KQ5: What is the effectiveness of CRT–D versus CRT–P in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with LVEF ≤35% and a QRS duration ≥120ms?

KQ6: What are the adverse effects or complications associated with CRT–D versus CRT–P implantation?

KQ7a: What is the effectiveness of alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar) versus conventional CRT techniques in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF ≤35% and a QRS duration ≥120ms?

KQ7b: Does the effectiveness of alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ8: What are the adverse effects or complications associated with alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar)?

KQ9: What is the effectiveness of His bundle pacing or CRT versus RV pacing in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF between ≥36% to ≤50% and atrioventricular block?

KQ10: What are the adverse effects or complications associated with His bundle pacing or CRT versus RV pacing in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF between ≥36% to ≤50% and atrioventricular block?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s)

KQ1–KQ8: Subjects of age ≥18, with a left ventricular ejection fraction ≤35% and a QRS duration ≥120 ms.

KQ9–10: Subjects of age ≥18, with an LVEF between ≥36% to ≤50% and atrioventricular block [We will use a recently published systematic review to address KQs 9–10].

Interventions

- Cardiac resynchronization therapy with a defibrillator (CRT–D)
- Cardiac resynchronization without a defibrillator (CRT–P)
- Alternative cardiac resynchronization therapy alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar)

Comparators

- CRT–D vs. implantable cardioverter defibrillator (ICD)
- CRT–P vs. optimal medical therapy
- CRT–D vs. CRT–P
- Alternative CRT techniques versus conventional CRT techniques

Outcomes

KQ1a, 3a, 5, and 7a (Effectiveness)

Clinical outcomes

- 6 minute hall walk distance
- Left ventricular end diastolic volume/volume index
- Left ventricular end systolic volume/volume index
- Left ventricular ejection fraction
- Packer Score [17]

Quality of life

- Minnesota Living with Heart Failure Inventory Score
- Kansas City Cardiomyopathy Score
- SF–36

Health outcomes

- Hospitalizations for heart failure
- All-cause mortality

KQ2, KQ4, KQ6, and KQ8 (Harms)

- Procedure related complications
- Length of hospital stay
- Pneumothorax
- Pocket hematoma
- Device Infection
- Cardiac perforation/tamponade
- Lead dislodgement
- Ventricular arrhythmias
- Death (within a week)
- Inappropriate ICD shocks (CRT–D and alternative CRT–D techniques only)

KQ1b, KQ3b, 7b (Subgroups)

- Age
- Gender
- Cardiomyopathy subtype
- QRS morphology
- Left ventricular ejection fraction
- NYHA class
- Atrial fibrillation

Timing

KQ1a, 3a, 5, and 7a, (Effectiveness)

- Outcomes from CRT–D, CRT–P, and alternative CRT techniques at 3–6 months, 1 year, and ≥2 year end-points

KQ2, 4, 6, and 8 (Harms)

- Outcomes from CRT–D, CRT–P, and alternative CRT techniques at any time point

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2019–02985 Filed 2–20–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–19–19SJ; Docket No. CDC–2019–0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Preventive Health and Health Services Block Grant Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC). This study will allow CDC to monitor awardees progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant awardees, and promote the use of evidence-based guidelines and interventions.

DATES: CDC must receive written comments on or before April 22, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0004 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without

change, all relevant comments to *Regulations.gov*.

Note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Preventive Health and Health Services Block Grant (OMB No. 0920–0106, exp. 7/31/2019)—Extension—Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Preventive Health and Health Services Block Grant (PHHSBG), Public Law 102–531, Public Health Service Act, provides funds to 61 awardees (50 states, the District of Columbia, two American Indian Tribes, and eight U.S. territories) and provides funding to address locally-defined public health needs in innovative ways. Block Grants allow awardees to prioritize the use of funds to address leading causes of death and disability. Block Grant funding also provides awardees with the ability to respond rapidly to emerging health issues, including outbreaks of diseases or pathogens. The PHHS Block Grant program is authorized by sections 1901–1907 of the Public Health Service Act.

CDC currently collects information from Block Grant awardees to monitor their objectives and activities (Preventive Health and Health Services Block Grant, OMB No. 0920–0106, exp. 7/31/2019). Each awardee is required to submit an annual application for funding (Work Plan) that describes its objectives and the populations to be addressed, and an Annual Report that describes activities, progress toward objectives, and Success Stories which highlight the improvements Block Grant programs have made and the value of program activities. Information is submitted electronically through the web-based Block Grant Information Management System (BGMIS).

CDC PHHS Block Grant program has benefited from this system by efficiently collecting mandated information in a format that allows data to be easily retrieved in standardized reports. The electronic format verifies completeness of data at data entry prior to submission to CDC, reducing the number of re-submissions that are required to provide concise and complete information.

The Work Plan and Annual Report are designed to help Block Grant awardees attain their goals and meet reporting requirements specified in the program's authorizing legislation. Each Work Plan objective is defined in SMART format (Specific, Measurable, Achievable, Realistic and Time-based), and includes a specified start date and end date. Block Grant activities adhere to the Healthy People (HP) framework established by the Department of Health and Human Services (HHS). The current version of the BGMIS associates each awardee-defined activity with a specific HP National Objective, and identifies the location where funds are applied.

There are no changes to the number of Block Grant awardees (respondents), or the estimated burden per response for the Work Plan or the Annual Report. The BGMIS does not collect data related to assessing aggregate outcomes. A separate information collection request, designed to assess cross-cutting outputs and outcomes resulting from Block Grant activities has been developed and is undergoing public comment.

Legislation requires awardees to be accountable for funds they receive by evaluating and reporting on program activities and health status on an annual basis. The BGMIS system allows CDC and awardees to measure performance, identifying the extent to which objectives were met and identifying the most highly successful program interventions. CDC requests OMB approval to continue the Block Grant information collection for three years. CDC will continue to use the BGMIS to monitor awardee progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant awardees, and promote the use of evidence-based guidelines and interventions. There are no changes to the number of respondents or the estimated annual burden per respondent. The Work Plan and the Annual Report will be submitted annually. The estimated burden per response for the Work Plan is 20 hours and the estimated burden per response for the Annual Report is 15 hours. Participation in this information collection is required for Block Grant awardees. There are no costs to respondents other than their time. Awardees continue to submit Success Stories with their Annual Progress reports through BGMIS, without changes.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
	Work Plan	61	1	20	1,220
	Annual Report	61	1	15	915
Total					2,135

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–02917 Filed 2–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0003]

National Health and Nutrition Examination Survey (NHANES) DNA Specimens: Guidelines for Proposals To Use Samples and Cost Schedule

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces reopening of the National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Survey (NHANES) DNA Specimen Repository for research proposals. Blood samples for DNA purification were collected from study participants, with their permission, during NHANES III (1991–1994), NHANES 1999–2000, NHANES 2001–02, NHANES 2007–08, NHANES 2009–10, and NHANES 2011–12 (Office of Management and Budget Control Numbers # 0920–0237/0920–0950). DNA samples are being made available to the research community for genetic testing. The information gained from research using these samples can be combined with the extensive amount of information available in NHANES which describes the prevalence/trends of disease, nutrition, risk behaviors, and environmental exposures in the US population.

A more complete description of this program follows.

FOR FURTHER INFORMATION CONTACT: NHANES Genetic Project Officer, Jody McLean M.P.H., Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, MD 20782, Phone: 301–458–4683, Fax: 301–458–4029, Email: *NHANESgenetics@cdc.gov.*

Authority: Sections 301, 306 and 308 of the Public Health Service Act (42 U.S.C. 241, 2421 and 242m).

SUPPLEMENTARY INFORMATION:

Background

NHANES is a program of periodic surveys conducted by NCHS. Examination surveys conducted since 1960 by NCHS have provided national estimates of the health and nutritional status of the U.S. civilian non-institutionalized population. The goals of NHANES are (1) to estimate the number and percentage of people in the U.S. population and designated subgroups with selected diseases and risk factors for those diseases; (2) to monitor trends in the prevalence, awareness, treatment and control of selected diseases; (3) to monitor trends in risk behaviors and environmental exposures; (4) to analyze risk factors for selected diseases; (5) to study the relation among diet, nutrition and health; (6) to explore emerging public health issues and new technologies; and (7) to establish and maintain a national probability sample of baseline information on health and nutritional status.

The availability of the NHANES III DNA samples has been previously announced in 2002 (67 FR 51585), 2006 (71 FR 22248), 2007 (72 FR 59094), 2009 (74 FR 45644), 2010 (75 FR 32191) and 2016 (81 FR 69822). NHANES III Phase II DNA samples (1991–1994) are from participants ages 12 or older (*see* NHANES III DNA Samples section for a description). For details about available NHANES III non-genetic data see *https://wwwn.cdc.gov/nchs/nhanes/nhanes3/default.aspx.*

Beginning in 1999, NHANES became a continuous, annual survey rather than a periodic survey. For a variety of reasons, including disclosure and reliability issues, the survey data are released as public use data files every two years. In addition to the analysis of data from any two year cycle, it is possible to combine two cycles to increase sample size and analytic options. Blood samples for DNA purification were collected from participants ages 20 years and older in survey years 1999–2002 and 2007–12. DNA samples are available as collections from NHANES 1999–2002 (NHANES 1999–2000 and 2001–02 samples available as one collection), and NHANES two-year cycles 2007–08, 2009–10, and 2011–12(*see* NHANES 1999–2002, 2007–08, 2009–10, and 2011–12 DNA samples section for a description). The availability of the NHANES 1999–2002 DNA samples has been previously announced (2007 [72 FR 59094], 2009 [74 FR 45644], 2010 [75 FR 32191], and 2016 [81 FR 69822]). The availability of the NHANES 2007–08 DNA samples has been previously announced (2009 [74 FR 45644], 2010 [75 FR 32191], and 2016 [81 FR 69822]). The availability of the NHANES 2009–10 DNA samples has been previously announced (2016 [81 FR 69822]). The data release cycle for the NHANES corresponding to the period in which samples were collected for DNA is described in the following web links:

https://wwwn.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=1999

https://wwwn.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=2001

https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2007

https://wwwn.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=2009

https://wwwn.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=2011

Identifiable health information collected in the NHANES is kept confidential. During the informed consent process, survey participants are assured that data collected will be used only for stated purposes and will not be disclosed or released to others without the consent of the individual in