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IRB Proposal
Title: Understanding patient perspectives in obtaining food insecurity resources identified by screeners of social determinants of health
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Background:

Social determinants of health (SDOH) influence modifiable factors of health in a population. At an individual level it has proven to impact health outcomes such as poorer glycemic control among adolescents with type 1 diabetes.[1] There are multiple funding initiatives to support universal screening of SDOH to better understand which particular determinants affect health outcomes, as well as to elucidate barriers to accessing specific resources. New York-Presbyterian was granted a CMS Accountable Health Communities Grant to implement universal screening of SDOH in primary care settings (ambulatory care network or ACNs), ED, and delivery units along with closed-loop navigation and referrals in order to test whether addressing SDOH can achieve the Institute for Healthcare Improvement's Triple Aim of improving population health, improving patient care and decreasing cost. This program is called ANCHOR, Addressing the Needs of the Community through Holistic Organizational Relationships. To date, this initiative has screened 5,000 patients and has found that food insecurity and housing issues represent the largest needs (30% of those screened). This model defines high-risk patients as those who had two or more emergency department visits in the past year and screened positive for at least one health-related social need. As per grant requirements, patients considered high risk are interviewed via phone 48 hours after screening by community resource coordinators who provide navigation services and referrals to community-based organizations to address identified needs.

Food insecurity is defined as the lack of accessible and affordable nutritious food.[2] The USDA found that approximately 12 percent of US households were food insecure at least some time during the year in 2017, with food insecurity rates highest for single mother households. The USDA also found that approximately 16 percent of households with children were food insecure.[3] The Food Bank for NYC found that 16 percent of New York City residents are food insecure, with food insecurity for New York City children at 22 percent.[4] A two-item hunger vital sign questionnaire has been developed and validated for screening low-income families with young children and is currently being utilized in ANCHOR screening.[5] Research about food insecurity screening programs have found that numerous barriers to accessing food exist for adult patients screened and referred to community resources including competing priorities, low health literacy, and disconnects between organizational and patient perceptions of food insecurity.[6]

To date, there is a lack of common outcome definitions for interventions addressing social determinants of health. Perla et al. 2017 propose three principles of defining successful SDOH interventions: 1) defining success from the patient's perspective, 2) tailor success by social need domain, or 3) define a range of success.[7] CMS utilizes the range of success approach where resolved navigation can be categorized as "resolved" or "successful." "Resolved" means that the beneficiary's need has been met. "Successful" means that the beneficiary made contact with a community service provider (CSP) that is expected to address the unmet need within the next six months. A beneficiary's need is 'expected' to be met if all three conditions are met: 1) community service provider has been contacted about the beneficiary's unmet need, 2) CSP has indicated it has the capacity to address the unmet need within the open navigation, and 3) This information has been communicated to the beneficiary. Unresolved navigation is categorized as "unavailable," "attempt failed," or "opt out." "Unavailable" indicates that a community service is unavailable or unable to address the beneficiary's unmet need within the open navigation period. "Attempt failed" means that the navigator attempted to contact the beneficiary on at least three separate consecutive occasions but was unable to reach the beneficiary. "Opt out" indicates that the beneficiary opted out of navigation services for the unmet need.

Study Aims:
Aim 1: Conduct in-depth interviews with pediatric caregivers who were screened through the ANCHOR program

Aim 2: Understand whether caregivers' perception of food insecurity need resolution is similar to or discordant with case categorization

Aim 3: Understand facilitators and barriers to accessing community-based resources

Aim 4: Develop a pilot community-based intervention to improve access to community-based food resources based on patient perspectives gathered through in-depth interviews

Study Design and Methods: This qualitative study will recruit a prospective sample of participants for in-depth qualitative interviews. It will draw from a subset of caregivers of pediatric patients screened by the ANCHOR program. The study objectives will be achieved by collecting and analyzing data from in-depth interviews conducted with a sample of ANCHOR-screened caregivers in order to explore experiences with screening and resource navigation as well as patient perceptions of need resolution.

Data Analysis: This study will include data collection through in-depth semi-structured interviews. Analysis of the interviews will take place using a modified grounded theory approach.[8,9] This will entail coding the data through open, axial, and selective codes using an iterative process that informs future interviews. A codebook will be created from this process. Additionally, analytical memos will be created to systematically

document contents of the data set, what is known about the data set during analysis, and what questions may be of interest as data collection proceeds.

Study Drugs or Devices: None

Study Instruments:
A draft in-depth interview guide for use with caregivers will be submitted with the IRB application. The interview guide will be revised as appropriate through an iterative process in order to optimize the quality of data obtained from interviews and its relevance to the research questions outlined in the research protocol and IRB application. Key themes to be addressed in the discussion guide include: 1) perceptions of resource navigation experience, 2) patient perspectives on whether their food insecurity need is resolved or unresolved and why, and 3) facilitators and barriers to accessing food. The guide will be adjusted using an iterative process based on how participants in initial interviews understand the questions and how well the questions in the guide elicit the desired information from participants. The guide will be used to help format discussion, but free flowing lines of informative conversation will be pursued even when this means that other aspects of the interview guide are omitted or discussed in much less detail due to time constraints on the interviews. In-depth interviews will be conducted over the phone. It is anticipated that each interview will take approximately 30 minutes. Interviews will be scheduled at a time that is convenient for caregivers.

Study Subjects: Inclusion criteria for this research are that study participants: 1) were screened through the ANCHOR screening program at a pediatric ACN site or pediatric emergency department, 2) are caregivers of pediatric patients ages 0-19 years old, 3) screened positive for food insecurity, 4) did NOT screen positive for any other social need, 5) have a food insecurity need is marked as closed (either resolved or unresolved, and 6) speak English primarily.

Recruitment: 10-20 caregivers who screened positive for food insecurity will be recruited to participate in one-on-one in-depth telephone interviews using a semi-structured interview guide. Recruitment will take place via a brief phone call.

Informed Consent Process: Informed consent will be obtained from the caregiver for participation in an in-depth interview. Participants do not need to give signed consent to participate in this study and may give verbal consent.

Confidentiality of Study Data: All audiotaped interviews will be uploaded from digital recorders and stored on a secure server maintained by Columbia University. Only study personnel will have access to study folders on the secure server. Once uploaded to the server, all audio recordings will be permanently deleted from the recorders used to conduct the interviews. Interviews will be transcribed by a member of the study staff and de-identified. De-identified transcripts will be used in analysis. Representative quotes will be used to discuss key themes that emerge from the proposed research, but the identity of participants will be protected and only pseudonyms and non-identifying

information about respondents will be used to contextualize the quotes included in presentations and publications of this research.

Potential Risks: The biggest risk participants may face in completing this study is inconvenience associated with participation. There are no anticipated medical risks associated with participation in the proposed research. Other than inconvenience, the only other anticipated risk is breach of confidentiality that might reveal to non-study personnel the identity of a given study participant.

Data and Safety Monitoring:
NA

Payment and Remuneration: Each participant will receive a $25 gift card to a pharmacy or big box store (e.g. Walgreens, CVS, Walmart) as remuneration for participation in the interview. Gift cards will be mailed to the participant's preferred address at the time of interview completion.

Potential Benefits: There are no anticipated direct benefits of participation in the proposed research for study participants apart from the fact that study participation will provide participants with an opportunity to share their thoughts and opinions on the topic under study. There is potential benefit of the proposed research for society insofar as the proposed research is likely to inform development of a food insecurity intervention.

Alternatives: Patients may choose not to be in this study.

Research at External Sites: Columbia University will be the only research site.

References:

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