Exploration Medical Capability
ConOps and Systems Engineering
Technical Interchange Meeting Summary

3/28/17

Jennifer Mindock
    Jeff Reilly
Michelle Urbina
    David Rubin
Melinda Hailey
    David Reyes
Andrea Hanson
    Tyler Burba
    Jeff Cerro
Kerry McGuire
    Chris Middour
Exploration Medical Capability
Systems Engineering
Introduction

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Impact Exploration Missions

• Exploration missions are gaining momentum!
• Apply systems engineering approaches to support early mission and flight vehicle development
  – Human health and performance scope is large
  – Impact overall mission and vehicle designs
Background

• Exploration missions present significant new challenges to crew health:
  – Long duration: 1-3 years
  – No medical evacuation
  – Communication delays, blackout periods
  – No resupply, prepositioning at best
  – Effects of space environment on human health are not completely known

• A medical system should maximize flexibility to enable a care provider to address conditions that were not considered in the initial design

• Medical technologies rapidly evolve

• Limited flight resources (e.g., mass, power, volume, data) require us to view medical system as an integrated part of flight system development

• Need new medical system development approach and requirements

• Need systems engineering approach

Photo credit: NASA

Exploration will be different...
From “System Engineering at JPL” training course material, June 1991.
Systems Engineering
From NASA Systems Engineering Handbook

What is Systems Engineering?
• A methodical, disciplined approach for the design, realization, technical management, operations, and retirement of a system

What is a “System”?
• Collection of different elements producing results not obtainable by elements alone
  – Elements = people, hardware, software, facilities ...
• Value created by relationship among parts - how they are interconnected

Systems Engineering IS:
• a way of looking at the “big picture” when making technical decisions
• a way of achieving functional, physical, and operational performance requirements
• the art and science of developing a system within opposed constraints
• a holistic, integrative discipline, wherein the contributions of e.g.,
  – structural engineers, electrical engineers, mechanism designers, power engineers, human factors engineers, and many more disciplines (medical!)
  are evaluated and balanced... to produce a coherent whole that is not dominated by the perspective of a single discipline.

2Comments on systems engineering throughout the handbook’s Chapter 2.0 are extracted from the speech “System Engineering and the Two Cultures of Engineering” by Michael D. Griffin, previous NASA Administrator.
Key Systems Engineering Points

• Team converges on same mental models
  – Of system, its context, its use, our way of working...
  – Applying aspects of Model-Based Systems Engineering using Systems Modeling Language (SysML)

• Enable technical communication with entities external to ExMC

• Tailoring is necessary
  – Not all SE processes fit all projects

• Tools are available for our use
  – We are not slaves to them
ExMC SE Mission

**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.**

<table>
<thead>
<tr>
<th>Needs</th>
<th>Approach</th>
<th>Benefit</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop system technical foundation</td>
<td>Apply structured, integrative science and engineering</td>
<td>Increase relevancy to exploration system maturation</td>
<td>Be open, unbiased, learning, and serving</td>
</tr>
</tbody>
</table>

- Develop ConOps
- Capture stakeholder expectations
- Define and manage requirements
- Capture and manage design
- Identify and manage disciplinary interfaces
- Plan and execute system V&V
- Inform system development decisions from scientific, technical perspective
- Identify tech dev and research needs
- Use a structured and disciplined approach to develop a med system addressing medical, behavioral health, human performance
- Enable effective coordination and integration with exploration mission engineering, operational, and technology development efforts
- Speak the same language as engineering and operations communities with respect to system design
- Provide regular and transparent communication to maintain programmatic and stakeholder situational awareness and provide insight into the med system development
- Develop and foster shared mental models within and external to crew health and performance community
- Develop relationships across disciplines and Centers to build trust and enable teamwork
- Enhance visibility and opportunities for influence current activities of groups that would not happen
- Foster learning of SE principles and practices
- Be both responsive to and anticipatory of stakeholder needs, keeping in mind stakeholders may be from anywhere in an org chart

Contact us if interested in this material in our Systems Engineering Management Plan
Organizational Context

1) Research
2) Risks
3) Design/techs
4) Standards
ExMC’s Purpose --> Needed Functions

**ExMC Mission:** To minimize mission medical risk through medical system design and integration into the overall mission and vehicle design.

What functions does the medical system need to provide?

- **Provide Comprehensive Health Management**
- **Manage Health Impacts Due to Environment**
- **Support Mission Task Performance**
- **Provide In-Flight Training**
- **Provide Task Execution Support**
- **Prevent**
- **Diagnose**
- **Treat**
- **Manage Long-Term Care**
- **Support Behavioral Health**
- **Provide Exercise**
- **Provide Food**
- **...**

Black text: medical system scope
Grey text: partially in medical system scope
Typical Product Expectations

• From 7120.5E NASA Space Flight Program and Project Management Requirements

• Example Mission Concept Review products - Pre-Phase A (Concept Studies)
  – Preliminary
    • Plans – Systems Engineering Management Plan, V&V Approach
    • Concept of Operations
    • Architecture
    • High-level system requirements
    • Traceability to higher level requirements
Example Products

We must communicate with exploration mission development activities effectively

“Problem space, not solution space”
Or “What, not How”

Do we have solutions? If no, research and tech dev required!

Systems Engineering Management Plan

Systems Engineering Tools (e.g., models, analyses)

Element Management Plan

Concept of Operations

Requirements

Architecture

Verif & Valid Approach

Technical Processes

- Stakeholder Requirements Definition
- Architecture Design

Technical Management Processes

- Decision Analysis
- Technical Planning

- Transition
- Validation
- Verification
- Integration
- Implementation

Delivered Capability

Decomposition

Realization

Design ↔ Product

“Problem space, not solution space”
Or “What, not How”

We must communicate with exploration mission development activities effectively.
How do we get there?

We’re starting here:

- System needs, goals
- Concept of Operations
- NASA Standards

Do we have the capabilities to meet the needs?

The needs identified by this work will drive future ExMC research.

Other sources of system requirements will be folded in as we move forward. ConOps is not the only source!
Upcoming Steps

• 3/28/2017 (TODAY): Hold Technical Interchange Meeting with Driving Stakeholders

• 4/2017: Draft Concept of Operations for Medical Care for an Exploration Mission (Mars Transit)

• Goal End FY17: Draft In-Flight Medical System Functional Requirements (Mars Transit)
Thank you
Medical System Concept of Operations for Mars Exploration Missions

ExMC Systems Engineering
Technical Interchange Meeting (TIM) 1
Medical System for Mars Transit

Presenters:
Michelle Urbina
Jeff Reilly
Melinda Hailey
What is a ConOps?

- high-level concept
- system needs & goals
- meet stakeholder expectations
- operational perspective
- informs development of requirements
Engaging Med Ops Stakeholders

- ConOps team actively engaging Med Ops community
  - Exploration Clinicians Working Group (ECWG)
    - Clinical advisement to the ExMC Element Scientist for the assessment, prioritization, and technical direction of ExMC made up of Physician (Ops or research), Pharmacy, Nursing, & Engineering disciplines.
    - SE approach
    - Level of Care Definition
    - Planned Operations
    - Unplanned Operations
    - Scenario Tree
    - Activity Diagram Example
  - Medical Operations Group (MOG)
    - Organizational status and issue discussion with Space & Occupational Medicine Branch Chief/Deputy Chief. Special Topics are welcomed at the end of the meeting and are either “Decisional” or “Informational” to allow the clinical expertise of the medical group to aid in decision making, if needed, or for awareness or opinion. The ConOps presentations were all information but opinion was request via an electronic evaluation.
    - Level of Care Definition
    - Planned Operations
    - Unplanned Operations
  - Crew Office
    - Met with clinician crew to introduce the ConOps ideas
Exploration Medical System
Needs and Goals
How do we get there?

1. System needs & goals
2. NASA Standards
3. Concept of Operations
4. System functional needs
5. System requirements
6. System architecture
7. Allocations
8. Subsystem requirements
System Needs & Goals

• Based on stakeholder expectations and constraints levied or imposed on the medical system
• Provide foundation for exploration medical system development
• Influence technical measures commonly used for insight into performance of the technical solution
• Establish basis for high-level requirements and quality attributes of the medical system

- Stakeholders' Needs
- Constraints
- Quality Attributes
- ConOps
- DRM
- System Allocations

System Goals

Architectural Drivers

Conceptual Architecture

System Specification

Design Alternatives

System Build

System Verification and Validation

Technical Measures
Exploration Medical System Goals

1. Comprehensive Health Management
2. Crew Autonomy
3. Continual Information Application and Learning
4. Capability Flexibility
5. Medical, Vehicle and Mission Systems Integration
6. Crew and the Medical System Integration
7. Ground Awareness
1. Comprehensive Health Management

• Provide comprehensive health management capabilities to enable mission task performance and mission success.

• In-flight care capabilities must span prevention, diagnosis, treatment, and long-term management for both clinical and well-being aspects of health.

• This includes resources such as skillsets, software, hardware, medication, to prepare for and execute medical operations, pharmacy operations, training, resource management, ethics considerations, data management and risk estimation.
2. Crew Autonomy

- Enable crew autonomy in medical task execution and decision-making.
- The mission physician astronaut serves as director of care during real-time medical events and is the primary source for in-mission medical decision making.
- Autonomous care model for exploration requires flight surgeons and other support staff to fill a consultant role.
- To support the physician astronaut this medical care paradigm requires enhanced vehicle capabilities and resources in the form of onboard medical references, smart diagnostics, integrated tools, and decision support systems.
3. Continual Information Application & Learning

- Support medical system capability enhancement over the mission lifetime.

- While little or no hardware or consumable enhancements are expected due to orbital mechanics and logistical limitations, updating medical system aspects such as the decision support, models estimating and predicting crew health and system status, and task training and execution with knowledge gained both in-mission and on the ground is desired.
4. Capability Flexibility

• Balance conflicting needs for medical system resource conservation (in design and in operation) with medical system operations.
• Flexibility is 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.
5. 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.
6. Crew and the Medical System Integration

• Minimize crew burden while using the medical system.
• The medical system should share a common user interface with the overall vehicle system to minimize crew training and cognitive burdens, reduce operations complexity, and lower mission medical risk.
• Provide an intuitive, interactive, and visually informative means for the crew to enter, access, and view information.
• Accounts for the various modes of data entry, input devices, computing platforms, and user preferences employed on the vehicle and incorporates human system interaction guidelines to reduce the cognitive burden of using the system.
7. Ground Awareness

• Maintain ground 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 and to provide support as needed.
Defining Medical Levels of Care for Exploration Missions
How do we get there?

- Interpretation of NASA Standard 3001 Levels of Care
- Basis for medical needs
HUMAN EXPLORATION
NASA’s Journey to Mars

EARTH RELIANT
MISSION: 6 TO 12 MONTHS
RETURN TO EARTH: HOURS

Mastering fundamentals aboard the International Space Station
U.S. companies provide access to low-Earth orbit

PROVING GROUND
MISSION: 1 TO 12 MONTHS
RETURN TO EARTH: DAYS

Expanding capabilities by visiting an asteroid redirected to a lunar distant retrograde orbit
The next step: traveling beyond low-Earth orbit with the Space Launch System rocket and Orion spacecraft

EARTH INDEPENDENT
MISSION: 2 TO 3 YEARS
RETURN TO EARTH: MONTHS

Developing planetary independence by exploring Mars, its moons and other deep space destinations
### NASA-STD-3001

#### Levels of Care

<table>
<thead>
<tr>
<th>Level 1</th>
<th>LEO &lt;8d</th>
<th>Space Motion Sickness</th>
<th>First Aid / Anaphylaxis Response</th>
<th>Basic Life Support</th>
<th>Private Audio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>LEO &lt;30d</td>
<td>Clinical Diagnostics</td>
<td>Ambulatory Care</td>
<td>Private Video</td>
<td>Private Telemedicine</td>
</tr>
<tr>
<td>Level 3</td>
<td>Post LEO &lt;30d</td>
<td>Limited Dental Care</td>
<td>Limited Advanced Life Support</td>
<td>Trauma Care</td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>Lunar &gt;30d</td>
<td>Medical Imaging</td>
<td>Dental Care</td>
<td>Sustainable Advanced Life Support</td>
<td>Limited Surgical Care</td>
</tr>
<tr>
<td>Level 5</td>
<td>Lunar/Planetary &gt;210d</td>
<td>Autonomous Ambulatory Care</td>
<td>Autonomous Advanced Life Support</td>
<td>Basic Surgical Care</td>
<td></td>
</tr>
</tbody>
</table>
Level of Care Influencers

- Mission and Objectives
- Risk
- Duration
- Time to Definitive Care
- Health and Performance
- Level of Training for Medical Provider
- Technology and Medical Advances
Level of Care Capabilities

- **Level 1**: LEO < 8d
  - Mission Risk: Low
  - In Flight Capability: Low
  - In Flight Decision Making: Low
  - Med Evac Capability: High

- **Level 2**: LEO < 30d
  - Mission Risk: Low
  - In Flight Capability: Low
  - In Flight Decision Making: Low
  - Med Evac Capability: High

- **Level 3**: Post LEO < 30d
  - Mission Risk: Low
  - In Flight Capability: Low
  - In Flight Decision Making: Low
  - Med Evac Capability: High

- **Level 4**: Lunar > 30d
  - Mission Risk: High
  - In Flight Capability: High
  - In Flight Decision Making: High
  - Med Evac Capability: Low

- **Level 5**: Lunar/Planetary > 210d
  - Mission Risk: High
  - In Flight Capability: High
  - In Flight Decision Making: High
  - Med Evac Capability: Low
Level of Care 1
LEO <8 days
Level of Care 2
LEO <30 days
Level of Care 3
Beyond LEO <30days
Level of Care 4
Lunar >30 days
Level of Care 5
Lunar / Planetary >30 days
First Aid Definition: Provide basic management for common injuries

First Aid example actions:
• Control minor bleeding through direct pressure
• Clean wounds
• Splint extremities
• Dispense, administer and track over the counter medications for control of pain and prevention of infection
# Level of Care Capabilities

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Level 5</th>
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<tbody>
<tr>
<td>LEO &lt;8d</td>
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<td>Ambulatory Care</td>
<td>Sustainable Advanced Life Support</td>
<td>Dental Care</td>
<td>Autonomous Advanced Life Support</td>
</tr>
<tr>
<td>Basic Life Support</td>
<td>Private Video</td>
<td>Limited Advanced Life Support</td>
<td>Trauma Care</td>
<td>Basic Surgical Care</td>
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<td></td>
</tr>
</tbody>
</table>
### Advanced Life Support Definition

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3 Limited</strong></td>
<td>Diagnosis and initial treatment for an emergent medical event.</td>
</tr>
<tr>
<td><strong>4 Sustainable</strong></td>
<td>Diagnosis and initial critical care treatment for an emergent medical event requiring ALS.</td>
</tr>
<tr>
<td><strong>5 Autonomous</strong></td>
<td>Diagnosis and critical care treatment for an emergent medical or traumatic event using medical information obtained from physical exam, clinical diagnostics and medical imaging. Rehabilitation and palliative care options will be provided.</td>
</tr>
</tbody>
</table>
### Advanced Life Support Example Actions

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3</strong> Limited</td>
<td>Reposition airway, insert airway adjuncts <em>and supraglottic airways</em></td>
</tr>
<tr>
<td><strong>4</strong> Sustainable</td>
<td>Reposition airway, insert airway adjuncts, supraglottic <em>and endotracheal airways</em></td>
</tr>
<tr>
<td><strong>5</strong> Autonomous</td>
<td>Reposition airway, insert airway adjuncts, supraglottic, endotracheal, <em>and surgical airways</em></td>
</tr>
</tbody>
</table>

* Implies increased capability as compared to lower levels of care
Levels I - III

Earth Reliant
Mission: 6 to 12 months
Return to Earth: Hours

Mastering fundamentals aboard the International Space Station
U.S. companies provide access to low-Earth orbit

Level III and IV

Proving Ground
Mission: 1 to 12 months
Return to Earth: Days

Expanding capabilities by visiting an asteroid redirected to a lunar distant retrograde orbit
The next step: traveling beyond low-Earth orbit with the Space Launch System rocket and Orion spacecraft

Level V

Earth Independent
Mission: 2 to 3 years
Return to Earth: Months

Developing planetary independence by exploring Mars, its moons and other deep space destinations

Concept of Operations
How do we get there?

- Concept of Operations
- System functional needs
- System requirements

- high-level concept
- system needs & goals
- meet stakeholder expectations
- operational perspective
- Informs development of requirements
Design Reference Mission (DRM)

New challenges to crew health

- Crew: 4
- Extensive transit and surface times:
  - Phase 1 (Earth -> Mars): 6-9mo
  - Phase 2 (Mars -> Earth): 6-9mo
- No evacuation to definitive care
- No regular resupply
- Limited real-time communication

Therefore, medical care will be different:

- Advanced care that is **autonomous from Ground**
  - Prevention, Diagnosis, Treatment, Long Term Management
- Inclusion of crewmember with **physician-level training**
  - Physician Astronaut is self-sufficient and relies on ground support for consults
## Exploration Medicine

**NASA-STD-3001: Levels of Care**

<table>
<thead>
<tr>
<th>Level</th>
<th>Mission Duration</th>
<th>Care Level</th>
<th>Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>LEO &lt;8d</td>
<td>Space Motion Sickness</td>
<td>First Aid // Anaphylaxis Response, Basic Life Support, Private Audio</td>
</tr>
<tr>
<td>Level II</td>
<td>LEO &lt;30d</td>
<td>Clinical Diagnostics</td>
<td>Ambulatory Care, Limited Advanced Life Support, Private Video, Private Telemedicine</td>
</tr>
<tr>
<td>Level III</td>
<td>Post LEO &lt;30d</td>
<td>Limited Dental Care</td>
<td>Limited Advanced Life Support, Trauma Care</td>
</tr>
<tr>
<td>Level IV</td>
<td>Lunar &gt;30d</td>
<td>Medical Imaging</td>
<td>Dental Care, Sustainable Advanced Life Support, Limited Surgical Care</td>
</tr>
<tr>
<td>Level V</td>
<td>Mars Expedition</td>
<td>Autonomous Ambulatory Care</td>
<td>Autonomous Advanced Life Support, Autonomous Basic Surgical Care</td>
</tr>
</tbody>
</table>

**EARTH RELIANT**
MISSION: 6 TO 12 MONTHS RETURN TO EARTH: HOURS

**PROVING GROUND**
MISSION: 1 TO 12 MONTHS RETURN TO EARTH: DAYS

**EARTH INDEPENDENT**
MISSION: 2 TO 3 YEARS RETURN TO EARTH: MONTHS
Overview of Medical Care

- **Planned Ops**
  - Preventive health and medical care needs that are expected or required to occur

- **Unplanned Ops**
  - Medical care needs based on symptoms or conditions that pose a risk to crew or mission objectives and are not expected nor required to occur but are addressed on an as-needed basis.
Divisions of Care

Self-Care
- Requires self-treatment by the patient and does not require consultation with a medically trained professional

Directed Care
- Requires more than basic medical decision making
- Requires formal medical training

Emergency Care
- Requires immediate intervention for a medical emergency
- Care can be initiated by any crewmember
- Care is assumed/directed by physician and becomes a Directed Care event once the patient is stabilized.
Additional Medical System Needs

Medical System Maintenance
- Requires preventive or corrective maintenance to medical system software applications or hardware

Performance Support
- Support of the crew for medical care including training and continued medical education
Autonomy Modes

- **Autonomous**
  - No expectation or no opportunity for ground input

- **Semi-Autonomous**
  - Expectation or desire for ground input when available
Scenarios

• Medical scenarios illustrate potential methods for maximizing crew health and well-being to maintain crew performance and enable mission success.

Activity Flowcharts

◦ Contain more generic activity representations that will be *used as a basis for system requirements and architecture development*.

Narratives

◦ Contain *representative descriptions* of medical conditions and medical system implementation details to provide a vivid picture to the reader.

◦ Implementation options and decisions such as sensors, user interface details, etc. will be defined as part of the subsequent system development products.

◦ These are not necessarily the system design solutions!
1. The current focus of the concept of operations is to portray the in-flight medical system envisioned for transit to Mars.

2. The scenarios are categorized into planned and unplanned medical operations.

3. Five medical scenario types organize the range of crew interactions with the medical system.

4. The medical system will support a range of autonomy from the ground.

5. Twelve scenarios are used to exemplify the interaction and breadth of the medical system.
Assumptions Examples

Assumptions for all scenarios

1. Caregivers have varying medical skill sets and the Medical System will complement the Caregiver's skillset.

2. The Medical System has varying levels of support and the Caregiver can utilize the system as much or little as desired.

3. The synchronization of in-mission and ground medical data systems depends on a variety of factors such as telemetry bandwidth, distance from earth, priority of data, etc.

4. All medical resources (e.g. equipment, medication, software) are considered a subset of the Medical System.

5. The Medical System will use the Vehicle System for communication to ground.

6. The vehicle system will monitor the environment.

Caregiver = the one crewmember who is the director of and primary provider of medical care.
- Usually the Physician Astronaut.
- The backup to the Physician Astronaut is considered the "caregiver" if the Physician Astronaut is the patient.
Scenario Example

Scenario Type: Unplanned, Self-Care, Autonomous from Ground

Storyline: Headache

Purpose
This scenario shows that the medical system can:
1. Assess resource availability
2. Assess resources for personalized medicine
3. Dispense resources
4. Track resources

Assumptions
• The “resources” in this scenario are medication.

Roles
PT = Patient
GS = Ground System
MS = Medical System

Purpose statements are provided with each scenario to illuminate system functionality that is unique to that particular scenario.
**Scenario Example**

**Scenario Type:** Unplanned, Self-Care, Autonomous from Ground

**Storyline:** Headache

---

**Activity Flowchart**

1. **Recognize Symptoms**
   - PT experiences symptoms
   - PT decides to treat symptoms

2. **Define Treatment Plan**
   - PT determines treatment plan
   - MS assesses contraindications
   - MS records and reports information

3. **Perform Treatment Plan**
   - MS assesses resources availability
   - MS dispenses resources
   - PT administers resources
   - MS records and reports information

4. **Perform Ground Synchronization**
   - MS synchronizes updated health record with GS

---

**Abbreviations:**
- PT = Patient
- GS = Ground System
- MS = Medical System
Scenario Example

**Scenario Type**: Unplanned, Self-Care, Autonomous from Ground

**Storyline**: Headache

For the past few hours a crewmember has been experiencing a headache strong enough to impede his work. He recognizes this headache as typical of those he has had in the past. He decides that there is no need to involve the Physician Astronaut and will treat it with acetaminophen, as he had the other headaches. He accesses his personal health record within the Medical System and logs his current problem and his desire for acetaminophen.

The Medical System quickly cross-checks the medical inventory system and determines that the acetaminophen supply is adequate and verifies that it is not contra-indicated for this crewmember. It then dispenses the proper acetaminophen dose to the crewmember, who grabs the pills and washes them down with some water from his drink bag.

The Medical System updates the crewmember’s health record with this new event, logs the medication administered, and updates the vehicle’s inventory tracking system. It also coordinates with the vehicle’s communication system to downlink the crewmember’s updated health record and synchronize the onboard and ground electronic health systems.
**Scenario Example**

**Scenario Type:** Unplanned, Directed Care, Autonomous from Ground

**Storyline:** Urinary Tract Infection

**Assumptions**
- The caregiver is a physician.

**Roles**
MS = Medical System  
PT = Patient  
GS = Ground System  
CG = Caregiver

**Purpose**
This scenario shows that the medical system can:
1. Prompt the initiation of an activity based on a protocol
2. Guide a crewmember during an activity
3. Suggest differential diagnoses
4. Provide relevant reference material
5. Suggest diagnostic tests
6. Interpret information gathered during an activity
Scenarios

1. Exercise
2. Family conference
3. Dental exam
4. Psychological conference
5. Continual medical education
6. Headache
7. Urinary tract infection
8. Dental abscess
9. Exercise hardware malfunction
10. Just-in-time training
11. Arm injury
12. Decompression sickness
Exercise Scenario

Scenario Type: Planned, Self-Care, Autonomous from Ground

Storyline: Exercise

Purpose
This scenario shows that the medical system can:
1. Prompt the initiation of an activity per the crewmember's schedule
2. Interpret information gathered during an activity
3. Provide exercise prescriptions
4. Create flags of potential issues using information from sensors

Assumptions
• The exercise equipment is part of the medical system.

Roles
CM = Crewmember
MS = Medical System
VS = Vehicle System
Summary

Concept of Operations

System functional needs

System requirements

System architecture

Allocations

Subsystem requirements

System needs & goals

NASA Standards

System needs & goals
Questions?
Backup
Abbreviations

- Semi- = Semi-autonomous
- Fam. Conf. = Family Conference
- Psych. Conf. = Psychological Conference
- CME = Continued Medical Education
- UTI = Urinary Tract Infection
- Exercise hw malf. = Exercise hardware malfunction
- JITT = Just-in-Time Training
- DCS = Decompression Sickness
Presentations

- **ECWG**
  - Level of Care V Definition 3.30.16
  - Planned Operations Kickoff 4.20.16
  - Planned Operations Follow-up 5.4.16
  - Unplanned Operations Kickoff 6.1.16
  - Unplanned Operations Update 6.15.16
  - Unplanned Operations Update 6.29.16– with Evaluation (2 responses)
  - ConOps Draft Review Kickoff 7.27.16
  - ConOps Draft Update and Review of Comments 8.10.16
  - ConOps Draft Finalization and Review of Comments 8.24.16
  - New SE approach and Scenario Tree & Activity Diagram Example 10.12.16– with Evaluation (4 responses)
  - Full Overview with New Terminology and Updated Scenario Tree & Activity Diagram Examples 1.11.17– with Evaluation (5 responses)

- **MOG**
  - Level of Care Definition _Informational 5.31.16– with Evaluation (4 responses)
  - Planned Operations _Informational 6.14.16– with Evaluation (9 responses)
  - Unplanned Operations _Informational 8.2.16– with Evaluation– with Evaluation (5 responses)

- **ExMC Forum**
  - Level of Care and Planned Operations 6.7.16– with Evaluation (0 responses)
  - Scenario Tree and Activity Diagram 10.18.16
  - Medical System Design Team Meeting: Updated Scenario Tree and Activity Diagram 12.6.16
  - Medical System Design Team Meeting: Guiding Principles 2.14.17

- **IWS**
  - ConOps Definition 2.9.16
  - ConOps Status 1.23.17
  - Level of Care 1.23.17

- **CB**
  - Overview and Level V definition 8.22.16

- **ExMC Center Leads Meeting**
  - Status 10.5.16

- **CH&S HQ**
  - Medical System ConOps Intro 12.6.16
Concept of Operations (ConOps): Developed early in Pre-Phase A, describes the overall high-level concept of how the system will be used to meet stakeholder expectations, usually in a time sequenced manner. It describes the system from an operational perspective and helps facilitate an understanding of the system goals. It stimulates the development of the requirements and architecture related to the user elements of the system. It serves as the basis for subsequent definition documents and provides the foundation for the long-range operational planning activities.”

System needs for the transfer vehicle need to be identified.
Level of Care I

• **NASA-STD-3001:**
  – Little perceived threat to health or life exists during training or that portion of the mission where medical intervention would be allowed.
  – The relatively short time and distance to definitive care allows for first-aid implementation without more advanced care.
  – Requires a minimum of first-aid capability and implementation plans for follow-on medical support.
Level of Care II

• **NASA-STD-3001:**
  – *A moderate level of risk exists that personnel may experience medical problems during training or that portion of the mission.*
  – *Preventive strategies shall be used to reduce the risk.*
  – *Intervention strategies shall be used to reduce the risk to an acceptable level with return to Earth available for more serious illness/injuries.*
  – *Level of Care Two shall provide for clinical diagnostics and ambulatory care capability in addition to basic life support.*
Level of Care III

• NASA-STD-3001:
  – A moderate to high level of risk exists that personnel may experience medical problems during training or that portion of the mission.
  – Preventive strategies shall be used to a greater degree to reduce the overall risk.
  – Intervention strategies shall be used to reduce the risk to an acceptable level, including an increased level of advanced care in the form of medications or equipment to include limited advanced life support, trauma care and limited dental care.
  – The ability to sustain a critically ill or injured patient for any length of time is limited by consumables, training and vehicle constraints.
Level of Care IV

• NASA-STD-3001:
  – Moderate to high level of potential risk exists that personnel may experience medical problems on orbit.
  – Risk to the mission is greater for medical issues beyond routine ambulatory medicine.
  – Preventive strategies shall be used to a greater degree to reduce the overall risk.
  – The ability to support chronic illness is limited.
  – Intervention strategies shall be used to reduce the risk to an acceptable level, including increasing levels of advanced care in the form of medications, equipment, training, or consumables over and above previous levels.
  – The scope of medical care available shall be limited or triaged because of availability of supplies, consumables, or mission risk.
Level of Care V

• **NASA-STD-3001:**
  – A high level of potential risk exists that personnel may experience medical problems on orbit at some time during the mission.
  – Preventive strategies shall be used to a greater degree to reduce the overall risk. The ability to support chronic illness is limited.
  – Intervention strategies shall be used to reduce the risk to an acceptable level, including increasing levels of autonomous advanced care in the form of medications, equipment, training, or consumables over and above those for previous levels.
  – The training and skill of the caregiver shall be at the physician level, because of the exclusively autonomous nature of the mission.
  – The scope of medical care available shall be limited or triaged because of availability of supplies, consumables, or mission risk.
  – Return to Earth is not a viable option for more serious illness/injuries. Impact to overall mission is greater.
  – In autonomous medical care concepts, the astronaut caregiver is self-sufficient in the immediate care phase and relies on Mission Control for consultation.
Self Care

- **Definition**: minor conditions self treated by crewmember
- **Who’s Involved**: patient/crewmember
- **Resources**: basic, e.g. “convenience medication pack”
- **Timeline**: none
- **Ground Role**: monitor supply consumption
- **Other**: resource use tracked automatically, medications dispensed balancing mission goals with appropriate care, “use report” available to ground and physician/CMO at all times
Directed Care

- **Definition**: Care that requires medical decision making or formal medical training
- **Who**: Physician Astronaut
- **Resources**: any and all required, mission impact or resource limitations may guide selection
- **Timeline**: routine to urgent, contact ground PRN
- **Ground role**: monitor ➔ consult ➔ decision support
- **Other**: automatic resource tracking, automatic logging of vitals/tests into EMR, ground EMR updated in near real-time*
Emergency Care

- **Definition**: A medical emergency that requires immediate action – a threat to life, limb or vision
- **Who**: Crewmember, CMO, Physician Astronaut
- **Resources**: any and all required, mission impact prediction will not guide selection in first 24 hours
- **Timeline**: no time to consult ground until later
- **Ground role**: none until stable, then supportive
- **Other**: automatic resource tracking, automatic logging of vitals/tests into EMR, ground EMR updated in near real-time*
Nominal Operations - Transit

• Countermeasures and Performance System
• Health Maintenance System
  – General Medical
  – Neuropsychological
  – Dental (new)
• Environmental Health System
  – Radiation
  – Acoustic
  – Other
• Human-System Interface (new)
• Research
Countermeasures

Countermeasures and Performance System

• Exercise Countermeasures
• Fitness Assessment – Muscle/Cardiovascular
• Private Exercise Conference
• Fitness for Duty
• Neurovestibular Countermeasures (new)
• Stress Management (new)

GOAL:
Maintain, assess and correct bone health, cardiovascular fitness, neurovestibular adaptation, and stress management.
Health Maintenance System

- General Medical
- Neuropsychological
- Dental

**GOAL:**
Perform periodic assessments that will capture medical, neuropsychological and dental problems early so that they can be addressed to minimize impact on crewmember.
Health Maintenance System

General Medical
• Periodic Physical Exam
• Periodic Eye Exam
• Periodic Laboratory Survey
• Private Medical Conference
• Pharmacy Reconciliation (new)
• Bone Health Evaluation
• Nutritional Assessment
In the last year ExMC has had 4 requests for medical needs and flight test objectives for the Proving Ground Vehicle.

IF WE DON'T GIVE THEM INFO THEY WILL GET IT SOMEPLACE ELSE!
HHP System Development

Science Focus

Engineering Focus

System Integration

Proving Ground

ISS Testing

Orion

SHFH

BHP

HH C

ExMC

SR
Medical Data Architecture

Ground Based and Vehicle Data Architectures:
• Performance Data
• Clinical Operational Needs
• Research Data Capture
• Long Term Health Information

• Flight Surgeon/BME
• External Consults

Mirrored delayed data presentation for situational awareness/support

Vehicle Exploration Medical System
• Crew Medical Officer
• Crew Medical Support

Real-Time Data Processing for Crew
Background

• Safe Passage: Astronaut Care for Exploration Missions
  – Developed by the Committee on Creating a Vision for Space Medicine During Travel Beyond Low Earth Orbit
  – Published in 2001 by the Institute of Medicine
  – Two major objectives
    • To assess what is known about the health effects of space travel
    • Provide recommendations on how health care during space travel could be approached

• Some recommendations have been implemented in LEO

• Remaining work for exploration missions
References
Engaging Med Ops Stakeholders

• ConOps team actively engaging Med Ops community
  – Exploration Clinicians Working Group
    • Clinical advisement to the Element Scientist for the assessment, prioritization, and technical direction of ExMC made up of Physician (Ops or research), Pharmacy, Nursing, & Engineering disciplines.
    • 3.30.16 Level of Care V Definition
    • 4.20.16 Planned Operations Kickoff
    • 5.4.16 Planned Operations Follow-up
    • 6.1.16 Unplanned Operations Kickoff
    • 6.15.16 Unplanned Operations Update
    • 6.29.16 Unplanned Operations Update
    • 7.27.16 ConOps Draft Review Kickoff
    • 8.10.16 ConOps Draft Update and Review of Comments
    • 8.24.16 ConOps Draft Finalization and Review of Comments
    • 10.12.16 New SE approach and Scenario Tree & Activity Diagram Example
    • 1.11.17 Full Overview with New Terminology and Updated Scenario Tree & Activity Diagram Examples
  – Medical Operations Group
    • Organizational status and issue discussion with Space & Occupational Medicine Branch Chief/Deputy Chief. Special Topics are welcomed at the end of the meeting and are either “Decisional” or “Informational” to allow the clinical expertise of the medical group to aid in decision making, if needed, or for awareness or opinion. The ConOps presentations were all information but opinion was request via an electronic evaluation.
    • 5.31.16 Level of Care Definition - Informational
    • 6.14.16 Planned Operations - Informational
    • 8.2.16 Unplanned Operations- Informational
Exploration Medical Capability
Systems Engineering
Technical Overview

3/28/17

Jennifer Mindock
Andrea Hanson
Tyler Burba
Jeff Cerro
Kerry McGuire
Jeff Reilly
Michelle Urbina
Chris Middour
David Rubin
Melinda Hailey
David Reyes
How do we get there?

We’re starting here:

The needs identified by this work will drive future ExMC research.
Con Ops Scenario Tree

- Narrative
- Activity flow chart
6.2.2.4. Narrative

The Medical System sends an alert to the Physician Astronaut and crewmember that a scheduled dental exam will start in ten minutes. The crewmember heads over to the medical bay and grabs a display, which uses biometric analysis to identify her and grants her access to her health record in the Medical System.

The Medical System starts the appointment by prompting her to review her health record documentation for accuracy and update if needed. Areas of review include, 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 crewmember, such as blood pressure, heart rate, oxygen saturation, temperature, and respiratory rate. These are all automatically saved to her health record and displayed back to her.

The Medical System then notifies the Physician Astronaut that the crewmember is ready for the dental exam. He arrives at the Medical Bay and begins by reviewing his patient’s history information from within the Medical System. He proceeds with the dental exam of the crewmember, populating the findings in the Medical System template.

As part of the routine dental exam, the Medical System prompts the Physician Astronaut to perform imaging. He receives guidance from it on how to perform the imaging and collects the desired images from the crewmember, which are immediately stored within her health record. The Medical System then analyzes and interprets the collected images and records its findings.

Because the Physician Astronaut is not a dentist, he prefers that the Medical System interprets the images and he reviews its findings. Nothing out of the ordinary is found, and the Medical System prompts the Physician Astronaut to perform preventive oral care on the crewmember. It records the preventive care within her health record and then coordinates with the vehicle’s communication system to downlink the updated health record and synchronize the onboard and ground electronic health systems.
**Scenario:** 08. Transit – IVA – Planned – Directed Care – Autonomous From Ground

**Context:** Dental Exam

**Assumption:**
1. CG is a physician.
2. CG is not a dentist.
3. This scenario does not lead to a condition
Identify Needed Functions

SysML Activity Diagram

Initiate Encounter

- activates_support_from_MS
  - Prompts caregiver and patient to initiate encounter

Perform History Collection
- Takes_history_from_PT
- Records_and_reports_information

Perform Vitals Collection
- Conducts_vitals_collection_on_PT
- Records_and_reports_information

Content is draft. Not for distribution.
Identify Needed Functions

SysML Activity Diagram

Perform Physical Exam
- Reviews_history_with_PT
- Conducts_physical_exam_on_PT
- Prompts_CG_for_physical_exam
- Records_and_reports_information

Perform Diagnostics
- Conducts_imaging_on_PT
- Prompts_imaging
- Guides_CG_through_imaging
- Interprets_imaging
- Records_and_reports_information

Prompts caregiver for physical exam
Prompts imaging

Content is draft. Not for distribution.
Identify Needed Functions

SysML Activity Diagram

Content is draft. Not for distribution.
Build Functional Decomposition

• Begin defining “Problem Space”
Build Functional Decomposition Cont.

Content is draft. Not for distribution.
Build Functional Decomposition Cont.

- Caregiver functions
  - Collects data
    - Reviews data
    - Interprets data
    - Makes decision
    - Verbal instructions
    - Activates support
  - Conducts imaging on PT
    - Conducts lab analysis on PT
    - Conducts manual vitals collection from PT
    - Conducts physical exam on PT
    - Gathers chief complaint from PT
    - Takes history from PT
Draft System Architecture

• Now begin bridging to “Solution Space”
**Example Flow to Requirements**

**Con Ops scenarios**
- **System functional needs**
  - Accept patient vital sign inputs
  - Interpret imaging
  - Prompts planned encounter

**Dental care scenario**

**System requirements**
- The Medical System shall accept patient vital sign inputs.
- The Medical System shall prompt crewmembers to initiate planned encounters.
- The Medical System shall guide the crewmember while obtaining medical images.
- The Medical System shall interpret medical images to support prevention.

**Architecture & Allocations**
- The In-flight Health Data System shall track planned encounters.
- The In-flight Health Data System shall...
- The Medical Appliances System shall...

**Subsystem requirements**
- The In-flight Health Data System shall...
- The Medical Appliances System shall...
- The Medical Appliances System shall...

Content is draft. Not for distribution.
Continuing Flow to Implementation
Strawman Examples Only

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Traceability

• When negotiations are necessary regarding capabilities to include (hardware and/or software), we are able to trace to impacted requirements and system functions
  – e.g., to NASA-Std-3001, other sources of parent requirements, ConOps scenarios

• Identify orphans – then why do we have this capability?

• Identify parents with no implementation – capability lacking
  ➔ RESEARCH NEED INFORMING TECHNOLOGY ROADMAP
Identify Interactions

Sequence Diagram

When requirements are negotiated, how are the interactions impacted?

Which interaction functions are owned by ExMC, and which by others?

- MS provides oral care supplies to CG
- MS accepts exam care info from CG
- MS provides updated health record info to vehicle system

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Capture Interfaces
Subset based on single scenario

Caregiver
- Prompts
  - Initiate encounter
  - Physical exam
  - Preventive care
  - Imaging
- Accepts Info
  - Vitals
  - Physical Exam
  - Oral Care
- Provides Info
  - Image Guidance
  - Image Interpretation
  - Patient History
- Dispenses Resources
  - Oral care supplies

Medical System

Health Record Info

Flight Vehicle System (Avionics in this example)

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Additional Vehicle Interface Examples

Connection System
- Host implementation of medical and bioinformatics data storage, processing, and decision support computation
- Transport data to the telecom system for transmission to ground or other mission assets

Separation System
- Distribute and condition power required by medical system hardware
- Provide vehicle structural support for medical system components
- Address layout and workflow constraints of the medical system

Takeoff System
- Provide bandwidth for transmission of medical data

Landing System
- Coordinate on provision of consumables needed for medical purposes, such as supplemental oxygen
- Coordinate on a shared crew information and user interface framework for medical and other vehicle operations
- Coordinate on required medical support for suited operations
- Coordinate on relevant bioinformatics

Natural & Induced Environmental Protection System
- Command & Data Handling System
- Propulsion System
- GN&C System
- Comm & Tracking System
- Crew Display & Controls
- Environmental Control System
- ISRU Acquisition System
- EVA Support System
- Manufacture & Assembly Systems
- Payload Provisions
- Payloads & Research
Supporting Trades and Prioritization

- Stakeholders’ needs, constraints
- System Architectures
- ConOps

System Model

Requirements
- System Alternatives
- System Architecture
- Interfaces
- Verification & Validation

Trade Space Evaluation

Analyses & Other Tools

- Simulations (e.g., risk assessments)
- Traceability assessments
- Design option characterizations
- Design option optimizations

Technical Management

- Technical Measures
- Risk
- Cost
- Schedule
- Documentation

- Research Prioritization
- Gap Closure Evidence
- Technical Measures

Content is draft. Not for distribution.
Summary

• Integrative, structured approach
  – Envisioning and guiding the development of an exploration medical system is a big job
  – This approach gives an organized path

• Develop system technical foundation

• Increase relevancy to exploration systems

*How we’re establishing the work:*
Thank you
Backup
Modeling Process

- What is the scenario narrative? What other systems are involved?
- How does the system behave?
- How does the system interface with other systems?
- What parts does the system have?
- How are system requirements allocated?
- What functions does the system need to provide?

Activity Diagrams
Sequence Diagrams
Subsystem Scenarios
Function Decomposition
Subsystem Requirements
System Requirements
System Architecture
System Scenarios
Notional System Block Diagram
CHP Level Only

Crew Health and Performance System Block Diagram

Flight System

In-Flight Crew Health and Performance System

Ground System

Ground Crew Health and Performance System

FSW, Telecom, Avionics, Power, Structures, ECLSS, EVA Systems, Robotic Assets, GNC

Researcher, Analyst, MCC, ASCR, FOD Trainer, Flight Surgeon

Crew as Physician

Crew as Explorer or Medical Patient

Work in Progress 9/1/16
Example Traceability to Requirements

Operational concepts

System functional needs

System requirements

Allocations

Subsystem requirements

Accept treatment plan inputs

Assess resource availability

Assess resources for personalized medicine

Dispense medical resources

The Medical System shall accept treatment plan inputs from a crewmember.

The Medical System shall assess medical resource availability.

The Medical System shall assess medical resource appropriateness for individual crewmembers.

The Medical System shall provide medical resources to a crewmember.

In-flight Health Data System

In-flight Medical Resources

Content is draft. Not for distribution.
Exploration Medical Capability
ConOps and Systems Engineering
Technical Interchange Meeting Summary

3/28/17

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How do we get there?

We’re starting here:

The needs identified by this work will drive future ExMC research.

Other sources of system requirements will be folded in as we move forward. ConOps is not the only source!
Example Products

We must communicate with exploration mission development activities effectively

“Problem space, not solution space”
Or “What, not How”

Do we have solutions? If no, research and tech dev required!

Systems Engineering Management Plan

Systems Engineering Tools (e.g., models, analyses)

Element Management Plan

https://dap.dau.mil/acquipedia/Pages/ArticleDetails.aspx?aid=9c591ad6-8f69-49dd-a61d-4096e7b3086c
# Looking Ahead to V&V

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Notional!

**Verification**

Did we build the right thing?

**Validation**

Did we build it right?
Upcoming Steps

• 4/2017: Draft Concept of Operations for Medical Care for an Exploration Mission (Mars Transit)

• Goal End FY17: Draft In-Flight Medical System Functional Requirements (Mars Transit)
<table>
<thead>
<tr>
<th>Medical system level doc</th>
<th>Purpose</th>
<th>Example content</th>
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| ConOps | • Captures how system will operate, usually in a time-sequenced manner  
• Communicate with stakeholders  
• Stimulates architecture and requirements development | • “What” activities will occur treating the medical system as a “black box”  
• High-level mission overview  
• Scenarios per mission phase with narrative text and activity diagram |
| Sequence Diagrams | • Captures interactions among system and operational users  
• Used to derive system functions, modes, interfaces, requirements | • Interactions among caregiver, patient, and medical system during a particular scenario  
• 1 or more sequence diagrams per activity diagram in ConOps |
| Activity Decomposition | • Captures details of activities not needed in system ConOps as the content is developed  
• Provides content for subsystem scenarios later | • Example: “Perform lab analysis” decomposes into urine and lab analysis |
| Functional Decomposition | • Captures system functions as identified from ConOps, Sequence Diagrams, Activity Diagrams and their decomposition  
• Informs scenario tree  
• Informs requirements development | • Defines prevent, screen, diagnose, treat, manage long-term care, etc.  
• Defines planned and unplanned medical operations  
• Likely include functional descriptions for maintaining health with countermeasures, periodic exams, assessments, etc. |
| Conceptual Design Architecture | • Initially capture high-level structural view of system | • System block diagrams  
• Medical resource types (medication, equipment, skill set, nursing, nutrition)  
• Roles of flight and ground mission personnel  
• Allocations of functions to system  
• Additional diagrams if need more information-rich visuals than what SysML supports |
<table>
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| Medical System Requirements                  | • Capture system-level functional, performance, and interface requirements | • "Shall" statements derived from 3001 Vol. 1, the ConOps, other diagrams, and decompositions
  • References Level of Care definitions
  • Includes "-ilities" (e.g., maintainability, adaptability, usability)
  • Indicates MOEs, MOPs, and TPMs |
| Medical System Interface Description          | • Capture scope of system and technical interface with external entities  | • Initially capture high-level functional interfaces
  • Evolve to mech, elec, info, etc. |
| Medical System V&V Approach                  | • Initially capture philosophy and high-level plans to inform infrastructure and collaboration development | • Initially address timeframes, planned methods, targets of opportunity for flight and analogs, integration approach |
| Level of Care Definitions (Sci doc, not SE)   | • Capture common reference definitions
  • Potential NASA-STD-3001 addition update? | • Components for each Level of Care |
| Medical System Level of Care Interpretation  | • Capture policy and ethics approaches                                   | • Interpretation of Levels of Care
  Letter (Sci doc, not SE)                     |                                                                          | • Assumptions of minimum set of conditions to treat |
Discussion Topics

1. Identify top level impressions.
2. Identify major concerns or missing aspects of the approach.
3. Are there additional groups we need to engage in the near-term?
4. Discuss ideas for subsequent meetings, TIM(s).
5. Review actions.
Thank you
Backup
What is the scenario narrative? What other systems are involved?

System Scenarios

How does the system behave?

Activity Diagrams

How does the system interface with other systems?

Sequence Diagrams

What parts does the system have?

System Architecture

How are system requirements allocated?

Subsystem Scenarios

Subsystem Requirements

What functions does the system need to provide?

Functional Decomposition

System Requirements

System Scenarios
Notional System Block Diagram
CHP Level Only

Crew Health and Performance System Block Diagram

Flight System

In-Flight Crew Health and Performance System

FSW  Telecom  Avionics  Power  Structures  ECLSS  EVA Systems  Robotic Assets  GNC

Ground System

Ground Crew Health and Performance System

Researcher  Analyst  MCC  ASCR  FOD Trainer  Flight Surgeon

Crew as Physician
Crew as Explorer or Medical Patient

Work in Progress 9/1/16