Undetermined cause of cardiac arrest during hemodialysis — Connecticut 2015-2016

Request for OMB Approval of a New Emergency Information Collection

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Supporting Statement A

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8. IRB Approval Letter

Data Collection for Undetermined cause of cardiac arrest during hemodialysis — Connecticut 2015-2016

PART A. JUSTIFICATION

- The purpose of this information collection is to perform expanded case-finding in order to determine the baseline frequency of cardiac arrest during dialysis.
- The methods of information collection: epidemiologic study which will include abstraction of demographic and clinical data from patient medical charts and interviews with patients and healthcare staff.
- The populations covered under this data request will include: (1) case patients who had cardiac arrests and patients who were receiving dialysis treatment at the same clinics at the times when the case patients had cardiac arrest will be selected for the investigation; and (2) healthcare staff at outpatient hemodialysis clinics where cardiac arrest cases occurred.
- Data will be analyzed using descriptive analysis.

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 an emergency 6-month approval for "Undetermined cause of cardiac arrest during hemodialysis — Connecticut 2015-2016."

Dialysis patients have higher mortality rates than the general population. According to the United States Renal Data System, sudden cardiac death is one of the leading causes of death among dialysis patients. However, sudden cardiac deaths and cardiac arrests that occur during dialysis treatment and are witnessed by dialysis clinic staff are not common. Published data reported a rate of 7 episodes per 1,000 patients-years for witnessed sudden cardiac arrest among dialysis patients.

In December 2015 and January 2016, the Connecticut Department of Public Health (CT DOH) received reports of six patients who experienced sudden and unexpected cardiovascular collapse and/or cardiac arrest during routine outpatient hemodialysis; three of the six expired. Four of these events occurred in one clinic: two on 12/18/2015, one on 12/19/2015 and one on 1/12/2016. The remaining two events occurred at two separate clinics: one on 12/18/2015 and one on 12/30/2015. These events occurred 30 to 135 minutes after the initiation of the dialysis treatment and not immediately following administration of a medication. Three of the affected patients had findings suggestive of possible anaphylactic reaction (airway edema noted clinically and/or during autopsy and elevated serum tryptase level). Preliminary investigation has not implicated a common medication or healthcare device used by affected patients.

Given the severity and urgency of the problem and potential for additional cases, The Connecticut Department of Public Health requested assistance from CDC to investigate the issue.

CDC is currently conducting an epi-aid to support the Connecticut Department of Public Health (CT DPH) with their investigation of these events. Because these events could be linked to a healthcare product (e.g., medical device or pharmaceutical) with widespread distribution, broad case-finding efforts are needed.

This information is essential to the CDC's ability to identify a cause of these events and prevent additional events from occurring.

Nationwide case finding will be implemented (through Epi-X or professional list serve). The target audience of the case finding will include, but not be limited to, state and local health departments, medical examiners, dialysis providers, and nephrologists. They will be asked to report any potential cases to CDC. Information on each case will be collected using a data collection form. Depending on the nature of each case, CDC may reach out to relevant healthcare facilities or healthcare staff for additional information and any prevention measures.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of Information Collection

The data collected from the investigation will be used to identify potential risk factors leading to sudden cardiac arrest among dialysis patients in order to prevent further adverse events. This request is to obtain OMB approval for conversations with patients and clinic staff (Attachment 3, 4 and 5), medical record abstraction from case patients (Attachment 7) which is not associated with any burden, and collection of information on other additional cases identified through case finding (Attachment 6).

CDC cannot reasonably comply with the normal clearance procedures due to the public harm that is reasonably likely to result if routine processing of this request is required, specifically cardiac arrests and death in patients exposed to a contaminated healthcare product. Therefore CDC requests a 6-month emergency clearance to conduct national case-finding and data collection for similar patient events.

3. Use of Improved Information Technology and Burden Reduction

Medical charts (electronic and paper) of case patients in Connecticut will be abstracted onto paper forms by the CDC team assisting CT DOH onsite. The data may be entered into an electronic database and used for future analysis. If available, information on cases identified through case finding may be submitted electronically via email to CDC using the data collection form; however, no personal identifiable information will be included in such email communication. We estimate that 10% of responses will be sent electronically. We do not expect any means of electronic transmission of patient data directly from a healthcare facility medical chart system.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of similar data regarding this particular type of event. CDC is communicating and coordinating with FDA colleagues who have queried their MedWatch systems.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. The information collected is critical to identify potential risk factors associated with cardiac arrest among dialysis patients and help preventing additional events. The findings from the activity may also help developing policies to provide safer care to dialysis patients.

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

The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

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

8a. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived.

8b. The efforts to consult outside the agency are outlined below:

The Connecticut Department of Public Health was the first agency to report the case-patients. CDC has been working with the following experts since 12/2015:

Matthew L. Cartter, MD, MPH
State Epidemiologist and Director of the Infectious Diseases Station
State of Connecticut Department of Public Health
(860) 509-7995
Matt.cartter@ct.gov

Richard Melchreit, MD
Healthcare Associated Infection Coordinator
State of Connecticut Department of Public Health
Richard.Melchreit@ct.gov

A CDC team is on-site at the clinics in Connecticut and working closely with the Connecticut Department of Public Health to identify the risk factors leading to those severe adverse events and prevent additional events.

CDC has also been working with colleagues at FDA on this issue since December, 2015.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

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

Individuals will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent, unless required by law upon the demand of a court or other governmental authority.

Whenever possible, data will be collected anonymously to ensure the privacy of survey response.

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. IRB approval was granted prior to commencement of any activities. The IRB application outlines the details regarding data collection, storage and use.

Privacy Impact Assessment Information

In this activity, no identifiable information of patients and staff at dialysis clinics will be collected. However, we will collect contact information (name, email, phone number) of persons (such as local health department staff) who report cases to CDC via case finding (Attachment 6). The information will be used for follow-up of the cases. Where applicable, these forms are maintained as a system of records under the Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems," last published in its entirety in the Federal Register, Vol. 57, No. 252, December 31, 1992, pp. 62812-62814, and updated December 29, 1993 and December 28, 1994.

CDC will treat information in a secure manner and will not disclose, unless otherwise compelled by law. Forms will be kept in a locked file cabinet when not in use and only CDC staff is accessible to the forms. Any electronic database that maintains such information will be kept in secure computers accessible to only CDC staff.

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

IRB Approval
The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment 8).

Justification for Sensitive Questions
In this activity, no sensitive questions will be asked.

12. Estimates of Annualized Burden Hours and Costs

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

Table 12-A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Patients	Questionnaire for patients who suffered from cardiac arrest but survived	4	1	30/60	2
	Questionnaire for other patients	40	1	30/60	20
Healthcare staff	Questionnaire for staff at the clinic	60	1	30/60	30
	Case finding for data collection	10	1	30/60	5
				Total	57

There will be no anticipated costs to respondents other than time. The 2014 U.S. median national hourly wage for all occupations is $17.09 (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000). This wage is assumed for general respondents because of the variety of types expected.

Registered nurses are often the persons interviewed at hospitals, so their mean hourly wage ($33.55) is used to represent the hospital staff wages.

Table 12-B: Estimated Annualized Cost to Respondents

Type of respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Patients	Case patient interview	2	$17.09	$34.18
	Other patient interview	20	$17.09	$341.80
Healthcare staff	Staff interview	30	$33.55	$1,006.50
	Data collection for case finding	5	$33.55	$167.75
			Total	$1,550.23

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

None.

14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is $26,329.20. This figure encompasses 100% FTE of two GS-12 employees and one GS-12 equivalent epi-elective student for six weeks doing data collection, 25% FTE of one GS-12 employee doing data analysis for two weeks, and ancillary information collection costs. The average hourly rate was obtained from the Office of Personnel Management's website (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2016/general-schedule/). The hourly rate for a GS-12 in metro Atlanta is $35.58.

Table 14-A: Estimated Annualized Cost to the Government

Estimated Annualized Cost to the Government per Activity and Total				
Activity	Time in hours required to perform activity	Number of employees performing activity	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost
Data collection	240	3	$35.58	$25,617.60
Data analysis	20	1	$35.58	$711.60
			Total	$26,329.20

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

Table 16.1

Project Time Schedule	
Activity	*Time schedule*
Data collection	One day after OMB approval
Data analysis	1-2 months after OMB approval
Generation of report	12 months after OMB approval

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

None.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. No certification exemption is being sought.

Attachments

1. Public Health Service (PHS) Act (42 USC 241).
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