SUPPORTING STATEMENT

Part B

Home Assessments for Patients and Families with Special Health Care Needs: Developing Tools, Communication Strategies, and Standards

Date: 4.09.20

Table of Contents

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Section 1: Respondent Universe and Sampling Methods **3**

Section 2: Procedures for the Collection of Information **3**

Section 3: Methods to Maximize Response Rates and Deal with No Response **4**

Section 4: Tests of Procedures or Methods to be Undertaken **5**

Section 5: Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data **5**

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List of Attachments

Attachment A- Drexel IRB Approval Letter- updated modification letter attached
Attachment B- CDC 0.1375B Agreement to Prohibit CDC from Receiving Identifying Key
Attachment C- Recruitment Flyer- updated flyer attached
Attachment D- Phone Recruitment Script (IRB Appendix H)- updated phone script attached
Attachment E- Informed Consent Document- updated informed consent attached
Attachment F- Demographic Intake Form (IRB Appendix A)- did not change
Attachment G- Disaster Preparedness Home Assessment Tool (IRB Appendix B)- did not change
Attachment H- Semi-structured Interview Guide (IRB Appendix C)- did not change
Attachment I- Assent Form- did not change

B. Collection of Information Employing Statistical Methods

Section 1: Respondent Universe and Sampling Methods

The Drexel University Dornsife School of Public Health will conduct this formative research by using a multi-method approach to data collection to develop and pilot a disaster preparedness home assessment tool tailored to children and youth with special health care needs (CYSHCN) and their families. Data collection will consist of surveys and semi-structured interviews. Using non-probability convenience sampling, caregivers of CYSHCN will be identified from pediatric primary care medical homes affiliated with the Pennsylvania (PA) Chapter of the American Academy of Pediatrics (PA AAP) Medical Home Program. Up to 200 caregivers of CYSHCN may be consented for study participation, with a final cohort of 100 caregivers to complete all data collection activities. The study team anticipates that it will take approximately 12 months to complete data collection on all 100 subjects.

Through the PA AAP Medical Home Program, the investigators for this project have strong working relationships with the medical home practices across PA needed for participant recruitment statewide. In addition, the primary investigator and professional staff on this project are housed within the Center for CYSHCN at St. Christopher’s Hospital for Children. The Center for CYSHCN is one of the largest clinical programs in the country serving this high-risk population, with over 3,000 patients. St. Christopher’s Hospital for Children is located in the center of North Philadelphia, and will be a recruitment site for participants residing in urban southeastern region of PA. The Drexel staff’s close relationship with St. Christopher’s Hospital for Children allows researchers to work with an especially medically and socially vulnerable population that is often difficult to reach.

Section 2: Procedures for the Collection of Information

Drexel received initial IRB approval on July 2, 2019 to conduct human subjects research for this project through their institution’s review board (IRB). A modification of the study protocol in response to the COVID-19 pandemic was approved by the Drexel IRB on April 1, 2020. The CDC Center for Preparedness and Response made a determination that this project is human subjects research in which CDC is not engaged. Attached includes the project’s Drexel IRB approval letter (Attachment A) and documentation of CDC’s non-engagement in research involving human subjects (Attachment B).

Caregivers of CYSHCN will be recruited by medical home practices affiliated with the PA AAP Medical Home Program. Practices will be provided with inclusion criteria for subject participation and may assist in informing eligible caregivers about the project. Practice staff will not participate in subject enrollment but will rather connect potential subjects to Drexel staff and provide a recruitment flyer (Attachment C).

Drexel staff will then connect with the interested participants and conduct a phone screening to confirm study eligibility (Attachment D). All potential subjects will be informed that participation is voluntary. If interested and eligible, Drexel staff will administer the informed consent document over the phone (Attachment E). Once consented, Drexel staff will administer the electronic Demographic Intake Form (Attachment F) via phone and schedule an appointment for the first home assessment visit (virtually via Zoom/telephonic or in-person) to field test the Disaster Preparedness Home Assessment Tool (Attachment G). It will be explained to subjects

that there will be a follow up home assessment visit and they will receive a total of two home assessment visits, virtually via Zoom/telephonic or in-person (final n=100 complete initial and follow up visits), both of which will involve data collection to test the instrument.

The trained personnel conducting the home visits will include a licensed social worker, bilingual (English/Spanish) community health worker, American Red Cross (ARC) first responder, and a durable medical equipment (DME) provider for children who have medical equipment needs. This study will use three instruments throughout the study to collect data: 1) demographic intake form 2) disaster preparedness home assessment tool and; 3) semi-structured interview guide (Attachment H). All questions requiring a caregiver response will be asked by study personnel and recorded electronically within the instrument by a study team member.

Initial Home Assessment Visit:
The disaster preparedness home assessment tool being tested will guide the home assessment visit and will be the only instrument for data collection during this first encounter. This electronic tool includes five overarching sections: medical/diagnostic section, medical equipment/assistive technology, description of home environment, emergency planning, and social determinants of health. Data will be collected by caregiver report, or home observation (as able during virtual via Zoom/telephonic visits) for each section by the appropriate member of the assessment team. A virtual/telephonic visit means that the caregiver will be on a videoconference in their home, and the study team will be on the same videoconference call from a separate location, administering the home assessment screening tool. Based on the needs identified by the assessment tool, additional resources and referrals may be provided to address gaps in preparedness identified from the home assessment tool.

Follow Up Home Assessment Visit:
The home assessment team will make a follow up visit 3-6 months after the initial visit. We anticipate by the follow up phase of this study that the home assessment team may be permitted to conduct in-person home visits, however, virtual via Zoom/telephonic visits will be conducted if the COVID-19 pandemic remains a health and safety concern. Using the same disaster preparedness home assessment tool (Attachment G), the team will collect data to gauge the appropriateness and sufficiency of instrument domains and questions, assess reliability and validity of instrument items, and improve understanding of what disability-related disaster preparedness gaps and specific population attributes and needs may benefit from subsequent development of targeted data collection instruments and interventions.

In addition to the follow up home assessment and data collection, caregivers will also be asked a few questions to provide feedback on their experience with the disaster preparedness home visiting process, to assess the acceptability and feasibility of the home assessment process and inform future refinement of the home assessment content and procedure. CYSHCN themselves may also be asked to participate in the interview, as appropriate based on their age and ability to participate, and with proper consent from legal guardian. Prior to the interview a Drexel staff member will administer the Assent Form (Attachment I) to the CYSHCN.

Section 3: Methods to Maximize Response Rates and Deal with No Response

As a result of our partnerships with the Centers for CYSCHN at St. Christopher's Hospital for Children and the PA AAP Medical Home Program, we do not anticipate any problems with the identification of participants for the data collection proposed in this study. This study benefits from the resources

available to the PA AAP with over 2,200 members, the Medical Home Initiative for CYSHCN in Pennsylvania with over 150 participating pediatric practices statewide, and the Center for CYSHCN at St. Christopher's Hospital for Children, with over 2,500 children in care. Prior to launching recruitment in each region across the state, we will facilitate conference calls to inform and engage practice staff on the benefits of the study, and how to easily refer interested subjects to Drexel staff.

Drexel staff involved in recruitment and consent have extensive experience working with our target population and conducting home visits in their professional roles. Our bilingual community health worker will lead recruitment for all Spanish speaking caregivers to eliminate any potential for miscommunication in translation. The expertise and relatability of our project staff, and their ability to describe the benefits of participation will contribute to successful response rates. In addition, caregivers will be offered a modest gift card ($50/home visit) as a token of appreciation for their participation. Lastly, as medical providers are known to be trusted sources of information, having the primary care provider, or staff, from their medical home introduce the project is anticipated to maximize response rates.

Section 4: Tests of Procedures or Methods to be Undertaken

The Disaster Preparedness Home Assessment Tool, Demographic Intake Form, and Semi-structured Interview Guide were reviewed, revised, and vetted with input from the Co-Investigators, CDC investigators, and subject matter experts. Caregiver feedback on a near final version of the tool was obtained.

Section 5: Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Frequencies and descriptive statistics will be used to reflect gaps in emergency preparedness identified by the Disaster Preparedness Home Assessment Tool from the first home visit. Changes in response from the initial visit to follow up home visit will be reviewed. Findings from the tool will be shared in aggregate with the CDC and used to further refine such a tool for the target population.

Transcripts from the semi-structured caregiver and CYSHCN interviews will be coded and analyzed for trends and themes. Thematic analysis will be conducted independently by at least two researchers and cross-checked for consistently. Nvivo software will be used.

Findings from this analysis will not be generalized beyond the scope of the study, or to broader populations.

The following individuals will be involved in the collection of quantitative and qualitative data:

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