Title of Project: PROspective Study of Perioperative Experience and Recovery (PROSPER)

SUMMARY

Patients undergoing major or minor medical procedures experience a variety of changes in quality of life. This post-acute care experience varies from procedure to procedure, and patient to patient. We will use a mobile phone application to establish baseline quality of life and follow up quality of life at specific post-procedure time intervals using validated NIH, World Health Organization, and other patient reported outcome measures. The mobile application used to conduct this study is CareEvolution's MyDataHelps, which is a commercially available app used to deliver electronic surveys and collect activity data from the mobile phone's data streams. We will use the mobile phone's existing data streams (heart rate, steps, and location services) to observe trajectories in activity before and after procedures. Additionally, we will integrate existing clinical data from the Multicenter Perioperative Outcomes Group (MPOG) research registry. MPOG serves as a multi-institutional collaboration with IRB-approved sharing of all electronic clinical data and administrative information. UM serves as the coordinating center for the limited-dataset MPOG research registry across more than 40 US hospitals. University of Michigan patients as well as patients of institutions participating in MPOG will be able to enroll in this study by installing a mobile application and then consenting using standardized language for mobile application research projects.

OBJECTIVE

The goal of this study is to assess the changes in quality of life of patients undergoing medical procedures. By establishing physical and behavioral patterns prior to a procedure, we will be able to determine the extent of the changes in quality of life that result from undergoing medical procedures at individual and collective levels.

SPECIFIC AIMS

1. Establish baseline quality of life and follow up quality of life at specific post-procedure time intervals.
2. Observe trajectories in activity before and after procedures using the mobile phone’s existing data streams.

BACKGROUND

There currently does not exist sufficient data to advise healthcare providers and patients to predict the time required to recover to previous baseline function, quality of life, and other aspects of health status. This study will provide a database to help society understand the trajectories of recovery from surgical procedures.

PI QUALIFICATIONS

Dr. Sachin Kheterpal is a tenured Associate Professor in the Department of Anesthesiology at the University of Michigan and Vice Chair for Strategy and Finance. He is faculty member at Center for Healthcare Outcomes & Policy (CHOP) and Institute for Healthcare Policy and Innovation. He is the founder, lead architect, and director of the Multicenter Perioperative Outcomes Group. He received his undergraduate, medical, and graduate business training at the University of Michigan. Dr. Kheterpal is

intimately aware of the uses and limitations of Anesthesia Information Management System (AIMS) data given his background as the founder and lead architect of a healthcare IT company that developed AIMS. This company was acquired by General Electric (GE) healthcare in 2000 and Dr. Kheterpal continued to mature his information technology, medical informatics, and large database experience. As an academic anesthesiologist, he has a track record of publishing large dataset analyses evaluating the relationship between intraoperative management and postoperative outcomes – several as lead articles with editorials in the leading journal of his specialty, Anesthesiology. His work has included several manuscripts using ACS-NSQIP data, merging ACS-NSQIP data with AIMS, and using AIMS hemodynamic, fluid, and depth of anesthesia data elements. He is a national leader in perioperative large dataset research and has authored several editorial and book chapters regarding the multiple uses of EHR data. He has given invited Visiting Professorships at top-tier academic institutions such as Johns Hopkins Medical Institute, Massachusetts General Hospital, University of Chicago, and Vanderbilt University Medical Center. He is on the editorial board of the pre-eminent peer-reviewed journal in our field, Anesthesiology.

METHODOLOGY

Subjects will download and open the mobile application, which will prompt them to a series of graphics that describe the process of participation. Participants will then be presented with the online consent form. If subject agrees to participate in the study, they will be asked for a finger-drawn signature.

Participants will be asked to complete a baseline survey prior to undergoing the medical procedure. Additionally, the application will access the participant's mobile phone's existing data streams to collect activity before the procedure and will continue to collect this data following the procedure. During certain post-procedure time points, participants will be asked to complete surveys concerning their physical activity, pain levels, mental health, and overall quality of life.

This study has 3 components: 1) active surveys, 2) passive activity data, and 3) electronic research registry data. Active surveys: Before and after surgery, patients will complete surveys concerning their quality of life, mobility, pain, mood, sleep, and satisfaction with the surgery. The surveys are short and validated using national data with thousands of patients. Passive activity data: The mobile application will also integrate with other data on the participants' mobile phones to record the number of steps taken each day, travel patterns, and other markers of activity. Passively collecting and analyzing this limited data allows researchers to understand how long it takes for a patient to get back to baseline function, defined by the patient's activity and travel levels before surgery. Electronic research registry data: MPOG was developed so that institutions across the globe can join together to pool their electronic perioperative data into a common research registry. This database includes valuable information regarding surgical procedures, general health, and medical results. By allowing us to integrate the active survey and passive activity data with this information, it will help us improve the surgical experience for all patients. The MPOG research registry data is collected using automated interfaces at each hospital and includes a limited dataset (no direct identifiers) when uploaded to the MPOG coordinating center at UM.

RECRUITMENT

The study requires ongoing recruitment in order to reach an appropriate number of participants. Recruitment is not research coordinator mediated and will be done exclusively by advertising the mobile application via flyers and other advertising/communication mechanisms.

All patients ≥18 years of age undergoing surgical or minor medical procedures requiring anesthesiology care are eligible for the study. Only patients receiving care from an MPOG institution are eligible for this study. Participants must be able to read English and follow study procedures. IRB approved pamphlets and flyers promoting the study will be posted in preoperative care areas. The consent process is completed within the application itself using the standard Apple ResearchKit platform.

Surgical and anesthesiology teams will be notified that patients will be recruited for the study, and flyers will be inserted in patients' pre-operative packets. Recruitment does not require direct interaction with the patient; therefore, no care interventions or recruiting staff is needed.

RESEARCH ACTIVITY

Like the University of Michigan, non-UM institutions will not be actively recruiting participants –research coordinators will not be approaching subject for enrollment. These institutions simply serve as a communication and advertising vehicle. The University of Michigan is the only site engaging in data collection. All research activities will be conducted at the University of Michigan.

CONSENT PROCESS

When a participant opens the mobile applications they are first presented with a series of ResearchKit (i.e., used by all Apple mobile research applications available on App Store) standardized graphics that lay out the process of participation:

1) Data gathering and feedback

2) How data are keep private

3) Data sharing for researchers

4) Survey data collection

5) Ability to withdraw at any time

After viewing the schematics and short text the participant is presented with the online consent form. They will be provided a link to visit the external website (www.mpog.org/PROSPER) that contains information about the study goals and the research team but will be forced to consent (or decline, or close their app) prior to participating in the study through our App. They also have to confirm that they are at least 18 years old, and currently live in the U.S. by clicking a checkbox and understand English.

After providing consent the participant is asked their name and for a finger-drawn signature.

STATISTICAL DESIGN

We will perform univariate analyses and association tests such as linear models for quantitative variables and logistic models for binary variables.

If there is an adequate number of enrolled subjects, we will stratify by age, gender, procedure type, and comorbidity burden. The participant's activity data and self-reported quality of life measures will be plotted against the population distribution.

BENEFITS AND RISKS

Society has no data to guide their decision making regarding how long and how well patients undergoing surgery return to normal function -- defined by things other than surgical outcomes. These data will help society understand the trajectories of recovery surgery. In addition, participants will be given the option to receive comparative and normative data. They can use the activity and survey data to monitor and modify, for example, their physical activity and compare themselves to other participants.

The only direct risk for this arm involves a breach in data security. This is a rare risk (< 1%). The infrastructure used to store this data is governed by UM Health Information Technology & Services servers and federal HIPAA security guidelines. The team involved has been collecting sensitive data for more than 10 years without any data breach events.

RETAINING DATA

Our study's benefits to participants, and to society, will only be realized if the subject data obtained through this study are compiled and kept. To reach thousands of participants, which will be necessary to achieve our study goals, will require ongoing recruitment and indefinite storage of existing limited dataset data. If data were deleted as subjects stopped participating, then the total sample size of available data would never grow to the extent required to conduct the proposed research and to obtain its benefits to society. Therefore, we give subjects full disclosure about the conditions of their participation at the very beginning, before they provide us with any data. In this way, there is no need to request further consents later in a subject's participation, after that subject has already provided data.

If a subject chooses to withdraw from the study, their data is removed from the primary research dataset. Any specific manuscript analyses already underway would continue to contain their data because the deidentification / de-linking process makes it impossible to identify a specific subject in a specific manuscript analysis. No future projects would contain their data.

PRIVACY

While logged into the mobile application, the subjects' privacy will be protected through industry standard electronic security, which is described in detail in that section of this application. By using the Apple ResearchKit platform, standard requirements used by all other Apple ResearchKit applications are met. This includes encrypted communication from the mobile device to the University of Michigan, and local encryption for any information stored temporarily on the device.

All correspondence with subjects, e.g., to their personal email, will be nonspecific. It will merely remind them that we value their participation and ask them to log back into the app and continue contributing to the study. Once logged back in, they will securely receive information about what specifically we need.

The data is linked to subject identifiers in the primary research dataset in one specific data structure. The linkage is necessary to allow integrating of third party data that the patient has consented to

integrate: electronic research registry, death certificate data, and in some settings, surgical registry or 3rd party payer data (Medicare, Blue Cross Blue Shield of Michigan) already present in MPOG electronic research registry dataset. All other data structures -- where survey data, activity data, etc. are stored -- do NOT contain any direct subject identifiers.

The identifiers are encrypted and only available to the software developers, analysts, and research coordinators responsible for data integration -- the "honest brokers".

All analytical datasets and datasets used by individual researchers will be stripped of these identifiers. The identifiers will be retained until either 1) the end of data collection or 2) when a subject requests that they be removed from the study (withdrawal procedures).

WITHDRAWAL AND TERMINATION OF STUDY PARTICIPATION

Subjects can stop participating in the study if they specifically request to be removed. Participants must contact us at mpog-prosper@med.umich.edu to notify us that they would like to withdraw.

We will respond to their request within 3 business days and will ask if they are sure about the withdrawal. They can also call us; all of our contact information can be found in the consent form, section “withdrawing”. Any requests for withdrawal will be logged in a central database and automated processes will ensure that each request is addressed.

Periodically, we will also implement quality control measures to ensure that survey answers are consistent and meaningful. Subjects providing answers that fail these quality control screens may also be excluded from the study. Data quality will be determined through embedded validity measures in existing surveys. For example, one validity measure might evaluate whether a subject is responding too quickly (e.g., faster than humanly possible, or many standard deviations below the mean response time).

If a subject chooses to withdraw from the study, their data is removed from the primary storage dataset. However, manuscript analyses already underway would continue to contain their data because the deidentification / de-linking process makes it impossible to identify a specific subject in a specific manuscript analysis. No future projects would contain their data.