Request for genIC Approval
CDC/ATSDR Formative Research and Tool Development

0920-1154

CIO: NCBDDD

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

PURPOSE AND USE OF COLLECTION:

The purpose of the survey is to understand current processes for transition from adolescent to adult CHD care, in order to develop educational materials aimed at improving these transition processes. Through this survey, the two funded sites will assess barriers to appropriate transition of care and parental understanding of the healthcare needs of their adolescent. The results from this survey will be used to develop educational modules targeted to healthcare providers that will address key knowledge and healthcare use gaps identified by the survey. We plan for the survey project to be completed by December 2017 and the educational modules developed and disseminated in Years 3-4. The ultimate audience for the results of this survey are clinicians, public health professionals, and stakeholders involved in CHD clinical care and the public health impact of CHD. Under FOA #CDC-RFA-DD15-1506, the proposed survey will be completed by two of the funded sites, Emory University and the New York State Department of Health (NYS DOH).

DESCRIPTION OF RESPONDENTS:

The target population for this study includes parents/guardians of adolescents with CHD. The survey instrument is the same for both Emory and NYS DOH. However, their administrative methods differ. Parents of adolescents will be surveyed through the following methods: 1) Emory: a clinic-based survey completed either remotely via the internet or in patient waiting rooms on an electronic tablet, and 2) NYS DOH: a mailed survey to parents of adolescents with CHD that have been identified by the New York Congenital Malformations Registry.

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.

2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: ___ Jill Glidewell _____

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [ ] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

> As a token of appreciation, an incentive will be provided to participants of the survey. Emory University will provide a $10 e-gift card upon completion of the survey. Upon completion/submission of the survey, participants will be asked to confirm an email address that they would like the incentive e-gift card to be emailed to and told that they will receive the gift card within 5 days. Surveys will not be considered complete if greater than 10 questions have been left blank/skipped. At the end of each work week, our study coordinator will batch email e-gift cards to the participants. All incentive e-gift cards will be provided electronically.
>
> As a token of appreciation, NYS DOH will include a $10 gift card upon completion of the survey along with a thank you letter.

BURDEN HOURS

Category of Respondent	Form Name	No. of Respondents	Participation Time (minutes)	Burden in Hours
Parent of adolescent with congenital heart defect	Emory site Survey	300	20/60	100
Parent of adolescent with congenital heart defect	New York site Survey	800	20/60	267
Totals				**367**

FEDERAL COST: The estimated annual cost to the Federal government is $8,975.00.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Emory University

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 project team will review the patient appointment logs for the participating clinics. Adolescent patients on the log (ages 11-17) with a diagnosis of congenital heart defect 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 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 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).

Upon reaching the parent/guardian via telephone, a member of the project team will explain the purpose of the survey and ask the parent/guardian if he/she would be willing to participate in the survey. If the parent/guardian responds affirmatively, the project team member will ask for a valid email address and will email the parent/guardian a participation link for the study and a token/password that may be only used once to access the secure link. Parents/guardians attending clinics outside of the metro-Atlanta region will only be provided the option of completing the survey remotely via internet. Parents/guardians attending the metro-Atlanta clinics will be will be given the option to complete the survey prior to the scheduled appointment or may complete the survey while waiting in the waiting room for the appointment scheduled that week.

Prior to each study day in the metro-Atlanta clinics, a member of the project team will review the eligible patients scheduled for the day and will check the project database to determine whether the parent/guardian has completed the survey yet. Once parents/guardians arrive in the waiting room, a project team member will approach any parents/guardians that have not completed the survey and ask them if they would like to do so at that time. If the parent/guardian agrees to participate in the survey, the team member will provide a brief overview of the survey and consent process and will give the parent/guardian a paper consent form and an electronic tablet to complete the survey.

New York State Department of Health

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 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.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

    [X] Web-based or other forms of Social Media

    [X] Telephone

    [X] In-person

    [x] Mail

    [X] Other, Explain

Data for the survey will be collected via REDCap online (either remotely via web link or on an electronic tablet).

1) Emory: a clinic-based, electronic survey completed by the parent/guardian of an adolescent, either remotely via the internet or in-person in patient waiting rooms using an electronic tablet. It is estimated that completion of the consent form and the survey will take approximately 15-20 minutes.

2) NYS DOH: a mailed, paper survey to parents/guardians of adolescents with CHD that have been ascertained from the New York Congenital Malformations Registry. The content of the survey is the same for both Emory University and NYS DOH and has been designed to assess barriers to transition from adolescent to adult care.

2. Will interviewers or facilitators be used? [ ] Yes [X] No

Please make sure all instruments, instructions, and scripts are submitted with the request.

Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

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TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is requested.

PURPOSE and USE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Briefly describe the targeted group/groups for this collection.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

Form: Provide the title of the information collection form.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group).

Burden in Minutes: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Estimate the annual cost to the Federal government for this collection.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.