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
Optimizing the Safety of Inter-Hospital Transfer

FUNDING
Funded by CRICO/RMF GRANT AWARD

VERSION DATE
November 23, 2020

SPECIFIC AIMS

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

Inter-hospital transfer (IHT), commonly performed to provide patients with more specialized care, involves transfer of patients between providers, settings and systems of care, leaving these patients vulnerable to the risks of discontinuity of care. Standardized communication tools, which have been successful at reducing patient harm among other similar hospital-based care transitions (i.e., intra-hospital patient handoffs), have been under-utilized during IHT to-date, leaving the process largely non-standardized and variable.

The overall goal of this proposal is to optimize patient safety during IHT to GMS, cardiology and oncology services, collectively comprising nearly 50% of all IHT to Brigham and Women's Hospital (BWH), by leveraging our pilot work to design, implement and rigorously evaluate a standardized communication tool to be used during IHT. We propose the following Specific Aims to accomplish this goal:

> **Aim 1.** Utilize pilot data and stakeholder input to revise the standardized accept note.
>
> **Aim 2a.** Implement the revised standardized accept note for all patients transferred from another acute care hospital to the GMS, cardiology, oncology and medical/cardiac ICU inpatient services at BWH.

Aim 2b. Shift the responsibility of documentation of the accept note from a diffuse group of individual clinicians to a small group of dedicated nurses within the Access Center.

Aim 3. Prospectively evaluate the impact of the intervention on patient safety outcomes, including: clinician-reported medical errors and adverse events, length of stay after transfer, rapid-response or code within 6-hours of transfer, ICU-transfer within 24-hours of transfer, and 3-day and in-hospital mortality.

BACKGROUND AND SIGNIFICANCE

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

Importance of Patient Safety Issue

The transfer of patients between acute care hospitals (inter-hospital transfer, IHT) occurs regularly: over 100,000 hospitalized Medicare patients undergo IHT yearly, with greater frequency among select patients with common medical diagnoses.

Though often necessary to provide specialized care, IHT practices are highly variable and expose patients to unnecessary *risks*. Similar to other care transitions like patient discharge or intra-hospital patient handoffs, **IHT exposes patients to known *risks of discontinuity of care that may result in patient harm, such as errors in communication and gaps in information transfer***. Moreover, patients undergoing IHT may be even more vulnerable to these risks than patients undergoing other care transitions, given the severity of illness in this patient population and the absence of protective factors to fill in gaps in communication, such as common electronic health records.

Existing literature has suggested that poor communication during IHT is common and is a significant contributor to adverse outcomes among this patient population. This poor communication includes missing clinical information, such as test results (leading to diagnostic errors or redundant testing), absent or misleading information about how sick a patient is (leading to mis-triage), and even the reason for the transfer (leading to confusion regarding expected care, therapeutic errors, and patient/family dissatisfaction). Clinicians caring for IHT patients after transfer commonly describe feeling unprepared to safely care for these patients due to incomplete patient information that accompany the patient at the time of arrival. Not surprisingly, sub-optimal communication during IHT has been associated with poor downstream outcomes such as prolonged length of stay and increased mortality.

Although the association between inadequate communication and patient safety outcomes during IHT has been established, solutions to optimize communication during IHT have been lacking. Though there has been suggestion of improved patient outcomes in IHT with use of a structured handover tool and when enhancing information exchange via existent electronic health record (EHR) platforms, implementation and evaluation of standard communication practices have yet to be rigorously studied among the IHT population. In summary, this proposal aims to address the *critical barrier* of *lack of evidence-based standardized communication during IHT* to optimize patient safety during this transition.

Scientific knowledge, technical capability, clinical practice, and malpractice risk

Current IHT practices are largely variable and non-standardized, with limited existent guidelines to direct clinical practice during IHT. The Emergency Medical Treatment and Active Labor Act (EMTALA) laws dictate that hospitals transfer patients requiring a more specialized service unavailable at the transferring institution, or when "medical benefits...outweigh the increased risks to the individual...", although these laws provide little practical guidance to clinicians during patient transfer. Other existent transfer-related guidelines are largely focused on equipment and expertise requirements for the physical transfer of the patient and/or are disease- or service-specific, rather than addressing inherent risks of discontinuity of care generalizable to all IHT patients, such as transfer of essential clinical information between transferring and receiving institutions.

Summary of Background and Significance

This proposal aims to design, implement and rigorously evaluate a standardized accept note in a population of patients that have high frequency of IHT, including patients transferred to the general medical (GMS), cardiology, oncology and ICU services at a large tertiary care hospital. This study will improve scientific knowledge by quantifying the patient safety impact of an intervention to improve communication of essential clinical information during IHT. If shown effective, the results of this study can be used to improve clinical practice by establishing evidence-based communication guidelines for broad dissemination. We will also establish technical feasibility by successfully implementing this tool within our EHR (Epic, Verona, WI), allowing for feasible adoption and dissemination to other institutions with similar EHR capabilities. Lastly, we will address malpractice risk by investigating a strategic intervention aimed at reducing known contributors to patient harm during IHT, a high-risk transition in care that involves transfer of high-acuity patients between providers, settings and systems of care.

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."

We will conduct a prospective 24-month interrupted time series (ITS) study during which we will implement the standardized accept note and evaluate impact on all measured outcomes post- versus pre-implementation, accounting for baseline temporal trends.

Eligible patient subjects will include any patient age 18 or older transferred from another acute care hospital to the GMS, cardiology, oncology or ICU (including medical and cardiac ICU) services at BWH during the study period. Because the intervention is not directly patient-facing, there will be no direct enrollment of eligible patients, and we will be requesting a waiver of written informed consent for patients. Thus, all eligible patients transferred during the study period will be included in the study. Assuming 1848 total patient transfers to GMS, cardiology, oncology and medical/cardiac ICU services at BWH per year, we anticipate including approximately 2,772 patients during the 18-month data collection period (9 months pre-implementation, 9-months post implementation). Data collection procedures are described in detail below.

Eligible clinician subjects (approached for survey completion to collect clinician-reported patient safety outcomes) will include any clinician who admitted an included transferred patient during the data collection period, using the methodology described below. Clinicians involved in patient admissions on GMS, cardiology, oncology and medical/cardiac ICU services include medicine resident physicians, attending hospitalist/nocturnist physicians, and/or physician assistants on any of the 3 included services. Given the described methodology of approach for survey administration and repeated offerings to opt-out of participation (see included "IntroductoryEmail" and "DirectedEmailSurvey1") we will be requesting a waiver of written informed consent for clinician subjects.

Full description of the research design and methods is as follows:

Overall strategy, work plan, data collection methodology

Aim 1*. Utilize pilot data and stakeholder input to refine the standardized accept note.*

Two parallel pilot initiatives and key stakeholder input will be used to develop the standardized accept note to be implemented during this study. The first pilot initiative aimed at improving communication during IHT to

GMS services. Stakeholder input was used to successfully design and implement a structured accept note template to be completed for all GMS patient transfers. The template was made accessible within Epic as a "dot-phrase" (i.e., a phrase starting with a period that automatically produces prespecified text). Components of the structured accept note are shown below in **Table 1**.

Table 1. Components included in structured accept note (pilot)[32]

"Logistical" components	"Clinical" components
Name of transferring hospital	Reason for transfer
Date of request	Consulting service expected (Y/N, if Y, who?)
Requesting physician name	Code status
Requesting physician contact information	Patient summary
Transferring floor contact information	Relevant comorbidities
	Current inpatient medications
	Last vital signs
	Pertinent exam findings
	Pertinent data (labs, imaging, microbiology)
	Expected plan on arrival

The second concurrent pilot initiative aimed at improving communication during direct hospital admission from oncology clinic to inpatient oncology services and similarly included creation of a structured pre-admission note template adapted from the I-PASS structured hand-off tool, shown to improve patient outcomes when used during intra-hospital patient hand-offs. This note was similarly accessible as a "dot-phrase" within Epic, and contained similar (but not identical) components to those used in the above pilot, including: (1) Illness severity: Documentation of the patient as "stable" or "watcher" (indicating the patient is at risk of becoming unstable); (2) Patient summary; (3) Action items: Documentation of the expected care plan on arrival; (4) Situational awareness: Documentation of code status and any social needs; and (5) Synthesis by receiver: Documentation of contact information for the referring outpatient clinician sending the patient for direct admission.

These two pilot versions of a structured accept note will be reconciled and refined using feedback gathered during these initiatives, along with key stakeholder input (below), to develop the standardized accept note that will be implemented in this study.

We will engage key stakeholders in the refinement and development of the final standardized accept note to be implemented in this study, including: Key representatives from the Access Center (Dr. Eric Goralnick, Medical Director of the Access Center and Co-I on this proposal; Samantha Andreasen, Acting Nursing Director of the Access Center; and Sheila Harris, Executive Director of Patient Access and Clinical Services; and to-be-identified Access Center staff); BWH quality and safety leadership (Dr. Mallika Mendu, Medical Director of Quality and Patient Safety) (please note that all mentioned stakeholders provided letters of support for this

proposal); and select frontline accepting clinicians and admitting clinicians from each included service (i.e., those who take transfer request calls and those who admit transferred patients at time of arrival) who will be recruited at the start of the study. Stakeholders will meet monthly during the 6-month period of finalization of the accept note.

Notably, we will ensure that the final version of the standardized accept note allows for flexibility within the templated fields to address the unique needs of the different included patient populations (e.g., prompts to include date/details of any prior cardiac catheterizations for cardiology patient transfers). This is similar to how IPASS allows for flexibility in the Patient Summary section for different populations while still standardizing communication.

Clinical information to populate the note will be collected during a 3-way conference call that occurs between the Access Center nurses, transferring clinicians, and accepting clinicians prior to all patient transfers (part of current workflow, see below Aim 2). The note will be documented and accessible within Epic, as it was during the pilot initiatives.

***Aim 2a**. Implement the revised standardized accept note for all patients transferred from another acute care hospital to the GMS, cardiology, oncology and ICU (medical, cardiac) inpatient services at BWH.*
***Aim 2b**. Shift the responsibility of documentation of the accept note from a diffuse group of individual clinicians to a small group of dedicated nurses within the Access Center.*

Currently, documentation of clinical information in advance of patient transfer to included services involves a diffuse group of clinicians who are responsible for both accepting the patient for transfer and are expected to document the patient accept note. For example, for GMS patient transfers, this responsibility for accepting patients for transfer and documenting their accept note falls to any of the over 50 hospitalist faculty who rotate weekly on the clinical service. This diffusion of responsibility is similar for cardiology and oncology service patient transfers as well. Collectively, these practices result in variable presence, timeliness and quality of accept note documentation in advance of patient transfer.

Thus, implementation of the standardized accept note will importantly include shifting responsibility for documentation of the note from this diffuse group of clinicians to a small group of dedicated nurses within the Access Center. Notably, the pilot initiative for GMS patient transfers included this shifted responsibility as part of the initiative; thus, the additional responsibility for accept note documentation among patients transferred to cardiology and oncology services (in addition to GMS services) will involve an expansion of the current role of Access Center nurses, rather than

introduction of an entirely new role. This expansion of responsibility of Access Center nurses is also supported by Access Center leadership (as was provided in letters of support for this grant proposal), contributing to the feasibility of this aspect of the proposal

Implementation of the standardized accept note will also involve education of Access Center nurses on its use (i.e., to familiarize them with the newly developed accept note template), and we have included a 3-month "wash-in" phase following implementation to allow for iterative feedback on its use, to improve the quality of documentation during the implementation period.

Of note, the shifting of responsibility of documentation of the new standardized accept note will not supplant the current role of the accepting clinician to make the clinical decision on acceptance or rejection of the transfer request. As is currently done, the Access Center nurse and accepting clinician participate in a conference call with the transferring clinician such that either can ask questions (and the Access Center nurse can hear all the answers and document them in the accept note template). In this way, the Access Center nurse can ensure that the minimum necessary information is collected and documented, while also including additional clinical information requested by the accepting clinician.

Aim 3. *Prospectively evaluate the impact of the intervention on patient safety outcomes, including: clinician-reported medical errors and adverse events, length of stay after transfer, rapid-response or code within 6-hours of transfer, ICU-transfer within 24-hours of transfer, and 3-day and in-hospital mortality.*

Study Design: We will conduct a prospective 24-month interrupted time series (ITS) study during which we will implement the standardized accept note and evaluate impact on all measured outcomes post- versus pre-implementation, accounting for baseline temporal trends.

Setting, Subjects, Eligibility, Enrollment: Eligible patients will include any patient age 18 or older transferred from another acute care hospital to the GMS, cardiology, oncology or medical/cardiac ICU services at BWH during the study period. Because the intervention is not directly patient-facing, there will be no direct enrollment of eligible patients, and we will be requesting a waiver of written informed consent for patients (see Organizational Internal Review Process, above). Thus, all eligible patients transferred during the study period will be in the study.

Instruments, Tests and/or Measurements: A trained research assistant (RA) will conduct surveys of admitting clinicians within 48-hours after IHT patient admission to obtain clinician- reported medical errors and adverse events, including medical errors resulting in patient harm (e.g., preventable and

ameliorable adverse events). The RA will use a central patient report derived from our EHR system that lists all transferred patients to included services on a daily basis Monday through Friday (including weekend transfers on Mondays) and will perform targeted EHR review to determine the admitting clinician for each patient. The RA will then email that clinician a link and instructions to complete a short survey via REDCap, a free, secure, HIPAA compliant web-based application hosted by Partners (see included "DirectedEmailSurvey1"). Survey questions, based on those from similar studies conducted by our group for other types of care transitions, will pertain to the clinician's care of the specific transferred patient and will ask about failures in communication (i.e., the presence of inaccurate or missing information, including missed or delayed diagnoses) and evaluate for any failures or delays in ordering or interpreting diagnostic studies, and delays in therapeutic care. The survey also asks about any adverse event (i.e., patient harm due to medical care), the severity of the event, and whether it was preventable or ameliorable (see "Appendix.ClinicianSurvey"). The RA will send 2 follow-up emails over the following 3 days (see "DirectedEmailSurvey.FollowUp"). After 3-days, any non-responding clinician will be contacted by the RA to conduct an in-person survey using an iPad linked to REDCap to improve response rate. All clinicians will be informed they have the right to opt out of any data collection activities at the beginning of the study and when requested to participate in these activities. Each participating clinician will receive a $5 gift card for each completed survey (currently submitting to Research Compliance for approval). All other outcome measures will be obtained via administrative data with help from a database analyst.

Primary and Secondary Outcome Measures:

1) Clinician-reported medical errors (primary outcome), measured as the total number of medical errors per patient

2) Presence of any adverse event after transfer (secondary outcome)

3) Preventable adverse event after transfer (secondary outcome)

4) Ameliorable adverse event after transfer (secondary outcome)

5) Length of stay of hospitalization after transfer (secondary outcome)

6) Rapid-response (i.e., "pre-code") or code within 6 hours of transfer (secondary outcome)

7) ICU-transfer within 24 hours of transfer (secondary outcome, excluding ICU patients)

8) Mortality, including 3-day mortality (within 3 days of transfer) and in-hospital mortality (secondary outcome)

9) Intermediate process outcomes, including presence, timeliness and completeness of accept note as measured by frequency of accept note availability at time of IHT patient arrival and frequency of inclusion of pre-specified data elements (secondary outcome)

Statistical Methods and Analytic Plan: All outcomes will be compared post- versus pre-implementation via ITS methodology, allowing us to evaluate for statistically significant changes in outcomes while accounting for baseline trends. Multivariable analyses will be utilized to adjust for potential confounders.

Covariates: Potential confounders will be collected via administrative sources and include basic patient demographics (age, gender, race, ethnicity), insurance, diagnosis category (using standard ICD-10 grouper algorithms on the principal problem on the Hospital Problem List on admission, which we have found to be more accurate than the billing diagnosis on admission), comorbidity (i.e., Elixhauser score), illness severity (eCART score on admission, which uses vital sign and laboratory data to predict cardiac arrest, ICU transfer, or death among hospitalized patients),36 clinical service at time of admission, and time of year of transfer (by quarter) to adjust for training effects on residents and seasonal case mix. To avoid over-testing, all patient characteristics will be entered into the analysis model. Non-significant collinear terms will be removed from the final models.

Subgroup analysis: We will conduct a limited number of *a priori* subgroup analyses to evaluate for differential effect of the intervention in different sub-populations of transferred patients by using interaction terms (subgroup*intervention) to determine effect modification. Specifically, we will stratify analyses by: 1) admitting service (GMS, cardiology, oncology, medical/cardiac ICU); 2) diagnosis category; and 3) severity of illness on admission (using the eCART score as described above).

Statistical techniques: For all analyses we will use a segmented regression analysis on all eligible patients, evaluating outcomes monthly during the pre-implementation and post-implementation periods (after the 3-month "wash-in" period). This approach quantifies both a "step" change in the level of outcome and a "slope" change in the trend of outcome. For our primary outcome (number of clinician-reported medical errors per patient), we will use multivariable Poisson regression models (SAS v9.4 statistical package, Cary, NC). For adverse events, preventable and ameliorable adverse events, and other dichotomous outcomes (rapid response/code, ICU-transfer, mortality, presence of accept note) we will use multivariable logistic regression models. For LOS, given its skewed nature we will use a multivariable generalized linear regression model assuming a gamma distribution with a log-link. We will use descriptive statistics to evaluate timeliness of accept note availability and inclusion of accept note data elements. For all analyses, the transfer episode will serve as the unit-of-analysis.

Outcomes reporting: Patient and transfer process characteristics will be presented descriptively using means with standard deviations, medians with

inter-quartile ranges, and proportions with 95% confidence intervals as appropriate. Each outcome will be reported as crude as well as adjusted and clustered effects with 95% confidence intervals. All analyses will be on an intention-to-treat basis. Two-sided p values < 0.05 will be considered significant. All analyses will be conducted using SAS (SAS v9.4 statistical package, Cary, NC).

Power and sample size: Based on previous data, we estimate a baseline rate of 25 reported medical errors per 100 patient transfers. With an alpha of 0.05, we will require an effective sample size of approximately 594 patient transfers during the 9-month pre-implementation period and 594 patients transfers during the 9-month post-implementation period to have 80% power to detect a 30% relative reduction to 17.5 errors per 100 patient transfers, as has been observed in similar studies. Assuming 1,848 total patient transfers to GMS, cardiology, oncology and medical/cardiac ICU services at BWH per year (1,368 per 9-months, internal data), while allowing for missed days of survey administration (i.e., during holidays), and accounting for a survey response rate of 90% (based on similar studies), we should easily achieve this sample size.

Given the large number of different clinicians likely to admit these patients across all services over the 18 months of data collection, the cluster size is likely negligible, therefore resulting in an effective sample size close to the actual sample size.

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.

Please see detailed description of study procedures above.

All study procedures will take place at BWH. There are no local site restrictions for the procedures described in this study.

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.

Current practices for inter-hospital transfer of patients to GMS, cardiology, oncology and medical/cardiac ICU services at BWH involves an expectation of documentation of clinical information in advance of patient transfer. However, this documentation is largely non-standardized and involves a

diffuse group of clinicians who are responsible for both accepting the patient for transfer and are expected to document the patient accept note. For example, for GMS patient transfers, this responsibility for accepting patients for transfer and documenting their accept note falls to any of the over 50 hospitalist faculty who rotate weekly on the clinical service. This diffusion of responsibility is similar for cardiology, oncology and ICU service patient transfers as well. Collectively, these practices result in variable presence, timeliness and quality of accept note documentation in advance of patient transfer.

We expect (our hypothesis) is that implementation of this standardized accept note, as well as centralization of accept note documentation, will be a marked improvement over current standard of care – leading to both improved frequency of documentation and quality of documentation. However, we do not know this for sure – that is why we are conducting the study. In other words, there is equipoise.

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.

Risks to subjects will be minimized by using procedures which are consistent with sound research design. Neither patients nor providers will be unnecessarily exposed to excess risk. The designed intervention is a local quality improvement initiative, with input from key stakeholders involved in the inter-hospital transfer process, and, as stated above, is hypothesized to be an improvement to current practices.

Additionally, all collected data is secured within the password-protected REDCap ecosystem – REDCap is a secure web application for building and managing online surveys and databases. Thus risks to data breach/patient confidentiality will be minimized.

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.

Ensuring safety of patient subjects: The intervention itself will rolled out on the specific study units (general medical, cardiology, oncology and medical/cardiac ICU services) as part of a quality improvement effort to change systems for best practice as described. We will conduct periodic data safety monitoring (see below) to ensure that the intervention is not

causing harm (e.g., increased adverse events, prolonged length of stay). Additionally, all patient-level data will be kept within Partners firewall, with only approved study staff access, thus minimizing risk to patient confidentiality/data breaches.

Ensuring safety of provider/clinician subjects: The nature of the study will be explained clearly to all providers prior to the start of the study and at all points of data collection from providers (i.e., survey administration, as described above), with clear instructions that clinician subjects are able to opt-out of participation in the study at any time. Although they are hospital employees, they will be under no pressure to complete the study surveys or participate. They will be told that all data will be presented in aggregate, and their supervisors will never see the results of their individual surveys or know whether or not they chose to participate in the study. They will be given the ability to opt out of the study then, or at any time thereafter.

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 foreseeable risks to patients of the study itself is mainly the risk of breach of confidentiality, and again, this risk will be minimized given the steps to preserve confidentiality noted below.

The risk or discomforts to admitting clinicians are the minor inconvenience of completing the surveys, and risks to confidentiality, which we will take every effort to minimize as described below.

The data collected from providers will not have any identifiers and will not be coded except to track who has completed surveys (e.g., in order to send a reminder as needed). All data will be collected with REDCap, a secure, HIPAA compliant web-based application hosted by Partners. Identifiers (i.e., on a survey cover sheet) will be removed prior to any analysis, and results will only be presented in aggregate. Additional data protection measures (see below) will also be taken to ensure protection and restricted access to all study related files and data.

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.

This project will advance the field by investigating a strategic intervention aimed at reducing known contributors to patient harm: sub-optimal communication and clinical information exchange within IHT, an understudied high-risk care transition. Additionally, if shown effective at reducing patient harm, the standardized accept note developed from this study can be adapted and used by other CRICO-insured institutions to address potential harm and malpractice risk related to IHT.

Given previous data that estimates an approximate baseline rate of 25 reported medical errors per 100 patient transfers, our anticipated sample size will be more than enough to have 80% power to detect a 30% relative reduction to 17.5 errors per 100 patient transfers, as has been observed in similar studies.

Impact on Department, Institution/Organization, and CRICO-wide Membership: If shown effective, our findings will provide convincing evidence that this intervention can and should be adapted for use among other CRICO-insured institutions to address potential harm and malpractice risk related to IHT. Importantly, the standardized accept note developed for this study will be generally accessible within the EHR (Epic). This has critical implications for future dissemination of this work, as this central accessibility will allow for easy modification and expansion to other services at BWH and all other Partners hospitals interested in mitigating patient safety risk during IHT, either via individual departmental efforts or as part of an organizational strategy to address this risk. Moreover, these interventions could be easily adapted for other CRICO member hospitals (e.g., note templates are part of all EHRs, not just Epic).

Impact on Health Care Providers: The intervention included in this proposal directly addresses health care provider-reported patient safety concerns regarding incomplete or insufficient availability of clinical information for IHT patients, as collected with our prior research on this topic. Thus, we anticipate that this proposal will benefit clinicians by improving the presence, timeliness, completeness and quality of clinical information available to them prior to patient transfer, thereby improving their ability to adequately prepare for and care for IHT patients.

Impact on the Field: This project will advance the field by investigating a strategic intervention aimed at reducing known contributors to patient harm: sub-optimal communication and clinical information exchange within IHT, an understudied high-risk care transition.

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 patients transferred from another acute care hospital to the GMS, cardiology, oncology and medical/cardiac ICU inpatient services at BWH will be eligible for the study. No group is categorically excluded from inclusion. Additionally, all admitting clinicians in the units targeted in the study (general medical, cardiology and oncology services) will be asked to participate in the study.

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 **https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Non-English-Speaking-Subjects.pdf**

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.

Eligible patients will include any patient age 18 or older transferred from another acute care hospital to the GMS, cardiology, oncology or medical/cardiac ICU services at BWH during the study period. Because the intervention is not directly patient-facing there will be no direct enrollment of eligible patients. We will request a waiver of written informed consent for patients on the grounds that the study is minimal risk and the intervention is being provided to all patients transferred to included services during the implementation period. Thus, all eligible patients transferred during the study period will be in the study.

A trained research assistant (RA) will conduct surveys of admitting clinicians within 48-hours after IHT patient admission to obtain clinician- *reported medical errors and adverse events*, including medical errors resulting in patient harm (e.g., preventable and ameliorable adverse events). The RA will use a central patient report derived from our EHR system that lists all transferred patients to included services on a daily basis Monday through Friday (including weekend transfers on Mondays) and will perform targeted EHR review to determine the admitting clinician for each patient. The RA will then email that clinician a link and instructions to complete a short survey via REDCap, a secure, HIPAA compliant web-based application hosted by Partners (see"DirectedEmailSurvey1"). As this email will contain patient identifiers, all emails will be sent from a Partners institutional email address and only to the clinician's institutional email address (i.e., no personal/private email addresses will be used). Survey questions, based on those from similar studies conducted by our group for other types of care transitions, will pertain to the clinician's care of the specific transferred patient and will ask about failures in communication (i.e., the presence of inaccurate or missing information, including *missed or delayed diagnoses*) and evaluate for any *failures or delays in ordering or interpreting diagnostic studies*, and *delays in therapeutic care.* The survey also asks about any *adverse event (i.e., patient harm due to medical care), the severity of the event, and whether it was preventable or ameliorable* (see "Appendix.ClinicianSurvey"). The RA will send 2 follow-up emails over the following 3 days (See "DirectedEmailSurvey.FollowUp"). After 3-days, any non-responding clinician will be contacted by the RA to conduct an in-person survey using an iPad linked to REDCap to improve response rate. All clinicians will be informed they have the right to opt out of any data collection activities at the beginning of the study and when requested to participate in these activities. If a clinician chooses to opt out of taking part in the study, they will not be approached about study participation again, either for the patient they were initially approached about or a future patient of theirs.

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

Each participating clinician will receive a $5 gift card for each completed survey. This will provide incentive but not enough to be coercive for participation. We are currently submitting this to Research Compliance for approval, though anticipate approval due to similar approved approaches with prior research.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf

Remuneration for Research Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Remuneration-for-Research-Subjects.pdf

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.

Consent procedures for patients - Because the intervention is not directly patient-facing, there will be no direct enrollment of eligible patients, and we will be requesting a waiver of written informed consent for patients.

Consent procedures for Admitting Clinicians – implied consent is obtained from the admitting clinicians as a function of filling out and submitting a survey response. All clinicians will be informed they have the right to opt out of any data collection activities at the beginning of the study and when requested to participate in these activities.

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:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Informed-Consent-of-Research-Subjects.pdf

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.

The principal investigator and data analyst will review all complaints and adverse events reported from patient and provider subjects each quarter. These will be reported to the study sponsor and Partners IRB annually or immediately if the complaint or adverse event is serious. In addition, the principal investigator and data analyst will review on a monthly basis adverse event rates, hospital length of stay, and 7-day readmission rates to ensure that the intervention itself is not causing harm compared with the pre-intervention period. If an increase in harm is suspected, we will report it to the IRB and take action as needed. Given the minimal risk of this study, we are not planning any automatic stopping rules or using a DSMB.

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

See Above

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 study analyst will review the study database monthly during the data collection period to ensure data integrity. Additionally, survey collection directly into REDCap will ensure data integrity with limited opportunity for errors in data transfer. Protocols will also be monitored quarterly to ensure adherence to the study protocol as approved by the IRB.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/DSMP-in-Human-Subjects-Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Reporting-Unanticipated-Problems-including-Adverse-Events.pdf

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.

The data collected from providers will not have any identifiers and will not be coded except to track who has completed surveys (e.g., in order to send a reminder as needed). Patient identifiers (i.e., to connect survey data collected from providers with data abstracted from administrative data sources) will be kept in a separate, password-protected file. Any patient identifiers will be removed prior to any analysis, and results will only be presented in aggregate.

All data will be collected through REDCap, a secure, HIPAA compliant web-based application hosted by Partners, and only accessible to IRB-approved

study staff. Additionally the iPad being used for this study will be linked to REDCap and will likewise be password protected.

All other files and electronic data will be stored on within databases in a shared file area within the Partners firewall on a Partners password-protected computer with anti-virus software. A database with the link from PHI (e.g., MRN) to subject ID number will be kept separate from the rest of the data. Only IRB-approved study staff trained in the protection of human subjects will have access to study 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.

N/A

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