

Maritime Illness Database and Reporting System (MIDRS)

OMB Control No. 0920-NEW

NEW

Formerly under *Foreign Quarantine Regulations* (OMB Control No. 0920-0134, expiration date 05/31/2019)

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The regulations at 42 CFR part 71 outline the respondent universe, which for this information collection request (ICR) includes a ship's master, medical staff, or other designated person on a passenger vessel carrying 13 or more passengers and within 15 days of arriving in a U.S. port from a foreign port. The ship's designated Maritime Illness Database and Reporting System (MIDRS) reporter, usually a medical crewmember, reports the aggregate number of passengers and crewmembers onboard who have experienced acute gastroenteritis (AGE) as defined by federal regulations at any time during the voyage. These aggregate numbers are derived from cruise line/passenger vessel owned medical documentation kept during the normal course of business when treating patients experiencing AGE symptoms. Individual case information is compiled on an AGE log using a standard format (Attachment 5b). Additionally, medical personnel ask the case what they ate, drank, and did in the 72 hours prior to symptom onset ("72 hour food/activity history", no standard form but template is provided in Attachment 5c). There are no sampling methods employed in this information collection.

In the event of an AGE outbreak, the respondent universe is potentially expanded to include any traveler who enters the United States by passenger vessel and experiencing AGE. This work is performed to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States.

B.2. Procedures for the Collection of Information

AGE illnesses are reported to CDC's Vessel Sanitation Program (VSP) via MIDRS, <https://wwwn.cdc.gov/midrs/GILogin.aspx>. MIDRS is an electronic reporting and surveillance system that offers a variety of options for submitting reports, including online submission using a common web-based portal, email, fax and phone. The Master of the vessel, the medical staff, or other designated staff receives self-reports of AGE illness from passengers and crew members onboard their ship, completes a medical assessment, and determines if that person meets the reportable case definition as outlined in 42 CFR 71.1 (b) ii (B) (Attachment 4a). If the ill person meets the AGE case definition, key data elements are recorded on a standardized AGE log (Attachment 5b; Attachment 4b, §4.1.2.1.3, p.62). AGE cases are asked about what they ate, drank, and did in the 72-hours prior to symptom onset ("72-hr. food/activity history") (no standard form, operational requirement can be found in Attachment 4b, §4.1.2.2.1, p.64) in order to identify a likely source of exposure and target response efforts.

AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active (symptomatic) AGE cases at any given port of call or at disembarkation. The AGE log

and 72-hour food/activity history are completed and maintained on the ship as part of the case's medical record owned by the cruise line; cruise lines decide how they are maintained onboard (e.g., electronic, paper). VSP reviews these records during operational inspections to confirm they are available if needed, and if there is an AGE outbreak or report of unusual AGE illness for a particular voyage.

Cruise ship medical staff are required to send a total number of AGE illness cases to VSP via MIDRS at the following designated times:

- 24 to 36 hours before arriving to a U.S. port from a foreign port; this report is required even when there are no cases of gastrointestinal illness (“Routine 24-hr Report”; Attachment 4b, §4.2.1.1.1, p.66)
- if the number of passenger or crew AGE reportable cases changes after the initial notification in the bullet above, but before the ship is 4 hours from arrival (“Routine 4-hr Report”; Attachment 4b, §4.2.1.1.2, p.66), and
- when 2% or more of the passengers or crew are ill with AGE illness, and then again when 3% or more of the passengers or crew are ill with AGE illness (“Special 2% or 3% Report”; Attachment 4b, §4.2.2.1.1, p.67). This report must be sent at any time the vessel is in the United States or within 15 days of arriving to a U.S. port

B.3. Methods to Maximize Response Rates and Deal with No Response

The requirements for reporting AGE illness data on passenger vessels in U.S. jurisdiction are codified in regulations in 42 CFR part 71 (Attachment 1C). If passenger vessel personnel fail to submit reports at the appropriate times during their voyage, they will receive a critical violation on their subsequent unannounced sanitation inspection, which affects the ship's overall inspection score, which is posted on VSP's public website for program transparency. CDC requires that AGE illness information be reported at certain times during a foreign to U.S. voyage (42 CFR 71.21). Not responding to this data collection is a violation of regulation.

B.4. Test of Procedures or Methods to be Undertaken

Data elements that are required to be submitted to MIDRS are standardized and have been used for monitoring purposes for several decades. Data elements required in the AGE Log and the 72 hour food/activity history are commonly requested during medical assessments during a normal course of treatment, have been vetted during public meetings with stakeholders, and have been requested by CDC for many years for the purpose of monitoring AGE illness as is mandated by federal quarantine laws.

The electronic system used for this information collection is continually updated and improved for quality of data collection and ease of use for the public, industry, and CDC program administrators.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Not applicable.

List of Attachments

Attachment 1. Authorizing Legislation

- 1a. 42 USC Section 264 – Quarantine and Inspection - Regulations to Control Communicable Diseases
- 1b. 42 USC Section 269 – Quarantine and Inspection – Bills of Health
- 1c. 42 CFR Part 71 – Foreign Quarantine Regulations

Attachment 2. 60-day Federal Register Notice

Attachment 3. Vessel Sanitation Program Delegation

- 3a. 1985 Federal Register Notice VSP in DGMQ
- 3b. 1987 Memo VSP from DGMQ to NCEH

Attachment 4. AGE Case Definition

- 4a. 42 CFR §71.1(b) ii
- 4b. VSP 2018 Operations Manual

Attachment 5. Medical Records

- 5a. MIDRS template
- 5b. AGE Log
- 5c. 72-hr Food/Activity history template
- 5d. Documentation of interviews to determine AGE illness status
- 5e. Documentation of 3-day pre-embarkation AGE illness assessment
- 5f. Documentation of Last Symptom and Clearance to Return to Work

6. Research Determination Form

Attachment 7. 42 CFR 71.21 (c) Recordkeeping - Medical logs (not a standardized form, captains provide logs)

Attachment 8. 42 CFR 71.21(c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival
(MIDRS screenshot)

Attachment 9. International Convention of Safety of Life at Sea

Attachment 10. Privacy Impact Assessment Form