



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 10/11/21

Title: Maritime Illness Database and Reporting System (MIDRS)
Project Id: 0900f3eb81d971d8
Accession #: NCEH-VSPT-8/5/21-971d8
Project Contact: Keisha A Jenkins
Organization: NCEH/ATSDR/DEHSP/WFEHSB/VSPT
Status: **Project In Progress**
Intended Use: **Project Determination**
Estimated Start Date: 04/30/2022
Estimated Completion Date: 04/29/2025
CDC/ATSDR HRPO/IRB Protocol #:
OMB Control #: 0920-1260

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	9/16/21	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		9/16/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA

ICRO:
PRA Applies

OMB Approval date: 4/2/19
OMB Expiration date: 4/30/22

9/16/21

Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Determination Start Date: 08/05/21

Description: OMB #: 0920-1260

IMS/CIO/Epi-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

This is an extension information collection request (ICR) for #Maritime Illness Database and Reporting System (MIDRS)# (OMB Control No. 0920-1260; expiration date 04/30/2022). The Vessel Sanitation Program (VSP) monitors AGE illness on passenger ships (#cruise ships#), conducts sanitation inspections and epidemiologic investigations when outbreaks occur, and formulates public health recommendations to prevent future transmissions and outbreaks. Cruise ships carrying 13 or more passengers and within 15 days of arriving in the U.S. from a foreign port are required to report the number of cases of AGE through CDC VSP#s Maritime Illness Database and Reporting System (MIDRS). The number of AGE cases is ascertained from a ship#s medical records, a line listing of AGE cases onboard (i.e., #AGE Log#) is provided to CDC#s VSP and a 72-hour food/activity history used to identify potential sources of illness exposure.

Objective:

VSP will analyze data from MIDRS, AGE Logs, and 72-hour food/activity histories using descriptive analysis methods to monitor AGE outbreaks and identify trends. Results are used to determine sources of exposure, identify clusters, high risk populations /groups, causative agents of cruise ship AGE outbreaks, inform outbreak management plans and prevention strategies, and improve cruise industry infection control procedures.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: No

Project does not incorporate elements of health Yes

equity science:

Measuring Disparities: Not Selected

Studying Social Determinants of Health (SDOH): Not Selected

Assessing Impact: Not Selected

Methods to Improve Health Equity Research and Practice: Not Selected

Other: Not Selected

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: General US Population

Tags/Keywords: Public Health Surveillance ; Gastroenteritis ; Outbreak investigation

CDC's Role: CDC is recipient of private data/specimens FROM an institution

Method Categories: Outbreak Investigation

Methods: The MIDRS data collection system is a syndromic surveillance system that receives AGE case information electronically through a web-based reporting portal or by email; data can also be submitted by phone, email or fax and entered into MIDRS by VSP. AGE cases reported to MIDRS are cumulative case counts 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 availability of records, and proper reporting of AGE illness cases and occurrence of AGE outbreaks for a particular voyage.

Collection of Info, Data or Biospecimen: The AGE Log and MIDRS reports are completed and submitted by cruise ship medical staff or other designated personnel who report AGE cases among passengers or crew aboard cruise ships carrying 13 or more passengers and within 15 days of arriving in the U.S. from a foreign port. AGE cases provide information for the 72-hour food/activity histories.

Expected Use of Findings/Results: VSP will analyze data from MIDRS, AGE Logs, and 72-hour food/activity histories using descriptive analysis methods to monitor AGE outbreaks and identify trends. Results are used to determine sources of exposure, identify clusters, high risk populations /groups, causative agents of cruise ship AGE outbreaks, inform outbreak management plans and prevention strategies, and improve cruise industry infection control procedures.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount

Other-	Staff Time Only				0.00
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HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavier

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identifiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Centers for Disease Control & Prevention	FWA00001413	07/30/26			

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Keisha Jenkins	05/12/2024				Program Official	brn0@cdc.gov	770-488-3096	VSP

Data

DMP

Proposed Data Collection Start Date: 4/30/22

Proposed Data Collection End Date: 4/29/25

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Country/Jurisdiction owns the data with protections under their laws and regulations

Public Access Justification: Cruise companies own their data

How Access Will Be Provided for Data: Confidential

Plans for Archival and Long Term Preservation:

Spatiality

Spatiality (Geographic Locations) yet to be added

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									



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