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NEW PHARMACOLOGY STUDIES ON THE ISS

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INTRODUCTION

It is known that medications degrade over time and that extreme storage conditions will hasten their degradation. This is the basis of the HRP Risk of Ineffective or Toxic Medications Due to Long Term Storage. Gaps include questions about the effects of the spaceflight environment and about the potential for safe use of medications beyond their expiration dates. There are also open questions regarding effects of the spaceflight environment on human physiology and subsequent changes in how medications act on the body; these unanswered questions gave rise to the HRP Concern of Clinically Relevant Unpredicted Effects of Medication. Studies designed to address this Risk and Concern are described below.

METHODS

The "*Development of Methods/Technologies for Medication Stability and Shelf-life*" showed that some (but not all) medications aged on the ISS for over a year still met required standards for safety and efficacy up to 9 months after their expiration dates. Preliminary data were reported last year at this meeting; the complete report has now been submitted for publication. Additional proposals for medication stability studies are in progress.

We have attempted to use existing data and non-intrusive methods as much as possible. In the "*Retrospective Analysis of Medication Usage During Long Duration Spaceflight*" study, data regarding medications used by ISS crewmembers was requested from LSAH and examined for trends in dosing as well as side effect frequency, severity or quality. The "*Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms and Adverse Effects During Missions*" study has the same aims, but uses a custom-designed iPad app to administer a streamlined custom medication use questionnaire to crew before and during their missions. The newly-approved "*Inflight Pharmacokinetic and Pharmacodynamic Responses to Medications Commonly Used in Spaceflight*" study will employ a more rigorous strategy – it will directly measure plasma concentrations of administered medications during flight and compare these measures to those from ground use of the same medications in the same individuals. Multiple measures of drug action will be collected to determine changes in pharmacodynamics (PD).

RESULTS

None of these studies has new data for reporting at this time. The "*Retrospective Analysis of Medication Usage During Long Duration Spaceflight*" task is being conducted in partnership with the JSC pharmacy, and is currently conducting analyses based on medication class – we expect periodic deliverables on specific topics over the coming year. The "*Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms and Adverse Effects During Missions*" study has completed 3 rounds of app testing in ground HERA missions, and began enrolling subjects for spaceflights as early as Fall 2015. "*Inflight Pharmacokinetic and Pharmacodynamic Responses to Medications Commonly Used in Spaceflight*" study was selected in the 2014 NRA, and has been adjusted to meet requirements for missions feasibility, as well as to address specific requests from Space Medicine. It is expected to begin later this year.

CONCLUSION

The JSC Pharmacology Discipline has identified for HRP the relevant unknowns of pharmacology in spaceflight. The ground-based evidence of risks due to degraded medications permitted the Risk of Ineffective or Toxic Medications Due to Long Term Storage to be accepted as an HRP Risk. The unknowns regarding potential spaceflight-induced alterations on pharmacokinetics or pharmacodynamics (PK/PD) are genuinely unknown, requiring the collection of evidence to determine the risk of spaceflight-induced PK/PD changes to the health and safety of the crew. Multiple studies are in progress to address these open questions before exploration missions commence.