Optimized Health-Related Social Needs Screening and Community Linkages
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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

Optimized Health-Related Social Needs Screening and Community Linkages: Implications for Closing the Gap and Achieving Health Equity

FUNDING

MGH Executive Committee on Community Health (ECOCH) Community Health & Health Equity Grant (primary); MGH Department of Emergency Medicine Faculty Research Fund

VERSION DATE

2/14/2019

SPECIFIC AIMS

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

Objective: To assess health-related social needs (HRSN) of emergency department (ED) patients and provide linkages to hospital- and community-based services and to understand the most effective method for HRSN screening in the challenging environment of the busy ED.

Hypothesis: Screening for HRSN in the challenging environment of the busy ED can be optimized for increased patient acceptability, improved time efficiency, and minimized disruption to the flow of emergency patient care.

Specific Aims:

Aim 1: To evaluate HRSN screening in the ED using oral and written modalities of the established Partners HealthCare HRSN screening tool.

Aim 2: To use qualitative methods to examine patient satisfaction with the process, explore barriers to screening, and identify salient HRSN missed by the established screener.

BACKGROUND AND SIGNIFICANCE

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

The Partners HealthCare HRSN screening tool is currently in use in the MGH ED to screen Medicare and Medicaid beneficiaries for unmet HRSN related to 9 major categories: transportation, food, housing, ability to pay utility bills, ability to pay for medicines, employment, education, childcare, and elder care. In its current form, HRSN screening is carried out as a one-on-one interview that can last up to an hour, conducted by the ED Medicaid navigator, with patients who present during weekday/daytime hours. Not all patients approached agree to the screening however (33-50% of patients approached for screening decline to participate), and patients have reported unmet needs outside of the 9 major categories screened.

Screening in the ED is exceptionally challenging. Patients may feel too ill to divert their attention from their state of health and must be readily available for the multiple interruptions for reassessments and diagnostic testing. Additionally, private spaces are not always available, and patients may feel embarrassed, or simply too exhausted, to discuss their needs. The most effective screening method for HRSN under these challenging conditions—in other words, the most acceptable to patients, the most efficient in identifying salient, pressing, and actionable barriers to health, and the least disruptive to the flow of emergency care—has not yet been identified. Finally, the impact of HRSN screening is greatest when coupled with streamlined linkages and referrals to community-based social services capable of acting upon the information obtained and assisting individuals to meet their health-related social needs.

The overarching goal of this project is to optimize HRSN screening in the ED. Screening in the health care setting can be achieved via oral (in-person interviews) or written (computer-based surveys) modalities. Using the established Partners HealthCare HRSN screener (permission for use granted), we will examine patients' satisfaction with the screening process

using both modalities. Additionally, we will evaluate HRSN identified and missed by the established screener to understand whether additional or alternative screening questions are relevant and needed for the ED patient population. Finally, we will provide participants with linkages and referrals to community organizations based on their identified unmet HRSN.

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."

A total of 200 ED patients will be recruited and randomized for this project.

Inclusion criteria: 1) age ≥ 18 years patients and either a parent/guardian of a pediatric/cognitively disabled patient in the MGH ED, 2) triaged to the Acute, CDU, Fast Track, Urgent, and Pediatrics areas, 3) English- or Spanish-speaking, and 4) capable of informed consent. *Exclusion criteria*: 1) patients unwilling to have the interview audio-recorded, 2) medically unstable patients, and 3) Section 12, lack of capacity medical hold (yellow paper), sexual assault, child abuse, and emotionally distressed patients.

Bilingual research assistants (RA) will screen patients for eligibility based on the above predetermined criteria. Potential study participants will be approached by trained RAs who will verbally consent patients for participation in the study. Patients who provide consent will be randomized to oral v. written (iPad) screening for completion of the Partners HealthCare HRSN screening tool. We plan to enroll 100 patients into each of the oral v. iPad screening groups, to examine potential differences in satisfaction and screening responses. A subset of enrolled patients will be invited to participate in an in-depth interview. Participants will be compensated $20 for the additional time to complete the interview component of the study. We will purposively sample enrolled participants to balance recruitment across 4 groups defined by screening strategy (oral v. iPad) and health literacy (high v. limited). The sampling strategy is purposive, designed to make sure the full range of themes is elicited within each prespecified group. We will enroll in the interview portion of the study until thematic saturation is reached in each of the four groups.

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.

Bilingual research assistants (RA) will screen patients for eligibility based on the predetermined criteria and approach eligible patients with a brief description of the study and opportunity for participation. Interested participants will complete a verbal consent process to reduce the barriers to participation, a brief demographic questionnaire, and an assessment of health literacy (Newest Vital Sign) followed by the Partners Healthcare HRSN screener randomized to an oral v. iPad screening strategy. Randomization will occur after consent. Randomization will be operationalized through use of use of a randomization list. We will make 500 randomization assignments for an expected study enrollment of 200.

After completion of the screening tool, participants will complete a secondary questionnaire asking about satisfaction with the process, the presence of additional HRSN not recorded by the Partners HealthCare screener, and their perspectives on screening. At the conclusion, all participants will be provided with standardized, bilingual list of community resources to address each of the screening domains. For patients who explicitly request assistance with making these connections, the clinical team will be informed, and a Social Services consult (or ED navigator consult when appropriate) will be recommended.

A subset of enrolled patients will be invited to participate in an in-depth interview. We have chosen to use qualitative interviews to identify the range of opinions regarding screening for HRSN in the ED setting. We will purposively sample to balance recruitment across 4 groups defined by screening strategy (oral v. iPad) and health literacy (high v. limited). The sampling strategy is purposive, designed to make sure the full range of themes is elicited within each prespecified group. Interviews are continued until thematic saturation is reached for each group, the point at which interviews are no longer revealing new information about the primary topic of interest. Although there is no formal sample size for qualitative studies, thematic saturation is generally reached by 12 interviews per group,[2] and therefore we anticipate completing 48 interviews. As we anticipate fewer Spanish-speaking participants based on ED demographics, all Spanish-speaking patients will be invited to participate in the qualitative interview to ensure a diverse representation of perspectives. These 30-minute qualitative interviews will cover

domains regarding screening preferences, barriers and facilitators to disclosure of HRSN in the ED, perception of screening practices, and the opportunity to identify HRSN that may have been missed by the Partners HealthCare HRSN screening tool. All interviews will be recorded, encryption-stored, professionally transcribed, and qualitative software will be used for analysis.

[1] Osborn CY, Weiss BD, Davis TC, et al. Measuring adult literacy in health care: performance of the newest vital sign. *Am J Health Behav*. 2007;31(Suppl 1):S36-46.

[2] Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods*. 2006;18(1):59-82.

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.

N/A

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.

Although it is not anticipated that any of the screening or qualitative interview questions will cause emotional discomfort or distress, participants are informed that they may decline to answer any questions and/or withdraw from the study altogether.

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.

Should a patient or parent wish to withdraw at any point they can do so. In addition, if the clinical team feels a patient is no longer appropriate to participate in the study (e.g., worsening disease of the patient or child, need for potentially distressing clinical communication), we will stop the interview and use only the portion of the data already collected.

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.

There are minimal risks to participation in this study. As we will be collecting participant names to avoid duplicate enrollment, there is the potential for loss of confidentiality. All study materials will be kept in a locked cabinet inside a locked office, and the screening log/record of names will be kept separately from the study files, also in a secure location. Audio-recordings of interviews will be transcribed by a HIPAA-compliant vendor who will produce anonymized versions of the files for qualitative analysis.

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.

Participants will be provided with a list of hospital- and community-based resources tailored to their specific HRSN as identified via the screening and interview process. We anticipate that this project will assist in the optimization of HRSN screening in the ED by identifying salient HRSN not included in the current Partners HealthCare screener, increasing patient acceptability of screening, improving time efficiency, minimizing disruption to the flow of emergency patient care, and creating a streamlined linkage and referral process with community organizations.

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.

No group of persons will be excluded from the research study based on gender, race, ethnicity, or health insurance status. We will enroll only patients >=18. For patients under age 18, parents/guardians will be approached for consent and participation.

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.

English- and Spanish-speaking patients will be approached for enrollment in this study.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.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.

Bilingual RA staff will round in the ED to identify potentially eligible patients. Patients will be approached in the ED by a CITI-certified RA and informed about the opportunity to complete a voluntary and anonymous HRSN screener. If the patient expresses interest in learning more, the trained RA will explain the study to the patient, answer all questions, and obtain verbal consent prior to proceeding with the HRSN screening +/- qualitative interview. A screening log with participants names will be kept to avoid duplicate enrollment.

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

For guidance, refer to the following Partners policies:
Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/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.

Informed consent for participation will be obtained from all adult patients and parent/guardians of underage (age < 18 years) patients. There will be no HRSN screener or qualitative interview participation by a child. We are asking only the parent/guardian who will participate in the verbal consent process, to participate in the study.

We are particularly interested in perspectives of participants with limited health literacy and concerned that written informed consent could be a disproportionate barrier to enrollment for patients with limited health literacy. Therefore, we request permission to obtain verbal informed consent to reduce literacy related barriers to participation. RAs will consent eligible patients and parents/guardians of eligible pediatric patients using a verbal consent process while individuals are in a private room. Parents will be given an information sheet in either English or Spanish.

We are requesting a waiver of written informed consent because the research meets the following criteria: The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. The study staff who explain the protocol and obtain consent are not part of the clinical team.

The RA will describe the key elements of consent to the participant including the potential risks and benefits of the study, protection of confidentiality of data, and the fact that their clinical care will be the same regardless of enrollment. Verbal informed consent will be documented by signature of the RA on the enrollment record.

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://partnershealthcare-public.sharepoint.com/ClinicalResearch/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.

There are minimal risks to participation in this study. As we will be collecting participant names to avoid duplicate enrollment, there is the potential for loss of confidentiality. All study materials will be kept in a locked cabinet inside a locked office, and the screening log/record of names will be kept separately from the study files, also in a secure location. Audio-recordings of interviews will be transcribed by a HIPAA-compliant vendor. Audio files will be uploaded electronically to the HIPAA-compliant transcription service and anonymized transcripts will be returned via email for qualitative analysis. Demographic information will be kept in a Partners REDCap database. Completed HRSN screeners and interview transcripts will be reviewed on an ongoing basis by the Co-PIs to identify protocol deviations requiring correction.

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

While we do not anticipate any safety risks to participants, all safety concerns will be reviewed by the Co-PIs within 2 business days of the report. Adverse events, if any, will be reported to the Partners' IRB through proper channels in accordance with PHS IRB 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 Co-PIs assume ultimate responsibility for monitoring and quality assurance of this research study. CITI-certified members of the research team will undergo training in the study protocol, confidentiality and consent procedures, and trauma- and culturally-sensitive cognitive interviewing. Interview transcripts will be reviewed on an ongoing basis by the Co-PIs, and deviations from the protocol will be addressed by additional training of the relevant research staff.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/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.

All study records will be kept in a locked cabinet in a locked office. Participant names will be recorded to avoid duplicate approaches for enrollment and the screening logs with names will be kept separately from the data files (identified only by study number), also is a secure location. ED RA staff are trained on data confidentiality procedures.

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