

dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-1122]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Congenital Heart Survey To Recognize Outcomes, Needs, and Well-being (CH STRONG)* (OMB Control Number 0920-1122, Expiration 07/31/2017)—Reinstatement with Change—National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC).

proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Congenital Heart Surveillance To Recognize Outcomes, Needs, and Well-being (CHSTRONG) (OMB Control Number 0920-1122, Expiration 07/31/2017)—Reinstatement with Change—National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Congenital heart defects (CHDs) are the most common type of structural birth defects, affecting approximately 1 in 110 live-born children. In prior decades, many CHDs were considered fatal during infancy or childhood, but with tremendous advances in pediatric cardiology and cardiac surgery, at least 85% of patients now survive to adulthood and there are approximately 1.5 million adults with CHD living in the United States.

With vast declines in mortality from pediatric heart disease over the past 30 years, it is vital to evaluate long-term outcomes and quality of life issues for adults with CHD. However, U.S. data on long-term outcomes, quality of life issues, and comorbidities of adults born with CHD are lacking. U.S. data is needed to provide insight into the public health questions that remain for this population and to develop services and allocate resources to improve long-term health and wellbeing.

The initial request for this project was one year, but there were delays in

recruitment due to challenges with tracking and tracing individuals for correct addresses. The three sites, Metro-Atlanta Congenital Defect Program (MACDP), University of Arizona, and University of Arkansas, decided to conduct more intensive and time-consuming tracking and tracing to identify more accurate contact information for all eligible individuals and for those individuals whose materials were returned as undeliverable. At MACDP, this required modifying a contract to include the task of tracking and tracing 2,313 individuals. While the large majority of tracking and tracing at all three sites took place in the first year of the project, including that for the 2,313 individuals above, an additional 1,115 mothers of eligible individuals need to be sent a contact information form to assist in locating their child. Due to these delays and changes in the recruitment process, CH STRONG data collection is expected to last an additional 24 months and conclude two years after receiving OMB approval.

Since July 2016, the three CH STRONG sites identified 9,228 individuals with CHD through their respective birth defects registries. The CH STRONG project has successfully tracked and traced 6,417 individuals for current contact information. To date, the three sites have sent recruitment materials to 3,651 individuals (40% of all individuals).

The purpose of this survey is to collect information on barriers to health care, quality of life, social and educational outcomes, and transition of care from childhood to adulthood among adults born with CHD. Currently, Congress has appropriated approximately \$4 million per year to CDC to conduct surveillance among adults with CHD.

CH STRONG will survey adults aged 18 to 45 years of age and born with a CHD as identified through the birth defects surveillance system in three participating sites in the United States. The information collected from this cohort will be used to identify the healthcare, educational, and social service needs of adults with CHDs. Findings will be reported through peer-reviewed publications, presentations at state and national conferences, and webinars and reports to partners who work on CHD. The findings will be used by national, state and local organizations to allocate resources and develop services and programs for adults with CHD.

With the information collected in this survey, the CDC, along with its partners, will have information on healthcare

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the

needs and quality of life among a U.S. population-based group of adults with CHD. This information will inform local, state, and federal resource allocation for services targeting U.S. adults with CHD, a group that is increasing in size and currently totals over 1.5 million. Additionally, clinicians will have information to counsel families of children with CHD on how to prepare for their child's future. Without the information, needed resource allocation and services for

adults and information on long-term outcomes for children with CHD are unknown.

Across the three sites, there are 2,766 individuals that were tracked and traced in the first year of the project, but have not yet been recruited to participate in the survey. Additionally, mothers of 1,115 individuals will be sent a letter and contact information form to assist in reaching their child. It is estimated that half of these mothers will complete the form (n=556); 85% (n=474) in English

and 15% (n=83) in Spanish. Therefore, with the 2,766 yet to be recruited, and the approximately 556 individuals that will be successfully tracked and traced through the mother's contact form, approximately 3,322 potential respondents will be contacted. It is expected that approximately 70%, or 2,325 respondents, will participate.

The total estimated annual burden hours are 563.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Individuals aged 18–45 years who were born with a congenital heart defect.	Survey questionnaire	1,661	1	20/60	554
English-speaking mothers of respondents.	Contact Information Form—English.	237	1	2/60	8
Spanish-speaking mothers of respondents.	Contact Information Form—Spanish.	42	1	2/60	1

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–18KS]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Zika Reproductive Health and Emergency Response Call-Back Survey, 2018” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on April 27, 2017 to obtain comments from the public and affected agencies. CDC received one comment, which was unrelated to the proposed information collection. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project.

The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Zika Reproductive Health and Emergency Response Call-Back Survey, 2018—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the World Health Organization reported the first local mosquito-borne transmission of Zika virus in the Western Hemisphere. Through the course of the outbreak, local transmission was identified in at least 50 countries or territories in the Americas; within the United States, widespread mosquito born transmission was documented in the territories of Puerto Rico and the U.S. Virgin Islands, with localized transmission in Florida and Texas. In addition, in the continental United States, there has been a large number of travel-related cases with infection occurring through mosquito born and sexual transmission.

In response to the Zika virus outbreak, and evidence that Zika virus infection during pregnancy is a cause of microcephaly and other adverse pregnancy and infant outcomes, CDC’s Emergency Operations Center was activated to respond to the Zika virus outbreak from January 22, 2016–September 29, 2017. Given the adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy, through this response CDC developed specific recommendations for preconception