17-ID-04

Committee: Infectious Disease

Title: Public Health Reporting and National Notification of Carbapenemase Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) for *E. coli*, *Klebsiella* spp. and *Enterobacter* spp.

I. Statement of the Problem

Carbapenemase-producing carbapenem-resistant *Enterobacteriaceae* (CP-CRE) are an emerging public health problem in the United States. Interventions to control the spread of CP-CRE require:

1) Uniform, consistent classification and count of CP-CRE both within and across public health jurisdictions to facilitate reporting CP-CRE data to professional audiences, policy makers, and the public
(2) Actionable epidemiology for healthcare facilities about CP-CRE detection, prevention and response.

The overall aim is containment of CP-CRE.

II. Background and Justification

In this position statement, CP-CRE is defined as:

- *E. coli, Klebsiella* spp., or *Enterobacter* spp. where the isolate is:
  - Positive for carbapenemase production by a phenotypic method

  OR

  - Positive for a known carbapenemase resistance mechanism by a recognized test

CP-CRE are an emerging and epidemiologically important threat. Since the first detection of CP-CRE in the United States in 1996 (1), CP-CRE have spread rapidly, with cases reported in 49 of 50 states (2). Infections with CP-CRE are difficult to treat and associated with high mortality rates (3). Carbapenem antibiotics are often used as the last line of treatment for infections caused by highly resistant bacteria, including those in the *Enterobacteriaceae* family. Increased antimicrobial resistance limits treatment options (4). CP-CRE contain mobile resistance elements that facilitate transmission of resistance to other Gram negative bacilli (5). Early detection and aggressive implementation of infection prevention and control strategies are necessary to prevent further spread of CP-CRE, especially novel CP-CRE. These strategies require an understanding of the prevalence or incidence of CP-CRE. The development and use of a standardized definition is central to this process. Application of this standardized definition through active public health surveillance will allow for timely public health action.

The detection of CP-CRE is complicated and carbapenem resistance among *Enterobacteriaceae* can be due to a variety of mechanisms (6). The mechanism of resistance among CRE that is currently of greatest public health concern is production of carbapenemase enzymes, most notably, *Klebsiella pneumoniae* carbapenemase (KPC) (7). Carbapenemases of concern include, but are not limited to, KPC, New Delhi metallo-β-lactamase (NDM), Verona integron-encoded metallo-β-lactamase (VIM), imipenemase (IMP) metallo-β-lactamase, and oxacillinase-48 (OXA-48). There is wide variability in the capacity of clinical and public health laboratories for the detection of CP-CRE. However, capacity is being built at the state and regional level (e.g. Antimicrobial Resistance Laboratory Network [ARLN]) (8). Please refer to additional operational guidance for assistance in implementation of this position statement.

Please refer to CSTE PS 15-ID-05 *Standardized definition for Carbapenem-resistant Enterobacteriaceae (CRE) and recommendation for sub-classification and stratified reporting* for details on the rationale of the phenotypic definition used for CRE and rationale for sub-classification and stratified reporting (9).

III. Statement of the desired action(s) to be taken

1. Utilize standard sources (e.g. reporting*) for case ascertainment for CP-CRE. Surveillance for CP-CRE should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of CP-CRE.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	
Death certificates		
Hospital discharge or outpatient records		
Extracts from electronic medical records	X	
Telephone survey		
School-based survey		
Other _____		

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for CP-CRE and add CP-CRE to the *Nationally Notifiable Condition List.*

☐ 2a. Immediately notifiable, extremely urgent (within 4 hours)
☐ 2b. immediately notifiable, urgent (within 24 hours)
☒ 2c. Routinely notifiable)

CSTE recommends that all States and Territories enact laws (statue or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.

Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: NNDSS is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends that a new condition be made nationally notifiable, CDC must obtain OMB PRA approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new *MMWR* year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.

3. CDC should publish data on CP-CRE as appropriate in *MMWR* and other venues (see Section IX).

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined above.

Terminology:
* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.
**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

4. Jurisdictions should stratify reports of cases of CP-CRE using the methods outlined in Section VII.

5. CSTE recommends that health departments and public health laboratories should work with clinical laboratories to collaborate for the identification and timely reporting of CP-CRE to infection control and public health authorities to ensure timely communication and intervention. Interfacility communication should be strongly encouraged (also see CSTE position statement 16-ID-09: Interfacility Communication to prevent and control healthcare-associated infections and antimicrobial resistant pathogens across healthcare settings (10)).

6. CSTE recommends that a working group be established that includes CSTE and CDC members to develop a message mapping guide.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of CP-CRE to facilitate its prevention and control; the aim is containment of CP-CRE.

V. Methods for Surveillance: Surveillance for CRE and CP-CRE should use the recommended sources of data and the extent of coverage listed in Table III.

The primary source of data will be the microbiology laboratory. The laboratory should report CP-CRE with all available quantitative and qualitative susceptibility data, results (positive, negative, intermediate) of phenotypic carbapenemase production tests as well as results (positive and negative) of any tests performed for resistance mechanisms (e.g., KPC PCR).to public health authorities. Healthcare facilities and clinicians who become aware of patients with CP-CRE should report these to public health authorities. Other data sources (e.g., death certificates or hospital discharge data) may be used as supplementary case finding methods; their yield is unknown)

VI. Criteria for case identification

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

Given the variability in capability to detect CP-CRE among clinical laboratories, consideration to the individual laboratory's capabilities is necessary when determining what results are reported to public health authorities. Which laboratory results are considered reportable is determined by whether a laboratory has the capability to detect CP-CRE or not.

Laboratories with the capability to detect CP-CRE should report to public health authorities any of the following laboratory results:

Enterobacter spp, *E. coli* or *Klebsiella* spp:

> Positive for known carbapenemase resistance mechanism (e.g., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction (PCR), Xpert Carba-R)
>
> OR
>
> Positive on a phenotypic test for carbapenemase production (e.g, metallo-β-lactamase test, modified Hodge test, Carba NP, Carbapenem Inactivation Method (CIM), or modified CIM (mCIM)).

Laboratories without the capability to detect CP-CRE should report all identified CRE to public health authorities, to include any of the following laboratory results:

Enterobacter spp, *E. coli* or *Klebsiella* spp:

Resistant to any carbapenem (minimum inhibitory concentrations of ≥4 mcg/ml for meropenem, imipenem, and doripenem or ≥ 2 mcg/ml for ertapenem)

Note: Negative PCR for all known resistance mechanism (e.g., KPC, NDM, VIM, IMP, OXA-48) if accompanied by positive phenotypic test for carbapenemase production (e.g., mCIM, CIM, CarbaNP) should be reported urgently to STLT public health (and isolate submitted to ARLN regional laboratory via state public health laboratory) as it could signify a novel carbapenemase.

Report to public health authorities a person whose healthcare record contains a diagnosis of CP-CRE, KPC, NDM, OXA-48, IMP or VIM or novel carbapenemase.

Note: STLT health departments may choose to expand the list of organisms reportable to Public Health beyond *Klebsiella* spp, *E. coli* and *Enterobacter* spp., especially if there is phenotypic evidence of carbapenemase production (e.g., mCIM), whether or not accompanied by known CP resistance mechanism. Isolates that are phenotypically positive for carbapenemase production, but negative for KPC, NDM, OXA-48, VIM, and IMP should be submitted to the regional laboratories of the ARLN for further characterization. For details see additional operational guidance for assistance in implementation of this position statement.

B. Table of criteria to determine whether a case should be reported to public health authorities

Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities.

Criterion	
Healthcare record contains a diagnosis of Carbapenemase producing Carbapenem resistant Enterobacteriaceae (CP-CRE), KPC, NDM, OXA-48, IMP or VIM or novel carbapenemase	S
Any isolate of *Enterobacter* spp, *E. coli,* or *Klebsiella* spp demonstrating carbapenemase production by a phenotypic method (e.g., Carba NP, CIM, mCIM)	S
Any isolate of *Enterobacter* spp, *E. coli,* or *Klebsiella* spp with a known carbapenemase resistance mechanism by a recognized test (e.g., PCR, Expert Carba-R)	S
If laboratories are unable to detect CP-CRE, (i.e, cannot test for carbapenemase production or resistance mechanism):	
Any isolate of *Enterobacter* spp, *E. coli*, or *Klebsiella* spp that is resistant to any carbapenem (minimum inhibitory concentrations of ≥4 mcg/ml for meropenem, imipenem, and doripenem or ≥ 2 mcg/ml for ertapenem)	S

S = This criterion alone is Sufficient to report a case.
* A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.

C. Disease-specific data elements

None

VII. Case Definition for Case Classification
Three conditions codes should be created:

- CP-CRE- *Klebsiella* spp.
- CP-CRE- *E coli*
- CP-CRE- *Enterobacter* spp.

1) Each condition code should be stratified by whether the cultures were **clinica**l (i.e., collected for the purpose of diagnosing or treating disease in the course of normal care) versus **screening/surveillance cultures** (i.e., collected for the detection of colonization and not for the purpose of diagnosing or treating disease). Because it can be difficult to differentiate screening cultures from clinical cultures based on microbiology records, screening tests should generally be limited to rectal, peri-rectal or stool cultures. Cultures from such sites can be assumed to be for screening unless specifically noted otherwise. Laboratory may also note screening culture for other sites (e.g., wounds, tracheostomy or central line sites). Laboratories do not need to change their practice; public health wants to identify all CP-CRE whether they come from screening or clinical cultures.
2) **Resistance mechanism** if known (e.g., KPC, NDM, OXA-48, VIM, IMP). Consider listing the number of instances of multiple resistance mechanisms within the same isolate (e.g., NDM + OXA-48)

A. Narrative: Description of criteria to determine how a case should be classified.

Confirmed: meets below laboratory criteria.

Clinical Criteria
None

Laboratory Criteria

Laboratory evidence of carbapenemase production in an isolate by a phenotypic method or positive for a known carbapenemase resistance mechanism by the specific testing methods, such as:

- Phenotypic methods for carbapenemase production:
  - Carba NP positive
  - Metallo-β-lactamase testing (e.g., E-test) positive
  - Modified Carbapenem Inactivation Method (mCIM) positive or indeterminate
  - Carbapenem Inactivation Method (CIM) positive
  - Modified Hodge Test (MHT) positive
  - Positive for phenotypic carbapenemase production (e.g., mCIM, CIM, CarbaNP) but negative by PCR (e.g., Xpert Carba-R) for all known resistance mechanisms (e.g. KPC, NDM, OXA-48, VIM, IMP)
- Molecular methods for resistance mechanism:
  - PCR positive (for KPC, NDM, OXA-48, IMP, or VIM)
  - Xpert Carba-R positive (for KPC, NDM, OXA-48, VIM, IMP)
  - PCR or Xpert Carba-R positive for novel carbapenemase

Case Classification

Confirmed
E. coli, Klebsiella spp., or *Enterobacter* spp. from any isolate that is

Positive for known carbapenemase resistance mechanism (e.g., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction (PCR), Xpert Carba-R)

OR

Positive on a phenotypic test for carbapenemase production (e.g., metallo-β-lactamase test, modified Hodge test, Carba NP, Carbapenem Inactivation Method (CIM), or modified CIM (mCIM)).

Notes:

1. Cases involving isolates that are phenotypically positive for carbapenemase production (e.g., mCIM), but negative for KPC, NDM, OXA-48, VIM, and IMP should be counted as confirmed CP-CRE. Isolates should be submitted to the regional laboratories of the ARLN for further characterization (potential novel carbapenemase).
2. A positive Modified Hodge Test (MHT) can be used to confirm CP-CRE for *Klebsiella* spp and *E. coli* but not *Enterobacter* spp. An isolate that tests positive on MHT but negative PCR for KPC, NDM, OXA-48, VIM and IMP should have additional characterization performed with another phenotypic test for carbapenemase such as mCIM.
3. If isolate is indeterminate on mCIM and negative by PCR for KPC, NDM, OXA-48, VIM and IMP, isolate should be tested using CarbaNP (at state public health laboratory or regional ARLN lab)

Please see additional operational guidance for assistance in implementation of this position statement, including performance characteristics of laboratory tests.

Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance

- Different organisms/species/carbapenemases are counted as separate events from other organisms/species/carbapenemases
- There is at least a 12 month interval from previous notification event for clinical cases.
- A person with a clinical case should not be counted as a screening/surveillance case thereafter (e.g., patient with known infection who later has colonization of GI tract is not counted as more than one case)
- A person with a screening case can be later categorized as a clinical case (e.g., patient with positive peri-rectal screening swab who later develops blood stream infection would be counted in both categories).

B. Classification Tables

Table VII-B. Criteria for defining a case of CP-CRE.

Criterion	**CONFIRMED** CP-CRE *Klebsiella* spp.	**CONFIRMED** CP-CRE *Escherichia coli*	**CONFIRMED** CP-CRE *Enterobacter* spp.
Laboratory evidence			
Klebsiella spp. isolated from any clinical specimen, including screening/surveillance swabs	N		
Escherichia coli isolated from any clinical specimen, including screening/surveillance swabs		N	
Enterobacter spp isolated from any clinical specimen, including screening/surveillance swabs			N
PCR positive (for KPC, NDM, OXA-48, VIM, or IMP)	O	O	O
Xpert Carba-R positive (for KPC, NDM, OXA-48, VIM, or IMP)	O	O	O
mCIM positive	O	O	O
CarbaNP positive	O	O	O

CIM positive	O	O	O
Metallo-β-lactamase test (e.g., MBL E-test) positive	O	O	O
Modified Hodge Test (MHT) positive	O	O	
Positive for phenotypic carbapenemase production (e.g., mCIM, CIM, CarbaNP) but negative by PCR (e.g., Xpert Carba-R) for all known resistance mechanisms (KPC, NDM, OXA-48, VIM, IMP) i.e., likely novel carbapenemase	O	O	O
Criteria to distinguish a new case			
Different organism/species/ carbapenemases are counted as separate events from other species/ carbapenemases	N	N	N
Not counted as previous case in last 12 months	N	N	N
A person with a clinical case should not be counted as a screening/surveillance case thereafter (e.g., patient with known infection who later has colonization of GI tract is not counted as more than one case)	N	N	N
A person with a screening case can be later categorized as a clinical case (e.g., patient with positive peri-rectal screening swab who later develops blood stream infection would be counted in both categories).	N	N	N

*should refer for CarbaNP testing; Please see additional operational guidance for assistance in implementation of this position statement, including performance characteristics of laboratory tests

S = This criterion alone is Sufficient to classify a case.
N = All "N" criteria in the same column are Necessary to classify a case. A number following an "N" indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the Absence of criterion as a Necessary component.
O = At least one of these "O" (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case. (These "O" criteria are alternatives, which means that a single column will have either no O
criteria or multiple O criteria; no column should have only one O.) A number following an "O" indicates that this criterion is only required for a specific disease/condition subtype

VIII. Period of Surveillance

Surveillance is expected to be ongoing, as this is an emerging pathogen.

IX. Data sharing/release and print criteria

- State and territorial health departments should report confirmed cases of CP-CRE to CDC.
- Division of Healthcare Quality Promotion (DHQP) staff should review, analyze, and summarize the national data at least monthly. Provisional state-specific CP-CRE disease case counts should be provided and updated at regular intervals in national summary reports displayed on the CDC website. These provisional data are used to: 1) Monitor the epidemiology and geographic spread of CP-CRE; 2) Provide timely information regarding regional and national trends in CP-CRE disease reporting to public health officials and others; and 3) Identify geographic areas where additional prevention and control efforts may be needed. In circumstances where there is a potential for an international health impact, data from these notifications may be shared with international partners.
- Provisional data on confirmed CP-CRE disease cases may be published weekly in the provisional Morbidity and Mortality Weekly Report (MMWR) tables and posted on a CDC DHQP website. Final

data should be published annually in the MMWR Summary of Notifiable Diseases and presented or published at scientific meetings.

- Additional tables and limited use datasets may be made available to researchers, pharmaceutical companies, media, and the general public upon request to CDC's DHQP. These final data are used to: 1) Monitor the epidemiology, incidence, and geographic spread of CP-CRE; 2) Identify geographic areas in which it may be appropriate to conduct analytic studies of control methods, risk factors, disease severity, or other public health aspects; and 3) Evaluate CP-CRE preparedness and response funding needs and allocate resources.

X. Revision History

Position Statement ID	Section of Document	Revision Description
15-ID-05	Statement of the desired action(s) to be taken	ADDED CP-CRE condition to the NNC list
15-ID-05	B: Table VII-B - Confirmed	CHANGED TO RESTRICT TO CP-CRE
15-ID-05	B/ Table VII-B - Confirmed	ADDED CIM
15-ID-05	B/ Table VII-B - Confirmed	ADDED mCIM
15-ID-05	B/ Table VII-B - Confirmed	ADDED Xpert Carba-R
15-ID-05	B/ Table VII-B- Confirmed	Removed Enterobacter spp from MHT positive
15-ID-O5	B/ Table VIIB New Case	Added resistance mechanism
15-ID-05	B Subclassification/ stratification	Added resistance mechanism

XI. References

1. Yigit H., et al. Novel Carbapenem-Hydrolyzing Beta-Lactamase, KPC-1, from a Carbapenem-Resistant Strain of *Klebsiella pneumoniae*. Antimicrobial Agents and Chemotherapy, 2001. 45 (4):1151-1161. DOI: 10.1128/AAC.45.4.1151-1161.2001
2. CDC. Healthcare-associated Infections: Tracking CRE. Available at http://www.cdc.gov/hai/organisms/cre/TrackingCRE.html
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4. Papp-Wallace, K.M., et al. Carbapenems: Past, Present, and Future. Antimicrobial Agents and Chemotherapy, 2011. 55(11): 4943-4960. DOI: 10.1128/AAC.00296-11
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6. Jacob, J., et al. Vital Signs: Carbapenem-Resistant *Enterobacteriaceae*. Morbidity and Mortality Weekly Report, 2013. 62(9): 165-170
7. CDC. Facility Guidance for Control of Carbapenem-Resistant *Enterobacteriaceae* (CRE). 2015. Available at: https://www.cdc.gov/hai/pdfs/cre/CRE-guidance-508.pdf
8. CDC. Antibiotic/Antimicrobial Resistance: Antibiotic Resistance Lab Network. Available at: https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-networks.html
9. CSTE position statement 15-ID-05: *Standardized definition for Carbapenem-resistant Enterobacteriaceae (CRE) and recommendation for sub-classification and stratified reporting*
10. CSTE position statement 16-ID-09: *Interfacility Communication to prevent and control healthcare-associated infections and antimicrobial resistant pathogens across healthcare settings*

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