

Information Collection Request

Extension

Million Hearts® Hypertension Control Challenge
OMB No. 0920-0976, Expiration Date 11/30/2022

Supporting Statement: Part A

Program Official/Contact:
Judy Hannan, RN, MPH
Telephone: (770) 488-4572
E-mail: jhannan@cdc.gov
National Center for Chronic Disease
Prevention and Health Promotion
Centers for Disease Prevention and Control
Atlanta, Georgia

September 12, 2022

CONTENTS

Overview

- A.1. Circumstances Making the Collection of Information Necessary
- A.2. Purpose and Use of the Information Collection
- A.3. Use of Improved Information Technology and Burden Reduction
- A.4. Efforts to Identify Duplication and Use of Similar Information
- A.5. Impact on Small Businesses or Other Small Entities
- A.6. Consequences of Collecting the Information Less Frequently
- A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- A.9. Explanation of Any Payment or Gift to Respondents
- A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
- A.11. Institutional Review Board and Justification for Sensitive Questions
- A.12. Estimates of Annualized Burden Hours and Costs
 - A12-A. Estimated Annualized Burden Hours
 - A12-B. Estimated Annualized Burden Costs
- A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
- A.14. Annualized Cost to the Federal Government
- A.15. Explanation for Program Changes or Adjustments
- A.16. Plans for Tabulation and Publication and Project Time Schedule
- A.17. Reason(s) Display of OMB Expiration Date is Inappropriate
- A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

List of Attachments

- 1a. Authorizing Legislation: Public Health Service Act
- 1b. Authorizing Legislation: COMPETES Act
2. 60-Day Federal Register Notice
- 3a. Application Form
- 3b. Confirmation email
4. Verification Form
5. Interview Guide
6. Screenshot of Challenge website
7. Example Business Associate's Agreement
8. Project Determination
9. Example Contractors Request for Charts Part 1
10. Example Contractors Request for Charts Part 2

Purpose: Nationally, the US hypertension control rate is only 48%. The purpose is to identify clinicians and healthcare systems that achieve exemplary rates of hypertension control, of at least 80% among their adult hypertensive patients age 18-85, and to identify the strategies used to achieve high rates of control.

Goal: To recognize Million Hearts Hypertension Control Champions that achieve a verified and validated 80% hypertension control rate and promote the strategies the Champions use to achieve high rates of control.

Intended Use: CDC will use this information to recognize exemplary clinical practices in hypertension control and identify and promote best practices for achieving high rates of control through web-based material and publications.

Methods: Clinical practices achieving hypertension control rates of 80% or greater voluntarily apply, through the Challenge.gov Million Hearts website by completing an Application Form that provides de-identified, aggregate information about the applicants' patient population and rate of hypertension control. A contractor will review electronic medical record code to verify the patient population included in the control rate, and validate the hypertension control rate of the patient population. Qualitative information will be collected through an in-person interview or telephone interviews with Champions.

Target Population: Respondents are clinicians, medical practices, and healthcare systems.

Analysis Plan: Data collected through the application and verification processes will be used to verify and validate the hypertension control rate for the reporting period for the applicant. The application form requests information on the hypertension prevalence of the patient population of the application. This information is also used in a CDC Hypertension Prevalence Estimator tool to identify if the applicant's self-reported hypertension prevalence is "reasonable".

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is an extension of the currently approved Million Hearts® Hypertension Control Challenge OMB package (**OMB No. 0920-0976**). OMB approval is requested for 3 years. CDC's authority to administer the

Million Hearts® Hypertension Control Challenge is provided by the Public Health Service Act (42 USC 241, see **Attachment 1a**), which provides CDC with the authority to conduct investigations and studies relating to the diagnosis, treatment, and control of diseases, and The America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act, Public Law 111- 358, **Attachment 1b**), which provides authority for CDC to hold challenges that further the Agency’s mission and provide cash awards.

Background

Cardiovascular disease is a leading cause of death for men and women in the United States, among the most costly health problems facing our nation today, and among the most preventable. Heart disease and stroke also contribute significantly to disability. High blood pressure, also known as hypertension, is one of the leading causes of heart disease and stroke. Currently, about 75 million American adults have high blood pressure and only about half (48%) have it adequately controlled. Hypertension and its associated diseases pose approximately \$48.6 billion in medical and lost productivity costs each year.

In September 2011, the Department of Health and Human Services (HHS) launched the Million Hearts® initiative (co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS)) to prevent one million heart attacks and strokes by 2017. This initiative has been extended through 2027. Achieving this goal means that 16 million more Americans must have their blood pressure under control, and will require concerted, system-level strategies to improve the management of hypertension. Phillips et al. first defined clinical inertia (2001) as acknowledgement of the problem, but failure to act.¹ They further explained that it “*is a problem of the health care professional and the health care system, and it is separate from patient-related issues of adherence and access to care.*” O’Connor et al. further explored clinical inertia and hypothesized physician factors account for 50% of clinical inertia, patient factors for 30%, and the remaining 20% due to office system factors.² Physician factors include: failure to diagnose and initiate treatment, reactive rather than proactive care, and failure to identify and manage comorbid conditions. System factors include: not using clinical guideline,

1 Phillips LS, Branch WT, Cook CB, et al. Clinical inertia. *Ann Intern Med.* 2001;135(9):825-34

2 O’Connor PJ, Sperl-Hillen JM, Johnson PE, et al. Clinical inertia and outpatient medical errors. In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. *Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology)*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb. Available at:

<http://www.ahrq.gov/downloads/pub/advances/vol2/OConnor.pdf>

decision support tools, or disease registries, and poor visit planning and communication between physician and staff. Germino³, in his discussion of pending revisions to clinical guidelines for hypertension control notes *“Attempts to improve BP control rates in this country remain an important aspect of the JNC (Joint National Commission) reports, but how do we do this beyond information? Education of both patient and health care personnel is of paramount importance”*

At least some of the system factors needed to address hypertension management can be addressed by identifying and disseminating successful solutions initiated by clinicians, practices, and healthcare systems. There is substantial scientific evidence about the types of system changes that improve hypertension control.^{4,5} Key levers include incorporating team based care, improving reimbursement, audit and feedback, supporting self-management, using registry data, physician and patient reminders, improving medication compliance, and the use of evidence-based standardized hypertension treatment protocols. What is lacking is implementation expertise with those systems and processes in order to promote best practices.

In 2013, CDC initiated the annual Million Hearts® Hypertension Control Challenge to assist in 1) identifying medical practices that had achieved exemplary levels of hypertension control in their patient populations, and 2) promoting dissemination and adoption of the hypertension control strategies utilized by these practices (OMB No. 0920-0976, exp. 7/31/2016). Information was collected to rate and rank candidates for recognition and to describe their clinical care processes. Million Hearts® Challenges were conducted and supporting information was collected and analyzed in 2013-2014 (for 2013 Million Hearts® Champions announced in 2014), 2014-2015 (for 2014 Champions announced in 2015), and 2015-2016 (for 2015 Champions announced in 2016), (2016-2017) for Champions announced in 2017, 2017-2018 (for Champions announced in 2018), 2018-2019 (for Champions announced in 2019), and 2019-2020 (for Champions announced in 2020). Through the Million Hearts® Challenges, CDC has recognized a total of 133 Million Hearts® Champions, across 40 states and the District of Columbia. See <https://millionhearts.hhs.gov/partnersprogress/champions/challenge.html>.

3 Germino, WFJNC 8: Expectations, Challenges, and Wishes—A Primary Care Perspective. *The Journal of Clinical Hypertension*, .2009; 11:573-576.

4 Walsh J, McDonald KM, Shojanian KG, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 3—Hypertension Care. Technical Review No. 9. (Prepared by Stanford University-UCSF Evidence-based Practice Center under Contract No. 290-02-0017). Rockville, MD: Agency for Healthcare Research and Quality, January 2005. AHRQ Publication No. 04-0051-3.

5 Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. *Cochrane Database Syst Rev*. 2010.

A.2. Purpose and Use of the Information Collection

The Million Hearts® team will collect applications for the Challenge during a 6-8 week period each calendar year. Applications will be collected via an online platform. The information to be collected will support the CDC and Million Hearts® purpose of improving and sustaining the control of hypertension through increased attention to hypertension at the clinical practice level and better understanding of successful implementation strategies at the clinical practice health system level. Specifically, identifying and recognizing exemplary clinical practices will (a) lead to deeper understanding about how to achieve better control rates, (b) bring widespread attention to achievable exemplar rates, (c) motivate clinicians to strive for better hypertension control rates, and (d) bring visibility to a wide range of organizations that invest in hypertension control.

To date, the Million Hearts® initiative has recognized 133 Hypertension Control Champions across 40 states. The initiative has generated 27 success stories since it started conducting the Challenge in 2012. The Hypertension Control Champions' success stories provide valuable lessons for other practices and systems that want to help patients achieve blood pressure control and reduce the risk for cardiovascular disease. By continuing the Challenge, the Million Hearts® initiative will be able to generate more success stories and gain further insight into strategies that are useful for achieving exemplary blood pressure control rates. Continuing the challenge will also motivate additional clinicians to achieve commendable blood pressure control rates among their hypertensive patients.

Information collection for the Challenge will be conducted in three steps.

1. The Million Hearts® Hypertension Control Champion Application Form (Attachment 3a) will be collected for up to 200 applicants per year. The web-based application form (**Attachment 6**) includes contact information for the applicant, demographic information about their clinical practice, data on their hypertension control rate, and information about the clinical system supports used to improve the hypertension control rate. It also includes submission of a minimal amount of data to provide evidence of clinical success in achieving hypertension control.

Based on previous experience, CDC anticipates that the vast majority (greater than 95%) of applicants will already use an existing hypertension control measure for reimbursement or quality reporting initiatives and so will have ready access to the data. Practices and healthcare systems use these data for a variety of internal and external purposes such as billing, tracking participant progress, marketing, and others. Use of an existing hypertension control

measure thus minimizes the respondent burden associated with participating in the Challenge.

Information collected through the application process will be used to rank approximately 40 finalists by hypertension control rate for data verification and validation. A CDC panel of judges will review the results of the data validation and background check to determine the Champions, based on validated control rate and background check results.

2. Up to 40 finalists with the highest preliminary scores will be asked to participate in a data verification and validation process. The Million Hearts® Hypertension Control Champion Data Verification Form (Attachment 4) will be used to verify finalists' application information and ensure the accuracy of submitted data. Verification and validation will be conducted by an independent organization such as the National Committee for Quality Assurance (referred to as a contractor), which has expertise in clinical data validation and is sensitive to and has expertise in privacy considerations. The Verification Form will be completed by the independent organization via phone and the validation will consist of a de-identified record review performed by a subcontractor.
3. Up to 35 Champions will be asked to participate in a semi-structured, qualitative interview (see **Attachment 5**, the Million Hearts® Hypertension Control Champion Interview Guide). The purpose of the interview is to obtain in-depth contextual information about the clinical strategies and facilitators used by highly successful clinicians and healthcare organizations to achieve exemplary hypertension control rates. The interview will be guided by three opening questions. The interviewer will guide the remaining discussion to gain in depth information on those questions. The interview will focus on the clinical supports, systems, and community linkages that support achievement of exemplary hypertension control rates.

CDC plans to recognize up to 35 Champions per year (from up to 40 finalists). In any given year the number of finalists may exceed the number of Champions that receive recognition. If a finalist declines to participate in the data verification process or the interview, or is determined to be ineligible, CDC will proceed to the next highest scoring finalist. If time and/or resources do not permit CDC to continue moving to the next highest scoring participant, CDC will reduce the number of Champions recognized.

The Million Hearts® Challenge is designed to identify currently successful organizations and clinical practices and obtain insights into the sustainable strategies that they've implemented to maintain high blood pressure control rates. The information gained will be used to develop and promote examples

of these successful clinical practices that result in better hypertension control rates. These insights can then be shared with other practices to motivate, inspire, and inform their future activities. For example, although some providers and healthcare systems routinely provide data on hypertension control rates to entities such as quality improvement committees, information is not collected or disseminated about the innovative clinic processes used to achieve hypertension control. The Million Hearts® Challenge will link success in clinical outcomes of hypertension control with information about procedures that can be used to achieve similar favorable outcomes so that the strategies can be replicated by other clinical practices and health care systems. Examples are available at <https://millionhearts.hhs.gov/partners-progress/champions/index.html>.

Descriptions of Champion's clinical and community strategies to improve hypertension control will be shared through CDC-developed written documents and other media with the broader goal of improving the quality of care delivered to hypertensive patients.

A list of Hypertension Control Champions will be publicly available with the consent of Champions. However, the published list will only name the organization and city/state the practice is located in (and Web address, if provided); it will not include the name of the organization's contact person or any other person's name, unless expressly requested by the Champion.

A.3. Use of Improved Information Technology and Burden Reduction

CDC designed this data collection to minimize the burden to applicants. The challenge platform is an easily accessible, web-based system accessible using a personal computer that supports the collection of a large number of challenge submissions. Having a centralized, consistent method to collect information helps to minimize errors and redundancy and is essential to the timely and accurate scoring of applications. The system allows for increased efficiency through electronic reporting by applicants. Providing a web-based application system will:

- Shorten the time period for collection of information using radio button or multi-select response buttons and short descriptive opportunities through a one-step process.
- Standardize the information collected.

Other information will be collected by telephone interview, personal interview, or site visit.

A.4. Efforts to Identify Duplication and Use of Similar Information

CDC examined three sources that collect provider performance data for credentialing, accreditation, or recognition of programs: the National Committee for Quality Assurance (NCQA); the Physician Quality Reporting System (PQRS); and Bridges to Excellence (BTE).

The National Committee for Quality Assurance (NCQA) is a not-for-profit organization dedicated to improving health care quality. NCQA recognizes clinicians who use evidence-based measures and provide excellent care to persons with cardiovascular disease through the Heart/Stroke Recognition Program. Recognition is based on self-reporting of a bundle of performance measures related to heart disease and stroke care and recognizes excellence based on a composite score. A relatively low proportion of the score is driven by hypertension control. The cost to purchase the raw data for Commercial, Medicaid and Medicare Quality Compass HEDIS data from NCQA is approximately \$29,000.

In addition, the fee to apply for recognition is \$580 - \$3,080, depending on the number of physicians reporting data for an organization. While not an exorbitant amount, the fee may pose a barrier to some potential applicants.

The Merit-based Incentive Payment System (MIPS)⁶ is a reporting program that ties payment to quality and cost efficient care and health outcomes. Primary care providers are required to provide quality data on 6 out of more than 60 quality measures. The pool of potential applicants using MIPS would be limited to those clinicians accepting Medicare patients. More importantly, MIPS has only three individual measures related to hypertension, and only one related to hypertension control. The measures relevant to hypertension are:

- Quality Measure 236 – Controlling High Blood Pressure
- CMS 65v8 – Improvement in blood pressure
- CMS22v4 – Screening for high blood pressure

Bridges to Excellence⁷ (BTE) is a not-for-profit organization developed by employers, physicians, health care services, researchers, and other industry experts with a mission to create significant leaps in the quality of care by recognizing and rewarding health care providers who demonstrate that they have implemented comprehensive solutions in the management of patients and deliver safe, timely, effective, efficient, equitable and patient-centered care.⁷ Providers who meet performance benchmarks can earn a range of incentives, sometimes including

⁶ Data available at <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2017-MIPS-Quality-Performance-Category-Fact-Sheet.pdf> and

substantial cash payouts. Insurers and employers fund these payouts from the savings they achieve through lower health care costs and increased employee productivity. The Hypertension Care Recognition Program is a BTE Clinician Recognition Program intended to identify clinicians who deliver high-value hypertension care to adult patients. The cost to apply for recognition varies with the method used to submit data and increases depending on the number of clinicians reporting and the type of data submission used. The highest level of recognition is a composite score of control for hypertensive patients, controlled hypertensive patients and 8 other measures, where a provider must score at or above the 50th percentile of all submissions for recognition. A BTE contracted data aggregator holds all data and only reports to BTE the level of recognition achieved by a provider or practice, not the actual data points. Extracting hypertension control data would require contracting with several data aggregator contractors, and would be costly.

HRSA Health Center Program

The Health Resources and Services Administration (HRSA) has implemented a Quality Improvement Awards (QIA) program that recognizes achievements in various categories of quality improvement. The categories recognized vary from year to year although those recognized receive monetary awards from the Department of Health and Human Services. For FY 2018 they were recognizing Federally Qualified Health Centers (FQHCs) who made at least a 10% improvement in one or more clinical quality measures (CQMs), and also recognizes FQHCs that are in the top quartile of all FQHCs for various CQMs. This program is limited to FQHCs.

While each of these existing systems has benefits, none of them fully meet the needs of Million Hearts Hypertension Control Challenge:

1. Entry that does not discriminate based on resources to apply.
2. Entry that is not limited to a pool of physicians affiliated with a specific reporting system.
3. Clear access to provider hypertension control data. While other recognition programs collect hypertension control data, the data would need to be extracted from each application at additional cost.
4. A combination of clinical and systems data in a format that allows comparison on a number of key selection criteria. Use of the alternate options would require interviews with a much larger pool of high performing clinicians to assess sustainability, effective systems, and high risk populations, prior to selection of champions, increasing the burden to those providers.

5. Encouraging a sense of competition among high performing providers.

Further, use of any of these mechanisms reaches only the select audience that responded to and was accepted by the sponsoring organization. Use of any of these measures would require a solicitation to each potential champion in that system to ascertain interest and approval to participate and access their data, approval and resources to disaggregate the hypertension control data if necessary, and request the same system-related information in the Million Hearts® Hypertension Control Champion Application Form. Using any of these mechanisms requires an individual solicitation and consent plan for a potentially large pool of candidates – more than for an open and voluntary application. It is likely that for best results, multiple contact attempts by government or contract staff would be required to solicit consent.

A.5. Impact on Small Businesses or Other Small Entities

Participation in the Million Hearts Hypertension Control Challenge is voluntary and does not impose any new data collection on applicants, but rather applicants report on existing data. This data collection does aim to provide equal access to both large and small clinical practices and healthcare systems. CDC anticipates that approximately 90% of applicants will be clinic-based practices and 10% will be healthcare systems, all from the private sector, including federally qualified health centers.

A.6. Consequences of Collecting the Information Less Frequently

The timeframe for data collection is aligned with an annual recognition program, requiring annual data collection. Provider data collections for other purposes may be used for submission to the Million Hearts® Hypertension Control Challenge as long as aligned with the NQF18 measure and collected within a reasonable timeframe (ending within 3 months of submission). Clinicians, practices, and health systems achieving 80% hypertension control rates are likely capturing this data through a registry or frequent electronic medical record review.

Current information must be collected for each annual challenge because:

1. The hypertension control data must be timely. Control rates may change over the course of a year given patient turnover, and financial implications of treatment in a rapidly changing healthcare environment. Collections less frequently than annually may result in inaccurate data or recognition of a provider whose performance has slipped below the required 80% control rate.

2. The challenge draws attention to the importance of hypertension control and collecting and reviewing data on a regular basis is an important step.

Less frequent information collection for the Million Hearts® challenge would have negative consequences for the quality of information used to evaluate applicants, and the types of best practices that CDC hopes to recognize through this challenge.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances related to the Million Hearts® Hypertension Control Challenge and 5 CFR 1320.5. The request fully complies with the regulation.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

- A. Federal Register Notice. A 60-day Notice was published in the Federal Register on December 21, 2021 (Volume 86, Number 242, pages 72239-72241; **Attachment 2**). CDC received 0 comments.
- B. Other Consultations. The Million Hearts® Hypertension Control Challenge was designed collaboratively by CDC staff, and Centers for Medicare and Medicaid Services staff, which includes physicians and epidemiologists and statisticians. National Committee for Quality Assurance staff were consulted on data verification procedures and participation. Ongoing collaboration and evaluation of the Challenge and data collection instruments will continue after each Challenge to refine and improve data collection.

A.9. Explanation of Any Payment or Gift to Respondents

Applicants will not receive a payment or gift for participating. Selected Champions will receive public recognition by CDC.

A.10. Assurance of Confidentiality Provided to Respondents

- A. Privacy Act Assessment. This Information Collection Request has been reviewed by the CIO Information Systems Security Officer in the National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act does not apply. Respondents (Challenge applicants) are clinicians, health care practices, and healthcare organizations. Each applicant seeking recognition must submit contact information, including the applicant's name, mailing and e-mail addresses, and

telephone number. Applications will be held in accordance federal record keeping requirements and will be destroyed either at the end of the challenge program or held for not more than five years after the end of the challenge program.

Applications will report only aggregate hypertension control rates. Data verification and validation as necessary for selected finalists will only be conducted through the use of an independent chart abstraction subcontractor or electronic medical record subcontractor, and only a summary of the number of medical records that passed the validation process will be conveyed to CDC. No individual or patient-level data will be included. No patient-level records are collected by or reported to CDC.

- B. Security. Access to the Challenge online application database will be controlled by a password-protected login and accessible by a minimal number of contract or CDC staff for the duration of the Challenge. CDC will maintain the applicant information and hypertension control data in password-protected files in a secure server. Selected Champions' practice name, city and state will be publicized and made available on the Million Hearts® website post selection with the consent of the Champion.

Information collection of the applications will be conducted according to a security plan that has been approved by CDC's Office of the Chief Information Security Officer (OCISO). Data collection risks, mitigating controls, and risk acceptance are documented through a CDC Third Party Web Application Privacy Impact Assessment on file at CDC.

Certain information (i.e. medical identification number, date of birth, date of hypertension diagnosis, and most recent blood pressure reading) required by a subcontractor is used for validation and verification of the applicant's self-reported hypertension control rate. This information will be maintained under secure HIPAA-compliant conditions and destroyed at the conclusion of the Challenge. An example Business Associate's Agreement (**Attachment 7**) will be signed between a contractor and the applicant assuring HIPAA compliance by both the contractor and the applicant. The Business Associate's Agreement speaks to the confidential nature of the information and the legal requirements for securing information. If an applicant is not willing to sign the Business Associate's Agreement, no personally identifying information would be required and the application would no longer be considered. Information for the data validation is stored temporarily by a subcontractor. The information is destroyed at the end of the validation. CDC does not have access to this information. User access will be determined by roles and responsibilities under a HIPAA-compliant Business Associates Agreement (**Attachment 7**). A subcontractor will provide access to only two employees who will validate the information. The subcontractor has defined role-based access control policies, file integrity checks, and

security managing software to limit access. Only HIPAA compliant web-based software is used and files are encrypted at rest on servers isolated from the internet. All files used for data validation are destroyed at the end of the validation. The contractor provides instructions to the applicant on how to securely transmit the requested information. Examples of the contractors request includes a Privacy Act Statement (**Attachment 9 and Attachment 10**).

- C. Consent. For applicants, consent to participate in the Challenge is attested to on the application form (**Attachment 3a**). The OMB approved application forms are available on the Challenge website for potential applicants to view. Un-attested forms will be excluded from review. Eligibility and rules for the Challenge are posted on the challenge website.
- D. Requirement to Respond. There is no requirement to respond, participation is voluntary. We require attestation that the applicant will participate in data verification and validation and recognition if selected as a finalist, however the applicant may decide to decline participation at any time. At the time the applicant is notified of their status as a finalist, the applicant may decline to participate.

A.11. Institutional Review Board and Justification for Sensitive Questions

The Million Hearts® Hypertension Control Challenge application does not collect sensitive information. The Challenge will collect a limited amount of information in identifiable form (IIF) for the applicants (e.g., clinic administrator or clinician), such as name, address, and contact information which is the type of information generally publicly available. The Challenge will collect information about activities conducted by the clinician, practice, or healthcare system that led to exemplary hypertension control, not personal information. CDC's data collection instruments do not collect patient level data. CDC has determined that the project is not considered human subjects research and will not require IRB review (see **Attachment 8**).

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Information is collected once annually. Expected respondents are clinicians, practices, or healthcare systems.

On an annualized basis, CDC estimates receipt of 200 Million Hearts® Hypertension Control Challenge Application Forms (**Attachment 3a**). Each application will report information on aggregate health outcomes and sustainable systems. Applications will

be submitted electronically through the challenge platform. The estimated burden per response is 30 minutes.

Up to 40 finalists will be selected for the data verification and validation process (see **Attachment 4b**), which will be conducted via phone with de-identified record review to verify and validate the information submitted on the application form. The verification and validation is estimated to require 2 hours of the applicant’s time. The burden is estimated on the maximum number of finalists who may be asked to participate in the data verification and validation process.

Up to 35 Champions will also be asked to participate in a semi-structured interview, estimated to take 1 hour (see **Attachment 5**). Interviews may be conducted in person or by telephone.

Burden estimates are based on the 2019 and 2020 challenges. The total estimated annualized burden is estimated at 215 hours, as summarized in Table A.12-A.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hr)	Total Burden (in hr)
Physician, practices and healthcare systems	Million Hearts® Hypertension Control Champion Application Form	200	1	30/60	100
Finalists	Million Hearts® Hypertension Control Champion Data Verification Form	40	1	2	80
Champions	Interview Guide: Million Hearts® Hypertension Control Champion	35	1	1	35

	Total	215
--	-------	-----

B. Estimated Annualized Cost to Respondents

Table A.12-B displays estimates of annualized cost to respondents for participation in the data collection. Estimates were derived using an average hourly wage from the Bureau of Labor Statistics, located at <https://data.bls.gov/oes/#/geoOcc/Multiple%20occupations%20for%20one%20geographical%20area>.

Million Hearts® Hypertension Control Champion Application:

1. An estimated 75% of respondents will be Administrative/Services managers in a physician’s office. Managers time is valued at \$49.70 per hour.
2. An estimated 25% of respondents will be physicians. Using general internists as a standard, physician time is valued at \$95.37 per hour.
3. The weighted hourly average value of time applied to the burden is \$61.12.

Data Verification Tool

1. It is estimated that respondents will be comprised of data managers, clinic staff, and physicians in equal proportions of 33.34% each.
2. Using general internists as a standard, physician time is valued at \$95.37 per hour. Data manager time is valued at \$42.81 per hour. Registered nurse, as a representative of clinic staff is valued at \$35.36 per hour.
3. The weighted hourly average value of time applied to the burden is \$57.62 per hour.

Interview Guide: Million Hearts® Hypertension Control Champion

1. It is estimated that 50% of respondents will be physicians and 50% will be clinic staff such as a registered nurses.
2. Physician time is valued at \$95.37 per hour. Registered nurse time is valued at \$35.36 per hour.
3. The weighted hourly average value of time applied to the burden is \$65.37.

The total estimated annualized cost to respondents is \$21,572.20.

Table A.12-B. Estimated Annualized Cost to Respondents.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Burden per Response (in hours)	Weighted Hourly Wage	Total Cost
Administrator/ Clinician	Million Hearts® Hypertension Control Champion Application form	200	1	30/60	\$61.12	\$6112.00
Data managers, clinic staff, physician	Data Verification Form	40	1	2	\$57.62	\$4,609.60
Clinicians or Clinic staff	Interview Guide: Million Hearts® Hypertension Control Champion	35	1	1	\$65.37	\$2,287.95
					Total	\$13,009.55

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC anticipates that clinics or healthcare systems with electronic medical record (EMR) systems are most likely to participate, but it is not a condition for application. The cost of an EMR is one that a growing number of practices and healthcare systems would have as part of routine business. Providers with offsite data management services may be required to submit a data request of the data manager. The 2012 Hypertension Control Champion, selected using a different process, indicated that data management and retrieval is a part of practice and is negligible for one data request. No capital or maintenance costs are expected. There are no additional start-up, hardware or software costs. Use of EMRs by office-based physicians has steadily increased for more than a

decade. By 2015, 87% had adopted an EMR, and in 2018 this is likely even higher (<https://dashboard.healthit.gov/quickstats/quickstats.php>).

A.14. Estimates of Annualized Cost to the Federal Government

Costs to the Federal government include the cost of CDC personnel time for Challenge oversight, and contractor costs for data site collection set up and maintenance, and verification and validation of data submitted by applicants.

The total estimated annualized cost to the Federal government does not include the selection of Champions or development of written recognition products.

A summary of costs is presented in Table A.14-1. The total estimated annualized cost to the Government is \$247,000.00.

Table A.14-1. Estimated Annualized Cost to the Federal Government.

Cost Type	Cost
CDC staff. 5% of GS-14 for system oversight.	\$7,000
Contractor costs for website and database development, maintenance and download of information in a usable format.	\$40,000
Contractor costs for validation of data submitted by selected Champions.	\$200,000
Total	\$247,000

A.15. Explanation for Program Changes or Adjustments

Burden has not changed from the burden shown in sections A.12-14.

A.16. Plans for Tabulation and Publication and Project Time Schedule

1. Time schedule. OMB approval is requested for three years. Champions will be announced annually in the fall of 2022, 2023 and 2024.
2. Publication Plan. Information collected through the Champion interviews will be published on the CDC Million Hearts® website, each calendar year, 2022, 2023, 2024 and 2025.

3. Analysis Plan. CDC will not use complex statistical methods for analyzing information. All applications will be ranked by hypertension control rate. The top finalists will be reviewed by a panel of judges for selection as Champions. Statistical analyses are not planned as results are descriptive and include identifying the number of applications submitted; the type of providers nominated; and the range, median and mean of hypertension control rates. This information will be used by CDC for program improvement. The information collected through qualitative interviews is primarily descriptive.

Table A.16.1

Project Time Schedule for 2022-2025	
OMB Approval	Not later than October 2022
Challenge FRN Written and Cleared	October-December 2022
Challenge Website Developed	January-February 2023
Challenge FRN Posted	February 2023
Challenge Launched	February 2023
Challenge Closed	April 2023
Data Validation	April-Aug 2023
Finalists Reviewed by CDC Judges	September 2023
Preparation for Announcing Champions	September 2023
Champions Announced	October 2023

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.