CommunityRx-Hunger (CRx-H) Study Protocol
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Study Protocol

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CommunityRx for Hunger (CommunityRx-Hunger or CRx-H)

Study Protocol: Original Approved Version

Principal Investigator: Stacy Tessler Lindau, MD, MAPP

UCHICAGO IRB # 20-0324

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A. Introduction

A1. Background

Food insecurity is a prevalent, modifiable and overlooked determinant of health and health disparities along socioeconomic and racial lines in the U.S.[1-3] When a child becomes seriously injured or ill, the parent becomes a caregiver, responsible for managing the significant tasks of living and coping with a child's illness while also managing self- and family care.[4,5] Hunger due to food insecurity can compromise decision-making and communication. Food insecurity can cause shame about failing to meet an ill child's basic needs and is stigmatizing.[6-8] The higher burden of food insecurity among lower income caregivers is a potentially mutable factor that likely contributes to socioeconomic disparities in adult and child health; self-efficacy has been associated with both food insecurity[9,10] and lower SES,[11,12] and is emerging as a key factor on the causal pathway linking illness management and coping processes to caregiver and child health.[13,5]

The Centers for Medicare & Medicaid Services (CMS), the American Academy of Pediatrics (AAP) and others are calling for healthcare-based screening and intervention to address food insecurity, endorsing growing evidence about deleterious effects on health and healthcare.[14-17] The AAP, with the Food Research & Action Center (FRAC), provides a web-based Toolkit to support adoption of food insecurity interventions in the clinical setting.[18] Most caregivers and healthcare providers agree it is acceptable for providers to address food insecurity and other basic needs, yet physicians rarely do.[19-22] Barriers include provider concerns about compromising satisfaction with care by causing feelings of stigma and lack of knowledge about community resources to address food insecurity and other health-related social needs (HRSNs).[19,20]

The CommunityRx-Hunger (CRx-H) intervention, described in this program of research, is an adaptation of CommunityRx (CRx), a proven clinical solution that systematically matches people, using evidence-based algorithms, to nearby community resources for wellness, self-care and caregiving.[23] CRx-H targets two key management processes, identified in Grey and colleagues' Self- and Family Management of Chronic Conditions Framework,[24] that align both with the AAP/FRAC Toolkit recommendations[18] and routine hospital discharge workflows. The current study aims to pretest the administration of the intervention and data collection protocols to inform the design of a larger randomized controlled trial.

A2. Purpose

This study aims to improve adult and child health by sensitively intervening to support food insecure caregivers with a hospitalized child. The target population is racially and ethnically diverse with a very high rate of food insecurity. The overall objective of the proposed program of research is to evaluate the health and healthcare impact of CommunityRx-Hunger (CRx-H), a scalable self- and family management intervention for food insecure caregivers of hospitalized children. The long-term goal of this research program is to promote public health and reduce health disparities due to socioeconomic disadvantage.

The over-arching aims of the program of research are:

A3: Aim 1

Among caregivers of hospitalized children who screen positive for food insecurity, evaluate the effects of CRx-H versus usual care on self-efficacy (primary outcome), severity of caregiver and child food insecurity, adult and child nutrition and health, and child healthcare utilization (secondary outcomes).

A4: Aim 2

Among all caregivers of hospitalized children (food insecure and food secure), evaluate the effects of CRx-H versus usual care on caregiver satisfaction with care (primary outcome), caregiver and child health and caregiver stigma during hospitalization (secondary outcomes).

Findings will yield an understanding of how best to leverage a child's hospitalization to sensitively and effectively intervene to support food insecure caregivers. Results will inform whether and how CRx-H should be implemented in practice. This research will inform science, policy and practice in the rapidly growing field of healthcare interventions to address food insecurity and other health-related social needs.

This pretest study aims to identify optimal processes for administering the planned intervention and to optimize the efficiency and flow of baseline and follow-up survey administration and interval communications with participants. Findings from this pretest will be used to inform the larger randomized trial.

B. Study Design

B1. Overview

The first step in the proposed program of research is to pretest administration of the intervention and data collection procedures to inform the design of a larger randomized controlled trial (RCT). Interviewers will administer both in-person and telephone-based surveys. Human subjects involved in this pretest include 10 food insecure caregivers and 10 food secure caregivers (20 caregivers total) and the hospitalized child (20 children total) of these caregivers. All human subjects will be consecutively screened for inclusion and enrolled as described in Section H. Type and Number of Experimental Subjects. Following screening, participants will be assigned to the CommunityRx-Hunger intervention, described below.

B2. CommunityRx-Hunger Intervention

Caregivers will receive CRx-H in addition to usual care. Near the time when a child is being prepared for hospital discharge, the CRx-H intervention will be initiated by a member of the research team. The intervention will include: (a) a brief, structured educational intervention about the common non-medical needs of families after a child's hospitalization, including the problem of food insecurity in households with children (e.g., "Did you know that 1 in 5 US households with children are struggling to access and afford healthy food, or enough food to

support a healthy lifestyle?") and co-occurring needs, like housing, legal and financial assistance, and transportation, (b) delivery and review of a HealtheRx for nearby, vetted resources to address these needs (SNAP/WIC enrollment, food support, services to meet other basic needs), and (c) coaching on how to activate community resources and the community resource navigator (a member of the research team), including a series of automated text messages.

The proposed CommunityRx-Hunger intervention includes a proactive text messaging protocol; we will pretest the text messaging protocol to ensure its smooth operation. All caregivers will receive, in addition to the educational component and review of the HealtheRx, an initial text message (during the discharge process) and can reply "stop" at any time to prevent additional messages. During this pretest, the navigator will respond to text messages within 24 hours during regular work days and within 48 hours of weekends or holidays. Table 2 describes the frequency and content of the first week of automated text messages sent to caregivers in the CRx-H intervention who do not reply "stop." The content of these messages is based on a text messaging experiment conducted during the CMMI HCIA CRx study.

Table 2. Frequency and content of CRx-H automated text messages

Frequency	Time frame	Content
Once	During the discharge process	"When you were getting ready to leave the hospital with your child, you agreed to receive text messages from us. I'm Kelsey. I'm available to help you find resources in your area. Do you need help?"
Weekly	Between discharge and 30 days post discharge	"Hi, this is Kelsey from your child's hospital team. I'm checking in to make sure you have the food and other resources you need. Are there resources I can help you with? Reply or call 773-844-2219 for help."

Eligible caregivers enrolled in the pretest will participate in an in-person baseline survey during the child's index hospitalization and a telephone-based follow-up survey 7 days following the child's discharge. Surveys will elicit self-reported data in the following domains: caregiver sociodemographic characteristics (e.g., age, race/ethnicity, sex (measured by self-reported gender) employment, household composition), health and healthcare characteristics (e.g., at both the caregiver and child level: health, severity of food insecurity, and nutrition; at the child level: healthcare utilization), knowledge, attitudes, beliefs and experiences (e.g., caregiver self-efficacy, satisfaction with care, healthcare-related stigma, knowledge of food and other related resource supports), and resource use characteristics (e.g., use of food or other related resource supports, enrollment in SNAP/WIC, contact with Community Resource Navigator). Additionally, we will access, collect and analyze data from the child's electronic medical record (EMR) for recruiting and other research purposes, including analysis of healthcare utilization data. The pretest will yield observations to optimize EMR chart abstraction processes.

B3. Duration

The duration of this protocol is approximately 6 months. This will allow for enrollment of participants into the pretest of the intervention and administration of baseline and one week follow-up survey. This timeframe will also allow for preliminary data analysis and presentation of findings to our CommunityRx-Hunger Advisory Board for feedback and iteration of our trial design.

B4. Location

Research under this protocol will be conducted by researchers in the Department of Obstetrics and Gynecology at the University of Chicago (located at 5841 S. Maryland Ave., Chicago, IL, 60637) and the Comer Children's Hospital (located at 5721 S. Maryland Ave, Chicago, IL 60637). Additional research (e.g., data preparation and analyses) will be conducted in Dr. Stacy Lindau's research laboratory, located in the Medical Center 2050, rooms R-311 and R-315.

B5. Special Precautions

Protected health information (PHI) will be collected for research purposes and special precautions will be made to protect these data. We will identify new admissions to the children's hospital via the EMR, accessing the patient's name, medical record number and other, non-PHI information for recruitment of caregivers. In addition to the unique identifier applied by the REDCap computer assisted personal interviewing (CAPI) software, we will use caregiver's name and telephone number to facilitate scheduling and completion of the follow-up survey at one week. We will collect patient name and medical record number (MRN) in order to access the child's EMR. Because we will compensate caregivers for participation in the telephone-based follow-up survey, we will use the caregiver's name and address or email address for compensation payment purposes.

Because PHI will be accessed and collected for this program of research, there is a risk of loss of confidentiality. To protect confidentiality, we will implement a plan to protect data in all its forms from improper use and disclosure using HIPAA compliant policies and procedures; see Section N. Procedures to Maintain Confidentiality for more information.

B5. Experimental controls and use of placebos

This pretest does not employ the use of experimental controls or placebos.

B6. Type and number of experimental subjects

Human subjects involved in this pretest includes 20 caregivers of hospitalized children, including 10 food insecure caregivers and 10 food secure caregivers. Additionally, 20 children (of the enrolled caregiver) will be enrolled. All caregivers will be screened for inclusion by accessing the electronic medical record to identify new hospital admissions and patient ZIP code. Caregivers will be recruited for study participation within 72 hours of their child's admission. All caregivers in this pretest will be assigned to the CRx-H intervention. We will only enroll one caregiver per hospitalized child. If multiple caregivers identify as providing equal care to the child, we will randomly select one caregiver.

B7. Inclusion criteria:

- Resides in the 16 ZIP code primary service area geography
- Has access to a cell phone and provide the research interviewer with the cell phone number
- Agrees to receive text messages from the study
- Self-identifies as the primary caregiver of a child younger than 18 years of age admitted to Comer Children Hospital's general, intensive care, or transplant units.

B8. Exclusion criteria:

- Caregivers of hospitalized healthy newborns
- Caregivers of children who are admitted for less than 24 hours or who are expected at baseline to be hospitalized more than 30 days
- Children who are wards of the state and/or families currently under investigation by the Department of Children and Family Services (DCFS)

C. Statistical analysis

The purpose of this research is to pretest our intervention administration and data collection procedures. We will collect baseline and one week survey data. To this end, preliminary descriptive statistics will be used to summarize, overall and by study arm, sociodemographic characteristics and primary and secondary outcomes at each measured time point. The mean, standard deviation, median, and inter-quartile range will be generated for continuous variables; frequency counts and percentages will be generated for categorical variables. We will evaluate the pretest data for missingness, systematic item non-response, and out of range values and prepare our data management analytic code.

D. Safety and Monitoring

D1. Potential Risks and Benefits

This program of research involves no more than minimal risk or no more risk than is encountered in routine medical and psychological examinations. The risks of participation in this protocol include a potential loss of confidentiality or psychological or emotional discomfort associated with the interview questions. Every effort will be made to ensure subject confidentiality and that risks due to loss of confidentiality are minimal compared to the protocols in place to protect human subjects' data. To date, more than 113,000 individuals have participated in CommunityRx intervention studies with no known adverse events or breaches of confidentiality. All data collected from human subjects will be collected using standard survey or abstraction procedures. Whenever possible, the surveys will be conducted in a private room in the clinical setting or via telephone. Psychological and/or emotional discomfort associated with the survey questions is possible. Subjects will be informed that they can decline to answer any question and can terminate the survey at any time. Explanatory and debriefing statements will be included in the surveys to help the interviewer monitor and respond appropriately to discomfort, including termination of the survey if necessary. Alternatives to participation include not participating in the research;

participation is completely voluntary. Additional protections against these risks are described in Sections M and N, Informed Consent and Confidentiality, respectively.

There is no direct benefit to human subjects involved in the research beyond the information provided during usual care and the CommunityRx-Hunger intervention. Participants, however, may gain personal satisfaction in contributing to research to address the humanitarian issue of food insecurity. Potential risks include a breach of confidentiality and are both minimal and reasonable in relation to the anticipated benefits to research participants and hospitalized children.

C. Monitoring of Safety

The proposed data collection presents no more than minimal risk or no more risk than is encountered in routine medical or psychological examinations. As described, no surveys will be conducted without explicit documentation of informed consent/assent and individuals will be provided with appropriate information about confidentiality when enrolling in the study and will indicate acceptance of these risks upon consent. Because we are not proposing a multi-site clinical trial, a Phase III trial, or a drug study, this study will not employ a Data and Safety Monitoring Board. Procedures are in place to ensure confidentiality and provide full informed consent as discussed below.

The Lindau Lab has listed the Principal Investigator and study coordinator phone numbers on all study correspondence and forms. The purpose of the phone numbers is to provide respondents with a number to call if they have questions about any aspect of the study. During the study, should a subject express intent to harm themselves or others, we will contact a health or public safety professional. We will give only the subject's name, contact information, and why we feel he or she is at risk of harming themselves or others. This report will not be linked to his or her survey information. Subjects have the right to refuse to speak to the mental health professional. If the interview procedure results in the observation of elder or child abuse, all research personnel will act in compliance with Illinois State law in regards to mandatory reporting of abuse.

Research staff will strictly adhere to the procedures for enrolling participants and collecting data as outlined by the investigators. At the conclusion of the study, all hard copy materials, with the exception of the consent copies, will be destroyed and electronic files will be deleted or archived in password-protected files. Informed consent documents will be stored for at least 3 years following the completion of the study (defined by the last publication related to the study). Due to the small sample sizes associated with the pretest, these data will not be made publicly available.

D2. Payment

Caregivers enrolled in the pretest will receive $15 in compensation for completion of the baseline interview (approximately 25 minutes) and $25 in compensation for completion of the one-week follow-up survey (approximately 30 minutes). Compensation will not be prorated for partial completion of the baseline and one-week follow-up surveys but every

effort will be made to allow for ample time to complete the surveys and participants can refuse to answer any question they do not want to answer. Participation is voluntary.

D3. Informed Consent

We will obtain written informed consent from all caregivers enrolled in the pretest. Because we propose to access, view and analyze data from the hospitalized child's electronic medical record, we will obtain assent from children between the ages of 7-17; we are requesting a waiver of assent for children under 7 years of age. Caregivers will be asked to also provide permission for the hospitalized child to participate in this research in this way. Because this study poses no more than minimal risk, permission from only one parent may be required. Research interviewers will guide caregivers through the informed consent document, providing statements to address: that the study involves research; the study's purpose, duration, procedures followed, risks and benefits, alternatives to participation, and confidentiality of records; to whom they should direct questions or contact in case of research-related injury; and statements regarding voluntary participation, refusal to participate, and discontinuation of participation. The researcher will provide adequate time for the potential subject to ask questions and will answer these questions before requesting the caregiver's signature. The informed consent process for caregivers enrolled in the pretest will take place in or near the patients' hospital room following recruitment, according to caregiver preference. We will obtain the caregivers signature to signify consent and on the same document, their permission. We will also document the provision of assent of the child between 7-17 years.

No surveys with human subjects will be conducted without explicit documentation of the informed consent process executed with each participant. Informed consent/assent documents will be iterated using approved consent documents from the recently completed CRx pragmatic clinic trial of patients (N=411) receiving care in the University of Chicago's Primary Care Group and Emergency Departments. The consent documents for that study were adapted from consent documents developed in collaboration with a literacy consultant and members of the community. Consent forms will only be available in English; forms will be printed in large font and written in easily understandable language. Consent documents will be printed in duplicate, with a copy each going to the respondent and to Lindau Laboratory receipt control. Paper forms will be kept secure in locked cabinets in locked rooms. Consent documents will be received at the Lindau Laboratory by Ms. Abramsohn, Director of Research and Data Governance, to confirm participation in the study for data collection, validation, and data analysis purposes. A final copy of all consent/assent documents will be submitted to the IRB for review and approval.

D5. Confidentiality

The proposed research with human subjects, as presented above, presents no more than minimal risk or no more risk than is encountered in routine psychological examinations. Any potential risks may be due to emotional or psychological discomfort associated with the surveys or a breach of confidentiality. As described in detail above, no surveys will be completed without explicit documentation of informed consent and individuals will be

provided appropriate information about privacy and confidentiality when enrolling in the study and will indicate acceptance of these risks upon consent.

The Lindau Laboratory has strict and secure procedures for protecting against and minimizing potential risks to human subjects' data. All survey data will be entered directly into REDCap, a password-protected database managed by the Center for Research Informatics (CRI) at the University of Chicago (cri.uchicago.edu). CRI provides a HIPAA-compliant data storage and computing environment that has achieved security accreditation by the Biological Sciences Division's Risk Management Group. Depending on connectivity capabilities at the time of the survey, data will either be saved to the secure servers in the Department of Ob/Gym at the University of Chicago via a secure wireless connection, or research staff will connect computers manually to Department of Ob/Gym servers at the end of each collection day. All devices used by researchers to collect or access research files will be encrypted. Only approved research analysts in the Lindau Laboratory will have access to files that link participant's PHI to their unique identifiers for the purposes of creating de-identified and limited datasets.

All hard copies of project materials will be stored in locked file cabinets in locked offices at University of Chicago. Servers in the University of Chicago Department of Ob/Gym are protected through a combination of a Microsoft-based firewall technology and the physical barrier of a Linksys router that is installed between the server and its internet connection. Laptop computers used to collect data will be encrypted and password protected. All data transmitted to secure servers will be encrypted. Analytic files will be de-identified prior to analysis, unless a limited dataset is needed to complete the analysis. Limited datasets will only be accessed by approved analysts on this IRB protocol, and will not be shared. Per the HIPAA Privacy Rule, any analytic datasets will limit the use or disclosure of PHI to the minimum necessary, if any at all, to accomplish the intended research purposes. These controls meet or exceed the strictness of practices legislated and enforced by the University of Chicago Biological Sciences Division and hospitals for protected health information.

Procedures are in place to ensure confidentiality and provide informed consent as discussed above. Numeric coding of surveys/interviews and secure containment of files that link participant's responses from PHI will also minimize this risk. Finally, the Lindau Laboratory will provide a contact phone number that will be included on all study correspondence and forms. The purpose of this phone number is to provide respondents with a single number to call if they have questions about any aspect of the study.

D6. Recruiting Methods

Researchers in the Lindau Laboratory will access electronic medical record (EMR) registration data to identify potential caregivers of newly admitted pediatric patients for inclusion in the pretest of this intervention based on ZIP code. Research interviewers will identify the hospital room number for the pediatric patient and, with permission of the patient's physician (to be obtains be Drs. Lindau or Burnet) approach potentially eligible caregivers (identified by a yellow wrist band given to caregivers upon admission) in the child's hospital room or unit (if admitted to the intensive care or transplant units). Research

interviewers will explain that the caregiver may be eligible for a research study and, if interested, further screen for eligibility.

D7. Notification of physician

Notification of the hospitalized child's treating physician for permission to enroll will occur using a multi-pronged approach. First, we will educate all treating physicians and residents working in the target units about the study during the pretesting phase and give treating physicians the opportunity to opt out of study participation. Secondly, we will use these education sessions to identify how treating physicians wish to be contacted for permission (e.g., via text, email, phone, text page or through the electronic medical record system). We will use that communication as documentation of treating physician permission. Lastly, we will also educate nursing staff about the study. Nurse engagement will be helpful should we need to reach a treating physician during clinical rounds.

D8. Anticipated coordination

Inter-departmental faculty coordination will be facilitated by regular research meetings attended by Dr. Lindau (PI) and other Co-Investigators and key personnel. Faculty will also regularly communicate by email and phone calls as necessary.

D9. Pregnancy test

Not applicable.

D10. Exclusion of women, minorities and/or children

This study will not exclude women, minorities or children.

D11. Drugs

No drugs will be given to subjects as part of this study.

E. BIBLIOGRAPHY

1. Coleman-Jensen A, Rabbitt M, Gregory C, Singh A. Household Food Security in the United States in 2015. Washington, D.C.: U.S. Department of Agriculture; 2016. Report No.: ERR-215.

2. Seligman HK, Schillinger D. Hunger and socioeconomic disparities in chronic disease. N Engl J Med. 2010 Jul 1;363(1):6–9. PMID: 20592297

3. Gundersen C, Ziliak JP. Food insecurity and health outcomes. Health Aff (Millwood). 2015 Nov;34(11):1830–1839. PMID: 26526240

4. Gibson MJ, Kelly KA, Kaplan AK. Family Caregiving and Transitional Care: A Critical Review. Family Caregiver Alliance, National Center on Caregiving; 2012.

5. Grey M, Schulman-Green D, Knafl K, Reynolds NR. A revised Self- and Family Management Framework. Nurs Outlook. 2015 Mar;63(2):162–70. PMID: 25771190

6. Bruce JS, De La Cruz MM, Moreno G, Chamberlain LJ. Lunch at the library: examination of a community-based approach to addressing summer food insecurity. Public Health Nutr. 2017 Jun;20(9):1640–1649. PMID: 28318465

7. Palakshappa D, Doupnik S, Vasan A, Khan S, Seifu L, Feudtner C, Fiks AG. Suburban Families' Experience With Food Insecurity Screening in Primary Care Practices. Pediatrics. 2017 Jul;140(1). PMID: 28634248

8. Purdam K, Garratt EA, Esmail A. Hungry? Food insecurity, social stigma and embarrassment in the UK. Sociology. 2016 Dec;50(6):1072–1088.

9. Martin KS, Colantonio AG, Picho K, Boyle KE. Self-efficacy is associated with increased food security in novel food pantry program. SSM - Popul Health. 2016 Dec;2:62–67. PMCID: PMC5757945

10. Kamimura A, Jess A, Trinh HN, Aguilera G, Nourian MM, Assasnik N, Ashby J. Food Insecurity Associated with Self-Efficacy and Acculturation. Popul Health Manag. 2016 Apr 28;20(1):66–73. PMID: 27124517

11. Tucker-Seeley RD, Mitchell JA, Shires DA, Modlin CS. Financial hardship, unmet medical need, and health self-efficacy among African American men. Health Educ Behav. 2015 Jun;42(3):285–292. PMCID: PMC4437974

12. Boardman JD, Robert SA. Neighborhood Socioeconomic Status and Perceptions of Self-Efficacy. Sociol Perspect. 2000 Mar 1;43(1):117–136.

13. Churchill SS, Kieckhefer GM. One Year Follow-up of Outcomes from the Randomized Clinical Trial of the Building on Family Strengths Program. Matern Child Health J. 2018 Feb 10;1–9. PMID: 29429134

14. Alley DE, Asomugha CN, Conway PH, Sanghavi DM. Accountable Health Communities - Addressing social needs through Medicare and Medicaid. N Engl J Med. 2016 Jan 7;374(1):8–11. PMID: 26731305

15. Council on Community Pediatrics, Committee on Nutrition. Promoting Food Security for All Children. Pediatrics. 2015 Nov;136(5):e1431-1438. PMID: 26498462

16. Billioux A, Verlander K, Anthony S, Alley DE. Standardized screening for health-related social needs in clinical settings: The Accountable Health Communities screening tool. [Internet]. Washington, D.C.: National Academy of Medicine; 2017. Available from: https://nam.edu/wp-content/uploads/2017/05/Standardized-Screening-for-Health-Related-Social-Needs-in-Clinical-Settings.pdf

17. Pooler J, Levin M, Hoffman V, Karva F, Lewin-Zwedling A. Implementing Food Security Screening and Referral for Older Patients in Primary Care: A Resource Guide and Toolkit [Internet]. AARP Foundation; 2016 Nov. Available from: http://www.aarp.org/content/dam/aarp/aarp_foundation/2016-pdfs/foodsecurityscreening_quickguide.pdf

18. Addressing Food Insecurity: A Toolkit for Pediatricians [Internet]. Washington, D.C.: Food Research & Action Center; 2017 Feb. Available from: http://frac.org/aaptoolkit

19. Garg A, Butz AM, Dworkin PH, Lewis RA, Serwint JR. Screening for basic social needs at a medical home for low-income children. Clin Pediatr (Phila). 2009 Jan;48(1):32–36. PMID: 18566347

20. Barnidge E, LaBarge G, Krupsky K, Arthur J. Screening for food insecurity in pediatric clinical settings: Opportunities and barriers. J Community Health. 2016 Aug 4;1–7. PMID: 27492774

21. Essel K, Burke MP, Weissman M, Dietz W. Exploring Food Insecurity Screening and Referral Practices of Pediatric Providers in Metropolitan Washington, DC. FASEB J. 2017 Apr 1;31(1 Supplement):297.7-297.7.

22. Colvin JD, Bettenhausen JL, Anderson-Carpenter KD, Collie-Akers V, Chung PJ. Caregiver opinion of in-hospital screening for unmet social needs by pediatric residents. Acad Pediatr. 2016 Mar;16(2):161–167. PMCID: PMC4794116

23. Lindau ST, Makelarski J, Abramsohn E, Beiser DG, Escamilla V, Jerome J, Johnson D, Kho AN, Lee KK, Long T, Miller DC. CommunityRx: A population health improvement innovation that connects clinics to communities. Health Aff (Millwood). 2016;35(11). PMID: 27834242

24. Grey M, Knafl K, McCorkle R. A framework for the study of self- and family management of chronic conditions. Nurs Outlook. 2006 Oct;54(5):278–286. PMID: 17027605

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Food insecurity is a prevalent, modifiable and overlooked determinant of health and health disparities along socioeconomic and racial lines in the U.S.[1-3] When a child becomes seriously injured or ill, the parent becomes a caregiver, responsible for managing the significant tasks of living and coping with a child's illness while also managing self- and family care.[4,5] Hunger due to food insecurity can compromise decision-making and communication. Food insecurity can cause shame about failing to meet an ill child's basic needs and is stigmatizing.[6-8] The higher burden of food insecurity among lower income caregivers is a potentially mutable factor that likely contributes to socioeconomic disparities in adult and child health; self-efficacy has been associated with both food insecurity[9,10] and lower SES,[11,12] and is emerging as a key factor on the causal pathway linking illness management and coping processes to caregiver and child health.[13,5]

The Centers for Medicare & Medicaid Services (CMS), the American Academy of Pediatrics (AAP) and others are calling for healthcare-based screening and intervention to address food insecurity, endorsing growing evidence about deleterious effects on health and healthcare.[14-17] The AAP, with the Food Research & Action Center (FRAC), provides a web-based Toolkit to support adoption of food insecurity interventions in the clinical setting.[18] Most caregivers and healthcare providers agree it is acceptable for providers to address food insecurity and other basic needs, yet physicians rarely do.[19-22] Barriers include provider concerns about compromising satisfaction with care by causing feelings of stigma and lack of knowledge about community resources to address food insecurity and other health-related social needs (HRSNs).[19,20]

The CommunityRx-Hunger (CRx-H) intervention, described in this program of research, is an adaptation of CommunityRx (CRx), a proven clinical solution that systematically matches people, using evidence-based algorithms, to nearby community resources for wellness, self-care and caregiving.[23] CRx-H targets two key management processes, identified in Grey and colleagues' Self- and Family Management of Chronic Conditions Framework,[24] that align both with the AAP/FRAC Toolkit recommendations[18] and routine hospital discharge workflows. The current study aims to pretest the administration of the intervention and data collection protocols to inform the design of a larger randomized controlled trial.

A2. Purpose

This study aims to improve adult and child health by sensitively intervening to support food insecure caregivers with a hospitalized child. The target population is racially and ethnically diverse with a very high rate of food insecurity. The overall objective of the proposed program of research is to evaluate the health and healthcare impact of CommunityRx-Hunger (CRx-H), a scalable self- and family management intervention for food insecure caregivers of hospitalized children. The long-term goal of this research program is to promote public health and reduce health disparities due to socioeconomic disadvantage.

The over-arching aims of the program of research are:

A3. Aim 1

Among caregivers of hospitalized children who screen positive for food insecurity, evaluate the effects of CRx-H versus usual care on self-efficacy (primary outcome), severity of caregiver and child food insecurity, adult and child nutrition and health, and child healthcare utilization (secondary outcomes).

A4. Aim 2

Among all caregivers of hospitalized children (food insecure and food secure), evaluate the effects of CRx-H versus usual care on caregiver satisfaction with care (primary outcome), caregiver and child health and caregiver stigma during hospitalization (secondary outcomes).

A4. Aim 3

Assess food insecure caregivers' perspectives about: (a) their experiences with and attitudes toward the CRx-H intervention, (b) the role of stigma as a barrier to self- and family management, and (c) how healthcare providers can sensitively and effectively intervene to support food insecure caregivers. This aim will inform implementation science for CRx-H and other healthcare-based interventions that address stigmatizing social conditions.

Findings will yield an understanding of how best to leverage a child's hospitalization or similar clinical encounter to sensitively and effectively intervene to support food insecure caregivers. Results will inform whether and how CRx-H should be implemented in practice. This research will inform science, policy and practice in the rapidly growing field of healthcare interventions to address food insecurity and other health-related social needs.

The pretest of this study aims to identify optimal processes for administering the planned intervention and to optimize the efficiency and flow of baseline and follow-up survey administration and interval communications with participants. This pretest also aims to understand our feasibility to conduct participant recruitment, enrollment, intervention delivery and data collection remotely given the shifting healthcare landscape in the current COVID-19 pandemic. Findings from this pretest will be used to inform the larger randomized trial, which aims to improve adult and child health by sensitively intervening to support food insecure caregivers with a hospitalized child.

B. Study Design

B1. Introduction

The first step in the proposed program of research is to pretest the double-blind, randomized controlled trial procedures and administration of the intervention and data collection procedures to inform the design of a larger randomized controlled trial (RCT). We will also test the feasibility of enrolling participants into a brief, qualitative survey at the end of their pretest participation. This interview will assess caregivers' perspectives on the impact of

COVID-19 pandemic on their child's health, caregiving and self-care and mimic the recruitment process used in the larger trial. Following completion of the pretest, we will implement a larger double-blind, randomized controlled trial using procedures described below.

Interviewers will administer telephone-based surveys; self-administration of a web-based follow-up survey will also be offered. We will enroll 660 caregivers (both food secure and food insecure, 20 caregivers enrolled in the pretest and 640 caregivers enrolled in the larger RCT). We will also attempt to enroll the child patient insofar as to view and collect dates of specific doctor's visits from their electronic medical record. All human subjects will be consecutively screened for inclusion and enrolled as described in Section P. Recruiting Methods. Following screening for eligibility (including food security status), consent and baseline survey collection, participants will be randomized to either usual care or usual care plus the CommunityRx-Hunger intervention using REDCap functionality. Once randomized, an electronic alert will be sent to the Clinical Trials Manager to assign an interventionist. The interventionist will contact the potential participant by phone or text to schedule a time to deliver the CommunityRx-Hunger intervention remotely via web-conferencing technology (e.g., Zoom, FaceTime) on their personal cell phone or an iPad or tablet. If an iPad or tablet is needed, researchers in the Lindau Laboratory will communicate with staff members in Child Life Services (CLS) to deliver iPads/tablets to the caregiver in the hospital, and provide a brief training on how to use the iPad/tablet and get connected to the web-based conferencing technology. Researchers in the Lindau Lab will also print a hard copy HealtheRx to networked printers in the CLS offices; Specialists will place this hard copy HealtheRx in the patient's paper chart for delivery at discharge. Child Life Services sees every child in the hospital as part of their usual daily operations and provides iPads/tablets to patients for their use. A letter of support from Jennie Ott, MS, Director of Child Life Services, describing their engagement in this study, is enclosed with this protocol. Usual care is described below in Section G. Use of Controls or Placebos.

B2. CommunityRx-Hunger (CRx-H) Intervention

Caregivers will receive CRx-H in addition to usual care. The intervention will include: (a) a brief, structured educational intervention about the common non-medical needs of families after a child's hospitalization, including the problem of food insecurity in households with children (e.g., "Many families with children find it hard to get enough healthy food. A child's hospital stay can make it even harder.") and co-occurring needs, like housing, legal and financial assistance, and transportation, (b) delivery and review of a HealtheRx for nearby, vetted resources to address these needs (SNAP/WIC enrollment, food support, services to meet other basic needs), and (c) coaching on how to activate community resources and the community resource navigator (a member of the research team), including a series of automated text messages.

Upon discharge, to "boost" the intervention delivered earlier in the stay by a researcher, the discharging nurse will hand a copy of the printed HealtheRx with the other printed discharge information. Of note, the HealtheRx has been delivered by hundreds of UCM nurses during discharge encounters with tens of thousands of patients and parents/caregivers in the UCM

pediatric and adult emergency department settings during two prior CommunityRx trials (IRB13-0771 and IRB14-0358). We know from these prior studies that nursing involvement will not negatively impact nurses' daily clinical workflows or nursing operations.

Two nurse researchers (Emily Cheng and Katelyn DeAlmeida) will oversee the delivery of the booster and liaise with the Lindau Lab to track fidelity of booster delivery. Researchers in the Lindau Lab will generate and print the HealtheRx for Child Life Specialists who will place it in the same folder outside the patient room where the nurses pick up the other paper discharge materials. In addition to handing caregivers the printed HealtheRx, the nurse may remind parents/caregivers that they will receive a text message from the navigator and that they can contact the navigator for help with resources. Nurses handing out the HealtheRx will not be serving in a research role. Nursing staff routinely provide supportive community resource information to patients and families as a function of their routine clinical discharge activities, using a range of information delivery methods that are neither standard, systematic nor particularly personalized to resources in an individual's community. When discharging patients whose parent/caregiver is enrolled in this study, the nurse will use the personalized HealtheRx as the mechanism for providing this information as a substitute for other strategies. Nurses will not be restricted in any way from sharing other information or using other modes of information delivery about supportive resources. Ms. Cheng and DeAlmeida have completed their Human Subjects training and will be added to the study protocol. A letter of support for this engagement from Emily Chase, PhD, RN (Senior VP, Patient Care Service and Chief Nursing Officer, UCM) is enclosed with this protocol.

In addition to the printed HealtheRx discussed during intervention delivery, the HealtheRx will be texted and emailed to the participant within 24 hours of intervention delivery, and again upon discharge as a booster of the intervention.

All caregivers randomized to the intervention will receive, in addition to the educational component and review of the HealtheRx, a series of proactive text messages to which the caregiver can reply "stop" at any time to prevent additional messages. The navigator will respond to text messages within 24 hours during regular work days and within 48 hours of weekends or holidays. The content of these messages is based on a text messaging experiment conducted during the CMMI HCIA CRx study; text message content will be submitted with this proposal for review.

All caregivers enrolled in this study will receive text messages to support scheduling and reminders for follow-up surveys.

All caregivers will complete the baseline survey during the child's index hospitalization and follow-up surveys at the following intervals following the child's discharge:

7 days
one month
three months
six months
12 months

In between the six month and 12 month survey, we will send caregivers a "check-in" text message reminding them of their 12 month survey and confirming their contact information.

Caregivers will be given the following options for completing the follow-up surveys:

1) over the phone during one session,
2) over the phone during multiple sessions
3) using a web-based survey.

Web-based surveys will be administered using REDCap.

Surveys will elicit self-reported data in the following domains:

caregiver sociodemographic characteristics (e.g., age, race/ethnicity, sex and gender, employment, household composition)

health and healthcare characteristics (e.g., at both the caregiver and child level: health, severity of food insecurity, and nutrition; at the child level: healthcare utilization)

knowledge, attitudes, beliefs and experiences (e.g., caregiver self-efficacy, satisfaction with care, healthcare-related stigma, knowledge of food and other related resource supports)

resource use characteristics (e.g., use of food or other related resource supports, enrollment in SNAP/WIC, contact with Community Resource Navigator).

Additionally, we will access, collect and analyze data from the child's electronic medical record (EMR) for recruiting and other research purposes, including analysis of healthcare utilization data. The pretest will yield observations to optimize EMR chart abstraction processes. If needed to supplement healthcare utilization data, we will obtain health insurance claims for the child. The informed consent/assent process will inform study participants of the rationale for accessing these data and request participants' permission to do so.

Following completion of their last follow-up survey, a purposeful sample of participants will be invited to complete an in-depth qualitative interview. Caregivers will be informed about the purpose of the study and, if interested, undergo informed consent (described below in Section M. Informed Consent). The interview administered during pretest will elicit caregivers' 1) perspectives on the impact of COVID-19 stay-at-home order on caregiving and self-care; 2) experiences with virtual or remote service delivery; and 3) comfort with web-based technologies for communication. The interview administered following the larger RCT will elicit caregivers' perspectives about: (a) their experiences with and attitudes toward the CRx-H intervention, (b) the role of stigma as a barrier to self- and family management, and (c) how healthcare providers can sensitively and effectively intervene to support food insecure caregivers.

To assess the dynamics of food security status over time, especially during a global pandemic, we are also going to evaluate food security scores and other screening data (e.g., parent and child patient age, ZIP code, dates of hospital admission and discharge, etc.) among all caregivers screened for inclusion (but perhaps not enrolled) in the study.

B3. Duration

The duration of this protocol is approximately four years. This will allow for ongoing recruitment of participants into the study and administration of baseline and all follow-up surveys and interviews. This timeframe also allows for data analysis and manuscript development and ongoing presentation of findings to our CommunityRx-Hunger Advisory Board for feedback.

B4. Location

Research under this protocol will be conducted by researchers in the Department of Obstetrics and Gynecology at the University of Chicago (located at 5841 S. Maryland Ave., Chicago, IL, 60637) and the Comer Children's Hospital (located at 5721 S. Maryland Ave, Chicago, IL 60637). Additional research (e.g., data preparation and analyses) will be conducted in Dr. Stacy Lindau's research laboratory, using networked computers located in the Medical Center 2050, rooms R-311 and R-315.

B5. Special Precautions

Protected health information (PHI) will be collected for research purposes and special precautions will be made to protect these data. We will identify new admissions to the children's hospital or Day Treatment Rooms via the EMR, accessing the patient's name, medical record number, certain dates (e.g., date of admission or appointment, anticipated date of discharge), caregiver name and contact information (often provided in the Demographics section of the EMR) and other, non-PHI information for recruitment of caregivers. In addition to the unique identifier applied by the REDCap computer assisted personal interviewing (CAPI) software, we will use caregiver's name, telephone number and email address to facilitate scheduling and completion of the follow-up surveys. We will ask participants to provide us with an alternative contact (e.g., name, phone number, email address) that we can reach out to if we should lose contact with the enrolled caregiver. We will ask participants to tell this person that they have listed them as an alternative contact for this study. We will collect patient name and medical record number (MRN) in order to access the child's EMR. From EMR data, we will abstract healthcare utilization data (e.g., doctor's visits, hospitalizations, emergency department visits) and access the child's health insurance payer and unique beneficiary identification to obtain their health insurance claims, if needed. Because we will compensate caregivers for their participation, we will use the caregiver's email and mailing address for compensation payment purposes.

Certain survey data elements collected in the REDCap database will be sent securely to Mosio, a secure text messaging platform, to facilitate the proactive text messaging protocol and manage survey scheduling and reminders for all participants and NowPow, a

systematic resource referral platform, to generate the HealtheRx for intervention participants. Elements of PHI sent to Mosio include the participant's name, telephone number and certain dates (e.g., date of study enrollment, date of discharge). Elements of PHI sent to NowPow to generate a personalized HealtheRx include: participant name, participant home address, date of birth and other non-PHI data elements. Data will be securely transferred from REDCap to Mosio and NowPow through a custom secure integration created by the Center for Research Informatics.

Qualitative interviews will be audio recorded and transcribed using AWS Transcribe by Amazon. AWS Transcribe has been reviewed by the University of Chicago Biological Sciences Division's Information Security Office and approved for this use. Interviews will be de-identified upon transcription.

Because PHI will be accessed and collected for this program of research, there is a risk of loss of confidentiality. To protect confidentiality, we will implement a plan to protect data in all its forms from improper use and disclosure using HIPAA compliant policies and procedures; see Section N. Procedures to Maintain Confidentiality for more information.

B6. Use of SFTP Server

NowPow will transfer files to the Lindau Lab by uploading them via Secure File Transfer Protocol (SFTP) to a dedicated location on a secure server; the files will then be retrieved by personnel in the Lindau Lab. All files will be end-to-end encrypted using a public RSA key generated by the Lindau Lab.

The SFTP server is maintained by the Research Computing Group in the Department of Public Health Sciences (Ryan Carter, Systems Administrator). It is located in a secure server room within the Billings Hospital building. The room is a dedicated server room with raised floor, redundant cooling and appropriate power and fire suppression systems. Access to the room is controlled and monitored via keycard, and a video surveillance system is used to continuously monitor access from within. In addition to machines belonging to Public Health Sciences, the room also houses systems belonging to the fMRI Unit and the Cancer Center. Only systems administrators from these three groups have access.

The SFTP server is located on a dedicated machine running only the SFTP service. All remote access to the SFTP server (both user and administrator access) requires key-based authentication (password authentication is disabled). The server is configured to place all users in their own "chrooted jail" upon login which strongly limits their access to a single root directory (i.e., the system can no longer reference paths outside that directory). In this case, this will be a dedicated directory created for use by NowPow and the Lindau Lab. Backups are encrypted and stored in a secure, physically separate location within the hospital. Backups are transferred to that location electronically. At no time are backups stored on portable media (e.g., tape or USB drives) or taken off-site.

B7. Experimental controls and use of placebos

Caregivers in this study will be randomized to either usual care or usual care plus the CommunityRx-Hunger intervention.

Caregivers randomized to usual care will receive information in the standard "Caregiver FYI Admissions Packet" from hospital admission staff about all available retail food options in the hospital and the self-serve food pantries operated by Feed1st. Due to the COVID-19 pandemic, availability and information about food resources in and around the hospital is changing rapidly. We will continue to work closely with Comer staff to keep this information up to date and posted in various places. In addition to food resources, this packet includes information about visiting hours, parking, hospital amenities, safety restrictions, and patient/caregiver rights and responsibilities. The Feed1st pantries are listed as a food resource for families in need of "free, nutritious food items." Signage in the Feed1st pantries include information for a Community Resource Navigator. Usual care also includes referral to social work according to the discretion of the healthcare team. Similarly, caregivers of patients seeking care in the Day Treatment Rooms will receive information about food resources around the hospital and have access to the Feed1st pantries and referral to social work as needed.

B7. Type and number of experimental subjects

Caregivers will be approached for enrollment using the methods described below in Section P. Recruiting Methods. All caregivers will be screened for inclusion by accessing the electronic medical record to identify new hospital admissions and patient ZIP code. Caregivers will be recruited for study participation within 72 hours of their child's admission. We will enroll up to 660 caregivers (20 caregivers enrolled for pretesting and 640 caregivers enrolled in the full RCT), and, if possible, the hospitalized child. We will only enroll one caregiver per hospitalized child. If multiple caregivers identify as providing equal care to the child, we will randomly select one caregiver.

B8. Inclusion criteria

- Speaks either English or Spanish
- Resides in the target ZIP code geography
- Has access to a cell phone and provide the research interviewer with the cell phone number
- Agrees to receive text messages from the study
- Self-identifies as the primary caregiver of a child younger than 18 years of age admitted to Comer Children's Hospital or for treatment in the Day Treatment Rooms.

B9. Exclusion criteria

- Minor caregivers who are not emancipated minors according to Illinois State law
- Non-parental minor caregivers
- Caregivers of hospitalized healthy newborns
- Caregivers of children who are admitted for less than 24 hours
- Caregivers of children hospitalized at that time with a diagnosis of disordered eating

C. Statistical Plan

We will collect screening, baseline and follow-up survey data. To this end, descriptive statistics will be used to summarize, overall and by study arm, sociodemographic characteristics and primary and secondary outcomes at each measured time point. The mean, standard deviation, median, and inter-quartile range will be generated for continuous variables; frequency counts and percentages will be generated for categorical variables. We will evaluate the data for missingness, systematic item non-response, and out of range values and prepare our data management analytic code. The main analyses will follow the principle of intent-to-treat. Additional a priori quantitative analyses will be conducted as needed to answer the research questions.

Qualitative interview data will be systematically collected and analyzed using directed content analysis.[25] Directed content analysis uses findings from extant literature to ask pointed questions about the concept under study and to structure coding of the qualitative data. We will operationally define codes in a codebook prior to data analysis. Initial analysis will begin with a full read of the interview transcripts for, upon first impression, instances of textual data that align with the codes in the codebook. Actual coding of textual data will occur upon second pass of the transcripts, using the codebook. Any textual data that were identified in the first-pass read of the transcript but not coded using the codebook will be given a new code. Two experienced qualitative researchers, Dr. Jessica Jerome (who has completed Human Subjects training and will be added to the IRB protocol) and Emily Abramsohn, MPH, will use ATLAS.ti[26] to independently code and analyze the qualitative data. After analysis of the first 5 interviews, using the principles of theoretical sampling,[27] both the sample strata and the interview guide will be evaluated and, if needed, revised to ensure compatibility with emerging theory about the self-management intervention. Drs. Lindau and Lowder, also experienced qualitative analysts, will read and code a sub-set of the transcripts and contribute their clinical expertise in interpretation of qualitative data. They will serve as adjudicators when consensus cannot be reached by the two primary coders. Based on our experience with several prior qualitative studies, interviews with 24 food insecure caregivers will be sufficient to reach theoretical saturation.[28, 29]

D. Safety and Monitoring

D1. Potential risks and benefits

This program of research involves no more than minimal risk or no more risk than is encountered in routine medical and psychological examinations. The risks of participation in this protocol include a potential loss of confidentiality or psychological or emotional discomfort associated with the survey or interview questions. Every effort will be made to ensure subject confidentiality and that risks due to loss of confidentiality are minimal compared to the protocols in place to protect human subjects' data. To date, more than 113,000 individuals have participated in CommunityRx intervention studies with no known adverse events or breaches of confidentiality. All data collected from human subjects will be

collected using standard survey or abstraction procedures. The surveys will be conducted via telephone or with a web-based survey link. Psychological and/or emotional discomfort associated with the survey questions is possible. Subjects will be informed that they can decline to answer any question and can terminate the survey or interview at any time. Explanatory and debriefing statements will be included in the surveys and interviews to help the interviewer monitor and respond appropriately to discomfort, including termination of the survey or interview if necessary. Alternatives to participation include not participating in the research; participation is completely voluntary. Additional protections against these risks are described in Sections M and N, Informed Consent and Confidentiality, respectively.

There is no direct benefit to human subjects involved in the research beyond the information provided during usual care and the CommunityRx-Hunger intervention. Participants, however, may gain personal satisfaction in contributing to research to address the humanitarian issue of food insecurity. Potential risks include a breach of confidentiality and are both minimal and reasonable in relation to the anticipated benefits to research participants and hospitalized children.

D2. Monitoring of safety

The proposed data collection presents no more than minimal risk or no more risk than is encountered in routine medical or psychological examinations. As described, no surveys will be conducted without explicit documentation of informed consent/assent and individuals will be provided with appropriate information about confidentiality when enrolling in the study and will indicate acceptance of these risks upon consent. Because we are not proposing a multi-site clinical trial, a Phase III trial, or a drug study, this study will not employ a Data and Safety Monitoring Board. Procedures are in place to ensure confidentiality and provide full informed consent as discussed below.

The Lindau Lab has listed the Principal Investigator and study coordinator phone numbers on all study correspondence and forms. The purpose of the phone numbers is to provide respondents with a number to call if they have questions about any aspect of the study. During the study, should a subject express intent to harm themselves or others, we will contact a health or public safety professional. We will give only the subject's name, contact information, and why we feel he or she is at risk of harming themselves or others. This report will not be linked to his or her survey information. Subjects have the right to refuse to speak to the mental health professional. If the interview procedure results in the observation or suspicion of elder or child abuse, all research personnel will act in compliance with Illinois State law in regards to mandatory reporting of abuse.

Research staff will strictly adhere to the procedures for enrolling participants and collecting data as outlined by the investigators. At the conclusion of the study, all hard copy materials will be destroyed and electronic files will be deleted or archived in password-protected files. Informed consent document files will be stored for at least 6 years following the completion of the study (defined by the last publication related to the study). Due to the small sample sizes associated with the pretest, these data will not be made publicly available.

D3. Payment

Caregivers enrolled in the pretest will receive $20 in compensation for completion of the baseline interview (approximately 25 minutes) and $25 in compensation for completion of each follow-up survey (approximately 30 minutes, administered at 7 days, one month, three months, six months and 12 months following hospital discharge). Caregivers will receive $50 in compensation for their participation in the qualitative survey (approximately 45 minutes). Baseline interview compensation will be provided in the form of an e-gift card and emailed immediately to the participant. Compensation for follow-up surveys will either be emailed (e-gift cards) or mailed (physical gift cards), based on participant preference. Compensation will not be prorated for partial completion of the baseline and follow-up surveys but every effort will be made to allow for ample time to complete the surveys and participants can refuse to answer any question they do not want to answer. Participation is voluntary.

D4. Informed Consent

Because we plan to conduct recruitment and enrollment for the randomized controlled trial remotely, we will employ e-consent procedures, facilitated by REDCap. We will obtain informed consent as follows:

Caregivers 18 years of age or older: We will obtain written informed consent via e-consent from all caregivers 18 years of age or older. Caregivers will provide their e-signature by typing their full name into a signature field. Caregivers will date the form and provide their e-signature to indicate their informed consent.

Caregivers 17 years of age and younger: We will obtain written informed consent via e-consent from all parental caregivers younger than age 18 who are eligible to consent for participation in research. Parental caregivers ages 17 years of age and younger will be eligible to participate if they are an emancipated minor under Illinois state law (750 ILCS 30/5). A child of such a parental emancipated minor may assent to participate in the study with parental permission, as described further below. Non-parental caregivers ages 17 and younger in Illinois cannot have guardian or custodial status; these individuals will therefore not be eligible to participate.

D5. Child assent

Because we propose to access, view and analyze data from the hospitalized child's electronic medical record and health insurance claims, we will obtain assent from a child between the ages of 7-17 who is the child of an enrolled caregiver. We are requesting a waiver of assent for children under 7 years of age and any children intubated or otherwise unable to provide assent. Inability to provide assent will be determined by the PI in conjunction with the treating physician. If and when a child between the ages of 7-17 regains assent capacity, assent will be obtained. Because this study poses no more than minimal risk, permission from only one parent may be required. We will attempt to obtain caregiver permission and child assent upon the caregiver's initial e-consent to the research. However, if the caregiver needs additional time to consider their child's participation, we will continue the discussion at each follow-up time point until the caregiver provides permission or refuses.

Research interviewers will guide caregivers through the informed consent document, providing statements to address: that the study involves research; the study's purpose, duration, procedures followed, risks and benefits, alternatives to participation, and confidentiality of records; to whom they should direct questions or contact in case of research-related injury; and statements regarding voluntary participation, refusal to participate, and discontinuation of participation. The researcher will provide adequate time for the potential subject to ask questions, and the e-consent procedures ask additional questions to assess subject comprehension. Once all questions have been discussed and answered, the researcher will request that the caregiver electronically sign the consent form by typing their full name into the signature field and verify their identity by confirming their child's date of birth. We will confirm child date of birth with the date that is recorded in the child's EMR. The caregiver will receive an electronic copy of the signed consent form for their records. We will also document caregiver's permission to approach and assent the child patient. If the parent should decide at a later time point that they do consent to their child's participation, we will send them a link to a blank version of the IRB-approved informed consent form and ask that they sign the line under "Permission for my Child's Participation." We will not re-consent participants at this point because the consent process as it stands takes ~15 minutes and repeating this process would be burdensome to the participant and not be necessary as we already have their consent for their own participation. Participants will receive a PDF copy of this form as an addendum to their existing consent form. The informed consent process will take place over the phone (either in the patients' hospital room or by the caregiver's personal phone) following recruitment. We are requesting a waiver of documentation of consent for participation in the qualitative interview, and will obtain verbal consent immediately before the interview. Similar to the process for consent for participation in the RCT, researchers will guide caregivers through an informed consent script and ask for their verbal consent before proceeding with the interview. A copy of the informed consent script will be emailed to the participant for their records. The informed consent document is enclosed in this submission for review.

No surveys or interviews with human subjects will be conducted without explicit documentation of the informed consent process executed with each participant. Informed consent/assent documents will be iterated using approved consent documents from the recently completed CRx pragmatic clinic trial of patients (N=411) receiving care in the University of Chicago's Primary Care Group and Emergency Departments. The consent documents for that study were adapted from consent documents developed in collaboration with a literacy consultant and members of the community. Consent documents will be written in easily understandable language and, in addition to English, be translated into Spanish. We have hired bilingual Research Assistants to enroll participants who speak Spanish or will make use of the hospital Language Line for interpretation and translation. Confirmation of consent will be collected and stored in REDCap for the RCT, or documented in REDCap for the interview, and only accessible to approved researchers to confirm participation in the study for data collection, validation, and data analysis purposes. A final copy of all consent/assent documents will be submitted to the IRB for review and approval.

D6. Confidentiality

The proposed research with human subjects, as presented above, presents no more than minimal risk or no more risk than is encountered in routine psychological examinations. Any potential risks may be due to emotional or psychological discomfort associated with the surveys or a breach of confidentiality. As described in detail above, no surveys will be completed without explicit documentation of informed consent and individuals will be provided appropriate information about privacy and confidentiality when enrolling in the study and will indicate acceptance of these risks upon consent.

The Lindau Laboratory has strict and secure procedures for protecting against and minimizing potential risks to human subjects' data. All survey data will be entered directly into REDCap, a password-protected database managed by the Center for Research Informatics (CRI) at the University of Chicago (cri.uchicago.edu). CRI provides a HIPAA-compliant data storage and computing environment that has achieved security accreditation by the Biological Sciences Division's Risk Management Group. Data will be saved to the secure servers in the Department of Ob/Gym at the University of Chicago via a secure wireless connection on a secure, password-protected tablet, or research staff will enter REDCap data directly on Ob/Gym departmental computers using the secure, password-protected Ob/Gym internet network. Data are backed up at the end of each collection day. Data will never be stored locally on tablets. Only approved research analysts in the Lindau Laboratory will have access to files that link participant's PHI to their unique identifiers for the purposes of creating analytic datasets.

REDCap will integrate electronically with the Mosio texting platform (www.mosio.com) to facilitate the text message protocol for human subjects in the intervention group and manage survey scheduling and reminders for all participants. To this end, REDCap will push the subject's name, telephone number and date of discharge to Mosio. Mosio provides a secure messaging and data storage environment and has been approved for use by the University of Chicago Information Security Office. Only approved researchers in the Lindau Lab will have access to data stored by Mosio and will have the ability to securely download data directly to computers within the Ob/Gym network.

REDCap will integrate electronically with NowPow (www.nowpow.com) to facilitate generation of the HealtheRx. Data will be pushed from REDCap to NowPow via a custom secure integration to create the participant's profile in NowPow, including name, address, date of birth and other non-PHI data. Any data sent to NowPow from REDCap to generate the personalized HealtheRx will be assigned a secondary unique ID in order to prevent any connection to the subjects' responses in REDCap. NowPow is seamless, secure and HIPAA-compliant. Data are backed up automatically and encrypted in-transit, at-rest, and end-to-end. De-identified metadata will be transferred to researchers in the Lindau Laboratory using a secure file transfer protocol (SFTP); details described above. All devices used by researchers to collect or access research files will be encrypted. Only approved research analysts in the Lindau Laboratory will have access to files that link participant's PHI to their unique identifiers for the purposes of creating analytic datasets.
Any hard copies of project materials will be stored in locked file cabinets in locked offices at University of Chicago. Servers in the University of Chicago Department of Ob/Gym are protected through a combination of a Microsoft-based firewall technology and the physical

barrier of a Linksys router that is installed between the server and its internet connection. Laptop computers used to collect data will be encrypted and password protected. All data transmitted to secure servers will be encrypted. Analytic files will be de-identified prior to analysis or limited to the minimum amount of data necessary to accomplish the intended research purposes per the HIPAA Privacy Rule. Any analytic datasets will limit the use or disclosure of PHI to the minimum necessary, if any at all, to accomplish the intended research purposes. Only IRB-approved researchers on this protocol will have access to the data. These controls meet or exceed the strictness of practices legislated and enforced by the University of Chicago Biological Sciences Division and hospitals for protected health information.

Procedures are in place to ensure confidentiality and provide informed consent as discussed above. Numeric coding of surveys/interviews and secure containment of files that link participant's responses from PHI will also minimize this risk. Finally, the Lindau Laboratory will provide a contact phone number that will be included on all study correspondence and forms. The purpose of this phone number is to provide respondents with a single number to call if they have questions about any aspect of the study.

D7. Recruiting methods

Researchers in the Lindau Laboratory will access electronic medical record (EMR) registration data to identify potential caregivers of newly admitted pediatric patients and patients seeking care in the Day Treatment Rooms for inclusion in based on ZIP code and anticipated discharge date. Research assistants will contact potentially eligible caregivers by 1) identifying the hospital room number for the pediatric patient and calling the bedside phone; 2) identifying the caregiver listed in the Demographics section of the EMR and sending a text message to the phone number listed; and 3) calling the phone number listed for the caregiver listed in the Demographics section of the EMR. Research interviewers will explain that the caregiver may be eligible for a research study and, if interested, further screen for eligibility. Recruitment scripts for the various modes of contact have been submitted for review with this protocol. If eligible, researchers will guide participants through the informed consent process as described in Section M. Informed Consent.

Once their participation in the RCT is complete, certain caregivers will be approached for inclusion in a qualitative interview. Researchers will contact caregivers by email, text message and phone. Research interviewers will explain that the caregiver may be eligible for a research study and, if interested, further screen for eligibility. Recruitment scripts for the various modes of contact have been submitted for review with this protocol. If eligible, researchers will guide participants through the informed consent process as described in Section M. Informed Consent.

D8. Notification of physician

Notification of the hospitalized child's treating physician for permission to enroll will occur using a multi-pronged approach. First, we will educate all treating physicians and residents working in the target units about the study during the pretesting phase and give treating physicians the opportunity to opt out of study participation. Secondly, we will use these

education sessions to identify how treating physicians wish to be contacted for permission (e.g., via text, email, phone, text page or through the electronic medical record system). We will use that communication as documentation of treating physician permission. Lastly, we will also educate nursing staff about the study. Nurse engagement will be helpful should we need to reach a treating physician during clinical rounds.

D9. Anticipated coordination

Inter-departmental faculty coordination will be facilitated by regular research meetings attended by Dr. Lindau (PI) and other Co-Investigators and key personnel. Faculty will also regularly communicate by email and phone calls as necessary.

D10. Pregnancy test

Not applicable.

D11. Exclusion of women, minorities and/or children

This study will not exclude women, minorities or children.

D12. Drugs

No drugs will be given to subjects as part of this study.

E. Bibliography

1. Coleman-Jensen A, Rabbitt M, Gregory C, Singh A. Household Food Security in the United States in 2015. Washington, D.C.: U.S. Department of Agriculture; 2016. Report No.: ERR-215.

2. Seligman HK, Schillinger D. Hunger and socioeconomic disparities in chronic disease. N Engl J Med. 2010 Jul 1;363(1):6–9. PMID: 20592297

3. Gundersen C, Ziliak JP. Food insecurity and health outcomes. Health Aff (Millwood). 2015 Nov;34(11):1830–1839. PMID: 26526240

4. Gibson MJ, Kelly KA, Kaplan AK. Family Caregiving and Transitional Care: A Critical Review. Family Caregiver Alliance, National Center on Caregiving; 2012.

5. Grey M, Schulman-Green D, Knafl K, Reynolds NR. A revised Self- and Family Management Framework. Nurs Outlook. 2015 Mar;63(2):162–70. PMID: 25771190

6. Bruce JS, De La Cruz MM, Moreno G, Chamberlain LJ. Lunch at the library: examination of a community-based approach to addressing summer food insecurity. Public Health Nutr. 2017 Jun;20(9):1640–1649. PMID: 28318465

7. Palakshappa D, Doupnik S, Vasan A, Khan S, Seifu L, Feudtner C, Fiks AG. Suburban Families' Experience With Food Insecurity Screening in Primary Care Practices. Pediatrics. 2017 Jul;140(1). PMID: 28634248

8. Purdam K, Garratt EA, Esmail A. Hungry? Food insecurity, social stigma and embarrassment in the UK. Sociology. 2016 Dec;50(6):1072–1088.

9. Martin KS, Colantonio AG, Picho K, Boyle KE. Self-efficacy is associated with increased food security in novel food pantry program. SSM - Popul Health. 2016 Dec;2:62–67. PMCID: PMC5757945

10. Kamimura A, Jess A, Trinh HN, Aguilera G, Nourian MM, Assasnik N, Ashby J. Food Insecurity Associated with Self-Efficacy and Acculturation. Popul Health Manag. 2016 Apr 28;20(1):66–73. PMID: 27124517

11. Tucker-Seeley RD, Mitchell JA, Shires DA, Modlin CS. Financial hardship, unmet medical need, and health self-efficacy among African American men. Health Educ Behav. 2015 Jun;42(3):285–292. PMCID: PMC4437974

12. Boardman JD, Robert SA. Neighborhood Socioeconomic Status and Perceptions of Self-Efficacy. Sociol Perspect. 2000 Mar 1;43(1):117–136.

13. Churchill SS, Kieckhefer GM. One Year Follow-up of Outcomes from the Randomized Clinical Trial of the Building on Family Strengths Program. Matern Child Health J. 2018 Feb 10;1–9. PMID: 29429134

14. Alley DE, Asomugha CN, Conway PH, Sanghavi DM. Accountable Health Communities - Addressing social needs through Medicare and Medicaid. N Engl J Med. 2016 Jan 7;374(1):8–11. PMID: 26731305

15. Council on Community Pediatrics, Committee on Nutrition. Promoting Food Security for All Children. Pediatrics. 2015 Nov;136(5):e1431-1438. PMID: 26498462

16. Billioux A, Verlander K, Anthony S, Alley DE. Standardized screening for health-related social needs in clinical settings: The Accountable Health Communities screening tool. [Internet]. Washington, D.C.: National Academy of Medicine; 2017. Available from: https://nam.edu/wp-content/uploads/2017/05/Standardized-Screening-for-Health-Related-Social-Needs-in-Clinical-Settings.pdf

17. Pooler J, Levin M, Hoffman V, Karva F, Lewin-Zwedling A. Implementing Food Security Screening and Referral for Older Patients in Primary Care: A Resource Guide and Toolkit [Internet]. AARP Foundation; 2016 Nov. Available from: http://www.aarp.org/content/dam/aarp/aarp_foundation/2016-pdfs/foodsecurityscreening_quickguide.pdf

18. Addressing Food Insecurity: A Toolkit for Pediatricians [Internet]. Washington, D.C.: Food Research & Action Center; 2017 Feb. Available from: http://frac.org/aaptoolkit

19. Garg A, Butz AM, Dworkin PH, Lewis RA, Serwint JR. Screening for basic social needs at a medical home for low-income children. Clin Pediatr (Phila). 2009 Jan;48(1):32–36. PMID: 18566347

20. Barnidge E, LaBarge G, Krupsky K, Arthur J. Screening for food insecurity in pediatric clinical settings: Opportunities and barriers. J Community Health. 2016 Aug 4;1–7. PMID: 27492774

21. Essel K, Burke MP, Weissman M, Dietz W. Exploring Food Insecurity Screening and Referral Practices of Pediatric Providers in Metropolitan Washington, DC. FASEB J. 2017 Apr 1;31(1 Supplement):297.7-297.7.

22. Colvin JD, Bettenhausen JL, Anderson-Carpenter KD, Collie-Akers V, Chung PJ. Caregiver opinion of in-hospital screening for unmet social needs by pediatric residents. Acad Pediatr. 2016 Mar;16(2):161–167. PMCID: PMC4794116

23. Lindau ST, Makelarski J, Abramsohn E, Beiser DG, Escamilla V, Jerome J, Johnson D, Kho AN, Lee KK, Long T, Miller DC. CommunityRx: A population health improvement innovation that connects clinics to communities. Health Aff (Millwood). 2016;35(11). PMID: 27834242

24. Grey M, Knafl K, McCorkle R. A framework for the study of self- and family management of chronic conditions. Nurs Outlook. 2006 Oct;54(5):278–286. PMID: 17027605

25. Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. Qual Health Res. 2005 Nov 1;15(9):1277–1288.

26. Coyne IT. Sampling in qualitative research. Purposeful and theoretical sampling; merging or clear boundaries? J Adv Nurs. 1997 Sep 1;26(3):623–630. PMID: 9378886

27. Mauri, Laura, and Ralph B. D'Agostino Sr. "Challenges in the design and interpretation of noninferiority trials." *New England Journal of Medicine* 377.14 (2017): 1357-1367. DOI: 10.1056/NEJMra1510063

Summary of major changes to the CommunityRx-Hunger RCT protocol, by research component

Per the recommendation of The University of Chicago's Institutional Review Board, V1 of this study's protocol, approved 2/11/2019, included only the study's pre-test protocol. Following completion of the pre-test, again per the IRB's recommendation, V1 was amended for the full trial (approved 11/3/2020). The majority of differences between V1 and V10 presented above include: a) planned differences between the pre-test protocol and full trial protocol (e.g., sample size, number of follow-up surveys) and b) revisions to allow remote enrollment of participants and remote administration of the intervention (conducted in person in the pre-test protocol) due to restrictions related to the COVID-19 pandemic. All changes were approved by the Institutional Review Board.

Other major changes made following approval of the full trial protocol include:

February 2021 three changes were made to accelerate the enrollment rate to compensate for COVID-19 pandemic-related delays in the trial launch:

- Expansion of ZIP code elgibility criteria
- Increase in baseline compensation to $20
- Updates to recruitment scripting and text messages

March 2021:

- Expansion of eligibility criteria to include caregivers of children hospitalized >30 days in the Neonatal Intensive Care Unit (a high need population, especially during the COVID-19 pandemic) to improve study generalizability
- Revision of procedures to obtain parental consent for access to their child's medical record data to allow this consent to occur after study enrollment (e.g., at a follow-up survey) when rapport was better established with participants