Change Memo for

"Emerging Infections Program Tracking of SARS-CoV-2 Infections among Healthcare Personnel"
(OMB Control No. 0920-1296)
Expiration Date: 10/31/2020

Contact:

Nora Chea, MD, MSc National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention 1600 Clifton Road, NE Atlanta, Georgia 30333 Phone: (404)-639-0025

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The Centers for Disease Control and Prevention (CDC) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request: "Emerging Infections Program Tracking of SARS-CoV-2 Infections among Healthcare Personnel (OMB Control No. 0920-1296)."

Background:

Healthcare personnel (HCP) are at risk of contracting COVID-19, the disease caused by SARS-CoV-2, during their interactions with suspected or confirmed COVID-19 patients or patients with unrecognized infections. 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 risks of SARS-CoV-2 infections among HCP in U.S. healthcare facilities remain unclear. Additional information about characteristics of infected HCP 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.

This project **(OMB Control No. 0920-1296)** includes HCP with COVID-19 (HCP cases) and HCP with direct or indirect exposures to COVID-19 patients but who do not become cases (HCP non-cases). Primary objectives are to determine the incidence of SARS-CoV-2 infections and identify factors associated with development of COVID-19 among HCP of participating 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). EIP assists 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.

The requested changes, summarized below, represent minor modifications to the previously-approved instruments to include: 1) additional response choices to questions about COVID-19 signs/symptoms, HCP's roles, areas of facility(ies) in which they work and where close contact with COVID-19 patient(s) occurred; 2) new or modified questions regarding the use of teleworking during timeframe of interest, contact with person(s) with COVID-19 who were not patients in healthcare facility(ies), the reuse and extended use of N95 respirators, the use of alternative or improvised equipment during care of COVID-19 patients, and flu vaccination; 3) modified denominator data collection form; 4) addition of an abbreviated form to capture HCP with a potential reinfection.

We are requesting these changes based on feedback from EIP interviewers and preliminary analysis of data reported to us so far.

As a result of these proposed changes, the estimated overall burden is expected to increase by 233 hours, from 2,300 to 2,533. The requested changes and justifications are described in more details below.

Proposed modifications to the Attachment 4 "Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2" Form:

We propose to add **three** new questions and modify one question, as follows: (New sub-question) Did you telework or work remotely from a location that is not a healthcare facility (such as from home)? All the time Some of the time Not at all Not sure (New sub-question) Did you have close contact with someone with COVID-19 who was not a patient during work in your facility? (Check all that apply) Coworker with COVID-19 Visitor with COVID-19 Someone else (NOT a patient) with COVID-19; can you specify? No Not sure (New question) Did you wear any alternative or improvised equipment during care of COVID-19 patients? Yes; answer Q25a No; go to Q26 Not sure; go to Q26 If yes, what alternative or improvised equipment did you wear? (Check all that apply) Face covering that was not a medical mask or respirator, such as a cloth face covering, bandana, balaclava A covering for clothing other than a medical gown, such as a lab coat, trash bag, or raincoat Improvised eye protection, such as a homemade face shield Other; can you specify? _____ **(New question)** When was the last time you received flu vaccine? MM/YYYY Not sure Never received flu vaccine (Modified question) Did you use any of the following practices when wearing an N95 respirator? (Check all that apply) I wore one N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters. I wore one N95 respirator for repeated close contact encounters with several patients, but I usually removed it ('doffed') after each encounter. I wore the same N95 respirator on multiple workdays. I wore a respirator, but I did not use any of these practices.

I did not use a respirator.

Others can you engeify?
Other; can you specify?
e propose to add the following response choices, as follows: "Fatigue or malaise", "Chest pain/tightness", "Congestion", and "Loss of appetite" to the question about signs and symptoms. Added response choices are highlighted below.
Have you had any of the symptoms in the table below? No; go to Q15
Yes; check all symptoms in the table below that apply; provide onset and resolution date for any symptom you had; write interview or form completion date as resolution date if you still
have the symptoms.
 If you have been diagnosed with COVID-19, check the symptoms you had during the <u>14</u> days before and on the specimen collection date of your first positive coronavirus test.
For example, if you had a nasal swab for coronavirus testing done on April 15, check any symptoms you had from April 1 through April 15. (MM / DD / YYYYY to MM / DD /
YYYY)

 If you have NOT been diagnosed with COVID-19, check the symptoms you had during the <u>14 days before and on</u> the specimen collection date of your most recent NEGATIVE coronavirus test result. (MM / DD / YYYYY to MM / DD / YYYYY)

Symptom	When did the symptom begin?		When did the symptom end?	
Felt feverish	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Documented fever ≥100.0°F	MM/DD/YYYY	Not sure	MM/DD/YYYY [Not sure
Chills	MM/DD/YYYY	Not sure	MM/DD/YYYY [Not sure
Dry cough	MM/DD/YYYY	Not sure	MM/DD/YYYY [Not sure
Productive cough	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Fatigue or malaise	MM / DD / YYYY	Not sure	MM / DD / YYYY	Not sure
Sore throat	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Runny nose	MM/DD/YYYY	Not sure	MM / DD / YYYY	Not sure
Shortness of breath	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Muscle aches	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Headache	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Chest pain/tightness	MM / DD / YYYY	Not sure	MM / DD / YYYY	Not sure
Nausea or vomiting	MM/DD/YYYY	Not sure	MM / DD / YYYY	Not sure
Diarrhea	MM/DD/YYYY	Not sure	MM / DD / YYYY	Not sure
Abdominal pain	MM/DD/YYYY	Not sure	MM / DD / YYYY	Not sure
Altered sense of smell or taste	MM / DD / YYYY	Not sure	MM / DD / YYYY	Not sure
<u>Congestion</u>	MM / DD / YYYY	Not sure	MM / DD / YYYY	Not sure
Loss of appetite	MM / DD / YYYY	Not sure	MM / DD / YYYY	Not sure
Other,	MM/DD/YYYY L	Not sure	MM/DD/YYYY	Not sure
Other,	MM/DD/YYYY	Not sure	MM/DD/YYYY	Not sure
Other,	MM/DD/YYYY	Not sure	MM/DD/YYYY [Not sure
Other,	MM/DD/YYYY	Not sure	MM/DD/YYYY [Not sure

• "Administrative staff", "Home health aide/caregiver", and "Nurse practitioner" to the question about roles in healthcare facility(ies)

What is your role(s) in the healthcare facility(ies) where you work? (Check all that apply)

Administrative staff	Licensed	practical nurse		Physician assistant
Chaplain	Medical a	ssistant		Physician (intern/residen
Environmental services worker	Nurse pra	<mark>ctitioner</mark>		Physician (fellow)
Facilities/maintenance worker	Nursing a	ssistant		Respiratory therapist
Food services worker	Nutritioni	st		Registered nurse
Home health aide/caregiver	Occupational therapist			Social worker
Laboratory personnel	Pharmacis	st or pharmacy person	nel	Speech therapist
Cytotechnologist	Phleboton	nist		Student
Histotechnologist	Physician (attending) Physical therapist			Ward clerk
Medical/clinical lab scientist				
Medical laboratory technician	Other; car	ı you specify?		
PhD laboratory scientist				
Other laboratory personnel				
Administrative offices	Laborat	ory	Pha	rmacy
Administrative offices	Laborat	ory	Pna	······································
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Dining room or cafeteria Emergency room/department		nical pathology		<mark>vate residence (home health</mark> lielogy department
Emergency room/department	An	atomic pathology	Rac	liology department
Emergency room/department Endoscopy room	An Otl	atomic pathology her laboratory type	Rac Rec	liology department ception area
Emergency room/department Endoscopy room Inpatient ward	An Otl Nursing	atomic pathology her laboratory type home ward	Rac Rec	liology department
Emergency room/department Endoscopy room Inpatient ward Intensive care unit	An Otl Nursing Operation	atomic pathology her laboratory type home ward ng room	Rac Rec	liology department ception area
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• "Cloth face covering" to the question about source control on COVID-19 patient(s) during contacts

VV.	which of the following was in place on COVID-19 patient(s) during your contacts:	(Check all that
ap	apply)	
	Surgical or procedure mask Cloth face covering N95 respin	rator
	Endotracheal or nasotracheal tube (for invasive mechanical ventilation)	
	Other; can you specify?	
	None	
	Not sure	

We also propose minor rewordings of some questions to improve clarity. (See attachment 1 for details)

Proposed modifications to the Attachment 3 "Denominator" Form:

We propose to modify denominator data collection form, as follows:

- Addition of instructions for collection of denominator data
- Addition of Table A for:
 - O Number of HCP who worked at the healthcare facility for at least 1 day during the month, stratified by employee HCP and non-employee HCP (required)
 - O Number of COVID-19 patients in the facility (optional)
- Simplification of Table B and making it optional for:
 - O Number of HCP who worked at the healthcare facility for at least 1 day during the month, stratified by job category (e.g., physicians, nurses, others)
 - O Total number of shifts worked during the month
 - O Total number of hours worked during the month

See **attachment 3** for the proposed "Denominator Form".

Proposed addition of the Attachment 2 "Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2: Possible Reinfection Form"

We propose the following modifications to the main "Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2" Form to create an abbreviated "Possible Refection Form" for HCP who potentially have reinfection with SARS-CoV-2 weeks or months after the initial infection.

- Removal of questions about demographics and comorbidities
- Simplification of questions about COVID-19 signs and symptoms and potential community exposures

See attachment 2 for proposed addition of "Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2: Possible Reinfection Form"

Justification:

The proposed additions and modification will allow us to maintain and enhance surveillance of COVID-19 among HCP working in U.S. healthcare facilities in the catchment areas of EIP's sites, one of the strategic priorities for CDC's COVID-19 response.

<u>Addition of new questions in "</u>Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2 Form"

Based on feedback from EIP staff performing interviews, when asked if they had any PPE concerns, some HCP cases mentioned used of alternative or improvised equipment and reuse/extended use of N95

respirators. Some HCP cases also mentioned contacts with co-workers who had COVID-19, while others mentioned they worked remotely during the timeframe of interest. Adding and modifying these questions will help to reduce the amount of free text in "Other, specify" field, standardize answers, and improve the accuracy and quality of data collected. We added a question about flu vaccination to assess a possible co-relation between flu vaccination and SARS-CoV-2 infections among HCP working in the participating HCFs as flu season is approaching.

Addition of response choices for existing questions in the Attachment 1 "Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2 Form"

Preliminary analysis of the existing data captured in "Other, specify" field identified additional commonly reported responses including, COVID-19 signs/symptoms, HCP roles, and areas of the facilities where HCP normally worked or where close contact with COVID-19 patient(s) occurred. Adding these response choices to the questions will help to standardize the common responses and improve the accuracy and quality of data collected.

Modifications of the Attachment 3 "Denominator Form"

One of the main project objectives is to estimate the incidence of SARS-CoV-2 infections among HCP working in participating healthcare facilities (HCFs). Collecting the number of HCP working in the participating HCFs by job categories (e.g., physicians, nurses, respiratory therapists) will allow us to compare incidences across different job categories. However, stratifying the denominator data with the level of granularity included in the old "Denominator Form" would result in a huge burden on the participating HCFs' staff and in some cases, HCFs may not be able to generate the requested granular denominator data. We simplified the "Denominator Form" to align with the National Healthcare Safety Network's "Healthcare Personnel Influenza Vaccination Summary Form" and made Table B of the form optional for reporting. We anticipate this approach will reduce burden on participating HCFs because most of them are already reporting these data to CDC, following the requirements by the Centers for Medicare & Medicaid Services. (See attachment 3)

Addition of the Attachment 2, "Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2: Possible Reinfection Form"

This project includes all HCP cases reported to EIP staff by participating healthcare facilities or state health departments. As a small number of HCP may re-test positive for SARS-CoV-2 weeks or months after their initial infections, we created an abbreviated version of the form ("Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2: Possible Reinfection Form"), focusing on recent exposures and changes since initial interview, for HCP who potentially have reinfection. We anticipate this approach will reduce burden for these HCP.

Other data systems:

The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) conducts population-based surveillance in the 10 EIP sites for laboratory-confirmed COVID-19-associated hospitalizations. Although COVID-NET includes one question on HCP status, it does not collect detailed information on patient care activities, PPE use, or community exposures. To supplement and enhance information on hospitalized HCP cases, we plan to collect the unique patient identification number(s) from COVID-NET to enable data linkage.

We estimate these changes will add two minutes to the previously approved burden for this data collection instrument. The previous burden calculated for "Assessment of Healthcare Personnel Exposed

to or Infected with SARS-CoV-2" form was 2,300 hours. As a result of the changes proposed in this change memo, the burden for this form will increase by 233 hours to 2,543 hours.

Type of	Form Name	Number of	Number of	Average	Total
Respondents		Respondents	Responses per	Burden per	Burden
1		1	Respondent	Response	(in
			F	(in hours)	hours)
				(=======)	
Healthcare	Assessment of	4,000	1	32/60	2,133
Personnel	Healthcare				
	Personnel				
	Exposed to or				
	Infected with				
	SARS-CoV-2				
	Form				
	Or				
	Assessment of				
	Healthcare				
	Personnel				
	Exposed to or Infected with				
	SARS-CoV-2:				
	Possible				
	Reinfection Form				
	Reinfection Form				
Occupational	No form	50	24	15/60	300
Health Nurses					
at Healthcare					
Facilities					
		F 0		D0/00	400
Occupational	Assessment of	50	6	20/60	100
Health Nurses	Healthcare				
at Healthcare	Personnel				
Facilities	Exposed to or				
	Infected with				
	SARS-CoV-2:				
	Denominator				
	Form				
Total) E))
1 Otal					2,533

Attachments:

- 1. Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2 Form
- 2. Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2: Possible Reinfection Form
- 3. Assessment of Healthcare Personnel Exposed to or Infected with SARS-CoV-2: Denominator Form
- 4. Emerging Infections Program Tracking of SARS-CoV-2 Infections among Healthcare Personnel" Protocol (version: July 14, 2020)