

Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms, and Adverse Effects During Missions

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Science Background

Medication usage records can be used as a relatively non-intrusive means of monitoring health. This has been attempted previously through crew medical records, but these records are incomplete from the perspective of a research pharmacologist.

Science Background

- **During the shuttle era, NASA operations did not include routine questioning of crewmembers about their medication use until after missions were complete.**
- **The (long!) questionnaire was on paper.**
- **Asking crewmembers to recall medication use from weeks before questioning made getting complete and accurate information virtually impossible.**



Science Background

This study will document medication usage of crewmembers before and during their missions. It will capture previously unrecorded data regarding medication use during spaceflight, including side effect qualities, frequencies and severities. The research-oriented data will be collected for research purposes, separate from medical records.

Dose Tracker employs an iOS application (app) for fast & easy collection of medication usage data from crewmember participants during their missions.

Hypothesis

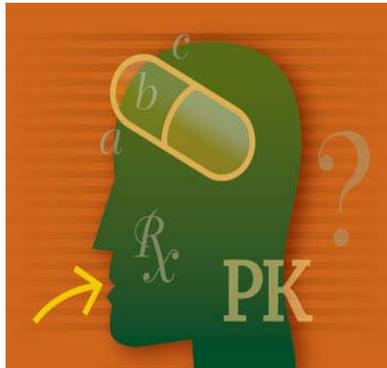
Until now, there has been no specific research conducted on medication usage during ISS missions, as opposed to shorter shuttle missions. The intent of Dose Tracker is to analyze the effects of taking various medications on long duration space missions to LEO vs. on Earth. We expect to see certain operationally-driven instances of medication use (for space adaptation syndrome, for instance). But the study hypothesis is that:

A crewmember's medication usage during an ISS mission will not differ greatly from their typical usage on Earth.

Investigational Goal:

Can medication usage data provide evidence of spaceflight-alterations in PK or PD?

Pharmacokinetics



How the body handles medications: absorption, distribution, metabolism, excretion

Pharmacodynamics



How the medication interacts with target molecules and biochemical pathways

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Specific Aims:

- 1. To gather enough data to indicate if there might be any pharmacokinetic or pharmacodynamic changes during spaceflight.**
- 2. To understand if there are any unusual side effects and/or adverse events from medication usage in space.**
- 3. To acquire sufficient in-flight medication usage data to power future studies and better protect the personal health of crewmembers.**

Measurement Approach

Research-oriented medication usage data will be self-reported by subjects for the entirety of their ISS missions. Ground data for each subject will be collected for a period of time that roughly matches the duration of their ISS mission, during a convenient pre-flight time period.

An iOS app was developed to enable crewmember subjects to record their own medication usage information as simply and efficiently as possible.

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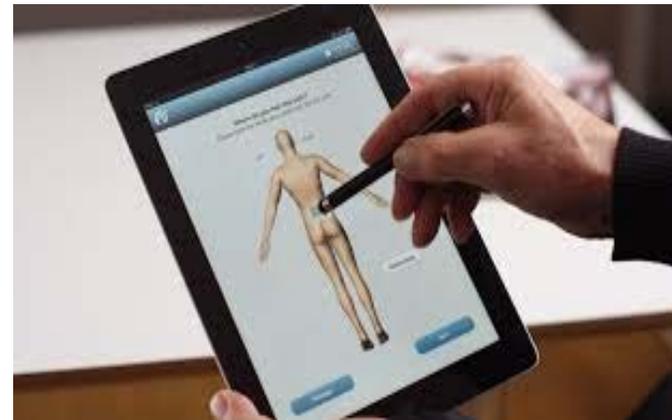
Reason for use of the ISS

This study requires use of the ISS because no ground analog has been validated as appropriate for pharmacology experiments.

Test/Session Descriptions

What is the Dose Tracker App?

Dose Tracker is an iPad application that will permit crewmembers to “track” all medication usage – prescription medications, over the counter medications (e.g., Advil, Tums), vitamins, minerals, supplements, etc.

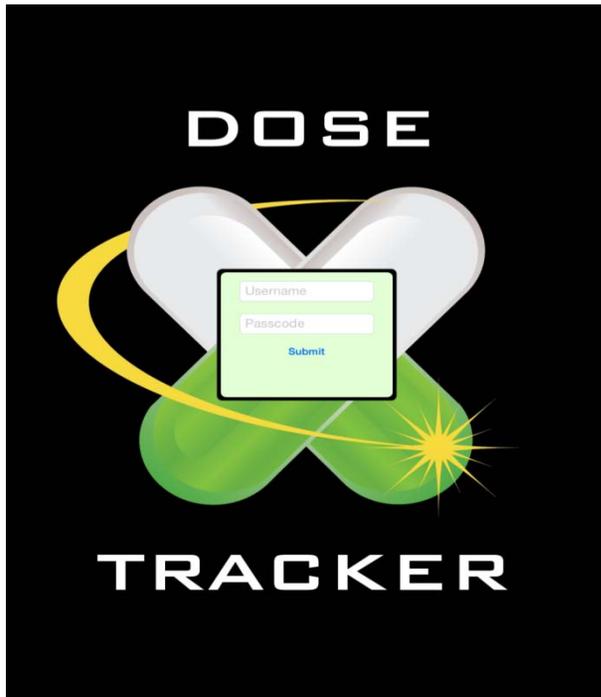


Test/Session Descriptions

The Dose Tracker Application will be used to permit fast and efficient collection of data regarding crewmembers' medication use on a near real-time basis, eliminating the current problems associated with recall over periods of weeks. Specific questions regarding medication use (somewhat different from the questions that physicians ask regarding patient health) will be asked of each participating crewmember.

The data collection process will be streamlined by using a flexibly programmed computerized survey application that leverages the limited medication choices aboard, the doses available, typical dosing frequency, and side effects associated with each medication to provide an individualized short questionnaire for each medication use by the crewmember.

Test/Session Descriptions



- **Once you log in, a question will appear for that week asking you if you have taken any medications for that week.**
- **If you haven't, choose "no" and the questionnaire will end.**
- **If "yes," simply proceed to fill out the questions that will follow.**

Its simplicity and design make Dose Tracker very user-friendly.

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Expected results

Previous studies have indicated that crewmembers' use of medications on short-duration spaceflight missions is roughly similar to what is seen for healthy individuals in adult ambulatory medicine.

We expect this study to show if the same is true for long-duration missions.

This information will be operationally useful for mission planning (what medications to provide, and in what quantities).

This study may also serve to highlight topic areas that require attention, by possibly indicating medications that are not as effective as expected, or those with unusual side effects during missions.

Earth benefits

The Dose Tracker iOS application could be used in other, non-spaceflight scenarios to collect medication usage information.

Knowledge gained from this study could provide additional insight into medication mechanisms of action, by highlighting possible radiation or gravitation influences on either PK or PD.

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Back up slides

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Experiment Design Overview

Preflight	Inflight	Postflight
Dose Tracker Familiarization Session	Dose Tracker sessions once per week in-flight	Dose Tracker session once during R+1 week
Dose Tracker Personalization (optional, pending crew preference)	Historical Photo	
Dose Tracker sessions once per week for duration equivalent to on-orbit mission (ground phase)		

Test/Session Descriptions

The success of this project will depend largely on the information that is entered. The more complete, honest and thorough your entries are, the more accurate our assessment can be.

As a reminder, only our research team will see these results; Dose Tracker data will not be shared with Medical Operations. All your data are strictly confidential; nothing attributable to an individual will be published.

Test/Session Descriptions

Pre-flight, crewmembers will be asked to complete the Dose Tracker App on the ground at least once per week for a duration equal to their in-flight mission (approximately 24 sessions). This will begin between L-12 and L-9 months from launch.

The crewmember will participate in a familiarization session pre-flight at which time they will learn how to enter data successfully into the Dose Tracker App on the iPad.

The application may be personalized with the crewmember's specific medication information, if the crewmember elects this option.

Test/Session Descriptions

Personalization of Dose Tracker

- 1) Default –list of medications already loaded onto the application (IMAK).**
- 2) Personal Meds –can include a list of personal medications (requires disclosure of personal pack contents).**
- 3) Chronic Meds–can pre-program entries for scheduled medication uses (pre-populated automatic pop-up window that only requires a single click if you took your medication as scheduled)**

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Risks & Discomforts

Test	Risks/Discomforts	Mitigation
Dose Tracker Session (if accidental release of data)	Loss of confidentiality of PHI. Risk of professional or personal embarrassment.	<i>Data will be coded and password protected by the investigators and are stored encrypted. Personal iPads are permitted; the software will have the security built into it.</i>

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Test Constraints

Test	Constraints
Dose Tracker Session	Will be performed every 6-8 days (once per week)

Entries may be made more frequently than once per week. If it's more convenient for you to enter a medication use at the time you take a dose, please do. If it's more convenient for you to enter medication uses on a daily basis, please do.

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Experiment Training Schedule

Session Title	Session Type	Timeframe	Duration	Location	Required for Operators	Required for Subjects
<i>NO TRAINING REQUIRED</i>						

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Summary

Preflight	Inflight	Postflight
<p>Dose Tracker Familiarization Session (no more than 30 days prior to start of Dose Tracker Ground Phase) -30 minutes for one session</p> <p>Dose Tracker Personalization (optional, pending crew preference) -5 minutes for one session</p>	<p>Dose Tracker (every 6-8 days starting on FD7 (± 1) - approximately 24 sessions per mission, 15 minutes per session)</p>	<p>Dose Tracker (R+1 week, 10 minutes per session)</p>
<p>Dose Tracker Ground Phase (First entry scheduled between L-12 and L-9 months from launch, then one session every 6-8 days for duration equivalent to on-orbit mission - approximately 24 sessions, 10 minutes per session)</p>	<p>Historical photo (10 minutes of reserve time once per mission)</p>	
<p>Total Time: 275 minutes (4.6 hours)</p>	<p>Total Time: 360 minutes (6 hours)</p>	<p>Total Time: 10 minutes</p>