Form Approved
OMB Control No. 0920-1011
Expiration Date: 12/31/2025

Case Report Form: Rapid Assessment of Carbapenemase-Producing Carbapenem-Resistant Enterobacterales (CP-CRE) among Children in U.S. Healthcare Settings, January 2023–March 2024

Table of Contents

CP-CRE among Children in U.S. Healthcare Settings, Jan 2023–Mar 2024

Abstractor Initials: _____ | **Date of abstraction (MM/DD/YYYY):** _____

Isolate Verification & CRF Eligibility

Reporting Jurisdiction: _____**Testing Jurisdiction:** _____ **Isolate Collection Date:** _____

Lab's Isolate Accession ID: _____ **Jurisdiction's Isolate ID:** _____ **NCBI WGS ID:** _____

Specimen type: ☐ Blood ☐ Cerebrospinal fluid (CSF) ☐ Bone ☐ Sputum ☐ Tracheal aspirate ☐ Bronchoalveolar lavage (BAL) ☐ Urine ☐ Wound ☐ Rectal swab ☐ Axilla/groin swab ☐ Other, specify: _____ ☐ Unknown

Organism Detected: _____*(If multiple CP-CRE organisms were detected from the same index isolate, report one of the organisms in this section and provide details on the other organism(s) under the "Additional Isolates" section.)*

Mechanism(s) of resistance detected: ☐ KPC ☐ NDM ☐ VIM ☐ IMP ☐OXA-48 ☐ Other, please specify: _____
*(Select ALL mechanisms detected on the same organism, i.e., multiple mechanisms like NDM/VIM–*E. coli*)*

Patient Age: _____ (years, months, weeks, days) **Patient Sex:** ☐ Male ☐ Female ☐ Unknown
months if <2 years, weeks or days if <1 month

Is this a duplicate record with another isolate? ***(i.e., reporting information on same isolate as another record [e.g., tested at state PHL and forwarded for additional testing at regional PHL])***
☐ Yes, specify REDCap ID of isolate for the initial testing public health lab: _____ ☐ No

Is this the only isolate reported for this patient from January 2019 through March 2024? ☐ Yes ☐ No
*If no, is this isolate the index isolate (first clinical CP-CRE isolate for this pediatric patient during time period)***?**
☐ Yes ☐ No, provide ARLN alert record ID of index isolate:_____

If only isolate in time period or the index isolate, complete following questions:
Jurisdiction's Patient ID:_____ **Is this patient part of a cluster or outbreak response?** ☐ Yes ☐ No ☐ Unknown
If yes:
Jurisdiction-assigned Outbreak ID: _____ **Is this patient the index case?** ☐ Yes ☐ No ☐ Unknown
(same ID as for performance measures, if applicable)

CRF eligibility: refer to REDCap form for implementation

1. Isolate collection date is from Jan 1, 2023, and March 31, 2024
2. Specimen type is clinical (i.e., not screening and not unknown)
3. Enterobacterales organism isolated?
4. CP gene mechanism detected?
5. Age < 18 years?
6. Not a duplicate REDCap record or first isolate tested at a public health laboratory
7. Only isolate reported during study period or identified as index isolate

If yes to all, complete remaining portion of CRF. Otherwise, thank you for your participation.

Records Reviewed to Complete CRF:

☐ Records from **ALL** inpatient admissions 12 months prior to index specimen
☐ Admission Note ☐ Discharge Note ☐ Consult Notes ☐ Flowsheets (e.g., PMH) ☐ Other: __

☐ Records from **SOME** inpatient admissions 12 months prior to index specimen
☐ Admission Note ☐ Discharge Note ☐ Consult Notes ☐ Flowsheets (e.g., PMH) ☐ Other: __

☐ Records from any outpatient visits 12 months prior to index specimen
If yes, which outpatient facility types: _____

☐ Prior patient/proxy interview
If yes, please specify: ☐ Patient ☐ Proxy

Date of most recent record reviewed (MM/YY/DDDD):_____

Sociodemographics

Patient race/ethnicity (please select all that apply):

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ Middle Eastern or North African
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Unknown/Not reported

Born in the U.S? Yes ☐ No ☐ Unknown
If no, country of birth: _____

State of residence: _____
Zip code of residence: _____

If not U.S. resident, country of residence: _____

In the 3 months PRIOR TO date of index specimen, what was the patient's primary residence (i.e., setting in which patient spent majority of their time)?

- ☐ Private residence
- ☐ LTCF
  - ☐ SNF
  - ☐ vSNF
- ☐ Residential care setting
  - ☐ group home
  - ☐ intermediate care
  - ☐ other: _____
- ☐ Inpatient (e.g., ACH, LTACH in the past 3 months)
- ☐ Other setting: _____
- ☐ Unknown/Not reported

Did the case-patient attend school in the 3 months PRIOR TO date of index specimen collection:

- ☐ Yes
- ☐ No
- ☐ Unknown

Did the case-patient attend daycare in the 3 months PRIOR TO date of index specimen collection:

- ☐ Yes
- ☐ No
- ☐ Unknown

(If age ≥ 14 years) **Did the patient work in the 3 months PRIOR TO date of index specimen collection?**

- ☐ Yes, specify: _____
- ☐ No
- ☐ Unknown

Clinical Context of Index Isolate & Related Outcomes

Reason for specimen collection:

- ☐ Clinical Suspicion/Diagnosis of Infection
- ☐ Routine Surveillance/Admission Screening
- ☐ Point Prevalence Screening
- ☐ Other: _____
- ☐ Unknown

Transmission-based Precaution(s) <u>at time of specimen collection</u>:

☐ Contact ☐ Droplet ☐ Airborne ☐ Other: _____
☐ Unknown ☐ None

Was there an infection associated with the index isolate?

□ Yes □ No □ Unknown

("No" includes cases where the CP-CRE was deemed to reflect colonization, such as a polymicrobial superficial wound swab)

If yes, type(s): *(see Appendix for definitions)*

- ☐ Pneumonia
- ☐ Skin/soft tissue infection
- ☐ Bone/joint infection
- ☐ Bacteremia/sepsis
- ☐ Endocarditis
- ☐ Urinary tract infection
- ☐ Other: _____
- ☐ Unknown

Healthcare setting at time of specimen collection: *specify jurisdiction's deidentified facility ID beside each selected jurisdiction type, as applicable*

☐ Acute care hospital (ACH): _____
(see Appendix for definitions)
- ☐ Freestanding children's hospital
- ☐ Non-children's hospital (e.g., general hospital)
- ☐ Non-freestanding children's hospital

☐ Critical access hospital (CAH): _____
☐ Long-term acute care hospital (LTACH): _____
- ☐ Pediatric ☐ General/adult ☐ Unknown

☐ Skilled nursing facility (SNF): _____
- ☐ Pediatric ☐ General/adult ☐ Unknown

☐ Ventilator-capable SNF (vSNF): _____
- ☐ Pediatric ☐ General/adult ☐ Unknown

☐ Inpatient rehabilitation facility: _____
- ☐ Pediatric ☐ General/adult ☐ Unknown

☐ Residential care setting _____
- ☐ Group home
- ☐ Intermediate care
- ☐ Other: _____

☐ Outpatient (e.g., primary care provider, urgent care, telehealth, etc.), please specify type and ID: _____
☐ Other, please specify type and IDs: _____
☐ Unknown

Jurisdiction deidentified ID for facility: _____ Facility zip code: _____

Reason for associated admission or outpatient visit: _____
(Usually reflected in chief complaint or explained in assessment & plan of primary provider's note. For example, "rash" or "admitted given concern for dehydration")

If the specimen was collected in an ACH, CAH, or LTACH: **What type of unit was the patient admitted to?**

☐ Intensive care unit (ICU), specify type if known:
- ☐ Medical (e.g., adult medical ICU)
- ☐ Pediatric
- ☐ Neonatal
- ☐ Pediatric Cardiac
- ☐ Other: _____

☐ Emergency department
☐ Burn unit
☐ Oncology unit
☐ Transplant unit
☐ Surgical ward
☐ Medical/subspecialty ward or step-down unit
☐ Other, please specify: _____
☐ Unknown

Was the patient admitted to an ACH at the time of or in the 7 days after the index isolate collection date?
(question not applicable if index isolate noted above to be collected while patient at ACH)
□ Yes □ No □ Unknown

If yes, please answer the following questions:
Admission date (MM/DD/YYYY): _____
Transmission-based Precaution(s) on admission: ☐ Contact ☐ Droplet ☐ Airborne ☐ Other: _____
☐ Unknown ☐ None

Was the patient screened for CRE on admission? □ Yes □ No □ Unknown

Discharge date (MM/DD/YYYY): _____ or ☐ Still Admitted
Primary admission diagnosis ICD-10 code(s): _____ ☐ Unknown
Primary discharge diagnosis ICD-10 code(s): _____ ☐ Unknown

Was the patient admitted to an ICU during hospitalization? □ Yes □ No □ Unknown
If yes, type(s):

- ☐ Medical (e.g., general non-pediatric-specific ICU)
- ☐ Pediatric
- ☐ Neonatal
- ☐ Pediatric Cardiac
- ☐ Other: _____
- ☐ Unknown

Additional notes on hospitalization: _____
(e.g., hospitalization course/summary as provided in discharge note)

Where was patient discharged to?

- ☐ Private residence
- ☐ LTCF
  - ☐ SNF
  - ☐ vSNF
- ☐ Residential care setting
  - ☐ group home
  - ☐ intermediate care
  - ☐ other: _____
- ☐ Other setting: _____
- ☐ Unknown/Not reported

Did the patient **die** within 30 days of the index isolate collection date? □ Yes □ No □ Unknown

If yes, Date of death (mm/dd/yyyy): _____ Cause of death: _____
Source of this information (death certificate, medical record, etc.): □ Death certificate □ Medical record
□ Other, *please specify:* _____

Medical & Healthcare Exposure History

Did the case-patient have any underlying medical conditions (including developmental and other neurocognitive conditions) **present at the date of index isolate collection**? □ Yes □ No □ Unknown

If yes, please list underlying medical conditions as listed in medical records (preferably in structured list such as "Problem list" or H&P [history and physical]). For specimens collected among outpatients, use records associated with the appointment when culture was collected as well as the most recent hospitalization in the 12 months prior:

If <2 years old:

Gestational age at birth (weeks): _____
(999 if unknown)

Did mother receive healthcare outside of the U.S. while pregnant? ☐ Yes ☐ No ☐ Unknown
If yes, which country/ies: _____

Multiple pregnancy (twins, triplets, etc.)?
☐ Yes ☐ No ☐ Unknown
If yes,
Did any siblings have known CP-CRE infection or colonization?
(Evidence of carbapenemase gene without organism identified would be considered colonization)
☐ Yes ☐ No ☐ Unknown
If yes:
What is/are the jurisdiction patient IDs for the siblings (*if applicable*):
_____
What is/are the laboratory IDs for the index specimen of the siblings (*if applicable*): _____

Did the case-patient have any history of colonization or infection with other MDROs?

ESBL: □ Yes □ No □ Unknown
MRSA: □ Yes □ No □ Unknown
VRE: □ Yes □ No □ Unknown
Clostridium difficile: □ Yes □ No □ Unknown
MDR P aeruginosa: □ Yes □ No □ Unknown
CR-Ab: □ Yes □ No □ Unknown

Did the case-patient receive any systemic (e.g., oral [PO], intravenous [IV], intramuscular [IM]) antibiotics in the **30 days BEFORE the time of index isolate collection? Note:** ***Please DO NOT include any topical medications.***

□ Yes □ No □ Unknown

- ☐ Amikacin
- ☐ Amoxicillin
- ☐ Amoxicillin/clavulanic acid
- ☐ Ampicillin
- ☐ Ampicillin/sulbactam
- ☐ Azithromycin
- ☐ Aztreonam
- ☐ Cefadroxil
- ☐ Cefazolin
- ☐ Cefdinir
- ☐ Cefepime
- ☐ Cefiderocol
- ☐ Cefixime
- ☐ Cefotaxime
- ☐ Cefoxitin
- ☐ Cefpodoxime
- ☐ Ceftaroline
- ☐ Ceftazidime
- ☐ Ceftazidime/avibactam
- ☐ Ceftizoxime
- ☐ Ceftolozane/tazobactam
- ☐ Ceftriaxone
- ☐ Cefuroxime
- ☐ Cephalexin
- ☐ Ciprofloxacin
- ☐ Clarithromycin
- ☐ Clindamycin
- ☐ Dalbavancin
- ☐ Daptomycin
- ☐ Delafloxacin
- ☐ Doripenem
- ☐ Doxycycline
- ☐ Ertapenem
- ☐ Eravacycline
- ☐ Fidaxomicin
- ☐ Fosfomycin
- ☐ Gentamicin
- ☐ Imipenem/cilastatin
- ☐ Levofloxacin
- ☐ Linezolid
- ☐ Meropenem
- ☐ Meropenem/vaborbactam
- ☐ Metronidazole
- ☐ Moxifloxacin
- ☐ Nitrofurantoin
- ☐ Omadacycline
- ☐ Oritavancin
- ☐ Penicillin
- ☐ Piperacillin/tazobactam
- ☐ Polymyxin B
- ☐ Polymyxin E (colistin)
- ☐ Rifaximin
- ☐ Tedizolid
- ☐ Telavancin
- ☐ Tigecycline
- ☐ Tobramycin
- ☐ Trimethoprim
- ☐ Trimethoprim/sulfamethoxazole
- ☐ Vancomycin IV
- ☐ Vancomycin PO
- ☐ Other (specify): _____

Did the patient stay overnight in a **country <u>outside</u> of the U.S. in the 12-months BEFORE index isolate collection date**? □ Yes □ No □ Unknown
If yes, please answer the following questions:

Country	Month/year of departure (MM/YYYY)	Duration of stay	Received healthcare?	If yes, details of healthcare received as inpatient (e.g., facility/unit type, surgical or other procedures)
			☐ Yes ☐ No ☐ Unknown	
			☐ Yes ☐ No ☐ Unknown	
			☐ Yes ☐ No ☐ Unknown	
			☐ Yes ☐ No ☐ Unknown	
			☐ Yes ☐ No ☐ Unknown	
			☐ Yes ☐ No ☐ Unknown	

Medical Tourism: Did the case-patient specifically travel to any countries **<u>outside</u> the United States** to receive healthcare?
□ Yes □ No □ Unknown
If yes, details: _____

Did the case-patient specifically travel to **the United States** for the purpose of receiving healthcare in the 12-months prior to index isolate collection?
□ Yes □ No □ Unknown
If yes, details: _____

Did the case-patient stay overnight (e.g., was admitted) at any of the following healthcare facility types within the U.S. in the 12 months BEFORE the index isolate collection?

Acute care hospital (ACH): □ Yes □ No □ Unknown
(see Appendix for definitions)
- ☐ Freestanding children's hospital
- ☐ Non-children's hospital (e.g., general hospital)
- ☐ Non-freestanding children's hospital

Critical access hospital (CAH): □ Yes □ No □ Unknown

Long-term acute care hospital (LTACH): □ Yes □ No □ Unknown
- ☐ Pediatric ☐ General/adult ☐ Unknown

Skilled nursing facility (SNF): □ Yes □ No □ Unknown
- ☐ Pediatric ☐ General/adult ☐ Unknown

Ventilator-capable SNF (vSNF): □ Yes □ No □ Unknown
- ☐ Pediatric ☐ General/adult ☐ Unknown

Inpatient rehabilitation facility: □ Yes □ No □ Unknown
- ☐ Pediatric ☐ General/adult ☐ Unknown

Residential care setting: □ Yes □ No □ Unknown
- ☐ Group home
- ☐ Intermediate care
- ☐ Other: ___

Other, please specify: _____

If ACH, any history of ICU stay during admission? □ Yes □ No □ Unknown

If yes, type(s): ☐ Medical (e.g., adult medical ICU) ☐ Pediatric ☐ Neonatal ☐ Pediatric Cardiac ☐ Other: _____ ☐ Unknown

Additional healthcare admission comments:_____

If no known 12-month inpatient (ACH or LTC) admission history (from prior question): **Did the case-patient receive any outpatient specialty/invasive care procedures (e.g., bronchoscopy, endoscopy, hemodialysis, etc.) in the U.S. in the 12-months BEFORE isolate collection?**

□ Yes □ No □ Unknown

- ☐ Bronchoscopy Procedure
- ☐ Endoscopy Procedure (e.g., esophagogastroduodenoscopy [EGD], colonoscopy)
- ☐ Hemodialysis
- ☐ Wound care
- ☐ Physical therapy
- ☐ Stoma care
- ☐ Outpatient infusion therapy (e.g., IVIG)
- ☐ Invasive urological procedure (e.g., VCUG [voiding cystourethrogram], ureteral re-implementation)
- ☐ Home health care, please describe:_____
- ☐ Outpatient Surgical Procedure
  If yes, please specify procedure: _____
- ☐ Other, please specify: _____

Additional outpatient healthcare comments:

Did the case-patient have any medical devices (e.g., urinary catheter, central venous catheter, etc.) or specialty care procedures (e.g., hemodialysis, wound care, urology procedures, etc.) in the **30 days BEFORE index isolate collection date**?
See Appendix 1 for the inclusion criteria and definitions of device/specialty care procedures

Device/Specialty Care Procedure	**Yes**	**Not recorded in MR**
Central Venous Catheter (e.g., PICC, IJ, Port, Hickman, PACs, UVC/UACs)	☐	☐
Dialysis ☐ Hemodialysis ☐ Peritoneal dialysis	☐	☐
Respiratory Devices/Care		
BiPAP/CPAP (non-invasive mechanical ventilation)	☐	☐
Endotracheal/Nasotracheal tube (Intubation)	☐	☐
Invasive mechanical ventilation	☐	☐
Tracheostomy tube	☐	☐
Enteral Feeding tube ☐ Nasogastric Tube ☐ Gastrostomy Tube (e.g., PEG tube, J Tube, G Tube)	☐	☐
Urinary catheter ☐ Invasive/Indwelling urinary catheter ☐ Intermittent/straight catheter ☐ Suprapubic catheter	☐	☐
Wound ☐ Chronic ulcer/wound (non-decubitus) ☐ Decubitus/Pressure Ulcer ☐ Surgical	☐	☐
Wound care	☐	☐
Other devices/procedures *If other, please specify:* _____	☐	☐

If <1 year old: **Was resuscitation performed at birth (i.e., anything beyond routine stimulation, cleaning/suctioning, and warmth), including but not limited to endotracheal suctioning for meconium, invasive or non-invasive ventilation (e.g., CPAP), placing umbilical lines, etc.?** ☐ Yes ☐ No ☐ Unknown

Did the case-patient have any surgical procedures in the **12 months <u>BEFORE</u> the index isolate collection date**? □ Yes □ No □ Unknown

Procedure type (e.g., wound debridement, appendectomy, transplant)	**Date of most recent procedure prior to index isolate (MM/DD/YYYY)**	**Location type(s) of procedure(s)**
		□ U.S. □ Non-U.S. □ Unknown

Additional Isolates

Did the patient have any <u>CRE isolates (with or without CP gene detection) or detection of a carbapenemase without isolation of an organism identified from clinical cultures collected in the 90 days AFTER</u> the index isolate (through June 30, 2024)? *(e.g., index isolate was NDM-E. coli from a sputum and the second positive isolate from this patient was an CRE E. coli (without any CP genes detected) from blood; or index isolate was NDM- E. coli detected from a wound and the second positive isolate was an NDM-Serratia marcescens from a blood specimen)*

☐ Yes, lab accession IDs: _____ ☐ No ☐ Unknown

If yes, are there additional isolates not captured by the above lab accession ID(s)? ☐ Yes ☐ No

If yes, please complete the following (one row per isolate):

Date of collection	*ARLN Alert ID(s):* *If more than one, list all*	Jurisdiction ID: *If different from ARLN*	WGS ID(s):	Specimen source	Mechanism(s)—organism(s) (if index had multiple mechanisms or organisms)

Did the patient have <u>history of CRE infection or colonization (or detection of a carbapenemase gene without isolation of an organism) PRIOR TO the study period (i.e., BEFORE 2023),</u> regardless of mechanism/organism combination?

☐ Yes, lab accession IDs: _____ ☐ No ☐ Unknown

If yes, are there additional isolates not captured by the above lab accession ID(s)? ☐ Yes ☐ No

If yes, please complete the following (one row per isolate):

Date of collection	*ARLN Alert ID(s):* *If more than one, list all*	Jurisdiction ID: *If different from ARLN*	WGS ID(s):	Specimen source	Mechanism(s)—organism(s) (e.g., NDM—E coli)

Additional Comments: