Protocol Summary and Statistical Analysis Plan

Does inpatient enrollment into a patient communication app (Patient Gateway) result in improved follow-up and survey completion rates after orthopaedic trauma?

NCT 2017P001594

Version Date 03/07/2018

PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Marilyn Heng, MD, MPH, FRCSC

PROTOCOL TITLE
Does inpatient enrollment into a patient communication app (Patient Gateway) result in improved follow-up and survey completion rates after orthopaedic trauma?

FUNDING
Department Funding

VERSION DATE
3/7/2018

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

This study aims to:
1. To determine if inpatient enrollment into a patient communication app (Patient Gateway) improves clinic follow-up of orthopaedic trauma patients.
2. To determine if inpatient enrollment into a patient communication app (Patient Gateway) improves survey completion rates after orthopedic trauma.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Follow-up in trauma is historically poor. As a result, outcomes from trauma are difficult to collect via surveys and are often significantly influenced by selection bias. Patient interaction apps like Patient Gateway are thought to facilitate greater participant involvement and adherence to treatment regimens. We explored if inpatient enrollment into Patient Gateway would improve clinic follow-up rates. Increasing follow-up rates could improve the quality of care delivered.

In addition, self-administered survey questionnaires are an important data collection tool in clinical practice, public health research and epidemiology. However, survey completion rates are typically poor in orthopaedic trauma.

With the evaluation of modern technology, electronic applications are being increasingly used in both hospital and personal settings. In our outpatient clinic, questionnaires to measure outcomes and monitor quality of care are

administered by staff members using hospital owned tablet devices. Recently, applications to complete these surveys on personal devices have been developed.

In a recent Cochrane review on the comparison of self-administered survey questionnaire responses collected using mobile apps versus other methods it was concluded that there are no data available on response rates. We will attempt to address this question.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

All Patient Gateway naïve patients aged 18 years or older able to consent for themselves, admitted to the hospital for an orthopaedic condition with the need for outpatient follow-up and access to the internet or a smartphone will be invited to participate in this study. Exclusion criteria will be patients unable to consent for themselves, inability to communicate in English, and no possession of a smartphone.

We will collect 240 patients; 120 in each group. Existing follow-up is assumed to be close to 70%, to detect a 15% difference at 95% CI, N=240.

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Eligible patients will be randomized into two groups; one group that is enrolled while an inpatient and another group that is just provided information about how to enroll. All patients eligible for participation will be approached during their hospital stay and asked for consent. Patients will be cluster randomized by week and after consenting, they will be assigned to the treatment arm randomized to that specific week. For intervention group, an explanation on the app will be provided by a trained research staff member and they will be fully enrolled in the app in the presence of this research staff member. In the period between hospital discharge and follow-up, patients using the Gateway app will be requested to fill out a survey on their personal device and will receive a notification of their upcoming appointment. We will monitor when patients return to clinic for their first, 90-day, and 1-year follow-up outpatient appointments. At 90 day and 1 year follow-up outpatient appointments, patients from both groups will be invited to complete a survey on a hospital owned tablet device per standard clinic protocol. In addition to the standard survey, two brief questionnaires on satisfaction with the electronic application and satisfaction with overall care

will be provided at the end of the regular survey (if already completed over the app; just the satisfaction questions will be administered).

Descriptive statistics will be used for demographic data. Logistic regression will be used for binary outcome data.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Not applicable as this study does not alter treatment or diagnosis in any way.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

The risk to subjects and their privacy is no more than minimal risk because all data that will be reviewed will be purely demographic and questionnaire data. Any protected (identifiable) health information will be de-indentified when the study has been completed. PHI will be stored on a password-protected Partners network computer with access limited to study staff. We will be using REDCap to collect survey responses, which is hosted behind the Partners Firewall.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Subjects who indicate that they do not wish to participate will not be included in the study.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

The one risk we can foresee is a breach of patient confidentiality. We will take the utmost care to ensure that confidentiality is maintained. Patient specific identifiers will be erased once data is collected and verified. The identifiers will be assessable for the shortest duration of time possible.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, “It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects.”

Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

There is no direct benefit to subjects who participate in this study. At a societal level, it is hoped that the results of the study will help improve clinic follow-up rates. Increasing follow-up rates could improve the quality of care delivered.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

All Patient Gateway naïve patients aged 18 years or older admitted to the hospital for an orthopaedic injury with the need for outpatient follow-up will be invited to participate without regard to race, ethnicity, or gender. Vulnerable populations will not be recruited.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Individuals who do not speak English will be excluded from this study because the surveys have not been validated for use through an interpreter.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
http://healthcare.partners.org/phsirb/nonengco.htm

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Subjects will be will be screened for eligibility by the Research Coordinator in close collaboration with the surgeon investigators. Study staff familiar with the study inclusion and exclusion criteria will review the daily inpatient list to identify potential subjects. Subjects eligible for inclusion will be approached by research study staff.

Subjects will be given plenty of time to weigh the risks and benefits of participation in the study. Investigators will reinforce with their own patients that participation is voluntary, that they do not have to participate, and the decision not to participate will not affect their care, now or in the future.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Subjects will receive no remuneration.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
http://healthcare.partners.org/phsirb/recruit.htm

Guidelines for Advertisements for Recruiting Subjects
http://healthcare.partners.org/phsirb/advert.htm

Remuneration for Research Subjects
http://healthcare.partners.org/phsirb/remun.htm

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

We are requesting a waiver of written consent. Subjects will be given a fact sheet outlining study information. All subjects will be given ample time to read the fact sheet and consider participating. The PI will reinforce with the potential subjects that they don't have to participate and that the decision to not participate will not affect their care at any time. When possible, if the PI is the treating physician, a Co-I, or experienced research coordinator will discuss the study with the subject and caregiver to avoid having the subject or caregiver feeling coerced.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:

Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the

planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

This is a non-invasive study and there will be no additional risk by participating in the study.

The principal investigator will take responsibility for regular reviews of the study progress and any concerns regarding subject safety. Study progress including data completion and entry will be discussed at protocol meetings to be held as needed during the duration of the protocol activity. The principal investigator will report adverse events or other unanticipated problems to PHRC as described in the PHRC policy on Adverse Event Reporting and Unanticipated Problems Involving Risks to Subjects or Others.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

This is a non-invasive study involving administration of questionnaires only and there will be no additional risk by participating in the study; however, if adverse events and / or unexpected events are encountered, they will be reported immediately to the PI and to the IRB in accordance with the IRB adverse event reporting guidelines.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in

accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The principal investigator and site responsible investigator are responsible for adherence to all IRB rules and guidelines. The research coordinator will be responsible for the accuracy and completeness of all forms, entries, and informed consent.

As an added quality assurance measure, study staff will hold weekly meetings to ensure adherence to protocol is maintained by all of the study staff as well as to monitor the status and quality of the study. A data audit of 25% of the data will be performed by either a research coordinator or an investigator to verify the accuracy of the data.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
http://healthcare.partners.org/phsirb/guidance.htm#13

Reporting Unanticipated Problems (including Adverse Events)
http://healthcare.partners.org/phsirb/guidance.htm#7

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

Care will be taken to preserve the confidentiality of patient information. Information specific to the study (the questionnaires and scores) will be maintained in a private database on a secure network, to which access is limited. Subject data will be kept on a protocol-specific, password-protected, Partners Healthcare System-maintained computer that is kept in a locked office. PHS computers maintain the latest anti-virus software and firewall protections. Only IRB approved staff will have access to these data.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

None of the information collected will be sent to research collaborators outside of Partners.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

No specimens/data will be stored at sites outside of partners for future use.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

No specimens/data will be received from sites outside of partners for future use.

Statistical analysis, study size

Descriptive statistics were used for demographic data. Differences between groups were assed using the chi-square or Fisher's exact test for categorical variables and the t-test and/or analysis of variance (ANOVA) for continuous variables. Demographic or treatment factors associated with improved follow-up or EPP use were assessed using forward stepwise logistic regression modeling to avoid overfitting. We also performed a sub-group analysis assessing the the effect of patient race and average median income. A robustness analysis exploring the likelihood of enrolling in an EPP or completing follow-up in all patients was also performed. Significance was set at $P < 0.05$. Stata software, version 14 (StataCorp), was used for all analyses.

An a priori power analysis was completed to determine sample size, we assumed an existing follow-up rate of 70%, and to detect an ~10 % difference in follow-up with an alpha of 0.05, we calculated an approximate sample size of 200 patients distributed equally between both groups.