

Information Collection Request

New

Million Hearts® Hospital/Health System Recognition program

Supporting Statement: Part A

Program Official

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REFERENCES

¹Kutney-Lee, A., Stimpfel, A. W., Sloane, D. M., Cimiotti, J. P., Quinn, L. W., & Aiken, L. H. (2015). Changes in Patient and Nurse Outcomes Associated with Magnet Hospital Recognition. *Medical Care*, 53(6), 550-557. <http://doi.org/10.1097/MLR.0000000000000355>

ATTACHMENTS

- Attachment 1a: The Public Health Service Act [42 U.S.C. 241]
- Attachment 1b: America Competes Reauthorization Act of 2010
- Attachment 2a: Million Hearts® Hospital / Health System Recognition Program Application
- Attachment 2b: Interview Guide: Million Hearts® Hospital/Health System Recognition Program
- Attachment 3: Million Hearts® Recognition Program Introduction
- Attachment 4a: Dear Colleague Letter
- Attachment 4b: Confirmation Email
- Attachment 5a: 60-day Federal Register Notice
- Attachment 5b: Public comments received from the 60-day Federal Register Notice
- Attachment 6: IRB Determination Form
- Attachment 7: Eligibility for Million Hearts® Hospital/Health System Recognition Program Participation
- Attachment 8: Million Hearts® Hospital / Health System Designation – Approach to Designee

Vetting



- Goal of the study: The Million Hearts® Hospital / Health System Recognition Program aims to recognize institutions that have implemented, are currently implementing, or are committing to implement Million Hearts® strategies. Resulting data will be reviewed to determine what Million Hearts® strategies applying instructions have been implementing, are currently implement or are committing to implement. Qualifying institutions will receive the Million Hearts® Hospital/Health System designation. Institutions that have achieved outcomes by implementing Million Hearts® strategies will receive additional emphasis.
- Intended use of the resulting data: Million Hearts® will use the resulting data for the purpose of recognizing institutions working to systematically improve the cardiovascular health of the population and communities they serve. It is important to highlight institutions that are using evidence-based strategies that promote improved cardiovascular health. Doing so provides an incentive for institutions to continue practicing these strategies and it also brings these strategies to the attention of other institutions.
- Methods to be used to collect: Data will be collected through the use of an electronic survey questionnaire.

A.1

Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR). CDC requests OMB approval for three years.

CDC's authority to collect this information is provided by the Public Health Service Act (42 USC 241, (see **Attachment 1a**) and also the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act, Public Law 111-358), (see **Attachment 1b**), which provides authority for CDC to hold challenges that further the Agency's mission.

Heart disease, stroke and other cardiovascular diseases (CVDs) kill over 80,000 Americans each year, accounting for one in every three deaths. CVD is the nation's number one killer among both men and women and the leading cause of health disparities across the population. Million Hearts[®], a national, public-private initiative co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), was established to address this issue.

Whether migrating towards value-based reimbursement or simply striving for a significant impact in reducing the devastation of heart attacks and strokes, clinical organizations are positioned to improve the health of the population they serve by implementing high-impact, evidence-based strategies. Achieving a Million Hearts[®] Hospital / Health System designation signals a commitment to not only clinical quality, but population health overall.

Published studies suggest that hospitals that are designated by a recognition program demonstrate more positive outcomes for patients and staff than hospitals that are not designated by a recognition program. For example, a study by Kutney Lee et al.¹ indicates that hospitals that received endorsement through the American Nurses Credentialing Center's (ANCC) Magnet Recognition Program exhibited better outcomes for patients including lower mortality and greater patient satisfaction.

Recognition programs implemented by CDC have also had great success. For example, Champions of the Million Hearts[®] Hypertension Control Challenge (**OMB No. 0920-0976**) have implemented best-practice strategies to improve hypertension rates among their patient populations. CDC has publically recognized these practices and has gained insight into the strategies that practices were using to effectively gain a high rate of hypertension control among their patient populations. Rather than recognizing applicants for their hypertension control rates, the Million Hearts[®] Hospital/Health System Recognition Program will recognize applicants that are using multiple strategies to address cardiovascular outcomes. Million Hearts[®] recognizes hospitals and health systems which have implemented strategies to improve the cardiovascular health among the populations and communities they serve through a focus on *Keeping People Healthy, Optimizing Care, Improving Outcomes for Priority Populations, and Innovating for Health (Attachment 3)*.

Applicants to the Million Hearts® Hospital/Health System Recognition Program, will do one or more of the following:

A.) Commit to implement policies that promote cardiovascular health

B.) Attest to the current policies and practices they are implementing to promote cardiovascular health

C.) Provide documentation of current policies that they are implementing and provide data that shows positive health outcomes as a result of those policies being implemented

A.2

Purpose and Use of the Information Collection

The Million Hearts® Hospital / Health System designation engages, equips, and supports leading clinical institutions across the country, given their direct connection to people at risk for CVD, as well as those who have had a cardiac or cerebrovascular event and remain at risk for having a subsequent event.

This recognition program will recognize institutions working to systematically improve the cardiovascular health of the population and communities they serve through the priority areas of *Keeping People Healthy*, *Optimizing Care*, *Improving Outcomes for Priority Populations*, and *Innovating for Health* (**Attachment 3**).

If Million Hearts® cannot implement this recognition program, then hospitals and health systems will not receive recognition for the evidence-based strategies that will promote improved cardiovascular health. Consequently, Million Hearts® would not be able to highlight these hospitals and health systems and the effectiveness of these evidence-based strategies.

The Million Hearts® Hospital/Health System Recognition Program application (**Attachment 2a**) will be collected for approximately 100 applicants per year. This estimate is based off of the number of applications received for the 2017 Million Hearts® Hypertension Control Champions Challenge (**OMB No. 0920-0976**). This program will be promoted through similar channels as the Control Challenge, including the Dear Colleague Letter (**Attachment 4a**), the Million Hearts® E-update, social media platforms and Challenge.gov. Therefore, since both recognition programs will be promoted through similar channels, Million Hearts® estimates the same number of applications for both programs.

Applicants will complete the Million Hearts® Hospital / Health System Recognition Program application (**Attachment 2a**), indicating the areas they are committing to implement Million Hearts® strategies; those strategies which they are currently implementing or have previously implemented; and those strategies for which they have achieved outcomes/results. Nomination information will be collected electronically and will be reviewed on a quarterly basis through a web-based online portal. Applicants will apply by completing the application form that includes information about the Million Hearts® strategies that they are committing to

implement, are currently implementing, or have already implemented and have achieved results. Estimated time to complete the form is 2 hours and 40 minutes (**Table A. 12-A**). The steps listed below outline the process for submitting an application:

- Applicants will create a free account on an external web platform.
- On this external web platform, the nominee will find the application for the Million Hearts® Hospital/Health System Recognition Program.
- After submitting a nomination on the challenge web platform, a confirmation email will be sent to the email address provided (**Attachment 4b**).
- Applicants may submit the application form during the submission period.

As mentioned above, the applicant will indicate whether they are committing, implementing, or have achieved outcomes/results with certain Million Hearts® strategies. A hospital may be in the process of implementing changes in support of benefit design outcomes, achieved results in blood pressure control, and committing to work with patients who have had a previous heart attack or stroke. The grid below lays out an example of a potential clinical entity’s status and corresponding data submission categories. The specific documentation requirements are detailed within the application.

Priority Area	Strategy	Phase (with required documentation categories noted)
Keeping People Healthy	Benefit design to advance employee health	Implementing – submit required attestation for those implementing
Optimizing Care	Cardiac rehabilitation referral initiation	Achieved – recommended outcomes for those achieving results
Improving Outcomes for Priority Populations	Work with patients who have had a previous heart attack or stroke	Committed – describe intended approach and outcomes for addressing past heart attack / stroke patients
Innovating for Health	Implementing telehealth strategies to track hypertension levels of patients in rural areas	Implementing – documentation supporting the efforts such as target population(s), policy or program materials, timeframe and measures being tracked

A funded partner will collect the data through applications via an online platform. The application will be hosted through a unique URL. Expected respondents are medical and health service managers. Applications for the Million Hearts® Hospital/Health System Recognition Program will be accepted continuously during the approved time period; CDC plans to continue

with the award and will apply for an extension so the data collected can be used in a timely fashion. The funded partner will collect this information in order to determine which strategies the applicant is committing to implement, is currently implementing or has achieved outcomes/results. All applicants with reported outcomes and a select number of those who are committing to implement or are implementing Million Hearts® strategies will be asked to participate in a semi-structured, qualitative interview. (**Attachment 2b**). The purpose of the interview is to obtain in-depth contextual information about the Million Hearts® strategies and facilitators to achieving improved cardiovascular outcomes among the applicant's patient population. The interview will be guided by three opening questions. The interviewer will guide the remaining discussion to gain in depth information on those questions. A list of Million Hearts® Hospitals / Health System designees will be publicly available with their consent. Selected applicants' practice name, city and state will be publicized post selection and pending the applicants' consent. For organizations, consent to participate in the Million Hearts Hospital/ Health System Recognition program is attested on the application form. Un-attested forms will be excluded from further review. Participation is voluntary.

A.3

Use of Improved Information Technology and Burden Reduction

One hundred percent of responses will be collected electronically via an online platform. Electronic submission of data reduces burden time for the respondent compared to data collection via paper and pencil format. 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. Providing a web-based nomination system will:

- Shorten the time period for collection of information using check box responses and short descriptive opportunities through one-step process.
- Standardize the information collected.

A.4

Efforts to Identify Duplication and Use of Similar Information

CDC examined three cardiac care designation programs in order to identify any similarities with the Million Hearts® Hospital/Health System Recognition Program. The first program examined was the National Committee of Quality Assurance's (NCQA) Heart/Stroke Recognition Program. Recognition is based on self-reporting of indicators including blood pressure control, use of aspirin or another antiplatelet, smoking and tobacco use cessation assistance, body mass index screening, and statin therapy for patients with cardiovascular disease. Another cardiac care designation program is the U.S. News & World Report: Best Hospitals for Cardiology & Heart Surgery. The designation criteria for this program include measures such as survival rates, patient safety, specialized staff and hospital reputation among other factors. The third program

examined was the Care Chex program, which scores hospitals on quality measures such as overall mortality, overall complications, readmissions, inpatient quality, and patient safety. While the above mentioned programs measure factors which are important for cardiac care, they do not include criteria which are based on the Million Hearts® strategies as outlined in the (Million Hearts® Hospital / Health System Recognition Program application (**Attachment 2a**)).

A.5

Impact on Small Businesses and Other Small Entities

Questions have been held to the absolute minimum required for the intended use of the data collection. Data is being collected in order to determine if respondents are committing to implement Million Hearts® strategies, currently implementing or have previously implemented and have achieved outcomes/results. Additionally, only 100 applications are anticipated out of a respondent universe of 5,500, and applying is voluntary.

A.6

Consequences of Collecting the Information Less Frequently

Respondents will fill out and submit applications once for their initial designation. At any time, institutions may respond to the additional requested information and/or data required to demonstrate they have achieved outcomes for a given strategy. For example, applicants who indicate that they are committing to implement a particular Million Hearts® strategy may submit another application later on to indicate that they are currently implementing that strategy or that they have achieved outcomes for that strategy. By not allowing applicants to apply, hospitals and health systems will not benefit from CDC's fidelity processes. Additionally, if data is not collected as frequently, the applicant cannot receive potential designation as a Million Hearts® hospital. Additionally, the applicant will not benefit from the engagement and partnership that comes with this designation program.

A7.

Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation of 5 CFR 1320.5.

A8.

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

- A. A 60 Day Notice was published in the Federal Register on (April 2, 2019) (Vol. 84, No. 63, pp. 12613-12615). A copy of this notice is provided as **Attachment 5a**. We received one non-substantive public comment (**Attachment 5b**).
- B. The Million Hearts® Hospitals or Health System Recognition Program was designed collaboratively by CDC and The National Association of Chronic Disease Directors.

Ongoing collaboration and evaluation of the program and data collection instrument will occur with each renewal to refine and improve data collection.

A9.

Explanation of any Payment or Gift Respondents

Respondents will receive no financial incentive for applying. Applicants who receive the Million Hearts® designation will receive public recognition by CDC.

A10.

Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC’s Privacy Office has reviewed this submission and determined that the Privacy Act does not apply (Privacy Narrative). The data collection does not involve collection of sensitive or identifiable personal information. No patient level data is collected. Respondents are organizational entities, not individuals. Application data will be filed and retrieved using the institution's name. Access to the Million Hearts® Hospitals/Health Systems Recognition Program nomination site will be controlled by a password protected login and accessible by a minimal number of funded partner or CDC staff. CDC will maintain the provider information and application data in password-protected files.

A11.

Institutional Review Board (IRB) and Justification for Sensitive Questions

CDC has determined that the project is not considered human subjects research and does not require IRB review (**Attachment 6**).

A12.

Estimates of Annualized Burden Hours and Costs

Information is collected at the time of submission, and exchanged periodically over the remaining three years. Expected respondents are medical & health service managers. On an annual basis, CDC estimates receipt of 100 Million Hearts® Hospital/Health System Recognition Program application forms (**Attachment 2a**). Applications will be submitted electronically. The estimated burden per response is 2 hours and 40 minutes. Individuals from Leavitt Partners and a doctoral cardiac rehab nurse from Rush University College of Nursing participated in the pilot testing of the Million Hearts® Hospital or Health System Program application.

Table A. 12-A. Estimated Annualized Burden Hours

Type of	Form Name	No. of	No. of	Average	Total Burden
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Respondent		Respondents	Responses per Respondent	Burden per Response (in hours)	Hours
Medical & Health Service Manager	Recognition Program Application	100	1	2 hours, 40/60	267
Medical & Health Service Manager	Interview Guide	60	1	30/60	30
Total					297

Table A.12-B displays estimates of annualized cost to respondents for participating in the data collection. Estimates were derived using an average hourly wage from the Bureau of Labor Statistics.

Million Hearts® Hospital/Health System Recognition Program application:

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

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Costs
Medical & Health Service Manager	Recognition Program Application	100	1	2 hours, 40/60	\$53.69	\$143.17
Medical & Health Service Manager	Interview Guide	60	1	30/60	\$53.69	\$26.85
Total						\$170.02

A13.

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

No capital or maintenance costs are expected. There are no additional start-up, hardware or software costs.

A14.

Annualized Cost to the Federal Government

Costs to the Federal government include the cost of CDC personnel time for project oversight and contractor costs for data site collection set up and maintenance.

A summary of costs is presented in **Table A.14-A**. The total estimated annualized cost to the Government is \$144,835.64. **Table A.14-A**

Cost Type	Cost
CDC staff. 4% of GS-15 for system oversight	\$4,835.64
Funded partner costs for website development and review of attestation of data submission and background checks	\$40,000
Costs for 3 separate funded partners to provide day to day management and delivery of project	\$100,000
Total	\$144,835.64

CDC Points of Contact

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A15.

Explanation for Program Changes or Adjustments

This is a new data collection request. Since the release of the 60-Day FRN, the wording of some application questions in **Attachment 2a** were revised so that applicants would be able to better understand the questions. This data collection tool was not revised in a way that would increase or decrease burden to the applicant.

A16.

Plans for Tabulation and Publication and Project Time Schedule

OMB approval is requested for three years. Anticipated data collection or nomination period will be ongoing for the three years. Champions will be announced on a quarterly basis.

Million Hearts® designees will be recognized on the Million Hearts® website and promoted via multiple communication channels, listed below. The successes and outcomes of clinical entities which have achieved results will be given additional, focused emphasis in these communications and promotional materials. Communication channels:

- Highlight in the Million Hearts® electronic newsletter;
- Use of the Million Hearts® logo on institution’s website;
- Use of an icon specific to those strategies where hospital has achieved results;
- Template press materials and newsletter announcements;
- Recognition through Million Hearts® communication and partner channels;
- Access to resources and support, and opportunity to exchange implementation tips and problem-solve with other Million Hearts® Hospitals and Health Systems;
- Connection to state health department Million Hearts® program

Statistical analyses planned for this project are descriptive, and include identifying the number of nominations submitted; the type of providers nominated; and a simple computation of the strategies for which applicants are committing to implement, currently implementing, or have previously implemented and have achieved outcomes/results.

Project Timeline	
Activity	Time Schedule
Announce the opportunity for hospitals and health systems to apply for the Million Hearts® Hospitals program	0 to 1 months after OMB approval

Data Collection	Ongoing during term of OMB approval
Selection of Million Hearts® Hospitals and Health Systems	Every 3 months
Announcement and publishing of Million Hearts® Hospitals and Health Systems	Every 3 months

The application is open to hospitals or healthcare systems that include clinicians and administrators providing direct services to adult patients.

The applicant must abide by the following eligibility rules (**Attachment 7**):

- (1) Shall have completed the application form in its entirety to participate in the competition under the rules developed by HHS/CDC;
- (2) Must have a data management system (electronic or paper) that allows CDC or their contractor to verify data submitted;
- (3) May not be a federal entity or federal employee acting within the scope of their employment;
- (4) Must not work on their application during assigned duty hours if they are an HHS employee;
- (5) Shall not be an employee of or contractor at/within CDC;
- (6) Must attest to being free from sanctions and current investigations for serious institutional misconduct (**Attachment 8**).

Prior to the launch of the Million Hearts® Hospitals /Health System Recognition Program, the online application will be reviewed and pilot tested by a small group of prospective applicants. Prior to the release of the web portal, testing will ensure that there are no flaws in the nomination form, form submission or access. Applications for the Million Hearts® Hospitals/Health Systems Recognition Program have not been used in previous projects or studies.

A17.

Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

A18.

Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

