Invited Paper

Prognostics and Health Management (PHM) for astronauts: a collaboration project on the International Space Station

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ABSTRACT

Long-duration missions bring numerous risks that must be understood and mitigated in order to keep astronauts healthy, rather than treat a diagnosed health disorder. Having a limited medical support from mission control center on space exploration missions, crew members need a personal health-tracking tool to predict and assess his/her health risks if no preventive measures are taken. This paper refines a concept employing technologies from Prognostics and Health Management (PHM) for systems, namely real-time health monitoring and condition-based health maintenance with predictive diagnostics capabilities. Mapping particular PHM-based solutions to some Human Health and Performance (HH&P) technology candidates, namely by NASA designation, the Autonomous Medical Decision technology and the Integrated Biomedical Informatics technology, this conceptual paper emphasize key points that make the concept different from that of both current conventional medicine and telemedicine including space medicine. The primary benefit of the technologies development for the HH&P domain is the ability to successfully achieve affordable human space missions to Low Earth Orbit (LEO) and beyond. Space missions on the International Space Station (ISS) program directly contribute to the knowledge base and advancements in the HH&P domain, thanks to continued operations on the ISS, a unique human-tended test platform and the only test bed within the space environment. The concept is to be validated on the ISS, the only "test bed" on which to prepare for future manned exploration missions. The paper authors believe that early self-diagnostic coupled with autonomous identification of proper preventive responses on negative trends are critical in order to keep astronauts healthy.

Keywords: Prognostics and Health Management (PHM), International Space Station (ISS), Crew Electronic Health Records (CEHR), Autonomous Medical Decision, Integrated Biomedical Informatics, healthcare autonomy paradigm, mHealth technology solutions.

1. INTRODUCTION

As space exploration community looks toward crewed space exploration missions beyond low-Earth orbit, the following two key distinctions from all manned space missions to date should be emphasized: first, the crew will spend significantly longer periods of time farther from reliable logistics depots; and second, early return or mission abort are not feasible options. Since emergency quick-return option is not feasible for such missions, high reliability and crew autonomy will become increasingly dominant design drivers in order to sustain crew health and performance. So the development and validation of new technologies to enable autonomous healthcare are critical to the success and safety of crewed space exploration missions. Such mature technologies should be based on increased self-sufficiency and integrated systems that employ autonomous monitoring and control. A properly collected and structured Crew Electronic Health Records (CEHR) coupled with PHM-based predictive diagnostics capability could be a key component of the technology. To keep astronauts healthy such onboard capabilities, that enable both early self-diagnostics of impending health issues and autonomous identification of proper responses to negative trends, are essential. Given the absence of real-time medical support from mission control center, personal health-tracking tools for health monitoring, health risk assessment and management are required for any crew member to predict her/his future health condition if no preventive measures are taken.

HH&P technology candidates for manned space exploration missions are identified in the NASA Roadmap.¹ The roadmap is a set of documents that consider a wide range of needed technology candidates for Human Health, Life Support and Habitation Systems as well as their development pathways for the next 10 years. The NASA's integrated technology roadmap¹ for Human Health, Life Support, and Habitation Systems (Technology Area 06 by NASA designation) focuses on development of particular technologies that enable long-duration, deep-space human exploration

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Micro- and Nanotechnology Sensors, Systems, and Applications VIII, edited by Thomas George, Achyut K. Dutta, M. Saif Islam, Proc. of SPIE Vol. 9836, 98360Y · © 2016 SPIE CCC code: 0277-786X/16/\$18 · doi: 10.1117/12.2222070 with minimal resupply consumables and increased independence from mission control center and ground-based personnel.

The international space community on the ISS program (ISSP), that includes universities, industry, and space agencies, is increasingly collaborating to timely address space exploration mission needs. As an example of such efforts a US/Canadian/Russian collaboration project on the ISS program was initiated in June 2015. The collaboration project, titled as "PHM for astronauts" is to validate a concept that bridges the Prognostics and Health Management (PHM) domain to healthcare delivery on manned space exploration missions. Employing PHM-based technologies, namely real-time health monitoring and condition-based health maintenance in terms of predictive diagnostics, the concept supports a shift from the telemedicine paradigm to that of health support autonomy. Additionally, this project is to validate the proposed PHM-based solutions on crew health maintenance in terms of predictive diagnostics; providing early and actionable real-time warnings of impending health issues that otherwise would have gone undetected.

This project is to prepare and conduct a space experiment series by principal investigators from Caltech, University of Arizona (UA), University of Ontario Institute of Technology (UOIT), PHM Society, AIAA Systems Engineering Technical Committee (AIAA SETC), Institute for Bio-Medical Problems (IBMP) of Russian Academy of Science, and the Korolev-based University of Technology. Since the International Space Station is currently the principle "testbed" to get crew and ground support personnel prepared for future manned exploration missions, the space experiment series is planned to run on the Russian Segment of the ISS (ISS RS).

2. THE PROJECT BACKGROUND, OBJECTIVES AND JUSTIFICATION

Manned space exploration missions bring numerous risks to crew health and performance. The risks must be understood and mitigated in order to keep astronauts healthy, rather than treat a diagnosed health disorder after the fact. The to-be-validated concept and corresponding related PHM-based technology solutions are to bridge both Prognostics and Health Management (PHM), an engineering discipline, and the Human Health and Performance (HH&P) domain. This should significantly mitigate the risks by focusing on efforts to reduce countermeasure mass and volume and drive the risks down to an acceptable level.

The Table 1 below is an excerpt from NASA's Roadmap¹ that identifies in particular couple of essential technologies relevant to the Human Health and Performance (HH&P). The current state of the art (SOA) for current practices on ISS missions, major challenges to mature the technology, and the recommended milestones and activities needed for future missions with a time-line to elevate the potential technology, as envisioned today, will be identified to a TRL 6. This is the minimum technology readiness level needed that enables manned space exploration missions.

Technology	SOA/practice	Current major challenge(s)	Recommended milestones/activities to advance to TRL 6 or higher
Autonomous medical decision	Screen-shots of paper procedures	Lack of standards in data output from various medical instrumentation	2012-20: Handheld, smart device that integrates with vehicle, hardware, crew/patient, healthcare giver or <i>healthcare provider</i> (<i>i.e., Integrated</i> <i>Medical Group</i>) and Mission Control
Integrated biomedical informatics	Separate systems that do not seamlessly interface	Integrated standards	2012-20: Integrated electronic medical/ <i>health</i> records (<i>EMR/EHR</i>), medical devices, inventory management system, procedures and utilizes a medical hardware communication standard

Table 1. An excerpt from "Human Health and Performance Technical Area Details."¹

The initiated project is a response to the following recommendations provided in the decadal report² by the Aeronautics and Space Engineering Board (ASEB) of National Research Council (NRC):

- "Interdisciplinary research is needed to better understand and document the etiology of particular medical conditions and to inform the development of effective countermeasures."
- "It is important to bring the programs to a Technology Readiness Level (TRL) that will enable effectiveness to be systematically evaluated."
- "Physiological changes due to microgravity and other effects of space may change the pharmacokinetic characteristics of medications, influencing both dosage and route of administration."
- "Increased efficacy can sometimes be achieved by customizing medications based on the individual patient's genetic profile."

The objectives of the "PHM for Astronauts" collaboration project are the following:

- Prepare and implement a space experiment series at the ISS RS in order to validate the PHM-based solutions on crew health maintenance in terms of predictive diagnostics providing early and actionable real-time warnings of impending health problems that otherwise would have gone undetected.
- Develop, and then deploy, utilize, and validate an autonomous health support technology that is based on wireless handheld devices, i.e. autonomous medical decision technology per NASA's designation.
- Develop, and then deploy, utilize, and validate an integrated biomedical informatics technology (per NASA's designation) with predictive diagnostics capability based on Crew Electronic Health Records (CEHR).

The NASA's integrated technology roadmap¹, coupled with the particular recommendations provided in the ASEB/NRC's decadal report², is a justification to run the "PHM for Astronauts" collaboration project on the ISS in order to enable crewed exploration space missions. The necessity of implementation of recommendations provided by experienced astronauts and cosmonauts in the next chapter is another justification on having the international collaboration project on the ISS.

3. WHAT MAKES THE PROJECT DIFFERENT

The technology solutions that are proposed by the unique US/Canadian/Russian collaboration project are based on wireless handheld devices and are a result of the paradigm shift from telemedicine to that of healthcare autonomy. A key component of the technology solutions is a Crew Electronic Health Records [CEHR] system with predictive diagnostics capability developed for crew members rather than for healthcare professionals. The novelty of the project is a validation of the PHM-based solutions on crew health maintenance in terms of predictive diagnostics providing early and actionable real-time warnings of impending health problems that otherwise would have gone undetected. In Popov et al. (2013),³ Fink et al. (2014),⁴ and Popov et al. (2016)⁵ we articulate the features and novelty that make the research project different from current healthcare delivery practice and projects that the space medicine community has been running on the ISS. Below is a discussion on some of the key features.

3.1 The crew requirements

Crew requirements on the healthcare technologies are an essential input to develop both of these technologies. These inputs have been provided by an experienced astronaut flown on the Space Shuttle as well as by an experienced cosmonaut who was a part of a number of ISS crews last few years. These requirements are discussed in Fink et al. $(2014)^4$ and could be summarized as follows:

- ✓ Focus on keeping the crew healthy by predicting a deterioration or impairment in their health before a sign is detected or a symptom is manifested;
- ✓ Autonomous healthcare support with predictive diagnostics capability, rather than a treatment caused by a medical condition;
- ✓ Self-monitoring in order to predict health compromises by providing early warnings on them;

- ✓ Wireless sensor network communicating with smartphones/tablets/handhelds (see examples at the NASA webpage [6] and in Fink et al. (2013)⁷ and (2014)⁸) that provide both root and contributing causes of, or factors leading to an impending failure, as well as a priority of the failure;
- ✓ Intuitive and customizable interface with user-friendly language designed for crew as the only end-user, rather than medical language with an interface designed for healthcare professional;
- ✓ Crew Electronic Health Records shall be non-attributed;
- ✓ Astronaut is the owner his/her non-attributed CEHR;
- ✓ Astronaut engagement on pre-flight, in-flight, and post-flight healthcare delivery.

In order to mitigate health-related risks on the project within the autonomous healthcare paradigm, the crew members should respectively be in control of their health maintenance unless a disorder symptom is identified or a disease is diagnosed. Given that predictive diagnostics capabilities are key factors to keep the crew healthy, it appears that in addition to the current practice and challenges on the ISS program, the new challenge for the ground support team is to provide the crew with more health assessment software applications rather than more pharmaceuticals.

3.2 Prognostics and Health Management (PHM) concepts and data processing algorithms

The current healthcare delivery practice within the research that the space medicine community is now running on the ISS; and it still focuses on detected signs and manifested symptoms in order to diagnose a medical condition, disease or disorder.³⁻⁵ A PHM-based concept suggests a Condition Based Management (CBM) concept with predictive diagnostics providing early and actionable real-time warnings of impending health problems that otherwise would have gone undetected.

Another PHM-based concept suggests real-time 24/7 streaming, monitoring and processing all available data generated by astronaut, rather than taking a regular snapshot of a limited dataset that ordered by the Integrated Medical Group (IMG), the ground support team. Unlike the current practice providing a limited colorless picture the particular concept enables panoramic data. This approach suggests evidence-based health maintenance,³⁻⁵ rather than a diagnostics and treatment that are limited to experience and knowledge of the ground support team as the healthcare provider on the ISS program. The data stream from the mHealth devices amounts to by far the largest and most comprehensive observational health trial ever conducted.

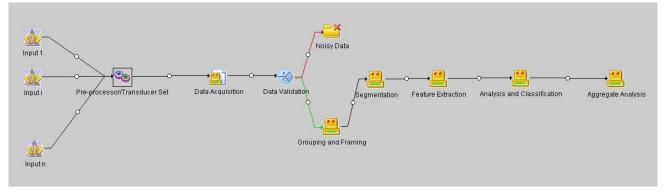
Like the approach taken to develop successful PHM systems in mechanical systems industry, a multidisciplinary, system engineering focused approach is the only one that allows to succeed on development of the PHM-based technologies to support crew health on manned space exploration missions. This is part of the engineering element for the Condition Based Management (CBM) concept that provides a focused approach to making this happen.

3.3 Real-time self-monitoring and processing

The current practice to measure glucose level is by pricking a finger and using a kit to test the drop of blood. This could be typically done only a few times a day. But there are COTS devices that make a continuous glucose monitor. It employs a wire the width of a hair inserted in the skin, attached to a small electronic device that transmits a signal to a phone, minute-by-minute. Crewmembers could follow how their body responds to certain foods, to stress, or to the time of day. By putting more knowledge in the hands of crewmembers, this data should theoretically help them take better care of themselves. It will also provide scientific insights into how well some drugs work, especially in terms of physiological changes due to microgravity and other effects of space that may change the pharmacokinetic characteristics of medications.

The following represents another example to illustrate advantages of real-time self-monitoring. An active man with no medical problems began to experience frequent, sudden episodes of exertional near-syncope and syncope. The episodes were not associated with any prodromal symptoms. A neurologic evaluation was unrevealing. A transthoracic echocardiogram demonstrated a structurally normal heart, and the patient's resting electrocardiogram (ECD) was normal. The person was provided with a cardiac monitoring gadget allowing recording and transmission of cardiac rhythms

through his smartphone. During an episode of near-syncope, he recorded runs of wide complex tachycardia lasting up to 6 seconds.



The real-time health data processing is represented by a standard dataflow in Figure 1 below.

Figure 1. Real-time health data monitoring and processing.

3.4 Health support autonomy paradigm and mHealth user interface

Unlike the telemedicine paradigm supported by medical paternalism, this project plans to validate this healthcare autonomy paradigm in order to meet the requirements for manned space exploration missions. It means that the crewmember is the one who to edit and share his/her CEHR contrary to the current practice of non-sharing EHRs that owned by Flight Surgeons of IMG as the healthcare provider. So the crewmember engagement is essential in terms of the paradigm shift.

The predictive diagnostics capability, as an essential component of the proposed technology solutions, is based on an autonomous crew health monitoring and a maintenance concept that increases the crew performance reliability and eliminates a "surprise" factor. Having built on the powerful foundation of predictive analytics, the predictive diagnostics indicates not only what is going to fail, but also does both root and contributing causes of, or factors leading to an impending failure, as well as a priority of the failure. The technology solutions are based on wireless handheld devices and are a result of a paradigm shift from tele-medicine to that of health support autonomy. A key component of the technology solution is a Crew Electronic Health Records [CEHR] system with predictive diagnostics capability, the system that is designed for crewmember as the ultimate end-user, rather than for healthcare professionals. An example of piece of workflow on tracking the CEHR is in Figure 2 below.

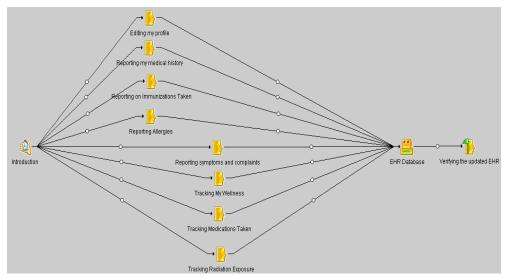


Figure 2. Tracking the Crew Electronic Health Records (CEHR).

In addition to standard EHR items, such as vital signs and body mass measurement, the following type of CEHR includes, but is not limited to:

- ✓ Nutritional and caloric intake;
- ✓ Circadian actigraphy;
- ✓ Sleep logs;
- ✓ Cognitive performance measurement tools;
- ✓ Physiologic audiometry;
- \checkmark Ocular tonometry;
- ✓ Visual acuity;
- ✓ Musculoskeletal assessment of muscle strength;
- ✓ Bone mineral density.

An example of a user interface developed for patients rather than for healthcare professionals is shown in Figure 3 below.

Health Status Recommendations	s 🌞 Programs
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Recommendations	 Huitson Togeordes Togeordes Weight
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Figure 3. A screenshot of the user interface developed by Mayo Clinic for NASA employees. Picture Credit: Mayo Clinic.

3.5 Computationally generated biomarkers

A biomarker is a health-related characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. Electrocardiogram [ECG] and laboratory tests, such as cholesterol level, blood sugar level are examples of biomarkers.

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A detailed discussion on computationally generated biomarkers can be found in Popov et al. (2013),³ Fink et al. (2014),⁴ and Popov et al. (2016)⁵.

4. THE SPACE EXPERIMENT SERIES

4.1 Conceptual architecture

Crews on the US Orbit Segment of the ISS (ISS USOS) widely use mobile wireless tablets such as iPad for their research projects. For example, the brief description of a Habitability Assessment of International Space Station (Habitability) investigation that collects observations about the relationship between crew members and their environment on the ISS could be found on NASA webpage [9] telling about the following: Up to six subjects document observations related to the relationship between crew members and their environment on the International Space Station. Each crewmember reports observations through an iPad application called iSHORT, which is designed for documenting these types of observations. The iSHORT application allows crew members to record videos of specific tasks, perform tours on the ISS for human factors engineers to study, and complete questionnaires.⁹

This research primarily addresses the Human Research Project (HRP) gap concerning tools that can be used to evaluate habitability concepts, and also contributes to risks related to team dynamics, sleep, and behavioral health.⁹ A screenshot of the iSHORT application interface is shown in Figure 4 below.

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Figure 4. A screenshot of the iSHORT application interface used on the ISS to document a new observation. Picture Credit: NASA.

Another iPad is used on the ISS RS to provide onboard training in order to maintain crew skills on responding to offnominal and emergency situations.

The conceptual architecture of proposed solutions on this project includes, but is not limited to the following three elements:

- A COTS wireless sensor network communicating with a dedicated handheld device;
- A dedicated handheld device, such as a tablet (e.g., iPad 2);
- A dedicated onboard back-end laptop.

In addition to the technology described on NASA webpage [6], another example of the conceptual architecture including the COTS wireless sensor network communicating with a smartphone application is shown in Figure 5 below. The wireless technology is to replace the obsolete Holter device being currently used on the ISS.



Figure 5. Another example of a wireless sensor technology for real-time ECG monitoring. Picture Credit: NASA.

The iPad in Figure 6 below is another one to be used on the ISS. The iPad is an essential part of the proposed technology solution architecture on the project and a dedicated piece of hardware that was delivered to Institute for Bio-Medical Problems (IBMP) of Russian Academy of Science for testing and prospective crew training on the project.



Figure 6. The dedicated iPad 2 with the engraved label as "PHM for Astronauts...The collaboration project on ISS" (highlighted in the yellow circle) delivered to Institute for Bio-Medical Problems (IBMP) of Russian Academy of Science for testing and prospective crew training.

4.2 3D Computer-automated Threshold Amsler Grid (3D-CTAG) test

The space experiment series consist is of a diverse series of research experiments. Since both cardiovascular disorder and Visual Impairment/Intracranial Pressure (VIIP) Syndrome have been identified by NASA as top spaceflight risks they have been chosen as first two space experiments on the collaboration project. One of them is the 3D Computer-automated Threshold Amsler Grid (3D-CTAG) test:¹⁰ a Web-based, integrated, and comprehensive visual field test & diagnosis system in order to study and reveal the relationship between intracranial pressure (ICP) and intraocular pressure (IOP) elevations that occur during long-term space travel and potentially associated visual field loss. Perturbations in the difference between IOP and ICP (i.e., translaminar pressure) affect the optic nerve, and the consequence of changes in either of these pressures can be dropout of signals carried from the retina to the visual system. Fink et al. (2013)⁷ and (2014)⁸ discuss in detail the integrated non-invasive visual field test & diagnosis system for the

identification, characterization, and automated classification of visual field defects caused by the spaceflight environment. The 3D-CTAG system^{7,8,10} provides the onboard Crew Medical Officer and crewmembers on space missions with an innovative, non-invasive, accurate, sensitive, and fast visual field test. The 3D-CTAG system includes a database for examination data, and a software package for the automated visual field analysis and diagnosis. The system will be used to detect and diagnose conditions affecting the visual field, while in space and post-mission on Earth, permitting the timely application of therapeutic countermeasures before astronaut health or performance are impaired. Moreover, the visual field test & diagnosis system requires only a touchscreen-equipped computer, tablet, or touchpad device shown in Figure 7, which may already be in use for other purposes (i.e., no additional payload), and a Webbrowser. The system can be applied in routine astronaut assessment (Clinical Status Exam), pre-, in-, and post-flight monitoring, and astronaut selection/screening.

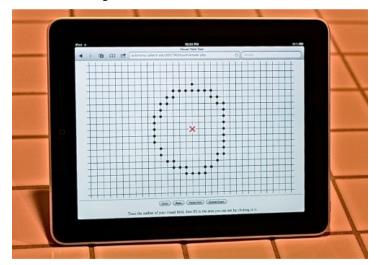


Figure 7. Comprehensive Visual Field Test & Diagnosis Systems Mobile, in space testing via iOS Device (here: iPad 2).^{7,8}

This integrated non-invasive visual field test and diagnosis system is ideally suited for deployment aboard the ISS in short order as a pilot project for PHM-based healthcare. The software package for automated visual field analysis and diagnosis represents a PHM-based concept and would be augmented with predictive diagnostics capabilities to predict the onset of ocular conditions to allow for timely countermeasures to maintain crew health, especially during long duration spaceflight. A couple of examples of the 3D-CTAG user interface are represented in Figure 8 below.



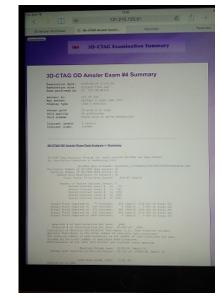


Figure 8. 3D-CTAG examination: test configuration and examination result summary pages.

5. CONCLUSION

The proposed PHM-based concept discussed in this paper is supported by technologies with predictive diagnostics capabilities and a pilot implementation of the technologies aboard the International Space Station. The project approach includes serially staged evaluations and augmented research/testing of the technologies throughout the effort. Resulting upgrades will regularly and efficiently provide advancements during these development phases.

The proposed technology – augmented with on-board predictive capabilities coupled with appropriate countermeasures against cardiovascular, musculoskeletal, and neurological or behavioral challenges associated with space flight – is critical for future human space exploration. It should be noted that nutritional countermeasures are also essential given the impact of diet and nutrition on human health both in space and on Earth. There will be also spin-off aspects and benefits involved: Broader scope aspects/contexts could become more important than individual parameters, such as steps walked in a day or resting heart rate. Taken together, a large number of people using tracking devices on Earth could gain invaluable insights into what works to make us healthier and fitter.

As datasets grow, and as algorithms are being developed and deployed to mine and analyze them for patterns, the usefulness of such technologies will grow. Researchers may use them to develop a better understanding of how treatments work, both in space and on Earth, or how vital signs respond minute-by-minute over large sample sets. The field of precision medicine, for instance, could employ these datasets to better customize prescriptions and other treatments. Researchers may also use these tracked data to figure out what works in the real world to improve health and fitness, rather than testing theories in the artificial conditions of a laboratory environment.

Since crew health and performance are primary critical concerns, using the above approaches, the space community on the ISS program could actively take advantage of the ISS-based research to extend human space mission durations while ensuring crew health and performance. The health risks are significant enough to drive decisions related to planning of exploration missions beyond low-Earth Orbit (LEO). This unique collaboration project on the implementation and validation of the proposed technologies with predictive diagnostics capability on the ISS will directly contribute to the knowledge base and advancements in managing health and human performance risks for space exploration.

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