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
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PROTOCOL TITLE
Optimal Medical "Teaming" on Resident Based Teams

FUNDING
None

VERSION DATE
March 1, 2019

SPECIFIC AIMS

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

The main objective of this study is to evaluate the colocalization of internal medicine residents on one clinical inpatient hospital floor for all their general medicine block rotations during the 2019-2020 academic year. Specifically, the aims of the study are to determine if colocalization improves familiarity with nursing staff, which in turn, improves team work, psychological safety, patient care and reduces burnout. Our hypothesis is that co-localization will increase familiarity between residents and nurses and result in improved psychological safety, team work and patient outcomes.

BACKGROUND AND SIGNIFICANCE

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

Teamwork is critical in delivering high quality medical care. Failures in team communication and coordination have been cited as significant contributors to medical errors. In large teaching hospitals, patients receive care from transiently

formed teams of nurses and residents who may only work together for as little as two weeks, as residents rotate through many clinical floors due to the complexity of resident scheduling. Unlike more established teams that work together over long periods of time, these transient groups are called "teaming;" a process where a group of diverse providers, with different roles, outlooks and levels of professional training *transiently* come together to carry out complex tasks. (A. Edmonson, Harvard Business School) A key risk in "teaming" is the lack of familiarity of team members as studies suggest familiarity promotes an environment of psychological safety, where team members feel safe speaking up, asking for help and admitting errors. These skills are important for both team work and patient safety. We hypothesize that in large residency programs where resident rotate on multiple floors, it is possible to improve the quality of "teaming" by increasing the frequency with which smaller groups of residents and nurses work together. As a result, we propose a randomized controlled trial on an inpatient general medical floor to study the effect of co-localizing residents with nursing staff. One cohort of residents will be assigned to complete all their general medical rotations on a single floor for the academic year. We will assess the impact on psychological safety, team work and patient care. We hypothesize by co-localizing residents with nursing, while these "teaming" are still transient, the slight increase in familiarity will promote a culture of psychological safety and improve team work. If benefits are found, resident scheduling can be adjusted in subsequent years.

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.”

Study Settings: Massachusetts General Hospital is an 1100 bed tertiary/quaternary medical center. The study will take place on the MGH general medical service which consists of 6 clinical nursing floors with 6 internal medicine residency training teams. Patients are randomly assigned to teams by the admitting department based on bed availability. The study will occur from June 25, 2019 to June 24, 2020.

Participants: The MGH internal medicine residency program has 190 residents who rotate through both outpatient clinics and inpatient ward rotations during their training. General medical teams consistent of 1 PGY-2 resident and 4 PGY-1 residents caring for 16-18 patients with 2 core teaching attendings. Resident teams rotate every 2-4 weeks, with PGY-2 residents working 4-6 weeks during the academic year on the general medical floors and PGY-1 interns working 16-20 weeks during the academic year. We anticipate the study will involve 40 PGY-1 residents and 20 PGY 2 residents on both the intervention and control team. Nurses in the study are the clinical nurses who work on each floor. There are approximately 40-50 nurses assigned to each clinical floor managed by a nursing director for that floor.

Inclusion criteria: Participants are: 1) PGY-1 and PGY-2 residents in the Department of Medicine Residency Program rotating on established clinical floors and 2) clinical nurses on two general medical floors. The residency program has decided to randomly co-localize PGY-1 and PGY-2 residents on the White 9 clinical floor. The White 8 clinical floor has been randomly chosen as the control floor. Nurses on both these floors would be invited to participate. The core teaching attendings, who have been grouped by floors for years, will not experience any change

to their schedule. *Exclusion Criteria:* Any residents or nurses not making the requirements outlined above.

We plan to randomize 16-18 PGY-1 residents in internal medicine at MGH, from the possible 74 PGY-1 incoming residents who agree to partake in the study, to one general medicine clinical floor for the academic year. These co-localized residents will complete their 16-20 weeks of scheduled rotation time on White 9. Similarly, we plan to randomize 6-8 PGY-2 residents from a possible group of 64 PGY-2 residents who agree to participate in the study, to one general medical clinical floor for the academic year. They will complete their 4-6 weeks of scheduled rotation time on White 9. Rotations will be completed in the normal 2 or 4 week block rotations, randomly assigned throughout the academic year. The resident team on this clinical floor will be made up of 4 PGY-1 residents with one PGY-2 as resident leader. The control arm will consist of the 20-24 PGY-1 residents and 8-10 PGY-2 residents who are scheduled for their first general medicine rotation on the control floor White 8. They will then be followed as they complete the rest of their general medicine rotations randomly assigned to any of the 5 different clinical floors. Nurses in the study are the clinical nurses who work on each floor. There are approximately 40-50 nurses assigned to each clinical floor managed by a nursing director for that floor.

Data Analysis

We plan to use bivariate analysis using t-tests and chi-squared tests to examine group differences for means and proportions, as appropriate. In particular, team performance by group and the proportions of the rated observations for the individually scored items, will be analyzed using chi-squared tests. For interprofessional communication by group, time-motion observation data will be

analyzed descriptively via totals, as well as via bivariate comparisons using both chi-squared tests and two-sample Wilcoxon rank-sum (Mann–Whitney) tests. Survey results will be analyzed using chi-squared tests to compare the proportions of responses to specific questions on the surveys. Finally, for patient related metrics by floor (control floor v. intervention floor), data will be obtained via an internal data warehouse (Epic) and will be analyzed descriptively using two-sample t-test for age, two-sample Wilcoxon (Mann-Whitney) rank-sum test for length of stay, and x2 for categorical variables (such as sex, race, etc.). Study data will be collected using REDCap. Given the small size of this study, a power calculation will not be done.

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.

To better understand the effect of co-localization we plan to evaluate 4 main sets of outcomes.

Given the complexity of the relationships in teaming and its effect on patient safety, we believe it is necessary to evaluate several different outcomes to better understand the effect of familiarity on team function.

1) Psychological safety, via observation of team rounds, four surveys of residents and nurses and group interviews of both residents and nurses, at the midpoint and end of the study.

2) Team performance of interns and nurses, through four surveys and group exit interviews of both residents and nurses, at the midpoint and end of the study.

3) Education, via review and evaluation of blinded and anonymous attending evaluations of the residents. These evaluations are already gathered by the residency program for educational purposes.

4) Patient Safety, via extracted blinded chart reviews of failure to rescue during rapid responses and ICU transfers.

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.

The intervention proposed in this study (colocalization of residents on one clinical floor) is within the bounds of standard of care. Resident normally rotate among 6 similar general medicine clinical floors. This group will have all their rotations on one of those 6 floors.

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 risks to participants in the study are minimal. For medical residents and nurses they may experience discomfort in the reflection required to accurately fill out survey materials and participate in focus groups related to perceived clinical performance. The risks to patients taken care of by teams in the intervention arm are no different than the risks associated with usual care.

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.

All participants in the study may opt out of participating in surveys or focus groups at any time.

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.

Please see commentary above. Partners IRB approved resources will be used for the administration of surveys to minimize the risk of resident and nursing survey results being lost.

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.

It is hoped that enhanced relationships between nursing and residents in the intervention arm, may improve team work and communication and provide better patient care with a reduction in ICU transfers.

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.

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.

N/A

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.

No specific recruitment procedures are outlined as participants will be enrolled based on the clinical floor or medical team they are assigned to by the residency scheduling program.

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

Remuneration will consist of $5 coffee central cards for completion of survey, if we are able to obtain grant funding.

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.

As the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context, we propose that oral consent be obtained from study participants at the start of the study and that implied consent be utilized for the completion of study related materials (e.g. survey forms and participation in focus groups).

Patients will not be directly involved, however the medical information of the patients taken care of by the predefined care team will be queried to determine patient outcomes over the period of the study. Given the number of patients cared for by the clinical teams over the course of the study (over 1000) and the intervention as not a deviation from existing standards of care, we propose that costs and resources expired for specific patient consent outweighs the benefits. In addition, all patient information accessed is that similar to which is utilized in a hospital based quality initiative project.

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.

All hospital level patient related data will be kept on partners computers and will only be accessible to appropriate study staff. All identifying material will be shredded at the completion of the study in accordance with HIPPA standards.

Given the minimal risk and no anticipated benefits associated with study participation, there is no related ongoing quality assurance or interim data analysis. Outcomes will be monitored as noted above.

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

We do not anticipate any adverse events, but will report unanticipated events to the IRB.

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 responsibility for maintenance of accurate records will and data integrity falls under the purview of the PI and the assigned research assistant. Data evaluation to ensure appropriate integrity will be ongoing.

For guidance, refer to the following Partners policies:
Data and Safety Monitoring Plans and Quality Assurance

http://healthcare.partners.org/phsirb/datasafe.htm

Adverse Event Reporting Guidelines
http://healthcare.partners.org/phsirb/adverse_events.htm

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.

All surveys will be administered via a Partners IRB approved site (e.g. Red Caps) to ensure the integrity and privacy of results collected.

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.

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.

N/A

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.

N/A