HRP'S HEALTHCARE SPIN-OFFS THROUGH COMPUTATIONAL MODELING AND SIMULATION PRACTICE METHODOLOGIES

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BACKGROUND: Spaceflight missions expose astronauts to novel operational and environmental conditions that pose health risks that are currently not well understood, and perhaps unanticipated. Furthermore, given the limited number of humans that have flown in long duration missions and beyond low Earth-orbit, the amount of research and clinical data necessary to predict and mitigate these health and performance risks are limited. Consequently, NASA's Human Research Program (HRP) conducts research and develops advanced methods and tools to predict, assess, and mitigate potential hazards to the health of astronauts. In this light, NASA has explored the possibility of leveraging computational modeling since the 1970s as a means to elucidate the physiologic risks of spaceflight and develop countermeasures [1-4]. Since that time, substantial progress has been realized in this arena through a number of HRP funded activates such as the Digital Astronaut Project (DAP) and the Integrated Medical Model (IMM). Much of this success can be attributed to HRP's endeavor to establish rigorous verification, validation, and credibility (VV&C) processes that ensure computational models and simulations (M&S) are sufficiently credible to address issues within their intended scope. This presentation summarizes HRP's activities in credibility of modeling and simulation, in particular through its outreach to the community of modeling and simulation practitioners.

METHODS: The HRP requires all M&S that can have moderate to high impact on crew health or mission success must be vetted in accordance to NASA Standard for Models and Simulations, NASA-STD-7009 (7009) [5]. As this standard mostly focuses on engineering systems, the IMM and DAP have invested substantial efforts to adapt the processes established in this standard for their application to biological M&S, which is more prevalent in human health and performance (HHP) and space biomedical research and operations [6,7]. These methods have also generated substantial interest by the broader medical community though institutions like the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to develop similar standards and guidelines applicable to the larger medical operations and research community.

DISCUSSION: Similar to NASA, many leading government agencies, health institutions and medical product developers around the world are recognizing the potential of computational M&S to support clinical research and decision making. In this light, substantial investments are being made in computational medicine and notable discoveries are being realized [8]. However, there is a lack of broadly applicable practice guidance for the development and implementation of M&S in clinical care and research in a manner that instills confidence among medical practitioners and biological researchers [9,10]. In this presentation, we will give an overview on how HRP is working with the NIH's Interagency Modeling and Analysis Group (IMAG), the FDA and the American Society of Mechanical Engineers (ASME) to leverage NASA's biomedical VV&C processes to establish a new regulatory standard for Verification and Validation in Computational Modeling of Medical Devices, and Guidelines for Credible Practice of Computational Modeling and Simulation in Healthcare.

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