Formative Assessment of Barriers to Transition from Adolescent to Adult for Individuals with Congenital Heart Defects

Supporting Statement – Section B

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Section B – Data Collection Procedures

1. Respondent Universe and Sampling Methods

Emory University:

Participants in this formative survey will include parents/guardians of adolescents (ages 11-17 as of July 1, 2017) with a congenital heart defect (CHD). Participants must be able to consent and complete the survey in English or Spanish. Parents/guardians may participate regardless of whether their child has maintained regular care intervals as recommended by the provider or is receiving only "intermittent" care.

Individuals will NOT be eligible for study participation if they are:

- Younger than age 18
- Not the parents/guardians of an adolescent (ages 11-17) with CHD
- Unable to consent to participation in the study
- Unable to complete the survey in English or Spanish

Data will be collected from parents/guardians of adolescent CHD patients attending any of the 22 Sibley Heart Center clinics in Georgia. Parents/guardians will be recruited based on the appointment logs of the Sibley clinic locations. Each week, a member of the Emory University project team will review the patient appointment logs for the participating clinics. Adolescent patients on the log (ages 11-17) with a diagnosis of CHD will be identified and contact information for the patient's parent/guardian(s) will be collected from the medical records database. A member of the Emory University project team will contact the parent/guardian via telephone to inquire whether he/she would be willing to participate in the survey. Each parent/guardian will be contacted three times. If the parent/guardian is outside of metro-Atlanta, they will be given the opportunity to complete the survey on the internet. If the parent/guardian is in metro Atlanta, they will be given the opportunity to complete the survey remotely via the internet or in-person in the clinic on an electronic tablet. If a parent/guardian cannot be reached after 3 tries, he/she will be removed from the initial contact list (he/she may still be approached in-person in the clinical setting).

Because these parents/guardians are currently engaged in obtaining care for their adolescent child and will be approached in the clinic while obtaining care, we expect a high participation rate of approximately 60%. Similar studies using pre-survey

invitations among targeted patient populations have seen response rates ranging from 25 to 75 percent.[i] [ii] [iii]

NYS DOH:

The target population includes parents (or guardians) of adolescents with CHD aged 11-17 whose residence at birth was in an 11-county surveillance region (Alleghany, Bronx, Cattaraugus, Chautauqua, Erie, Genesee, Monroe, Niagara, Orleans Westchester, Wyoming). We will use simple random sampling to select 1000 individuals from this cohort in order to obtain a sample that is representative of our population overall. We have limited our survey sample size to 1000 due to budgetary considerations. We will mail survey packets to be completed by one parent/guardian for each of the randomly selected adolescents. The surveys will be addressed to "Parent or guardian of *insert adolescent name*" rather than using the name of the parent. We anticipate a response rate of 80%, or 800 surveys.

2. Procedures for the Collection of Information

Emory University:

- Data for the formative survey will be collected via REDCap online (either remotely via web link or on a tablet/Ipad in the clinic setting).
- Upon signing the informed consent, the parent/guardian will complete the survey in the clinic setting on an electronic tablet (or remotely via the internet). It is estimated that completion of the consent form and the survey will take approximately 15-20 minutes.
- All electronic data captured for this study will be automatically uploaded to the secure Emory University REDCap system. REDCap is a mature, secure web application for building and managing online surveys and databases. REDCap provides an encrypted, backed-up place to store the data and facilitates compliancy with Emory's HIPAA policies and procedures.
- If the participant is completing the survey in-person in the clinic setting, Emory University rules require the informed consent to be completed on paper. Paper consent forms collected in the clinic will be kept in locked file cabinets to which only members of the study staff have access. Participants that complete the survey remotely via the internet will complete an electronic informed consent form.
- For the purposes of analysis, data will be downloaded out of the REDCap database for use with statistical packages (SAS, STATA, SPSS). Only de-identified data will be downloaded out of the REDCap system and all data files will be kept in password-protected electronic files on the secure research drives of Emory University.
- Emory will provide a $10 e-gift card electronically upon completion of the survey.

NYS DOH:

Current mailing addresses will be obtained for each randomly selected adolescent with a CHD using records provided by the New York State Immunization

Information Service (NYSIIS), a registry containing immunization history and accompanying contact information for individuals under the age of 19 in New York. In cases where an updated address for the adolescent cannot be found using NYSIIS, we will use the LexisNexis® Accurint® tracing tool. We will trace adolescents directly if they are between the ages of 13 and 17 and we will trace the mothers of the adolescents if the adolescents are between the ages of 11 and 12 because Accurint does not store any information for individuals under the age of 13. We will also trace the mother in cases where there is no information in Accurint about an adolescent aged 13 or older. If the mother is determined to be deceased, we will trace the father. Parent information to be used for tracing will be obtained using the NY State Department of Health's Congenital Malformations Registry (CMR).

We are making the assumption that adolescents with CHDs aged 11-17 are still living at home, therefore the most recent address on file for the adolescent in NYSIIS/Accurint should be the address for their parent or guardian as well. Surveys will be addressed to the parent/guardian of the identified adolescent to obtain one response for each adolescent with a CHD.

We will send a pre-notification letter to potential respondents using the most recent address we have on file one week prior to the initial survey mailing. One week later, the survey instrument will be mailed to the parents/guardians of the randomly selected adolescents with CHDs with a cover letter explaining the purpose of the survey and a pre-paid, pre-addressed envelope for returning the completed survey. One week after the initial survey mailing, we will send a reminder postcard to all participants. A month after the initial mailings have gone out, a second survey packet will be mailed to each non-respondent including a cover letter, another copy of the survey instrument and another pre-paid, pre-addressed envelope. Thank you letters will be mailed to respondents after the survey administration period has ended with accompanying $10 pre-paid gift cards. As hardcopy surveys are returned, the responses will be manually entered into a Microsoft Access database. Survey data will ultimately be exported from Access to SAS for analysis. A timetable for our mailings is below.

Date	Mailing
June 24, 2017	Pre-notification letter
June 30, 2017	First survey mailing*
July 7, 2017	Reminder postcard
July 31, 2017	Second survey mailing**
August 30, 2017	Thank you letters***

*Mailing includes a cover letter, the survey instrument and a pre-paid, pre-addressed return envelope
**Mailing includes a cover letter, the survey instrument, and a pre-paid, pre-addressed return envelope
***Mailing includes a thank you letter and a $10 pre-paid gift card

No identifiable data will be collected on the survey instrument itself, though we will be accessing identifiable data from CMR, the Statewide Planning and Research Cooperative System hospital discharge database (SPARCS), NYSIIS, and Accurint in order to identify our cohort and prepare the survey mailings. Specifically, we will be identifying each adolescent's name, date of birth, residential address at birth, updated residential address, CHD ICD-9-CM diagnosis codes, parent names and parent dates of birth. Parent names and parent dates of birth will only be used in instances where address tracing cannot be performed for the adolescent directly.

Each selected adolescent will be assigned a corresponding ID number that will be used on the survey instrument to track which of their parents have responded. The crosswalk between ID numbers and personally identifiable information will be stored as a table in a password-protected Access database accessible only to members of the NYS DOH Congenital Heart Defects Surveillance team. Survey responses along with the corresponding ID numbers will be entered into a separate table in the Access database by members of the NYS DOH Congenital Heart Defects Surveillance Team as completed surveys are returned. The returned hardcopy surveys will be kept in a locked filing cabinet accessible only to members of the NYS DOH Congenital Heart Defects Surveillance Team. We will not use nor report any identifiable data in our analyses.

3. Methods to Maximize Response Rates and Deal with No Response

Emory University:

We will maximize response rates through several measures:

a) Pre-screening of patient/parent dyads to ensure that only parents/guardians of eligible adolescent patients are contacted for the study.

b) Recruiting parents/guardians who are already engaged in obtaining care for their adolescent child with CHD at the clinic location;

c) Recruiting via two methods – telephone recruiting (with up to 3 calls) and in-clinic recruitment.

Parents/guardians who do not respond (or are not reached) after three tries via telephone, will be dropped from the call list. However, for those in metro-Atlanta clinics, they will again be approached in-person during the upcoming clinic visit for their child. Given the opportunity to reach these parents in two ways and during a time period when they are focused on securing care for their child with CHD, we anticipate a high response rate of approximately 60%.

NYS DOH:

We will employ a variety of methods to increase response rates in our sample, including incentives, promised incentives, pre-notification letters (Attachment 3), reminder postcards (Attachment 6), two survey mailings (Attachment 1), pre-paid return envelopes, thoughtful formatting, personalization, and the exclusion of questions that ask for personally identifiable information. We also believe that the survey topic is of interest to this population which should encourage participation.

A personalized pre-notification letter will be sent to potential participants one week prior to the initial survey mailing. The letter will explain the purpose of the survey (Attachment 4) and request the reader's participation. In the first survey mailing, we will include a cover letter (Attachment 4), the survey instrument (Attachment 1), and a pre-paid, pre-addressed envelope for returning the completed survey. We will also inform potential participants that they will receive a $10 gift card for returning the survey to us. A month after the first mailing, we will follow up with a second mailing to non-responders that contains a cover letter with instructions. Again we will enclose a pre-paid, pre-addressed envelope for returning the survey. We believe the survey topic will motivate parents of adolescents with CHDs to respond. We also elected to exclude questions asking for identifiable information in an effort to reduce survey abandonment. New York State Department of Health letterheads will be included on all survey documentation to lend legitimacy to the survey. The envelopes used in mailings will mention the adolescent with a CHD by name to personalize the survey mailing, as will the pre-notification letter, reminder postcard, and the cover letters in the survey mailings.

4. Test of Procedures or Methods to be Undertaken

The survey instrument and procedures were developed through extensive conversation with experts – clinicians, researchers, and community partners/advocates at both the Emory and New York locations - and include components, such as the Barriers to Care Questionnaire (BCQ), which has been previously validated for adolescents with chronic diseases. Given these are previously validated components, we are not planning a pilot test prior to OMB review. We plan to pilot test the survey with public health professionals and parents simultaneously with OMB review.

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

Statistical consultation was provided by the following individuals currently employed at Emory University.

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Hoffman, Trenton 404-727-5741; trenton.cole.hoffman@emory.edu

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Statistical consultation was provided by the following individuals currently employed at the New York State Department of Health.

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Wan-Hsiang Hsu, 518-473-7922; Wan-Hsiang.Hsu@health.ny.gov

Tabassum Insaf, 518-402-7950; Tabassum.insaf@health.ny.gov

Kristin Sommerhalter, 518-402-7985; Kristin.sommerhalter@health.ny.gov

The NYS DOH Congenital Heart Defects Surveillance Team within the Bureau of Environmental and Occupational Epidemiology at the New York State Department of Health will be responsible for all collection and analysis of survey data. In addition to the individuals mentioned above, data collection and analysis may be performed by:

Claire McGarry, 518-402-7765; Claire.mcgarry@health.ny.gov

Erin Dauerer, 518-402-7950; erin.dauerer@health.ny.gov

[i] Bulkley J, Stoneburner A, Leo M, Clark A, Beadle K, Vesco KK. Design, implementation, and response rates from an online patient survey to assess genitourinary symptoms and related health care experiences of postmenopausal women. J Patient Cent Res Rev. 2016;3:225.

[ii] Horevoorts NJ, Vissers PA, Mols F, Thong MS, van de Poll-Franse LV. Response Rates for Patient-Reported Outcomes Using Web-Based Versus Paper Questionnaires: Comparison of Two Invitational Methods in Older Colorectal Cancer Patients. Eysenbach G, ed. *Journal of Medical Internet Research*. 2015;17(5):e111. doi:10.2196/jmir.3741.

[iii] Kosinski L, et al. P-208 Project Sonar: Improvement in Patient Engagement Rates Using a Mobile Application Platform. Inflammatory Bowel Diseases. 22. March 2016.