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

Print Date: 2/13/25

Title:	Call for Cases - Serious Adverse Events After Ceftriaxone Administration
Project Id:	0900f3eb82510bbd
Accession #:	NCEZID-ORT-2/12/25-0f3b5
Project Contact:	Rebecca Pierce
Organization:	NCEZID/DHQP/PRB/ORT
Status:	**Pending Regulatory Clearance**
Intended Use:	**Project Determination**
Estimated Start Date:	02/17/2025
Estimated Completion Date:	12/31/2025
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0900f3eb8218c567

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	2/13/25	Peterson_James M. (iyr1) CIO HSC
PRA: **PRA Applies**		2/13/25	Vice_Rudith (nhr9) OMB / PRA

Description & Funding

Description

Priority:	Higher Priority
Date Needed:	02/25/2025
Priority Justification:	We have received preliminary reports of serious adverse events, including 8 deaths, following ceftriaxone across 5 jurisdictions since Dec 24 and anticipate data collection needs in >9 jurisdictions.
CDC Priority Area for this Project:	Readiness and Response
Determination Start Date:	02/13/25
Description:	CDC has received reports of serious adverse events, including 8 deaths, after ceftriaxone receipt from 5 state jurisdictions since 12/9/24. A national call for cases was issued on 2/7/2025 as part of urgent efforts to identify/characterize adverse events associated with ceftriaxone to protect patient safety. HSR determination currently under Multi Jurisdiction Outbreak Response determination (Non-research). We now anticipate reports from > 9 jurisdictions, submitting for appropriate PRA review.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Submitted through IMS Clearance Matrix:	Not selected
Primary Scientific Priority:	Not selected
Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	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	To characterize serious adverse events and proximal exposures, including receipt of ceftriaxone (or related products, e.g., co-administered medications, reconstituting products), medication administration practices, and other potentially explanatory clinical factors (such as known infection, other underlying medical condition, or exposure to a medication or medical product other than ceftriaxone).
Objective:	Jurisdictions will gather information on case-patients via medical record abstraction, interviews with hospital staff, and direct observations so that epidemiological analyses can be conducted to better ascertain risk factors for serious adverse events following ceftriaxone. Objectives of this investigation include: 1. Describe clinical and epidemiologic characteristics of severe adverse events associated with injections received in reporting healthcare facilities. 2. Conduct case finding to assess extent of severe adverse events after receipt of injectable ceftriaxone. 3. Evaluate injection safety practices and provide recommendations to correct injection

	safety breaches, medication tampering, and errors in medication handling or administration, if identified. 4. Facilitate collaboration and communication with state, local and federal public health partners to implement applicable control measures. 5. Conduct laboratory evaluation or testing of medical products that may be associated with adverse events, as appropriate.
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:	New Collection of Information, Data, or Biospecimens ; Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials
Target Populations to be Included/Represented:	General US Population ; Patient
Tags/Keywords:	Drug-Related Side Effects and Adverse Reactions ; Patient Safety ; Epidemiology
CDC's Role:	CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight
Method Categories:	Outbreak Investigation
Methods:	A national call for cases was issued via CDC on 2/7/2025 through the Epi-X platform requesting that public health authorities report adverse events, occurring after September 1, 2024, that meet the following criteria: 1) Occurred within 6 hours after receipt of injectable ceftriaxone in a non-ICU setting, and 2) Resulted in death or required cardiopulmonary resuscitation, and 3) Not attributed by the treating provider(s) to a cause other than ceftriaxone administration. A case report form will be shared with jurisdictions reporting cases so that they can conduct medical chart abstraction to obtain patient-level information and informal interviews with healthcare facility staff to inform adverse event clinical presentation and identify risk factors related to medical products and formulations received, medication administration practices, and underlying medical conditions. CDC will perform secondary analysis of deidentified data, provide epidemiologic support to jurisdictions, coordinate with FDA on product monitoring, testing, or recalls, and will issue appropriate guidance to public and partners regarding injection and medication safety.
Collection of Info, Data or Biospecimen:	Jurisdictions will be responsible for conducting medical chart abstraction and informal interviews with healthcare facility staff. CDC will be responsible for receiving case report forms, conducting epidemiological analyses, providing infection prevention and control guidance, and laboratory testing of isolates in the event of suspected microbial contamination.
Expected Use of Findings/Results and their impact:	CDC will use findings to recommend medication safety measures, including those related to injection safety, antimicrobial stewardship, and adverse event monitoring as well as to define new or emerging clinical syndromes associated with medication receipt. Findings will be shared with state and local partners to identify and prevent medication adverse events. Findings may also be shared with relevant stakeholders and/or published in scientific journals to disseminate investigation outcomes.
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 require review by a CDC IRB or HRPO?	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 HIPAA 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	No Selection

specimens	
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Will you be working with an outside Organization or Institution? No

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	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Dumbani Kayira	06/26/2026	12/14/2025		12/13/2025		Co-Investigator	kvj2@cdc.gov	265-177-5188	MEDICAL PRODUCTS SAFETY BRANCH
Kiran Perkins	08/20/2026		08/07/2016			Co-Investigator	guu9@cdc.gov	404-639-1161	PREVENTION AND RESPONSE BRANCH
Radhika Agarwal	10/03/2027	10/29/2027				Co-Investigator	udw9@cdc.gov	- -	OUTBREAK RESPONSE TEAM

Data

DMP

Proposed Data Collection Start Date:	2/12/25
Proposed Data Collection End Date:	12/31/25
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:	CDC will receive de-identified information. Jurisdictions will retain ownership of all the data collected.
How Access Will Be Provided for Data:	CDC will maintain coded data in a CDC REDCap database and/or case report forms submitted by the jurisdictions. These will only be accessed by the investigation staff.
Plans for Archival and Long Term Preservation:	The final REDCap database and/or case report forms will be downloaded and stored in a secure network in and on a password protected computer in order to archive the data. Jurisdictions will retain ownership of all the data collected.

Spatiality

Country	State/Province	County/Region
United States		

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
	Peterson_James M. (iyr1) CIO HSC	02/13/2025	Original determination of non-research public health surveillance.	HS Research Determination Memo	051024SC-NR-signed.pdf
Current	Pierce_Rebecca (xqu5) Project Contact	02/12/2025	Cleared Epi-X call for cases.	Other-Enter new type	Epi-X Call for Cases- Serious Adverse Events Ceftriaxone - Jan 2025 (1).pdf
Current	Pierce_Rebecca (xqu5) Project Contact	02/12/2025	E-clearance documentation for 2/7 call for cases	Other-Enter new type	E-Clearance- Call of Cases Clearance Summary - Serious Adverse Events Following Ceftriaxone Injection (1).pdf
Current	Pierce_Rebecca (xqu5) Project Contact	02/12/2025	CRF for call for cases	Data Collection Form	CDC Case Report Form - Serious Adverse Events Following Ceftriaxone Injection.pdf