

Emerging Infections Program

Tracking of SARS-CoV-2 Infections among Healthcare Personnel

Request for OMB approval of a New Information Collection

April 22, 2020

Supporting Statement A

Contact:

Nora Chea
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404)-639-0015
Email: xdc7@cdc.gov

Table of Contents

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

- **Goal of the study:** The goal of this information collection is to inform guidance for healthcare facilities to protect the healthcare workforce from the effects of COVID-19, the disease caused by the novel coronavirus SARS-CoV-2. The healthcare workforce is a critical asset during this pandemic. Protecting healthcare personnel (HCP) is an essential component of protecting patients.
- **Intended use of the resulting data:** The data collected from this project will be used to inform guidance for healthcare facilities to protect the healthcare workforce—a critical asset during this pandemic. Additionally, data will be used to: 1) determine the extent of COVID-19 among HCP from a subset of U.S. healthcare facilities; 2) describe characteristics of HCP infected with SARS-CoV-2, including clinical activities and personal protective equipment (PPE) use; and 3) compare exposures and other characteristics of HCP cases and HCP non-cases (HCP who tested negative for SARS-CoV-2) to identify risk factors or protective factors for COVID-19.
- **Methods to be used to collect:** There are two components of this project: Option 1 is prospective surveillance for HCP with COVID-19. Option 2 is a HCP case/non-case comparison. The project will be conducted by the Emerging Infections Program (EIP), a network of 10 state health departments and their local public health and academic partners. For option 1, EIP staff will obtain lists of HCP COVID-19 cases from state or local health departments, or from occupational health departments or infection control programs in participating healthcare facilities. For option 2, in selected healthcare facilities in which HCP non-cases are also included, lists will be obtained from occupational health departments or infection control programs. For options 1 and 2, EIP staff will interview HCP cases and non-cases by telephone or will send HCP an electronic form to complete (e.g., REDCap survey).
- **The subpopulation to be studied:** The subpopulation includes HCP participating in the delivery of care to COVID-19 patients in healthcare facilities.
- **How data will be analyzed:** (e.g., logistic regression) Data will be aggregated across participating EIP sites and healthcare facilities for analyses. Descriptive analyses and multivariable logistic regression modeling will be performed.
-

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) requests a 180-day emergency approval for a new information collection, “Emerging Infections Program Tracking of SARS-CoV-2 Infections among Healthcare Personnel.”

Since the World Health Organization was first notified of a cluster of respiratory infections in Wuhan City, China on December 31, 2019, the novel coronavirus, SARS-CoV-2, has caused more than 820,000 infections and 45,000 deaths in the United States (U.S.) and more than 2,500,000 infections and 170,000 deaths worldwide as of April 21, 2020. Overall, 20–30% of cases in the U.S. have required

hospitalization, resulting in a huge burden on healthcare personnel (HCP) and U.S. healthcare systems (<https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm>).

HCP are at risk of contracting COVID-19, the disease caused by SARS-CoV-2, during their interactions with patients with suspected or confirmed infection with COVID-19 or patients with unrecognized infection. A recent contact investigation conducted by a hospital, local and state health departments, and the Centers for Disease Control and Prevention (CDC), identified 121 HCP with high, medium, or low risk exposures (classified according to CDC guidance for HCP with potential exposure to patients with COVID-19) to a single COVID-19 hospitalized patient (the first individual infected based on community transmission of COVID-19) in Solano County, California (OMB Control No. 0920-1011, expiration date 04/23/2020). Of these exposed HCP, 43 developed symptoms consistent with COVID-19 and three tested positive for SARS-CoV-2. Similar events have occurred in many other jurisdictions across the U.S.

Given the novel nature of this virus, little is known about specific risk factors for SARS-CoV-2 transmission, particularly among HCP exposed in healthcare facilities. Furthermore, as community transmission has become widespread and hospitals and other healthcare facilities are caring for rapidly increasing numbers of infected patients, the incidence of COVID-19 among HCP remains unclear. Additional information about characteristics of infected HCPs and any associated risk and protective factors is urgently needed to inform guidance for healthcare facilities to protect the healthcare workforce—a critical asset during this pandemic. The safety of U.S. HCP has been recognized as a national priority by a congressional committee and members of congress have contacted CDC to requesting actions to protect HCP during this pandemic.

This data collection is authorized under section 301 of the Public Health Service (PHS) Act, [42 U.S.C. section 241(a)] (Attachment 1).

2. Purpose and Use of Information Collection

We propose to conduct tracking and interviews of HCP with COVID-19 (cases) and exposed HCP without COVID-19 (non-cases) to describe characteristics of HCP with COVID-19 and identify factors associated with development of COVID-19 among HCP of healthcare facilities within catchment areas of CDC's Emerging Infection Program (EIP) Healthcare-Associated Infections-Community Interface Activity (HAIC), a network of 10 state health departments and their local public health and academic partners.

The EIP conducts population-based surveillance for community and healthcare-associated pathogens of public health importance, which is currently approved under OMB Control No. 0920-0978 (expiration date: 04/30/2022). The EIP also conducts special projects pertaining to the prevalence of healthcare-associated infections and antimicrobial use in hospitals (No. 0920-0852; expiration date: 10/31/2022) and nursing homes (No. 0920-1165; expiration date: 02/29/2020). EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases. In addition to population-based surveillance, the EIP sites conduct applied public health research and other special projects to describe population at risk and evaluate the impact of prevention efforts. The 10 EIP sites

are: California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon and Tennessee, and are funded through a Cooperative Agreement with CDC to perform the activities noted above. More information about the work of EIP HAIC is available at: <https://www.cdc.gov/hai/eip/index.html>. Many of these routine activities have been put on hold during the COVID-19 pandemic and have been instructed to prioritize COVID-related surveillance and special projects over their routine CDC-funded surveillance and special epidemiology projects. Up to 10 EIP sites may participate in this information collection.

EIP sites that participate in this project may choose to implement one or both project options below:

- Option 1: Tracking of SARS-CoV-2 infections among HCP;
- Option 2: Assessing risk factors for infections among HCP exposed to patients with COVID-19 in healthcare facilities.

EIP site staff will identify a convenience sample of healthcare facilities within the EIP catchment areas. Hospitals and nursing homes are prioritized for inclusion, but other types of facilities may participate. Each EIP site will seek to identify three or more facilities to participate.

For option 1, EIP staff will obtain line lists of HCP cases and contact information from local or state health department partners or in some cases from a healthcare facility's occupational health department (e.g., from occupational health nurses) or infection control programs. To minimize burden on healthcare facilities, EIP staff will obtain HCP lists and contact information from health departments whenever possible. Many EIP staff are state health department employees or affiliated academic partner employees and have access to these data that already exist in the health department. The burden from generating the line list from an existing database is minimal. For option 2, EIP staff may work directly with a healthcare facility's occupational health department or infection control program to obtain HCP names and contact information because this option requires identification and data collection from HCP non-cases (HCP who tested negative for SARS-CoV-2).

For both options, EIP staff will collect data from all HCP included in this project via telephone interviews using an introductory script and Exposure Assessment Form (see Attachment 4 and Appendix 3 of Attachment 3) or a self-administered electronic case report form (see Attachment 4) after they receive line lists of HPC cases or non-cases. Questions included in the exposure assessment form focus on patient care activities that happened during 14 days before the first positive result for SARS-CoV-2 for HCP cases and 14 days before most recent negative results for SARS-CoV-2 for HCP non-cases.

The standardized Exposure Assessment Form we are proposing to use is a modification of an existing, OMB-approved form (OMB Control No. 0920-1011, expiration date 04/23/2020).

The data collected from this project will be used to: 1) determine the incidence of COVID-19 among HCP working in participating healthcare facilities; 2) describe characteristics of HCP exposed to or infected with SARS-CoV-2, including clinical activities and personal protective equipment (PPE) use; and 3) compare exposures and other characteristics of HCP cases and exposed HCP that do not become

cases to identify potential risk factors or protective factors for COVID-19 that may warrant further study.

Due to the potential for ongoing harm to HCP from the COVID-19 pandemic, CDC requests an emergency clearance to gather information to inform guidance for healthcare facilities to protect the healthcare workforce—a critical asset during this pandemic.

3. Use of Improved Information Technology and Burden Reduction

Some EIP sites may opt to administer the HCP case report form/questionnaire electronically rather than via a phone interview. Only the minimum amount of information necessary is requested. We do not expect this data collection to affect the work duties of HCP. This is because hospitals and other healthcare facilities typically have policies that require HCP with COVID-19, or HCP with symptoms consistent with COVID-19, to be excluded from work and self-isolated at home.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has provided intensive technical assistance to state and local health departments since the beginning of this pandemic. We are not aware of any data collection from HCP with COVID-19 at this level of detail and scale. CDC assisted in one investigation in Solano County, California in which 37 HCP were interviewed. Due to the small number of HCP cases, we could not detect statistically significant differences in exposures and were not able to conduct multivariable analysis. This county is not within the catchment area of the California EIP site, and so would not be included in the proposed data collection.

We consulted with Epidemiologic Data Analysis Unit of the Healthcare Infection Control Team in the Health System and Worker Safety Task Force of the CDC's Emergency Operation Center and have confirmed there is no duplicative effort being implemented by other CDC's teams. A recent report from this unit on HCP with COVID-19 was published in the MMWR (<https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e6.htm>). Analysis of data from the COVID-19 case report form revealed the "healthcare personnel variable" was complete in only 16% of the 315,531 COVID-19 cases reported to CDC, supporting the need for a separate and dedicated effort to further understand COVID-19 among HCP is necessary.

5. Impact on Small Businesses or Other Small Entities

This data collection does not primarily involve small business entities, but could include employees associated with small hospitals and other healthcare facilities, such as critical access hospitals or small long-term care facilities.

Questions have been held to the minimum required for the intended use of the information.

6. Consequences of Collecting the Information Less Frequently

COVID-19 has been declared a pandemic and little is known about specific risk factors for SARS-CoV-2 transmission, particularly among HCP exposed in healthcare facilities. Since healthcare workers are at the forefront of treating patients infected with COVID-19, it is extremely important for CDC to collect this information to better understand the characteristics of HCP with COVID-19 such as demographics, underlying conditions, and patient care activities and to identify exposures that are significantly associated with COVID-19 among HCP. Less frequent data collection could result in a small number of interviewed HCP cases and non-cases and the lack of statistical power to detect significant differences in exposures which could significantly reduce the usefulness of the data to inform safe practices in healthcare facilities.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this survey (Attachment 2).

B. We have been consulting with Principal Investigators and project staff of the 10 EIP sites on our weekly conference calls since the inception of planning for this project in mid-March 2020. We also consulted with them by emails and individual phone calls. As of April 13, all 10 EIP sites have committed to implementing Option 1, two sites (i.e., NM and OR) have committed to implementing Option 2, and three sites (i.e., CT, NY, and CO) are considering Option 2. Funding has been provided to each of the 10 EIP sites to support this work. Both protocol and exposure assessment form have been reviewed by all EIP sites and their comments have been incorporated. We also shared the protocol and exposure assessment form with experts from the National Institute of Occupational Safety and Health and incorporated their feedback. NIOSH expert will be part of the project team. We are also inviting them to participate in work group calls with EIP sites to discuss plans to implement this project.

CDC also consulted with CSTE during a CDC/CSTE COVID-19 Core Group Call on April 22, 2020 in which 19 members representing 14 jurisdictions attended. The project was deemed important and necessary as states and territories continue to experience outbreaks among HCP of healthcare facilities under their jurisdictions. Metrics and findings that we will be able to produce from this project will serve as an important tool for identifying issues and/or measuring successes in combatting the outbreaks in the EIP states and elsewhere.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts will be provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act does not apply.

EIP sites are responsible for ensuring that site-initiated electronic communications with HCP comply with applicable information security and privacy standards.

CDC staff will follow procedures for assuring and maintaining privacy during all stages of data collection. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law.

Direct personal identifiers such as HCP name or contact information (e.g., phone number or email address) will not be transmitted to CDC. All other information will be transmitted to CDC using a REDCap database. Data will be stored securely and indefinitely on CDC share drives with restricted access and appropriate encryption as determined by information security standards at CDC.

This public health response was determined to be Not Human Subjects Research and does not require IRB approval (Attachment 5).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that this information collection is not research involving human subjects. IRB approval is not required (Attachment 5).

Justification for Sensitive Questions

While CDC does not believe this package contains sensitive questions, respondents may feel otherwise, given their potential COVID-19 diagnosis. The case report form includes questions about HCP's underlying conditions, including immunocompromising conditions, and smoking.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The estimated burden to respondents is summarized in Table 12-A below.

Option 1

We estimate that each EIP site will recruit five healthcare facilities to participate in Option 1 (10 EIP sites x 5 healthcare facilities =50 healthcare facilities). We estimate that five EIP sites will obtain line lists of HCP cases from existing databases at state health departments and five sites will get the line lists from the occupational health nurse or similar staff member/department within each healthcare facility (n=25). We estimate that it will take EIP site staff five minutes to generate a line list from an existing database and take an occupational health nurse 15 minutes to gather and transmit this information to the EIP sites. This information will be collected from the occupational health nurse within each healthcare facility or from the state health departments once per week over the course of 24 weeks. Receiving a line list less frequently than weekly may further impact HCP recall bias during the interviews or form completion. According to

preliminary unpublished data submitted to COVID-NET, CDC’s surveillance system for tracking laboratory-confirmed COVID-19-associated hospitalizations, 33 HCP cases have been reported during a 4-week period from 21 hospitals (This number is subject to change as more data get submitted to CDC). Using these data with a 20% hospitalization rate for COVID-19 cases (MMWR article (<https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm>), we estimate there will be a total of 165 healthcare personnel reported from 21 hospitals (or 7–8 HCP per hospital per month). To account for possible increase in number of HCP with COVID-19 in the coming months, we estimate that there will be 12 HCP cases per healthcare facility per month and as many as 3,600 HCP cases will be reported from 50 healthcare facilities during the 6-month period.

Option 2

We estimate that five EIP sites will implement Option 2 with all five healthcare facilities in each site (n=25). We estimate that it will take an occupational health nurse 15 minutes to generate a line list of HCP non-cases (HCP who tested negative for SARS-CoV-2) and transmit the information to EIP sites. According to our sample size calculation for Option 2, we aim to include 400 HCP non-cases from the participating healthcare facilities.

Each Exposure Assessment Form (Attachment 4) will take approximately 30 minutes to complete. This estimate is based on experience using an earlier version of the form in field investigations. We estimate that as many as 4,000 healthcare personnel (3,600 HCP cases for Option 1 and 400 HCP non-cases for Option 2) within a variety of job categories will participate in the HCP interviews.

Table 12-A. 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)
Healthcare Personnel	Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2	4,000	1	30/60	2,000
Occupational Health Nurses at Healthcare	No form	50 (25 each for Option 1 and Option	24	15/60	300

Facilities		2)			
EIP or state health department employee	No form	5	24	5/60	10
Total					2,310

B. Estimated Annualized Burden Costs

There will be no anticipated costs to respondents other than time. To calculate the burden costs, we averaged the national estimate of the average hourly wage for the following occupations: registered nurses, healthcare technologists and technicians; healthcare practitioners and technical occupations; and healthcare support occupations. The average wage for each of these occupations was obtained from the Department of Labor, Bureau of Labor & Statistics, May 2019 (https://www.bls.gov/oes/current/oes_nat.htm).

Table 12-B. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Healthcare Personnel	Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2	2,000	\$28.81	\$57,620.00
Occupational Health Nurses at Healthcare Facilities	No form	300	\$37.24	\$11,172.00
EIP or state health department staff	No form	10	37.24	372.4
Total				\$69,164.40

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection is \$5,527.20. This includes 50% FTE of a GS-13 employee for 40 hours for data collection (\$46.06 per hour x 40 hours = \$1,842.40) and 80 hours for data analysis at \$46.06 per hour in metro Atlanta (\$46.06 per hour x 80 hours = \$3,684.80), https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/ATL_h.pdf.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Data collection	\$1,842.40
Data analysis	\$3,684.80
Total Cost	\$5,527.20

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Data collection	1 week to 6 months after OMB approval
Preliminary data analysis	As frequently as weekly, depending on the availability of EIP resources to rapidly interview HCP and transmit data to CDC for analysis
Data analysis	12-15 months after OMB approval
Generation of report	18 months after OMB approval; interim reports may also be generated, as appropriate

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment 1 – Authorizing Legislation

Attachment 2 – 60-Day Federal Register Notice

Attachment 3 – Protocol

Attachment 4 – Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2

Attachment 5 – Research Determination Form

