

## **THE PATHWAY TO A SAFE AND EFFECTIVE SPACEFLIGHT MEDICATION FORMULARY: EXPERT REVIEW PANEL RECOMMENDATIONS**

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### **PURPOSE**

Exploration spaceflight poses several challenges to the provision of a comprehensive medication formulary. This formulary must accommodate the size and space limitations of the spacecraft, while addressing individual medication needs and preferences of the crew, consequences of a degrading inventory over time, the inability to replace used or expired medications, and the need to forecast the best possible medication candidates to treat conditions that may occur. The Exploration Medical Capability (ExMC) Element's Pharmacy Project Team has developed a research plan (RP) that is focused on evidence-based models and theories as well as new diagnostic tools, treatments, or preventive measures aimed to ensure an available, safe, and effective pharmacy sufficient to manage potential medical threats during exploration spaceflight. Here, we will discuss the ways in which the ExMC Pharmacy Project Team pursued expert evaluation and guidance, and incorporated acquired insight into an achievable research pathway, reflected in the revised RP.

### **METHODS**

The ExMC Pharmacy Project RP will seek research efforts that concentrate on four major focus areas: formulary selection, formulary potency and shelf life, formulary safety and toxicity, and novel technology and innovation, such as portable real-time chemical analysis, innovative drug therapies, and dosage and delivery platforms. In early spring 2017, the ExMC Pharmacy Project Team assembled a diverse group of pharmaceutical scientists and clinicians to review, evaluate (based on scientific merit and operational feasibility), and provide guidance for baselined RP draft. The Expert Review Panel (ERP) members were given three opportunities to review the RP and provide input and recommendations for improvement. Prior to the ERP meeting, the panelists received the RP, and an online survey containing questions designed to assist the panelists with developing a comprehensive evaluation of, and recommendations for improving, the RP. During the ERP meeting, the panelists participated in discussion groups moderated by Pharmacy Project Team members to review pre-meeting survey input, and provide additional input for each of the four RP focus areas. Finally, the panelists again received the online survey following the meeting as a final opportunity to adjust their pre-meeting evaluations based on an improved understanding of the project and relative views from fellow panelists. The ERP submitted over 42 recommendations for RP revision; which were vetted and prioritized by the Pharmacy Project Team based on the ability to deliver: the greatest benefit from limited resources, feasible and realistic project accomplishments, and scientific relevance and benefit.

### **RESULTS**

The ERP recommended improvements to the language of RP "Critical Questions;" use of evidence-based selection criteria to prioritize prospective formulary medications; identification, incorporation, and documentation of best practices from the literature and relevant analogs to aid with formulary selection; and use of a structured approach for stability testing. The ERP further emphasized the need for directed evaluation of the impact of space radiation on drug degradation, the importance of pharmacokinetics and pharmacodynamics on drug safety and effectiveness, and use of focused experimental project investments to characterize drug stability of selected medications. Lastly, the ERP recommended that the Project Team delay the pursuit of novel technologies until they are either necessary or demonstrate sufficient advancement or benefit for their acceptance and incorporation.

### **CONCLUSION**

This approach to RP evaluation and revision allowed for the highest level of scrutiny to ensure a robust and appropriate path towards successful delivery of a medication formulary for exploration class missions. The revised RP, with ERP guidance, has provided the level of scientific merit and the comprehensive approach necessary to allow the Pharmacy Project Team to reach its research goals. The next phase will see the Pharmacy Project Team execute this revised RP, gather sufficient data, and build the knowledge base required to deliver a safe and effective pharmaceutical formulary for exploration spaceflight.