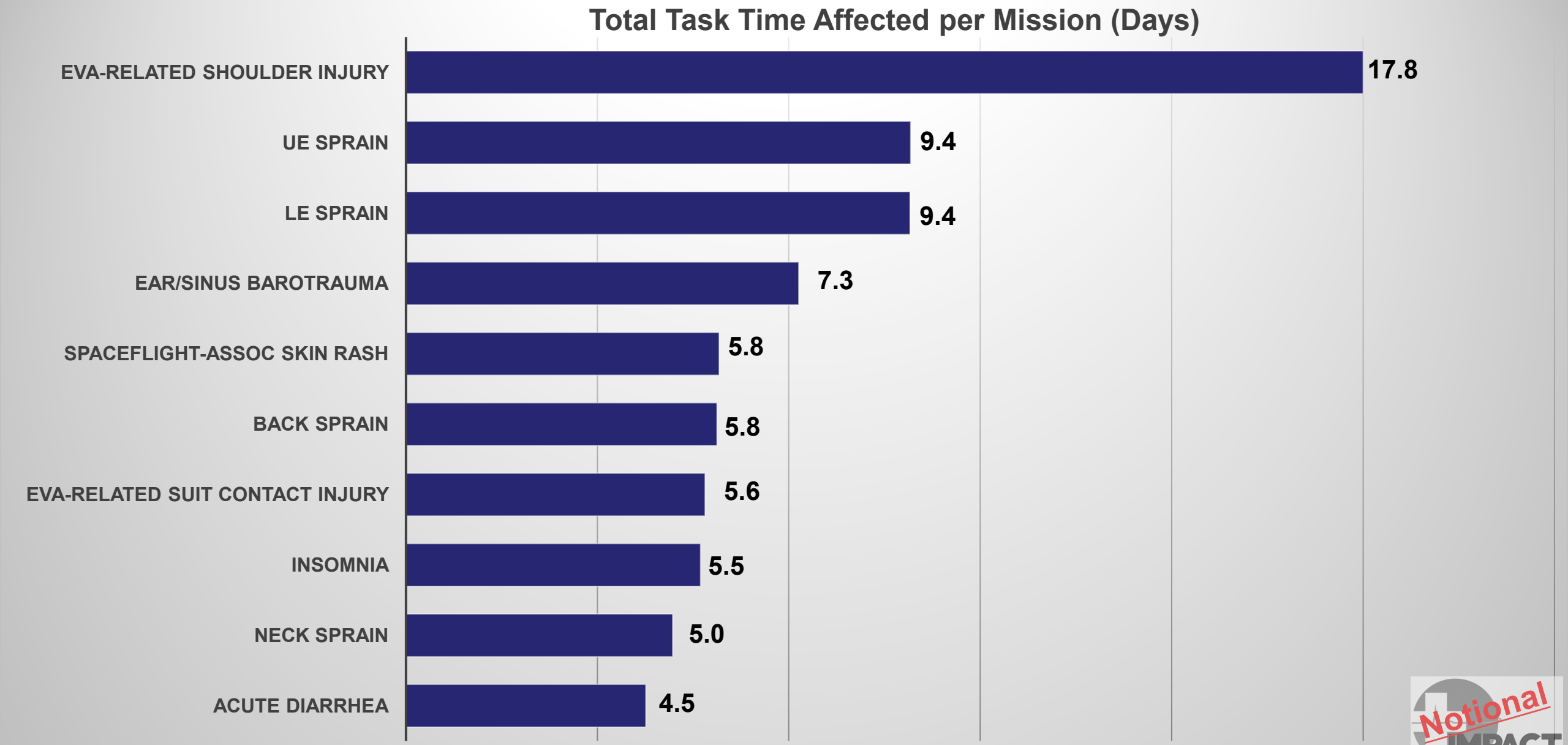


Notional

Notional LOCL Top Diagnostic Capabilities

- **History**
- **Vitals, Primary Assessment (Circ, Airway, Breathing), Capnography**
- **Physical Exams: Oropharyngeal, Cardiac, Pulmonary, Abdominal, Neuro, MSK, skin**
- **Ground-based Communication**
- **Venipuncture; intravenous and intraosseous access**
- **Lab result interpretation**
- **Ultrasound performance and interpretation**
  - Abdominal, Pulmonary, Cardiac

TTA – Crewmember Days per Mission

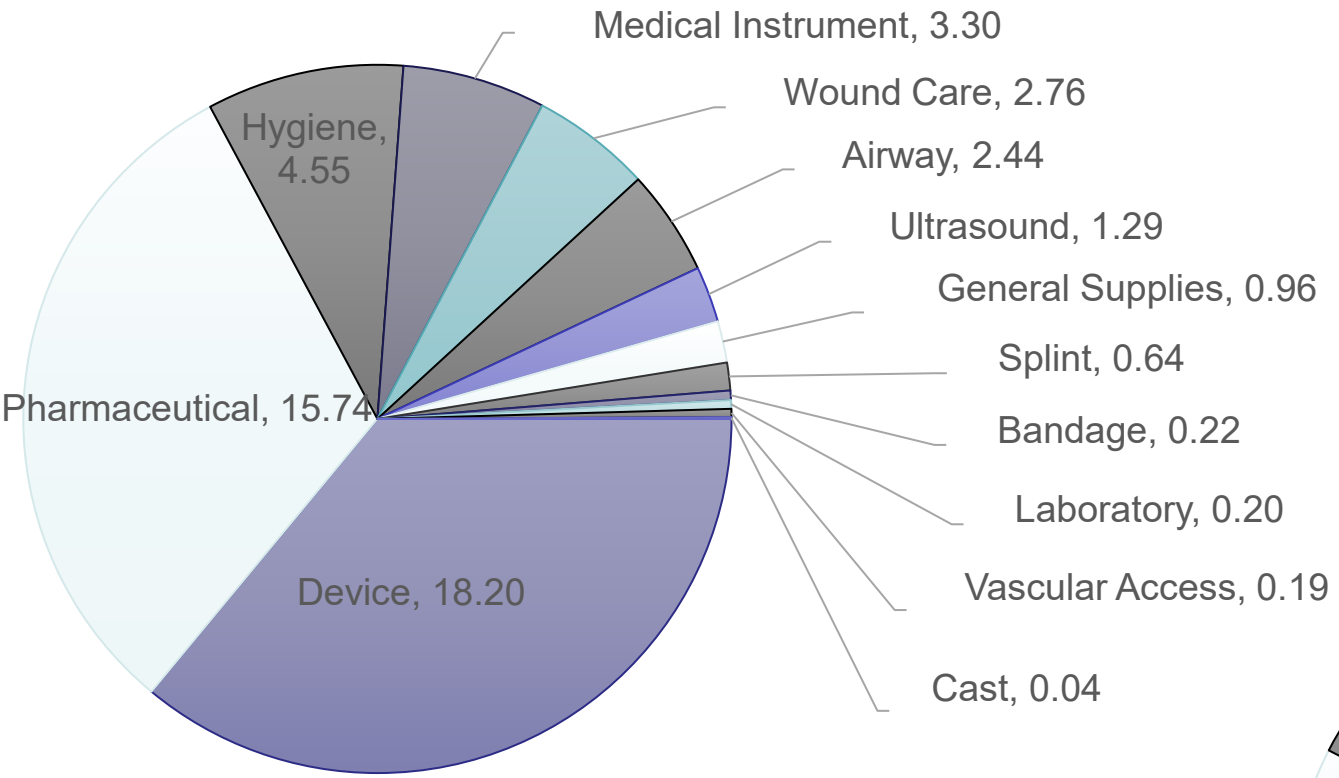


Notional IMPACT

Introduction to the Med System Contents

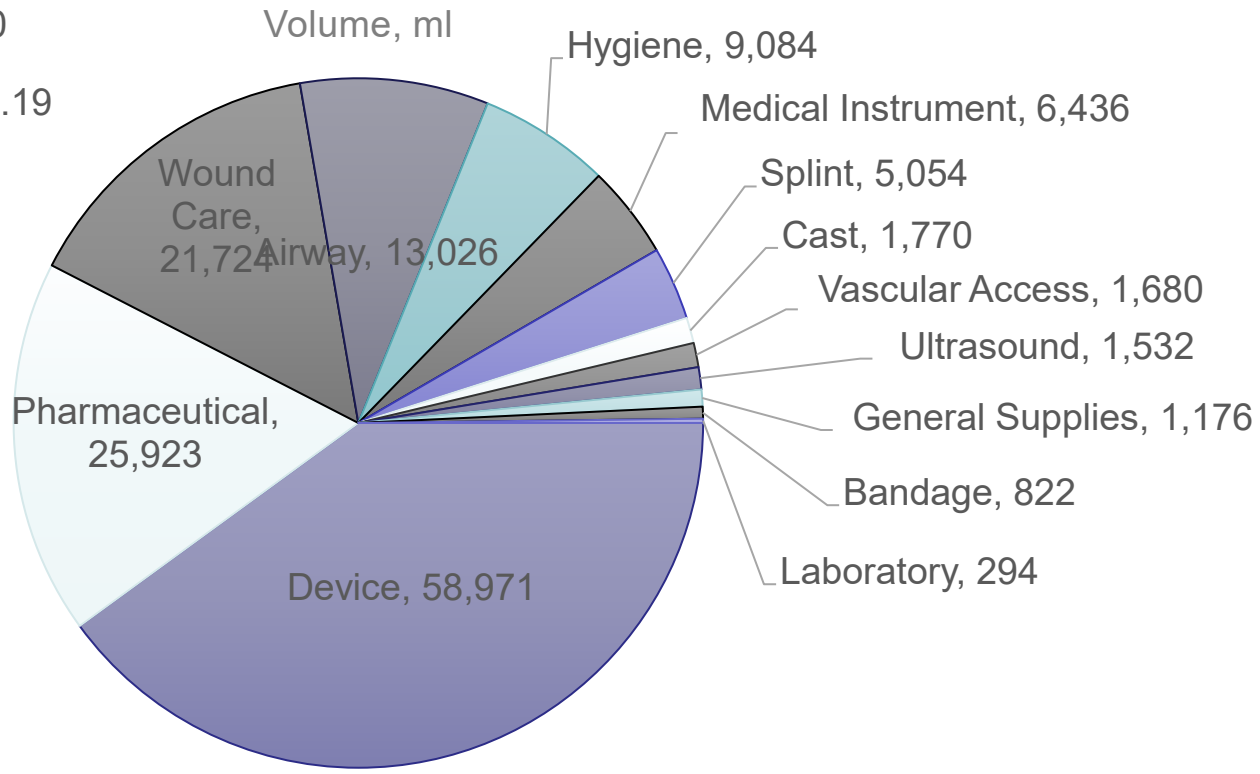
Resource Name	Resource Quantity	Total Resource Mass (kg)	Total Resource Volume (mL)
Device - Lifepak 15 Device	1	9.100	29,400.000
Pharmaceutical - Intravenous - Pre-Filled Sodium Chloride 0.9% Solution 1000mL	4	4.120	4,800.000
Hygiene - Instrument Disinfectant	9	2.556	3,663.000
Pharmaceutical - Topical - Moisturizing Cream 5ml	24	1.683	3,384.000
Wound Care - Bandage - 4 Inch Rolled Gauze	68	1.564	7,888.000
Device - Alpha Stim CES Device	1	1.500	9,800.000
Pharmaceutical - Topical - Diclofenac Sodium 1% 0.5 Inches	10	1.389	4,836.811
Pharmaceutical - Oral - Benzocaine And Menthol Lozenge 15mg/3mg	594	1.348	1,637.005
Device - Lifepak 15 Device Power Supply	1	1.300	3,802.000
Pharmaceutical - Topical - Mupirocin 0.25 inch	36	0.955	1,330.277

Overview of Resources by Mass in the Medical System



Total Mass
Limit 50 kg

Total Volume
Limit 150 L



Notional IMPACT

IMPACT Future Updates

- Mission Segments – optimize resources across the missions and within given phases (e.g., Orion, Gateway)
- Perform trades on Knowledge, Skills, Abilities (KSA) of crew
- Refinement of medical evacuation risk
- Expanded medical condition list
- Weighting of resources (relative contribution to outcome)
- What features would you like to see?

Overall Conclusions

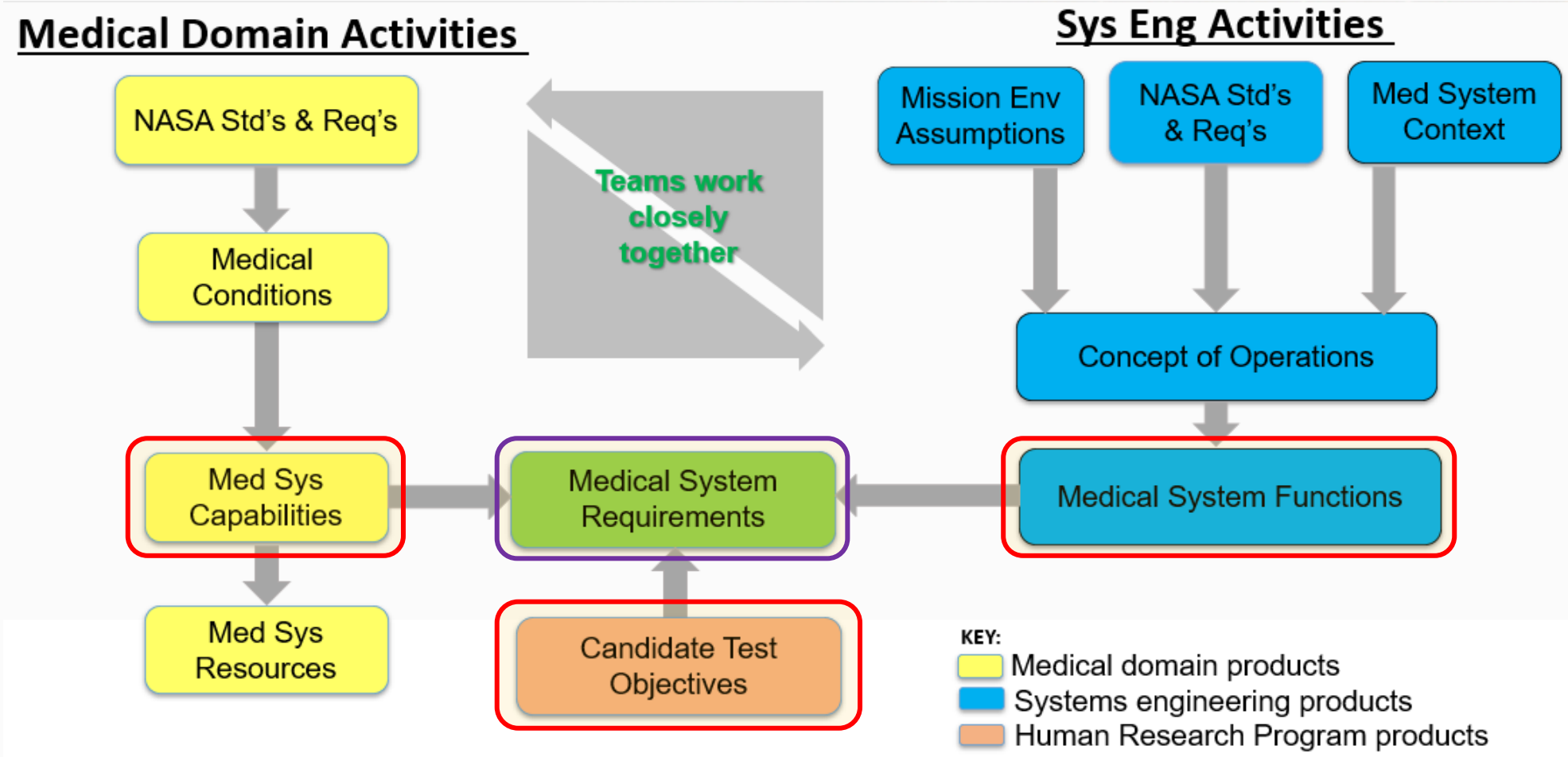
- **We need a quantitative method to estimate medical risk for exploration missions**
- **IMPACT has sophisticated capabilities to define a medical system's capabilities by trading off medical risk against system resources**
- **Progressive updates to increase fidelity**
- **NASA plans to start using IMPACT for medical risk modelling in 2024**
  - Very interested in work with commercial providers – please talk to us!

MEDICAL SYSTEM DESIGN



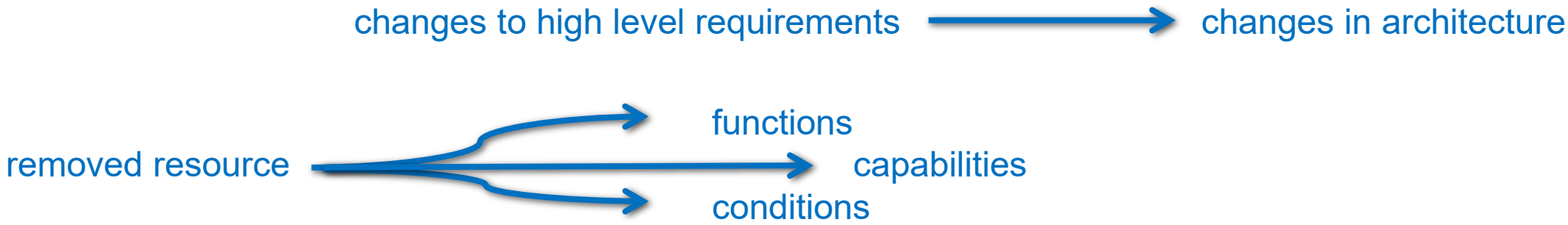
Medical System Design Approach

- An interdisciplinary process of integrating clinical and systems engineering inputs to generate recommendations for medical system design



Why model-based systems engineering (MBSE)?

- Using a model-based systems engineering (MBSE) approach has been identified by the Office of the Chief Engineer as **best practice** for system design and is consistent with the use of digital architectures by Exploration Programs.
- MBSE enables users to **visualize** the medical system functions, conditions, capabilities, and resources and understand how they all trace to medical system recommended requirements.
- As a starting point **for any program to tailor a set of requirements** that best suit respective vehicle and mission needs, the MBSE medical system model is designed to be flexible and modifiable such that **changes can propagate throughout the model** without significant manual effort.

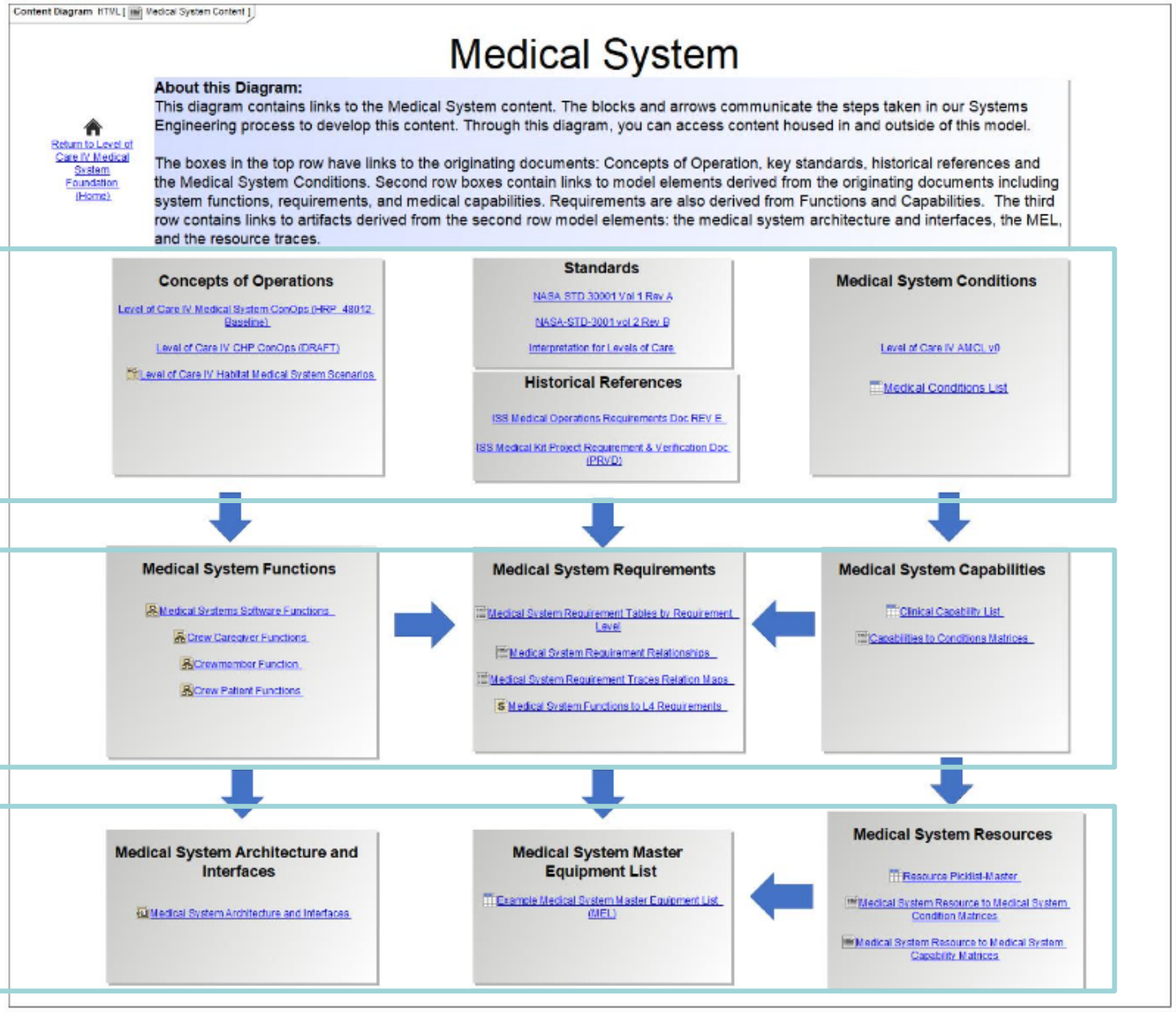


Exploration Medical System Models

High-level system vision and scope

Functions + Capabilities = Requirements

Resulting Outputs including:
- Medical system architecture
- Medical system master equipment list
- Medical system resources



Medical System Foundation for Level of Care IV: Long-Duration Lunar Orbit and Lunar Surface

Version 1.0 (Current)

A Medical System Foundation is a system model that contains both Systems Engineering products and Clinical Data. It is meant to serve as a starting point for NASA programs that are developing mission- and vehicle- specific medical systems. New users of this web report are recommended to reference the accompanying context, process and history document while viewing the report: Medical System Foundation for Level of Care IV Long-Duration Lunar Orbit and Lunar Surface: Context, Process, and Project History.

The Medical System is a subsystem of the Crew Health and Performance (CHP) system; it interfaces with the other CHP subsystems and vehicle systems external to the CHP system. The Medical System Foundation model captures systems engineering and clinical content and the relationships that exist between and among them. The model includes a Concept of Operations (ConOps), a list of functions traceable to the ConOps content, requirements derived from the functions, a set of medical conditions that could occur in-flight, medical capabilities, and example resources that could be used to diagnose or treat these conditions.

Information about the Medical System Foundation

Navigation Support

Model Stakeholders and Architecture

Contact Information and Model Version

Context, Process and Project History

Glossary and Acronyms

Applicable Documents

Reference Documents

System Inputs

The guiding inputs of the Medical System Foundation Model include NASA standards, program-specific requirements related to medical care, and assumptions regarding mission operating environments and interfaces between the Medical System and other systems.

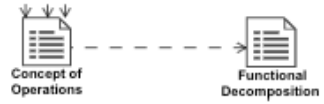


Concept of Operations and Functional Decomposition

The Medical System Foundation systems engineering content consists of a Concept of Operations (ConOps) and System functions.

The ConOps includes stakeholder needs, system goals, mission constraints, operating environments, and representative scenarios that highlight potential needs the system must fulfill.

System functions and subfunctions are derived from the ConOps via a functional decomposition process. These functions served as an input to the requirements development process.



Clinical Content

The Medical System Foundation clinical content includes medical conditions and the derived clinical capabilities and associated resources needed to diagnose and treat those medical conditions. The clinical capabilities served as an input to the technical requirements derivation process. These contents as well as the traceable relationships between them live in this section.



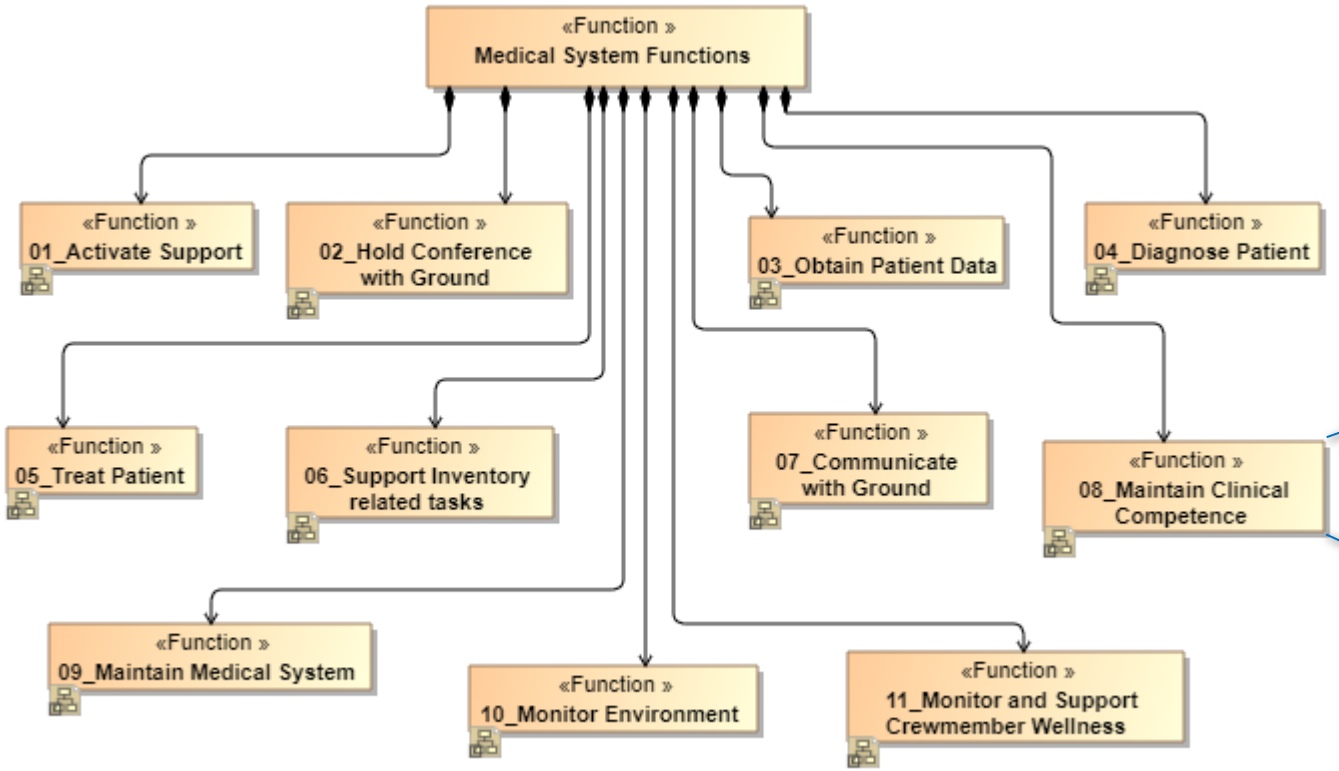
Technical Requirements

The Medical System requirements represent the functional and non-functional System needs and are driven by the content documented in the ConOps (e.g., scenarios and functions), clinical capabilities, NASA standards and historical documents, and parent system requirements. Interface requirements were also developed, which represent medical needs that are allocated to other systems based on the proposed system architecture. The Medical System functional, non-functional, and interface requirements are defined within NASA as Level 4 and have traces to their Level 2 and 3 parent requirements, NASA Standards and historical documents, and the clinical capabilities.

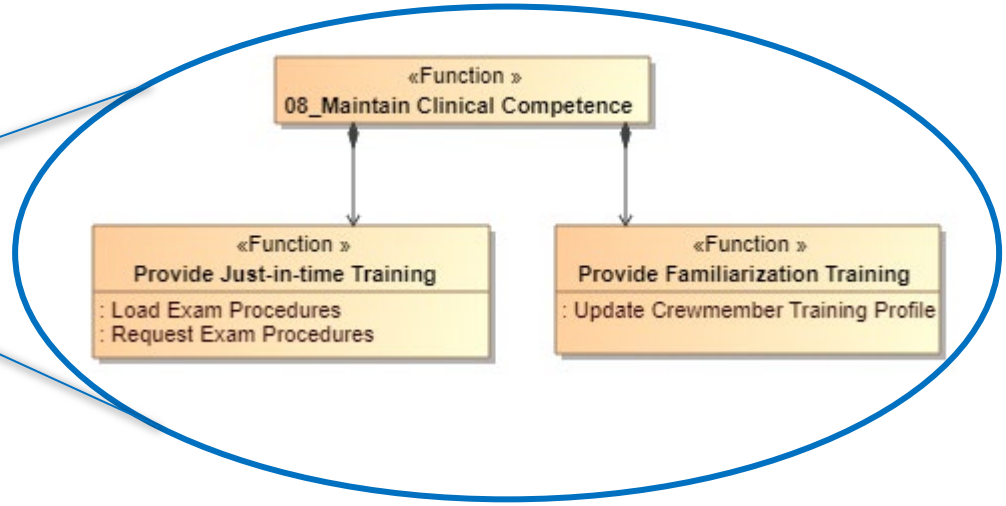


Medical System Functions

Function blocks represent key system features and were used to derive representative medical scenarios.



Subfunctions and mapped activities from scenario activity diagrams



New Medical Condition List Scoped to Exploration



The conditions list was derived from the following sources:

- Lunar Extravehicular Activity (EVA) Incapacitation Condition List (No Link available)
- Artemis Phase I: Functional Medical Concept of Operations Condition List (No Link available)
- The EL Team Condition List (Not available outside of NASA)
- Evidence Library Pilot Project Rochester Epidemiology (REP) Study Condition List (Unpublished)
- Evidence Library Pilot Project Spaceflight Condition List (Not available outside of NASA)
- Evidence Library Pilot Project Toxic Exposures and Injuries Condition List (Not available outside of NASA)
- IMCL Historical Spaceflight Condition List (Unpublished)
- IMM-GEN 309, Rev 1: IMM Medical Conditions List (IMCL) (IMM Portal Access Required)
- JSC-65722: Exploration Medical Condition List (EMCL) (Not available outside of NASA)

1	ICL1_Abdominal Wall Hernia
2	ICL2_Abnormal Uterine Bleeding
3	ICL3_Acute Coronary Syndrome
4	ICL4_Acute Radiation Syndrome
5	ICL5_Allergic Reaction (Mild To Moderate)
6	ICL6_Altitude Sickness
7	ICL7_Anaphylaxis
8	ICL8_Appendicitis
9	ICL9_Arthritis, Acute
10	ICL10_Atrial Fibrillation/Atrial Flutter
11	ICL11_Barotrauma (Ear/Sinus Block)

Clinical Capabilities

This section includes the following:

- Clinical capability tables
- Conditions ←→ Capabilities mappings



cification | Appears in

Clinical Capability List

#	Name	Owner
1	Access E.H.R.	Configure Environment for Care
2	Acoustic - Attenuated	Personal Protection
3	Acoustic - Noise Cancelling	Personal Protection
4	Acoustic - Non-Attenuated	Personal Protection
5	Adequate assessment/diagnostic skills (ability to recognize and appropriately treat infection early before progression to sepsis	In-Flight Prevention
6	Adequte EMU sizing	In-Flight Prevention
7	Airway - Abdominal Thrust/Chest Compression	Perform Procedures
8	Airway - Airway Adjuncts	Perform Procedures
9	Airway - Chemical	Personal Protection
10	Airway - Endotracheal Intubation	Perform Procedures

Medical Resources

This section includes the following:

- Medical resources lists
- Medical resources mappings
  - Resources → capabilities
  - Capabilities → resources
  - Resources → conditions

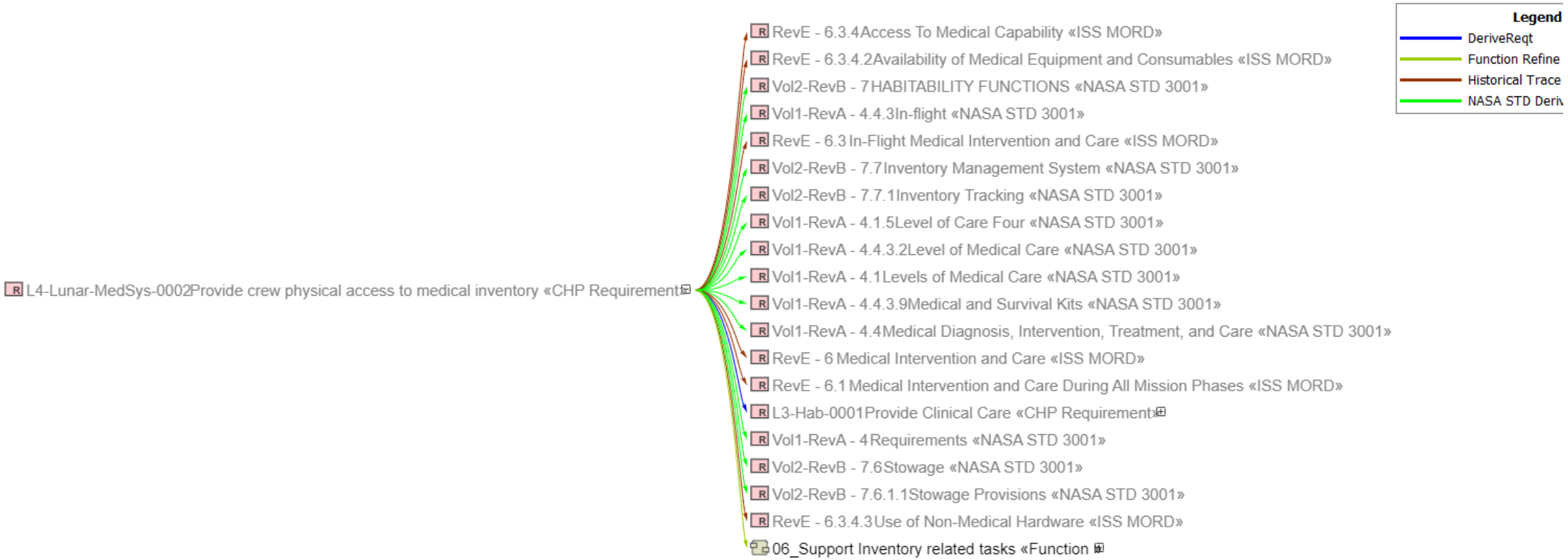
Template Master Equipment List

#	Medical Resources	volume per unit	mass per unit	average power consumption per unit
1	Airway - Bag Valve Mask	6218.8908 cc	0.5806 kg	0.0 W
2	Airway - Device - Capnography Nasal Cannula	509.703239 cc	0.091172 kg	0.0 W
3	Airway - Device - Capnography Sensor	0.0 cc	0.0 kg	0.0 W
4	Airway - Device - Invasive Airway Tube Capnography Adaptor	199.3506 cc	0.031751 kg	0.0 W

Technical Requirements

Traces to:

- **Medical System functional, non-functional, and interface requirements**
- **Medical system requirement relationships**



EXPLORATION MEDICAL CAPABILITY

Questions?

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