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

Print Date: 8/31/23

Title:	Enhanced public health surveillance for cyclosporiasis in the United States
Project Id:	0900f3eb821e6c67
Accession #:	CGH-ET-8/15/23-e6c67
Project Contact:	Anne Straily
Organization:	CGH/DPDM/PDB/ET
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	08/28/2023
Estimated Completion Date:	09/30/2026
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1198

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	8/22/23	Abel_Jason A. (jza5) CIO HSC
PRA: **PRA Applies**		8/31/23	Abel_Jason A. (jza5) OMB / PRA

ICRO: **PRA Applies**	OMB Approval date: 9/30/20 OMB Expiration date: 9/30/23	8/31/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	08/28/2023
Determination Start Date:	08/15/23
Description:	Cyclosporiasis is a nationally notifiable diseases in the United States. In jurisdictions where cyclosporiasis is reportable, healthcare providers and laboratories are required to report cases of illness to their state or local health department. The Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) is used by health officials at the state or local health department to interview patients with reported cases of cyclosporiasis and collects clinical and travel history, produce consumption, and restaurant and grocery store exposures. Health departments notify CDC of cases of nationally notifiable and reportable diseases so that CDC may compile national-level data for the United States. CDC uses this data to monitor, measure, and alert healthcare providers, public health partners, and the public to outbreaks and other public health threats and collaborates with the US Food and Drug Administration (FDA) to conduct traceback investigations for implicated food vehicles. This protocol does not describe a specific study, rather it describes the receipt and use of cyclosporiasis surveillance data by epidemiologists at CDC that was collected using the CDC-designed CNHGQ.
IMS/CIO/Epi-Aid/Lab-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
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	: Cyclosporiasis is a nationally notifiable diseases in the United States. In jurisdictions where cyclosporiasis is reportable, healthcare providers and laboratories are required to report cases of illness to their state or local health department. The Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) is used by health officials at the state or local health department to interview patients with reported cases of cyclosporiasis and collects clinical and travel history, produce consumption, and restaurant and grocery store exposures. Health departments notify CDC of cases of nationally notifiable and reportable diseases so that CDC may compile national-level data for the United States. CDC uses this data to monitor, measure, and alert healthcare providers,

	public health partners, and the public to outbreaks and other public health threats and collaborates with the US Food and Drug Administration (FDA) to conduct traceback investigations for implicated food vehicles.
Objective:	Public health surveillance data collected about confirmed and probable cases of cyclosporiasis shows where and how often the disease occurs in a particular area, who is affected (demographic, clinical, and epidemiological characteristics), how they are affected (course of clinical illness and care received), and how they were potentially infected (produce consumption and restaurant and grocery store exposures). This information enables state and local health officials and CDC to understand where cyclosporiasis is occurring, how cyclosporiasis can be prevented, which groups are most heavily impacted, identify outbreaks, identify disease trends and, work with partner agencies (e.g., FDA) and other external stakeholders to implement measures to mitigate and control the spread of disease.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	Programmatic Work
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Cyclosporiasis ; Public Health Surveillance ; Foodborne Diseases
CDC's Role:	CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens
Method Categories:	Outbreak Investigation; Surveillance Support
Methods:	Public health surveillance for cyclosporiasis is ongoing. In states where cyclosporiasis is reportable, cases of cyclosporiasis are reported to the state or local health department. Participants (patients diagnosed with cyclosporiasis) are then interviewed at least once by state or local public health officials, although follow up with patients involved in an outbreak or other public health investigation may be necessary. State or local health officials may be contacted by CDC epidemiologists for additional information depending on the course of the investigation; CDC staff do not contact or interview patients. Analysis of surveillance data collected via the CNHGQ is also continual and includes both descriptive analyses and exploratory studies where exposure information is re-analyzed as new cases are reported to identify potentially emerging signals that may indicate a particular produce item or point of sale/service as a source of illness. The study population are U.S. residents diagnosed with cyclosporiasis. The cyclosporiasis case definition was determined by the Council for State and Territorial Epidemiologists (CSTE). Cases are identified by electronic laboratory reporting of positive test results to the state or local health department; physicians may also report cases to their state or local health department. The number of cases reported will vary by location and over time. Patients diagnosed with cyclosporiasis are interviewed by state or local public health officials in jurisdictions where the disease is reportable using the CNHGQ or a state-adapted version of it. That information is then transmitted to CDC electronically. CDC epidemiologists receive and compile reported case data into a database using a specially designed R-shiny tool for further analysis. Key variables that are collected include demographic, clinical and travel history, and exposure data. The data are analyzed continually, utilizing both descriptive and exploratory methods to determine both national level disease estimates (e.g., case counts by year, state, sex, race/ethnicity, age) and identify trends in disease occurrence. Data are stored electronically in a secured folder by disease with restricted access only

	for staff working with and granted access to that data. Patients diagnosed with cyclosporiasis are assigned a unique case ID by their state or local health department and this case ID is provided on data sent to CDC. Data are stored electronically in a secure folder by disease with restricted access only for staff working with and granted access to the data. Electronic data are retained indefinitely. Any paper forms received are entered into that disease#s electronic database and the paper copy destroyed.
Collection of Info, Data or Biospecimen:	Patients diagnosed with cyclosporiasis are interviewed by state or local public health officials in jurisdictions where the disease is reportable using the CNHGQ or a state-adapted version of it. That information is then transmitted to CDC electronically.
Expected Use of Findings/Results and their impact:	Key variables that are collected include demographic, clinical and travel history, and exposure data. The data are analyzed continually, utilizing both descriptive and exploratory methods to determine both national level disease estimates (e.g., case counts by year, state, sex, race/ethnicity, age) and identify trends in disease occurrence. Surveillance data are compiled and shared or discussed with state and local health departments depending on the needs of the jurisdiction or investigations that may be occurring at the time. During the cyclosporiasis season (typically May through August, although cases can be reported as late as September), a weekly epidemiological update is compiled and distributed via email to state and local health departments as well as FDA and internal CDC partners (e.g., Division of Foodborne Waterborne and Environmental Diseases/Outbreak Response and Prevention Branch). Surveillance data may be compiled and published as surveillance summaries or summaries of notable events. Cyclosporiasis surveillance data may be combined with other data (e.g., Cyclospora genotyping data) to better understand the occurrence of disease in the United States. Any of these analyses may be published in the scientific literature or presented at scientific conferences.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding yet to be added .....

HSC Review

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

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 identfiable 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

Institutions yet to be added .....

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
Anne Straily	07/21/2026		06/02/2024		Principal Investigator	yzv2@cdc.gov	404-718-1422	Epidemiology Team
Lauren Ahart	07/05/2026		09/05/2025		Co-Investigator	nox7@cdc.gov	404-718-3207	Epidemiology Team

Marion Rice	01/30/2026	12/10/2024	01/13/2026		Co-Investigator	lnv1@cdc.gov	404-718-6865	Epidemiology Team
Susan Montgomery	06/26/2026	06/24/2024			Program Lead	zqu6@cdc.gov	404-718-4731	Epidemiology Team

Data

DMP

Proposed Data Collection Start Date: 8/28/23

Proposed Data Collection End Date: 9/30/26

Proposed Public Access Level: Public

Public Access Justification: Case surveillance data for nationally notifiable disease

How Access Will Be Provided for Data: Data use agreement

Plans for Archival and Long Term Preservation: Data will be stored electronically.

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...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	08/31/2023	NOA 0920-1198 (2020)	Notice of Action	NOA 0920-1198_2020.pdf
Current	Straily_Anne (yzv2) Project Contact	08/30/2023	Updated protocol with correct OMB control number.	Protocol	Protocol for CNHGQ_updated.docx
Current	Straily_Anne (yzv2) Project Contact	08/15/2023	CNHGQ	Data Collection Form	CNHGQ 2021_fillable.pdf
Current	Straily_Anne (yzv2) Project Contact	08/15/2023	OMB/PRA template form	Paperwork Reduction Act Form	OMB-PRA template for DPDM_CNHGQ renewal.docx
	Straily_Anne (yzv2) Project Contact	08/15/2023	Protocol for collection and use of surveillance data via CNHGQ	Protocol	Protocol for CNHGQ.docx
Current	Straily_Anne (yzv2) Project Contact	08/15/2023	DPDM Project determination form	Other-Project determination form	338035-A_DPDM-Proj-Det-Form-4-508_Cyclo Surveillance.pdf