Adverse Health Outcomes Associated with Medical Tourism Surveillance System

Request for OMB approval of a New Information Collection

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Supporting Statement A

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Table of Contents

Goal of the study: To improve data collection by capturing informative demographic, clinical, and risk factor information from cases of adverse health outcomes linked to medical tourism (travel by a U.S. resident outside of the United States for the purpose of receiving healthcare or a U.S. resident presenting to a U.S. healthcare facility after receiving medical care outside the United States).

- Streamline and improve data capture by updating medical tourism adverse health outcome forms including identical paper and electronic versions of the forms.
- Identify cases of adverse health outcomes linked to medical tourism.
- Collect demographic, clinical, and epidemiologic information to identify links and trends among cases of adverse health outcomes linked to medical tourism.
- Work with CDC partners, state, and local jurisdictions to identify and respond to outbreaks among medical tourists returning from travel and presenting for care in the United States.
- Identify prevention measures that can be used in education, communication, and guidance for travelers and clinicians.

- **Intended use of the resulting data:** This system will be used to detect outbreaks and trends in cases to identify prevention measures and improve awareness of risks associated with medical tourism.
- **Methods to be used to collect:** CDC will send the case intake form (Form 1), upon request, to state/local health departments investigating adverse health outcomes linked to medical tourism. Form data will be collected and stored in an electronic database. CDC will review data weekly to assess potential epidemiologic links*. When cases appear to be associated, CDC will reach out to appropriate internal and external partners for further information and to coordinate a response, if needed. Health departments may be asked to complete the enhanced surveillance form (Form 2).

*Possible epidemiologic links between cases of adverse health outcomes involving medical tourists can include, but are not limited to, clinics where procedures are performed and timing of procedures associated with adverse health outcomes.

- **The subpopulation to be studied:** U.S. residents who traveled outside the United States for the purpose of receiving healthcare or U.S. residents presenting to a U.S. healthcare facility after receiving medical care outside the United States.
- **How data will be analyzed:** Frequencies will be calculated in an electronic database or exported and analyzed in SAS or R.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration Health (DGMH) requests a 3-year approval for this new information collection.

To achieve DGMH's mission, the Travelers' Health Branch (THB) conducts public health surveillance to prevent, detect, and respond to communicable disease threats to the United States by inbound and outgoing international travelers and develops evidence-based guidance to prevent illnesses, hospitalizations and deaths among global travelers.

Medical tourism has been associated with a variety of adverse health outcomes including serious infection, importation of antibiotic-resistant pathogens to the United States, and death.[1,2] Outbreaks among medical tourists are inherently difficult to detect as patients who receive care at the same clinic abroad may reside in different states across the U.S. In addition, infections acquired from health care abroad may not be locally or nationally reportable and there is no national surveillance system or mechanism for states to link cases between jurisdictions for medical tourism-related adverse health outcomes.

THB has provided technical support for outbreaks among medical tourists, coordinating efforts between state and local health departments and with appropriate divisions at CDC. Collaboration with these groups is essential to ensuring an effective response when an outbreak is detected. If the source or risk factors of an adverse health outcome can be detected which leads to an intervention, additional adverse outcomes may be reduced or eliminated, providing public health benefit. The information collected through this surveillance will help CDC detect outbreaks and trends in cases to identify prevention measures and improve awareness of risks associated with medical tourism.

1. Chen LH, Wilson ME. The globalization of healthcare: implications of medical tourism for the infectious disease clinician. Clin Infect Dis. 2013 Dec;57(12):1752-9. doi: 10.1093/cid/cit540. Epub 2013 Aug 13. PMID: 23943826; PMCID: PMC7107947.
2. Schnabel D, Esposito DH, Gaines J, Ridpath A, Barry MA, Feldman KA, Mullins J, Burns R, Ahmad N, Nyangoma EN, Nguyen DB, Perz JF, Moulton-Meissner HA, Jensen BJ, Lin Y, Posivak-Khouly L, Jani N, Morgan OW, Brunette GW, Pritchard PS, Greenbaum AH, Rhee SM, Blythe D, Sotir M; RGM Outbreak Investigation Team. Multistate US Outbreak of Rapidly Growing Mycobacterial Infections Associated with Medical Tourism to the Dominican Republic, 2013-2014(1). Emerg Infect Dis. 2016 Aug;22(8):1340-1347. doi: 10.3201/eid2208.151938. PMID: 27434822; PMCID: PMC4982176.

The information collection for which approval is sought is in accordance with CDC DGMH's mission to prevent, detect, and respond to communicable diseases that impact safe global movement to, from, and within the United States. This mission is supported by Section 361 of the Public Health Service Act (Attachment A1), regulations found in 42 Code of Federal Regulations part 70 (Attachment A2) and 71 (Attachment A3), and also supported under general authorities provided by Sections 301 (Attachment A4) and 311 in the Public Health Service Act regulations (Attachment A5).

2. Purpose and Use of Information Collection

The purpose of this information collection is to improve data collection by capturing informative demographic, clinical, and risk factor information from cases of adverse health outcomes linked to medical tourism (travel by a U.S. resident outside of the United States for the purpose of receiving

healthcare or a U.S. resident presenting to a U.S. healthcare facility after receiving medical care outside the United States).

This information collection will allow DGMH to:

- Streamline and improve data capture by updating medical tourism adverse health outcome forms including identical paper and electronic versions of the forms.
- Identify cases of adverse health outcomes linked to medical tourism.
- Collect demographic, clinical, and epidemiologic information to identify links and trends among cases of adverse health outcomes linked to medical tourism.
- Work with CDC partners, state, and local jurisdictions to identify and respond to outbreaks among medical tourists returning from travel and presenting for care in the United States.
    - Identify prevention measures that can be used in education, communication, and guidance for travelers and clinicians.

This information collection aligns with THB's mission to prevent, detect, and respond to communicable disease threats to the United States by inbound and outgoing international travelers and to develop evidence-based guidance to prevent illnesses, hospitalizations and deaths among global travelers.

DGMH's Travelers' Health Branch will send the case intake form (Form 1 (Attachment C)), upon request, to state/local health departments investigating adverse health outcomes among returned medical tourists.

Health departments will obtain verbal consent from patients before interviewing them (Attachment E). Participation is voluntary.

Form data will be collected and stored in an electronic database. THB will review data weekly to assess for potential epidemiologic links*. When cases appear to be associated, THB will reach out to appropriate internal and external partners for further information and to coordinate a response, if needed. Health departments may be asked to complete the enhanced surveillance form (Form 2 (Attachment D)).

*Possible epidemiologic links between cases of adverse health outcomes involving medical tourists can include, but are not limited to, clinics where procedures are performed and timing of procedures associated with adverse health outcomes.

3. Use of Improved Information Technology and Burden Reduction

Form data will be collected and stored on restricted-access files in an electronic database on secure CDC servers. The One CDC Data Platform (1CDP) is the unified data platform supporting CDC's everyday

work as well as public health emergency response. It connects CDC and partners to shared tools, capabilities, and data in one place. 1CDP is also being used to host other surveillance databases in THB, DGMH, and several other surveillance programs at CDC. 1CDP will allow THB to better prepare for, detect and respond to public health threats quickly.

4. Efforts to Identify Duplication and Use of Similar Information

THB is the only group within CDC that collects data on adverse health events among medical tourists. Often, the CDC Division of Healthcare Quality Promotion is incidentally notified about these events (adverse health outcomes in medical tourists) and subsequently notifies the Travelers' Health Branch. However, there is no standardized data collection instrument for state/local health departments to notify CDC of these events. Currently established healthcare-acquired infection surveillance systems do not collect information that is relevant to identifying these cases (e.g., international travel history), that is relevant to identifying the burden of these events (e.g., cost to the patient), or that provides information that will aid in creating prevention strategies for this at-risk group. Collecting this information will allow CDC to identify epidemiologic links among adverse health outcomes associated with medical tourism cases around the United States and will inform recommendations to reduce the risk of adverse health events for international travelers receiving surgeries, treatments, or procedures outside the United States.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Medical tourists can introduce extremely drug-resistant infections that are rare or nonexistent in the United States and have limited treatment options. The importation and spread of these infections pose significant risks to public health, safety, and the financial stability of American hospitals and healthcare systems. This will be an ongoing information collection. Without effective surveillance, outbreaks related to medical tourism may go undetected or be delayed in response, leading to substantial financial burdens on both the American healthcare system and taxpayers burdens that could potentially be avoided.

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

We are electing to choose the less-detailed standard of answer choices for the question regarding race/ethnicity. The more detailed standard includes answer choices for collecting information about sub-categories of ethnicity, which is outside the scope of this data collection.

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. A 60-day Federal Register Notice was published in the *Federal Register* on August 9, 2024, vol. 89, No. 154, pp. 65358-65359 (Attachment B1). CDC received 4 public comments related to this notice (Attachment B2; B4-B6) and has provided a response in Attachments B3 and B7.

B. No consultations outside of CDC occurred.

9. Explanation of Any Payment or Gift to Respondents

N/A

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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act applies. A Privacy Impact Assessment is included as part of this submission (attachment G).

Data will be kept private to the extent allowed by law.

The medical tourism case investigation information falls into the Minor Research Records category for records retention requirements. This data will be stored in an electronic database. We will maintain the data for at least six years post completion of the entry, and then the data will be deleted.

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

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required. Please see the attached human subjects determination (Attachment F).

Justification for Sensitive Questions

We are electing to choose the less-detailed standard of answer choices for the question regarding race/ethnicity. The more detailed standard includes answer choices for collecting information about sub-categories of ethnicity, which is outside the scope of this data collection.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

THB scheduled informational sessions with nine state/local health jurisdictions to gather feedback on this data collection instrument. After each session, the forms (Form 1 (Attachment C) and Form 2 (Attachment D)) were emailed to participants with instructions to report how long it took them to complete each form. Time estimates were calculated by averaging the reported time it took to complete each form by each state/jurisdiction.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State/Local Health department staff	Form 1 Medical Tourism Case Intake Form (Part B-Medical Chart Abstraction)	50	15	5/60	63
Ill persons who have experienced an adverse health outcome related to medical tourism	Form 1 Medical Tourism Case Intake Form (Part A-Interviews)	750	1	10/60	125
Ill persons who have experienced an adverse health outcome related to medical tourism	Form 2 Medical Tourism Enhanced Surveillance Form	500	1	0.5	250
TOTAL					438

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State/Local Health department staff	Form 1 Medical Tourism Case Intake Form (Part B-Medical Chart Abstraction)	63	$39.13*	$2,465.19
Ill persons who have experienced	Form 1 Medical Tourism	125	$21.39**	$2,673.75

an adverse health outcome related to medical tourism	Case Intake Form (Part A-Interviews)			
Ill persons who have experienced an adverse health outcome related to medical tourism	Form 2 Medical Tourism Enhanced Surveillance Form	250	$21.39**	$5,347.50
Total				$10,486.44

*National 50% (median) percentile estimate for epidemiologists, Department of Labor Occupational Employment and Wages, May 2023. https://www.bls.gov/oes/current/oes191041.htm

**National 50% (median) percentile estimate for office and administrative support occupations, Department of Labor Occupational Employment and Wages, May 2023. https://www.bls.gov/oes/current/oes430000.htm

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

We anticipate staff resources to be minimal, as the system will be integrated with systems and tools already provided by CDC, especially compared to the amount of time and level of effort staff are putting into responding to current medical tourism outbreaks without any informatic support.

Staff (FTE)	Average Hours	Average Hourly Rate	Total Average Cost
Epidemiologist – (GS-12); Epi project development and project management, data management, data analysis, publication, and dissemination of results	200	$44.90	$8,980.00
Estimated Total Cost of Information Collection			**$8,980**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This will be a recurring data collection. Three years from the OMB approval date are requested. Information will be shared with collaborators from DHQP for healthcare-associated infection/antimicrobial resistance investigations and public health surveillance. Other CDC programs may be informed as appropriate. Information collected may also be analyzed and disseminated in publications. Appropriate approvals will be obtained prior to any analyses. A summary of findings will be posted on the THB Medical Tourism webpage annually.

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

A1: Section 361 of the Public Health Service Act

A2: 42 CFR Part 70

A3: 42 CFR Part 71

A4: Section 301 of the Public Health Service Act

A5: Section 311 of the Public Health Service Act

B1: Published 60-Day FRN

B2: Public Comment #1 from 60-Day FRN Notice

B3: Response to Public Comment #1 from 60-Day FRN Notice

B4-B6 Public Comments #2-4 from 60-Day FRN Notice

B7: Response to Public Comment #4 from 60-Day FRN Notice

C: Form 1 Medical Tourism Intake Form Part A and Part B

D: Form 2 Medical Tourism Enhanced Surveillance Form

E: Consent Script

F: Human Subjects Determination

G: Privacy Impact Assessment