Pediatric Hepatitis-Adenovirus Case Control Evaluation, United States, 2022 – 2026

CSTLTS Generic Data collection Request
OMB No. 0920-0879

Supporting Statement – Section B

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Program Official/Project Officer
Name: Jacqueline Tate
Title: Principal Investigator
Organization: Division of Viral Diseases, Centers for Disease Control and Prevention
Address: 1600 Clifton Road, MS H24-5, Atlanta, GA 30329
Phone number: 404.639.4559
Email: jqt8@cdc.gov

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Section B – Data collection Procedures

1. Respondent Universe and Sampling Methods

Data on up to 10 responses will be collected by up to 52 respondents (public health officials in up to 52 state, local, tribal and territorial health departments). No sampling strategy will be used to select jurisdictions; all state, local, tribal, and territorial health departments may participate in this evaluation, however, we expect only a subset will participate based on available resources. Respondents include public health officials from state and local health departments, who will work with clinicians, infection preventionists, and other hospital staff to complete standardized medical chart abstractions on matched controls matched to persons under investigation for pediatric hepatitis of unknown etiology (PUIs). Public health officials will also work with parents and/or caregivers of PUIs and controls to administer a standardized questionnaire ("exposure questionnaire") on demographics, health history, and potential risk factors and exposures. The state, local, tribal and territorial health departments are in a unique position to provide CDC with these data because they represent the jurisdictions where this public health threat exists.

2. Procedures for the Collection of Information

Medical chart abstraction: controls

Data will be collected via a standardized chart review form for controls (Attachment A – Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form: Controls) and respondents (public health officials from up to 52 jurisdictions in the United States) are recruited through routine calls (weekly or biweekly) in which at least one representative from each of the 52 jurisdictions is invited to attend. A summary (see Attachment F – Summary of Routine Calls) of the following information is discussed in these routine calls explaining:

- The purpose of the data collection, and why their participation is important.
- Instructions for participating
- Method to safeguard their responses
- That participation is voluntary
- The expected time to complete the instrument
- Contact information for the project team

Exposure questionnaire: PUIs

Data will be collected via a questionnaire for PUIs (Attachment B – Pediatric Hepatitis of Unknown Etiology - Exposures Questionnaire [Parental Interview]) and respondents (public health officials from up to 52 jurisdictions in the United States) are recruited through routine calls (weekly or biweekly) in which at least one representative from each of the 52 jurisdictions is invited to attend. A summary (see Attachment F – Summary of Routine Calls) of the following information is discussed in these routine calls explaining:

- The purpose of the data collection, and why their participation is important.

- Instructions for participating
- Method to safeguard their responses
- That participation is voluntary
- The expected time to complete the instrument
- Contact information for the project team

Exposure questionnaire: controls

Data will be collected via a questionnaire for PUIs (Attachment C –Pediatric Hepatitis of Unknown Etiology - Exposures Questionnaire CONTROL [Parental Interview]) and respondents (public health officials from up to 52 jurisdictions in the United States) are recruited through routine calls (weekly or biweekly) in which at least one representative from each of the 52 jurisdictions is invited to attend. A summary (see Attachment F – Summary of Routine Calls) of the following information is discussed in these routine calls explaining:

- The purpose of the data collection, and why their participation is important.
- Instructions for participating
- Method to safeguard their responses
- That participation is voluntary
- The expected time to complete the instrument
- Contact information for the project team

After respondents receive the initial invitation to participate, respondents may choose to participate in this in-depth evaluation at any time. Respondents will be reminded at each biweekly call that they are invited to participate in this in-depth evaluation. If a jurisdiction expresses interest in participating, a follow-up email is sent offering to discuss the investigation via a call with CDC. Jurisdictions who decide not to participate are considered non-responders, although they may choose to participate at any time in the future.

Completed medical chart abstractions and exposure questionnaires will be transmitted to CDC via secure ShareFile after which data will be entered by CDC staff into an established REDCap database. ShareFile is a file sharing and uploading service for CDC staff to securely share files and folders with each other and external partners. REDCap is a secure web application for building and managing databases and is located behind the SAMS firewall, which is only accessible using CDC credentials. Alternatively, jurisdiction public health officials may enter data directly into the REDCap database should they choose to do so. Data collected during the assessment will be tabulated and shared only in aggregated form; no personally identifiable information will be shared.

3. Methods to Maximize Response Rates Deal with Nonresponse

Although participation in the data collection is voluntary, the project team will make every effort to maximize the rate of response. The data collection instrument was designed with

particular focus on streamlining questions to allow for skipping questions based on responses to previous questions, thereby minimizing response burden. Data collection will be conducted for PUIs and controls based on consent.

Following distribution of the invitation to participate in the data collection conveyed during the routine weekly/biweekly calls with jurisdictions, (see Attachment F – Summary of Routine Calls), jurisdictions may choose to participate in the in-depth evaluation on a rolling bases. Jurisdictions who do not respond about participating by the next biweekly call will receive a reminder during the biweekly call (see Attachment F – Summary of Routine Calls) urging them to participate in the investigation and complete the data collection instruments on a rolling basis. Jurisdictions who decide not to participate are considered non-responders, although they may still participate at a later date if they so choose.

Respondents (i.e. participating jurisdictions) are asked to complete the data collection instruments on a rolling bases as PUIs and control are identified, and to complete the forms within 90 days of identifying a PUI or control. Participating jurisdictions who do not complete the data collections instruments within 90 days of identifying a PUI or control will receive at least one reminder to complete the data collection instruments, and those who do not respond within 30 days from the reminder will be considered non-responders/incomplete data collection forms.

4. Test of Procedures or Methods to be Undertaken

The estimate for burden hours of the medical chart abstraction for controls (Attachment A – Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form: Controls) is based on the burden hours reported for medical chart abstraction of PUIs during the initial investigation. During this initial investigation, the average time to complete the medical chart abstraction for PUIs, including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 45 minutes. Given the similarities between the forms for PUIs and controls, completion of the medical chart abstraction for controls is approximately the same as for PUIs.

The estimate for burden hours of the questionnaire for PUIs (Attachment B – Pediatric Hepatitis of Unknown Etiology - Exposures Questionnaire [Parental Interview]) is based on the burden hours reported by public health professionals from jurisdictions that identified PUIs during the initial investigation. In the initial investigation, the average time to administer and complete the exposure questionnaire for PUIs, including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 45 minutes.

The estimate for burden hours of the questionnaire for controls (Attachment C –Pediatric Hepatitis of Unknown Etiology - Exposures Questionnaire CONTROL [Parental Interview]) is based on the burden hours reported by public health professionals from jurisdictions that identified PUIs during the initial investigation. In the initial investigation, the average time to administer and complete the exposure questionnaire for PUIs, including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 45 minutes. Given the similarities between the forms for PUIs and controls, completion of the exposure questionnaires for controls is approximately the same as for PUIs.

The medical chart abstraction and exposure questionnaires in this submission are based on the forms utilized in the initial investigation, though they have been improved and refined based on feedback from jurisdictions over the course of the initial investigation and have been adapted for collection from matched controls. As of September 30, 2022, the six jurisdictions that expressed interest in participating in the in-depth evaluation reviewed the forms for the in-depth evaluation.

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

Name: Jacqueline Tate
Title: Principal Investigator
Organization: Centers for Disease Control and Prevention
Address: 1600 Clifton Rd, Atlanta, GA 30333
Phone: 404-639-4559
Fax (if applicable)
Email: jqt8@cdc.gov

Name: Julia Baker
Title: Epidemiologist
Organization: Centers for Disease Control and Prevention
Address: 1600 Clifton Rd, Atlanta, GA 30333
Phone: 404-827-4928
Fax (if applicable)
Email: nwk0@cdc.gov

Name: Olivia Almendares
Title: Epidemiologist
Organization: Centers for Disease Control and Prevention
Address: 1600 Clifton Rd, Atlanta, GA 30333
Phone: 404-629-3428
Fax (if applicable)
Email: gtt1@cdc.gov

Name: Anita Kambhampati
Title: Epidemiologist
Organization: Centers for Disease Control and Prevention
Address: 1600 Clifton Rd, Atlanta, GA 30333
Phone: 404-718-3123
Fax (if applicable)
Email: wyc4@cdc.gov

Name: Jordan Cates
Title: Epidemiologist
Organization: Centers for Disease Control and Prevention
Address: 1600 Clifton Rd, Atlanta, GA 30333
Phone: 770-286-1306
Fax (if applicable)
Email: ntm6@cdc.gov

Name: Neha Balachandran
Title: Contractor
Organization: Centers for Disease Control and Prevention
Address: 1600 Clifton Rd, Atlanta, GA 30333
Phone: 404-718-7246
Fax (if applicable)
Email: nuu9@cdc.gov

LIST OF ATTACHMENTS – Section B

Note: Attachments are included as separate files as instructed.

F. Attachment F – Summary of information conveyed during routine calls with 52 jurisdictions invited to participate in the pediatric hepatitis-adenovirus case control evaluation