Committee: Infectious Disease

Title: Change in Case Definition from Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) to Carbapenemase-Producing Organisms (CPO)

☒ Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 17-ID-04

Synopsis: This position statement updates the case definition to expand Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae to Carbapenemase-Producing Organisms. It also expands acceptable laboratory criteria and the timeframe for counting new clinical cases.

I. Statement of the Problem

Carbapenemase-producing organisms (CPO), including but not limited to Enterobacterales, Acinetobacter baumannii and Pseudomonas aeruginosa, are an emerging public health problem in the United States. Interventions to control the spread of CPO require:

1. Uniform, consistent classification and counts of CPO both within and across public health jurisdictions to facilitate reporting CPO data to professional audiences, policy makers, and the public, and
2. Actionable epidemiology of CPO for healthcare facilities and public health officials to enable effective prevention, detection, and response to these organisms.

The overall aim of this position statement is to facilitate the containment of CPO through standardized surveillance practices. By expanding a) the organisms included for notification, b) the laboratory testing methods involved in identification, and c) the timeframe for counting new clinical cases, this position statement improves accounting of potential new antimicrobial resistant threats that may arise quickly or frequently.

II. Background and Justification

CPO are an epidemiologically important group of multidrug-resistant pathogens classified by the Centers for Disease Control and Prevention (CDC) as an urgent threat to public health. Since the detection of Klebsiella pneumoniae carbapenemase (KPC)-producing Klebsiella pneumoniae in the United States in 1996, CPO have spread throughout the country and include many organism-carbapenemase combinations. Infections caused by CPO are difficult to treat and associated with high mortality. CPO commonly contain mobile genetic elements, such as plasmids, that can facilitate transmission of resistance genes within and between bacterial species and in turn, facilitate transmission between patients. Early detection and implementation of infection prevention and control strategies are necessary to prevent further spread of CPO.

The previous position statement limited the case definition of carbapenemase-producing organisms to Escherichia coli (E. coli) and Enterobacter and Klebsiella species (spp.). Recent studies have shown, however, that other genera in the Enterobacteriales order (e.g., Citrobacter, Morganella, Serratia, Providencia, Proteus) and non-fermenting bacteria (Pseudomonas, Acinetobacter) play an important role in the epidemiology of CPO. These organisms have been implicated in multijurisdictional outbreaks in healthcare settings. Additionally, the use of screening methods such as polymerase chain reaction (PCR)-based culture independent diagnostic tests (CIDT) may yield positive results for a specific carbapenemase gene but not identify an organism.

Laboratory criteria and case definitions in the previous position statement described both phenotypic and genotypic carbapenemase testing methods that did not include next generation sequencing (NGS). While that was appropriate to detect commonly identified carbapenemase genes in the United States (Klebsiella pneumoniae, Escherichia coli).
pneumoniae carbapenemase (\textit{bla}KPC), oxacillinase-48 (\textit{bla}OXA-48), New Delhi metallo-\(
\beta\)lactamase (\textit{bla}NDM), Verona integron-encoded metallo-\(
\beta\)lactamase (\textit{bla}VIM), and imipenemase (\textit{bla}IMP)), additional carbapenemase genes have become relevant to the epidemiology of CPO. These include, but are not limited to, Seoul imipenemase (\textit{bla}SIM), German imipenemase (\textit{bla}GIM), Sao Paulo metallo-\(
\beta\)lactamase (\textit{bla}SPM), Guiana extended spectrum (\textit{bla}GES), and other OXA genes with carbapenem hydrolysis activity (e.g., \textit{bla}OXA-181, \textit{bla}OXA-232, that are less likely to be detected using commercially available nucleic acid amplification tests (NAAT). NGS, however, would detect these and other less common carbapenemase genes. Furthermore, NGS has become more accessible and widely-used to detect and characterize carbapenemase genes.\textsuperscript{13} Thus, this position statement includes NGS in the laboratory criteria and other carbapenemase genes in the case definition.

The previous version of this position statement also included a reference to a specific timeframe (12 months) to determine new clinical cases; however, accumulating data have shown the difficulty of clearing CPO colonization. Additionally, public health response does not rely on the time between identification of the same organism/carbapenemase combination for a given patient. These facts eliminate the need for a temporal requirement for counting new cases.

Expansion of the previous case definition will facilitate a more comprehensive understanding of CPO prevalence and incidence across jurisdictions. This expansion, which includes any CPO identified by existing methods or NGS across any amount of time, will also inform targeted public health action.

\textbf{III. Statement of the desired action(s) to be taken}

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for CPO.
   A. Utilize standard sources (e.g., reporting\textsuperscript{*}) for case ascertainment for CPO. Surveillance for CPO should use the recommended sources of data to the extent of coverage presented in Section V.
   B. Utilize standardized criteria for case ascertainment for CPO presented in Section VI and Table VI in Technical Supplement.
   C. Utilize standardized criteria for case classification for CPO presented in Section VII and Table VII in Technical Supplement.

2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for \textit{CPO} and update \textit{CPO} on the \textit{Nationally Notifiable Condition List}.
   \begin{itemize}
   \item [\checkmark] Immediately notifiable, extremely urgent (within 4 hours)
   \item [\checkmark] Immediately notifiable, urgent (within 24 hours)
   \item [\checkmark] Routinely notifiable
   \end{itemize}

3. CSTE recommends that all States and Territories enact laws (statute 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\textsuperscript{**} to CDC.

4. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget Paperwork Reduction Act (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.

5. CDC should publish data on CPO as appropriate (see Section IX).

CSTE recommends the following case statuses be included in the CDC Print Criteria:

- ☒ Confirmed
- ☐ Probable
- ☐ Suspect
- ☐ Unknown

6. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority to conduct public health surveillance follow the recommended methods outlined in this standardized surveillance position statement.

*Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Conditions List to CDC.*

### IV. Goals of Surveillance

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

### V. Methods for Surveillance: Surveillance for CPO should use the recommended sources of data and the extent of coverage listed in Table V.

The primary source of data is from the microbiology laboratory. The laboratory should report CPO with all available quantitative and qualitative susceptibility data, results (positive, negative) of phenotypic carbapenemase production tests, as well as results (detected, not detected) of any tests (e.g., NAAT or NGS) performed for a carbapenemase gene to public health authorities. Healthcare facilities that become aware of patients with CPO should report these cases (clinical and screening) to public health authorities. Other data sources, such as electronic medical records or established health information exchange (HIE), may be used as supplementary data.

**Table V. Recommended sources of data and extent of coverage for ascertainment of cases of CPO.**

<table>
<thead>
<tr>
<th>Source of data for case ascertainment</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Population-wide</td>
</tr>
<tr>
<td></td>
<td>Sentinel sites</td>
</tr>
<tr>
<td>Clinician reporting</td>
<td>X</td>
</tr>
<tr>
<td>Laboratory reporting</td>
<td>X</td>
</tr>
<tr>
<td>Reporting by other entities, specify: acute care hospitals, long-term care facilities, and outpatient settings</td>
<td>X</td>
</tr>
<tr>
<td>Death certificates</td>
<td></td>
</tr>
<tr>
<td>Hospital discharge or outpatient records</td>
<td></td>
</tr>
<tr>
<td>Data from electronic medical records</td>
<td>X</td>
</tr>
<tr>
<td>Telephone survey</td>
<td></td>
</tr>
<tr>
<td>School-based survey</td>
<td></td>
</tr>
<tr>
<td>Other, specify: N/A</td>
<td></td>
</tr>
</tbody>
</table>
VI. Criteria for case ascertainment

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

Given the variability in capacity to detect carbapenemase production among clinical laboratories, consideration of the individual laboratory’s capacity is necessary when determining what results should be reported to public health authorities. The laboratory criteria for reporting below are limited to those laboratories that can detect carbapenemase production phenotypically or detect carbapenemase genes, both of which should be reported to public health authorities based on the listed criteria.

Laboratories without the capacity to detect carbapenemase production phenotypically or to detect carbapenemase genes should submit carbapenem-resistant specimens for which the isolated species is not intrinsically resistant, in accordance with current CLSI minimum inhibitory concentration (MIC) interpretive criteria for carbapenem resistance, to a laboratory with capacity for further characterization (i.e., state public health laboratory). Examples of species with intrinsic resistance include Proteus spp., Providencia spp., and Morganella morganii, which are intrinsically resistant to imipenem, and Pseudomonas spp. and Acinetobacter spp., which are intrinsically resistant to ertapenem.

CPO may include but are not limited to E. coli and Klebsiella, Enterobacter, Pseudomonas, Acinetobacter, Citrobacter, Proteus, Providencia, Morganella, Serratia, and Raoultella spp.

A1. Clinical Criteria for Reporting
N/A

A2. Laboratory Criteria for Reporting
Laboratories with the capacity to detect carbapenemase production phenotypically or to detect carbapenemase genes should report to public health authorities any of the following laboratory results for any specimen:

- Positive phenotypic test* result for carbapenemase production, with or without identification of a specific carbapenemase gene**, OR
- Positive molecular test*** result detecting a carbapenemase gene**, OR
- Detection of a carbapenemase gene** by NGS‡, OR
- Specimen positive for a carbapenemase gene** without bacterial species identification, (e.g., Xpert Carba-R rectal swabs, other CIDT)

* Phenotypic testing methods include but are not limited to: metallo-β-lactamase test, modified Hodge test, Carba NP, carbapenem inactivation method (CIM), modified carbapenem inactivation method (mCIM), EDTA-modified carbapenem inactivation method (eCIM), or immunochromatography tests (ICT). Isolates that are phenotypically positive for carbapenemase production but negative for a carbapenemase gene via a molecular test should be submitted to a laboratory with capacity for further characterization as necessary.

** Common carbapenemase genes include: blaKPC, blaNDM, blaVIM, blaIMI, blaOXA-48, but other carbapenemase genes include but are not limited to: blaSIM, blaGIM, blaSPM, other OXA genes, etc.

*** Molecular tests for carbapenemase genes include but are not limited to: Xpert Carba-R, VERIGENE, Streck ARM-D, Cepheid, validated laboratory-developed NAAT, etc.

‡ It is not necessary to report organisms with known chromosomal carbapenemase genes, including but not limited to SME+ Serratia marcescens, unless they have additional non-chromosomal carbapenemase genes.

A3. Epidemiologic Linkage Criteria for Reporting
N/A

B. Disease-specific data elements to be included in the initial report
Specimen source
Collection date
Organism/carbapenemase gene results
Antimicrobial Susceptibility Testing (AST) results
Indication for testing (i.e., clinical or screening)
VII. Case Definition for Case Classification

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

A1. Clinical Criteria
N/A

A2. Laboratory Criteria

Confirmatory laboratory evidence:

- Positive phenotypic test* result for carbapenemase production in a specimen, OR
- Positive molecular test** result detecting a carbapenemase gene*** (with or without organism identification), OR
- Detection of carbapenemase gene*** by NGS‡

Presumptive laboratory evidence:
N/A

Supportive laboratory evidence:
N/A

* Phenotypic testing methods include but are not limited to: metallo-β-lactamase test, modified Hodge test, Carba NP, carbapenem inactivation method (CIM), modified carbapenem inactivation method (mCIM), EDTA-modified carbapenem inactivation method (eCIM), or immunochromatography tests (ICT).

** Molecular tests for carbapenemase genes include but are not limited to: Xpert Carba-R, VERIGENE, Streck ARM-D, Cepheid, validated laboratory-developed NAAT.

*** Common carbapenemase genes include: blaKPC, blaNDM, blaVIM, blaIMP, blaOXA-48, but other carbapenemase genes include but are not limited to: blaESBL, blaOXA, blaSPM, other OXA genes, etc.

‡ It is not necessary to report organisms with known chromosomal carbapenemase genes, including but not limited to SME+ Serratia marcescens, unless they have additional non-chromosomal carbapenemase genes.

Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.

A3. Epidemiologic Linkage
N/A

A4. Case Classifications

Confirmed: Any specimen that meets the confirmatory laboratory evidence.

Probable: N/A

Suspect: N/A

The following provides guidance for health departments to use for the further classification of CPO cases. Each CPO report should be stratified by whether the specimen was clinical (i.e., collected for the purpose of diagnosing or treating disease in the course of normal care) versus screening (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 specimens from clinical specimens based on microbiology records, screening cases should generally be limited to CPO identified in rectal, peri-rectal, axilla, groin, or stool specimens. Specimens from such sites can be assumed to be for screening unless specifically noted otherwise. Laboratories may also note screening specimens from other sites (e.g., wound, tracheostomy or central line...
sites). Laboratories do not need to change their practice; public health wants to identify all CPO whether they come from screening or clinical specimens.

Each report should also specify carbapenemase gene(s) when known (e.g., bla_{KPC}, bla_{NDM}, bla_{OXA-48}, bla_{VIM}, bla_{IMP}, etc.), listing all genes within the same specimen (e.g., NDM+ OXA-48+ \textit{E. coli}).

**B. 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**

- A specific organism/carbapenemase combination in a person should be counted as a separate case from other organism/carbapenemase combinations in the same person (e.g., KPC+ \textit{K. pneumoniae} vs. NDM+ \textit{E. coli}). A specific organism/carbapenemase combination can include a carbapenemase gene(s) without an organism detected (e.g., NDM+ no organism vs. NDM+ \textit{E. coli}).
- A person classified as a clinical case should not be counted as a screening case thereafter for the same organism/carbapenemase combination (e.g., patient with known NDM+ \textit{E. coli} infection who later has NDM+ \textit{E. coli} colonization should not be counted as a separate case).
- A person classified as a screening case can be later counted as a clinical case with the same organism/carbapenemase combination (e.g., patient with NDM+ \textit{E. coli} peri-rectal screening swab who later develops NDM+ \textit{E. coli} blood stream infection would be counted twice, once in each category). This is the only way that the same organism/carbapenemase combination can be counted twice for the same person.
- A case with a known carbapenemase but unknown organism should only be counted once for that carbapenemase (e.g., an NDM+ screening case is later screened at a different facility and tests NDM+ positive and no organism is identified again).

**VIII. Period of Surveillance**

Surveillance is expected to be ongoing.

**IX. Data sharing/release and print criteria**

CSTE recommends the following case statuses* be included in the ‘case’ count released outside of the public health agency:

- Confirmed
- Probable
- Suspect
- Unknown

* Which case statuses are included in the case counts constitute the “print criteria.”

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.

Production of national data summaries and national data re-release for non-NNCs:

- Prior to release of national data summaries CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwgreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.
X. Revision History

<table>
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<tr>
<th>Previous PS ID</th>
<th>Section of Document</th>
<th>Revision Description</th>
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<tr>
<td>17-ID-04</td>
<td>VI. Criteria for case ascertainment</td>
<td>Expanded organism list to include any organism, added next generation sequencing (NGS) identification</td>
</tr>
<tr>
<td>17-ID-04</td>
<td>VII. Case Definition for Case Classification</td>
<td>Expanded organism list to include any organism, added NGS identification, update New Clinical Case timeline from 1 year to lifelong</td>
</tr>
<tr>
<td>17-ID-04</td>
<td>B: Table VI-B – Confirmed</td>
<td>Expanded organism list to include any organism, added NGS identification</td>
</tr>
<tr>
<td>17-ID-04</td>
<td>B: Table VII-B – Confirmed</td>
<td>Expanded organism list to include any organism, added NGS identification, update New Clinical Case timeline from 1 year to lifelong, removed separate organism columns</td>
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<td>15-ID-05</td>
<td>Statement of the desired action(s) to be taken</td>
<td>ADDED CP-CRE condition to the NNC list</td>
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<td>15-ID-05</td>
<td>Table VII-B – Confirmed</td>
<td>CHANGED TO RESTRICT TO CP-CRE</td>
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<td>ADDED CIM, mCIM, eCIM, Xpert Carba-R, Cepheid</td>
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<td>Table VII-B – Confirmed</td>
<td>Removed Enterobacter spp. from MHT positive</td>
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<td>Table VII-B – New Case</td>
<td>Added resistance mechanism</td>
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<td>15-ID-05</td>
<td>B Subclassification/stratification</td>
<td>Added resistance mechanism</td>
</tr>
<tr>
<td>N/A</td>
<td>15-ID-05</td>
<td>Created a standardized surveillance case definition for Carbapenem-resistant Enterobacteriaceae (CRE).</td>
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</tbody>
</table>

XI. References


XII. Coordination

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Additional co-authors are included in Appendix 1.
Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>CPO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Criteria for Reporting</strong></td>
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<tr>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Laboratory Criteria for Reporting</strong></td>
<td></td>
</tr>
<tr>
<td>Positive phenotypic test* result for carbapenemase production, with or without identification of a specific carbapenemase gene**</td>
<td>S</td>
</tr>
<tr>
<td>Positive molecular test*** result detecting a carbapenemase gene**</td>
<td>S</td>
</tr>
<tr>
<td>Detection of a carbapenemase gene** by next generation sequencing (NGS)†</td>
<td>S</td>
</tr>
<tr>
<td>Specimen positive for a carbapenemase gene** without bacterial species identification</td>
<td>S</td>
</tr>
<tr>
<td><strong>Epidemiologic Linkage Criteria for Reporting</strong></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
- S = This criterion alone is SUFFICIENT to report a case.
- *Phenotypic testing methods include but are not limited to: metallo-β-lactamase test, modified Hodge test, Carba NP, carbapenem inactivation method (CIM), modified carbapenem inactivation method (mCIM), EDTA-modified carbapenem inactivation method (eCIM), or immunochromatography tests (ICT). Isolates that are phenotypically positive for carbapenemase production but negative for a carbapenemase gene via a molecular test should be submitted to a laboratory with capacity for further characterization as necessary.
- **Common carbapenemase genes include: blaKPC, blaNDM, blaVIM, blaIMP, blaOXA-48, but other carbapenemase genes include but are not limited to: blaSIM, blaGIM, blaSPM, other OXA genes, etc.
- ***Molecular tests for carbapenemase genes include but are not limited to: Xpert Carba-R, VERIGENE, Streck ARM-D, Cepheid, validated laboratory-developed NAAT, etc.
- † It is not necessary to report organisms with known chromosomal carbapenemase genes, including but not limited to SME+ Serratia marcescens, unless they have additional non-chromosomal carbapenemase genes.
Table VII. Classification Table: Criteria for defining a case of CPO

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Confirmed</th>
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<tbody>
<tr>
<td><strong>Clinical Evidence</strong></td>
<td>N/A</td>
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<tr>
<td><strong>Laboratory Evidence</strong></td>
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<tr>
<td>Positive phenotypic test* result for carbapenemase production in a specimen</td>
<td>S</td>
</tr>
<tr>
<td>Positive molecular test** result detecting a carbapenemase gene*** (with or without organism identification)</td>
<td>S</td>
</tr>
<tr>
<td>Detection of carbapenemase gene*** by next generation sequencing (NGS)‡</td>
<td>S</td>
</tr>
<tr>
<td><strong>Epidemiologic Linkage Evidence</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Criteria to distinguish a new case:</strong></td>
<td></td>
</tr>
<tr>
<td>A specific organism/carbapenemase combination in a person should be counted as a separate case from other organism/carbapenemase combinations in the same person.‡‡</td>
<td>N</td>
</tr>
<tr>
<td>A person classified as a clinical case should not be counted as a screening case thereafter for the same organism/carbapenemase combination.</td>
<td>N</td>
</tr>
<tr>
<td>A person classified as a screening case can be later counted as a clinical case with the same organism/carbapenemase combination.</td>
<td>N</td>
</tr>
<tr>
<td>A case with a known carbapenemase but unknown organism should only be counted once for that carbapenemase.</td>
<td>N</td>
</tr>
</tbody>
</table>

Notes:
S = This criterion alone is SUFFICIENT to classify a case.
N = All “N” criteria in the same column are NECESSARY to classify a case.
* Phenotypic testing methods include but are not limited to: metallo-β-lactamase test, modified Hodge test, Carba NP, carbapenem inactivation method (CIM), modified carbapenem inactivation method (mCIM), EDTA-modified carbapenem inactivation method (eCIM), or immunochromatography tests (ICT).
** Molecular tests for carbapenemase genes include but are not limited to: Xpert Carba-R, VERIGENE, Streck ARM-D, Cepheid, validated laboratory-developed NAAT.
*** Common carbapenemase genes include: blaKPC, blaNDM, blaVIM, blaIMP, blaOXA-48, but other carbapenemase genes include but are not limited to: blaSIM, blaSIM, blaSPM, other OXA genes, etc.
‡ It is not necessary to report organisms with known chromosomal carbapenemase genes, including but not limited to SME+ Serratia marcescens, unless they have additional non-chromosomal carbapenemase genes.
‡‡A specific organism/carbapenemase combination can include a carbapenemase gene(s) without an organism detected.
Appendix 1. Additional Co-Authors

Numbering continues from Section XIII of the accompanying position statement.

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