VHA 2017 Guideline for Control of Carbapenemase Producing-Carbapenem Resistant *Enterobacteriaceae* (CP-CRE)

MDRO Prevention Office

National Infectious Diseases Service

Veterans Health Administration

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Table of Contents

Introduction

Untreatable and hard-to-treat infections due to Carbapenemase Producing-Carbapenem Resistant *Enterobacteriaceae* (CP-CRE) (previously known as Carbapenem-Resistant *Enterobacteriaceae* (CRE)) are on the rise among patients in US medical facilities. According to the Centers for Disease Control and Prevention, about 4% of US acute care and 18% of long-term acute care hospitals reported at least one patient with a CRE infection during the first half of 2012, and CRE infections have been reported from 42 states during the last 10 years (CDC CRE Vital Signs). These bacteria are resistant to all or nearly all of the antibiotics available to clinicians today with the result that mortality from some infections, such as those of the bloodstream, can be as high as 50%. Medical facilities in several states and countries have reduced CRE infection rates by using aggressive prevention and control measures.

The purpose of this Guideline is to standardize laboratory identification, surveillance, and reporting of CP-CRE and provide recommendations for optimal prevention and control of infections due to these bacteria. This is a critical time for VHA in which CP-CRE infections can be controlled if addressed in a rapid, coordinated, and consistent effort by doctors, nurses, laboratory staff, medical facility leadership, and health department partners.

This version of the Guideline is an update of the 2015 Guideline for Control of Carbapenem-Resistant *Enterobacteriaceae* disseminated to the field March 19, 2015 incorporating many of the recent recommendations from the November CDC 2015 CRE Toolkit. The primary updates are in laboratory testing methods. Like its predecessor, this Guideline remains a working document designed to assist VA infectious diseases physicians, healthcare epidemiologists, infection prevention and control professionals, MDRO prevention coordinators, clinical microbiologists and others involved in the detection, prevention, and control of CP-CRE within VA facilities.

Carbapenems, including doripenem, ertapenem, imipenem, and meropenem, are broad-spectrum antimicrobial agents. They have been used to treat serious infections caused by bacteria that are highly resistant to other antibiotics. In some cases, carbapenems are considered antibiotics of last resort.

The *Enterobacteriaceae* are gram-negative bacteria, many of which are normal residents of the human intestine. *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Serratia marcescens*, and *Citrobacter freundii* are representatives of this group. These organisms often are associated with community-acquired infections such as urinary tract infections and pneumonia. They also cause healthcare-associated infections including pneumonia, urinary tract infections, bacteremia, and infections associated with central lines, urinary catheters, and ventilators.

Carbapenem resistance among *Enterobacteriaceae* may result from several mechanisms. In one, *Enterobacteriaceae* acquire genes that produce enzymes (carbapenemases) with the ability to inactivate carbapenems directly. These bacteria are referred to as carbapenemase-producing *Enterobacteriaceae*. The genes for these enzymes are typically located on

plasmids that facilitate transmission within and between bacterial species. Examples of carbapenemases include KPC (*Klebsiella pneumonia* carbapenemase), NDM (New Delhi metallo-β-lactamase), VIM (Verona integron-encoded metallo-β-lactamase), and OXA (oxacillinase). The FDA recently approved molecular tests to identify bacteria carrying these genes which greatly enhance the sensitivity and specificity of testing and the timeliness of reporting. In another mechanism, the bacteria become carbapenem resistant through the production of β-lactamases (ampC or ESBLs) in combination with decreased cell wall permeability through porin channel alterations. This occurs most commonly in *Enterobacter* spp., *Serratia* spp., and *Citrobacter* spp. Bacteria can be carbapenem-resistant (CRE) using either the AmpC or ESBL/porin channel or carbapemase production mechanisms. We are focusing on the latter, and for that reason will henceforth refer to the bacteria in this guideline as CP-CRE.

This Guideline is focused on detecting carbapenem resistance in *Escherichia coli, Klebsiella pneumoniae/oxytoca*, *Enterobacter cloacae*, and other *Enterobacter* spp. due primarily to the carbapenemase-production mechanism. Low level intrinsic resistance can also be found in other members of the *Enterobacteriaceae* (*Proteus*, *Morganella* and *Providencia*). These bacteria can cause healthcare-associated infections. However, they are less of a concern for infection prevention and control.

This Guideline is comprised of a series of four algorithms developed to help VA facilities identify, monitor, and perform infection prevention and control for CP-CRE. Specifically these algorithms are designed to help:

1. Optimize the clinical microbiology laboratory approach to the screening, identification, evaluation, and reporting of CP-CRE (Algorithm 1).
2. Facilitate baseline and ongoing surveillance for CP-CRE (Algorithm 2).
3. Optimize Infection Prevention and Control for CP-CRE in acute care and Community Living Center settings when CP-CRE are found (Algorithms 3 and 4).

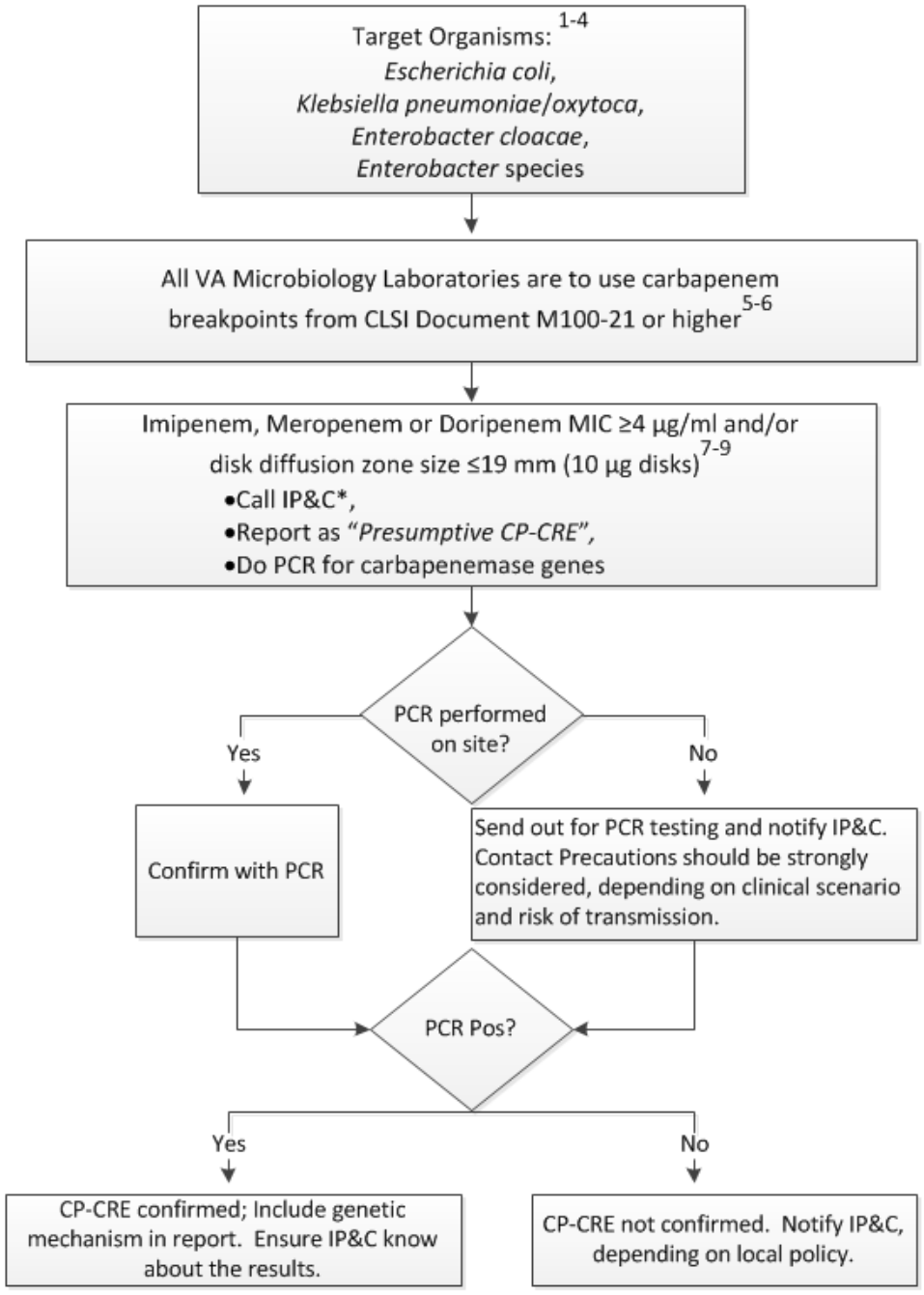
Footnotes accompany each algorithm to provide further details or explanation.

This Guideline provides minimum expectations for identification and infection control and prevention activities for all VHA facilities. Although a local facility may choose to institute more technically sophisticated or stringent approaches for the identification and control of CP-CRE than are recommended in this Guideline, such approaches should not deviate significantly from accepted professional and ethical norms.

Additional information for laboratory and clinical staff is available on the MDRO website at Carbapenemase-producing Enterobacteriaceae (CP-CRE).

Questions or comments should be addressed to the VHA MDRO Prevention Office at vha04mrsapro@va.gov.

Algorithm 1: Clinical Microbiology Laboratory Detection and Confirmation of Carbapenemase Producing-Carbapenem Resistant *Enterobacteriaceae* (CP-CRE)

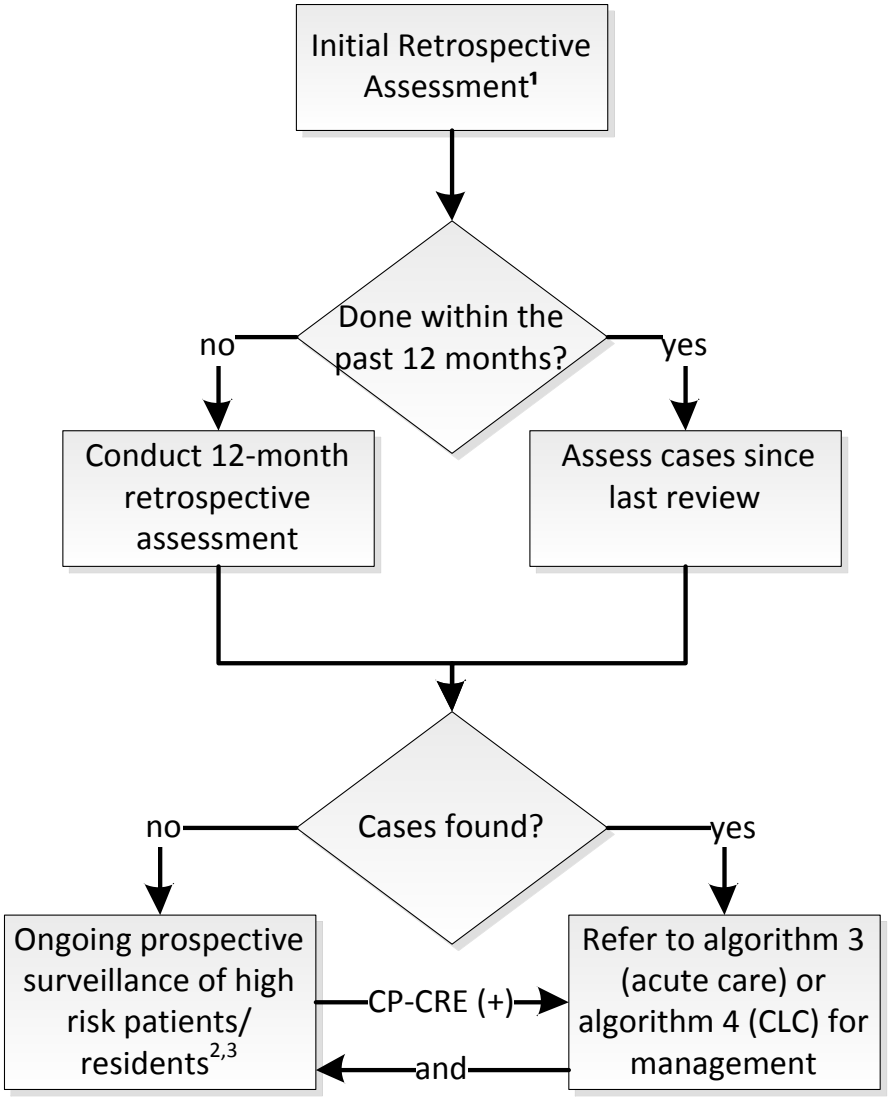


*IP&C = Infection Prevention & Control

Footnotes:

1. *Escherichia coli, Klebsiella pneumoniae/oxytoca*, *Enterobacter cloacae*, and other *Enterobacter* spp. that meet the definition of CP-CRE are a priority for detection and containment in VHA acute- and long-term care (CLC) settings.
2. *Morganella morganii*, *Proteus* spp., and *Providencia* spp. that have low levels of intrinsic resistance to the carbapenems are not part of the VHA CP-CRE surveillance definition.
3. Carbapenem-resistant *Acinetobacter baumannii* and *Pseudomonas aeruginosa* are not *Enterobacteriaceae* and are excluded from the CP-CRE guidelines at this time.
4. Local Infection Prevention and Control (IP&C) personnel in consultation with Pathology & Laboratory Medicine Services should decide if *Enterobacteriaceae* not listed in Algorithm 1 or *Acinetobacter baumannii* or *Pseudomonas aeruginosa* with carbapenem resistance (MIC ≥4 ug/ml or disk diffusion zone ≤19mm) need to be worked up using this algorithm.
5. All VA Microbiology labs should be using CLSI M100-S21 or higher. It is no longer best practice to use the older CLSI breakpoints for carbapenems (S20 or lower). Note: The 2017 toolkit targets carbapenem resistant organisms; this is different than the 2015 toolkit which targeted carbapenem non-susceptible organisms.
6. If doing PCR for CP-CRE in-house, it is recommended to set up all purity plates associated with susceptibility testing on gram negative rods with a 10ug meropenem disk. The PCR assay that is FDA cleared requires testing of colonies from the edge of the zone or close by for optimal accuracy.
7. Ertapenem resistance had been used as a screening tool for CP-CRE. However, with the newer carbapenem breakpoints, this has proven to be too non-specific for meaningful interpretation. Therefore ertapenem should not be used to screen.
8. An FDA approved PCR is now commercially available for detection of CP-CRE, along with verification kits. It is recommended that VA Clinical Laboratories adopt this testing for detection of CP-CRE and the specific mechanisms causing carbapenem resistance. CP-CRE isolates for PCR verification can be obtained from CDC at (http://www.cdc.gov/drugresistance/resistance-bank/currently-available.html).
9. Assure processes are in place for notifying local Infection Prevention and Control (IP&C) personnel when CP-CRE are suspected or identified in the clinical microbiology laboratory. *E. coli, K. pneumoniae/oxytoca*, *E. cloacae*, and other *Enterobacter* spp. from clinical cultures or surveillance screening that meet or are likely to meet the definition of CP-CRE (above) should be reported as soon as possible to other clinical personnel (as determined by the local facility) caring for the patient/resident. Depending on local policy, IP&C may also wish to be notified about carbapenem-resistant organisms that are not PCR positive.

Algorithm 2: Initial Assessment and Ongoing Surveillance for CP-CRE in Acute Care and CLC Facilities



Footnotes:

1. Initial Retrospective Assessment: Search for previously unrecognized patients/residents with bacteria meeting the CP-CRE definition (see Algorithm 1) recovered from clinical cultures or surveillance screening within the past 12 months. This can be done by:
    a. Reviewing a line-listing of potential bacteria (*E. coli, K. pneumoniae/oxytoca*, *E. cloacae*, and other *Enterobacter* spp.) obtained from the local clinical microbiology laboratory (sorted by species and carbapenem resistance).

b. Reviewing the most recent local facility antibiogram (ideally updated within the past 12 months). If *E. coli, K. pneumoniae/oxytoca*, *E. cloacae*, and other *Enterobacter* spp. are not 100% susceptible to doripenem, imipenem, and meropenem, patients/residents with non-susceptible isolates should be identified, if possible, by reviewing the database used to develop the antibiogram and their potential role in transmission within the facility evaluated.

2. Ongoing Prospective Surveillance.

   a. Once the initial retrospective assessment has been completed, facilities should consider doing admission screening of high-risk candidates (see 2b below) in the following situations if:

      i. The facility has an incidence of new CP-CRE patients ≥1 per month based on the retrospective review. This should include cases considered community- and hospital-acquired.

      ii. The facility has CP-CRE cases, and the rate continues to increase despite implementation of core prevention measures (Appendix B).

      iii. The facility has a CP-CRE outbreak.

      iv. The facility is in a region known to have a high prevalence of CP-CRE.

      v. The facility wishes to be more aggressive than core prevention activities.

   b. An admission screening algorithm should be developed and customized based on local epidemiological considerations. The algorithm should be reviewed at least annually by the Infection Control Committee. Possible high-risk candidates for screening might include:

      i. Patients/residents previously colonized or infected with CP-CRE. In VA facilities, this may be indicated by an Infection Control flag in the CWAD (Crisis notes, Warnings, Allergies, and Directives) section of CPRS or in the Patient Record Flags (PRF) section. (N.B. Although it may be known that these patients were previous carriers of CP-CRE, repeated screening might provide useful information for assessing continuing carriage and making a decision about the need for future Contact Precautions).

      ii. Transfers from a facility known to have CP-CRE.

      iii. Transfers from a Long-Term Acute Care Hospital (LTACH) or chronic ventilator facility.

      iv. Persons who have been recently hospitalized outside the U.S.

      v. Patients/residents who have received solid organ or bone marrow transplantation.

vi. Others as designated by local infection prevention and control.

3. When patient/resident screening is indicated, obtain and process specimens as follows.

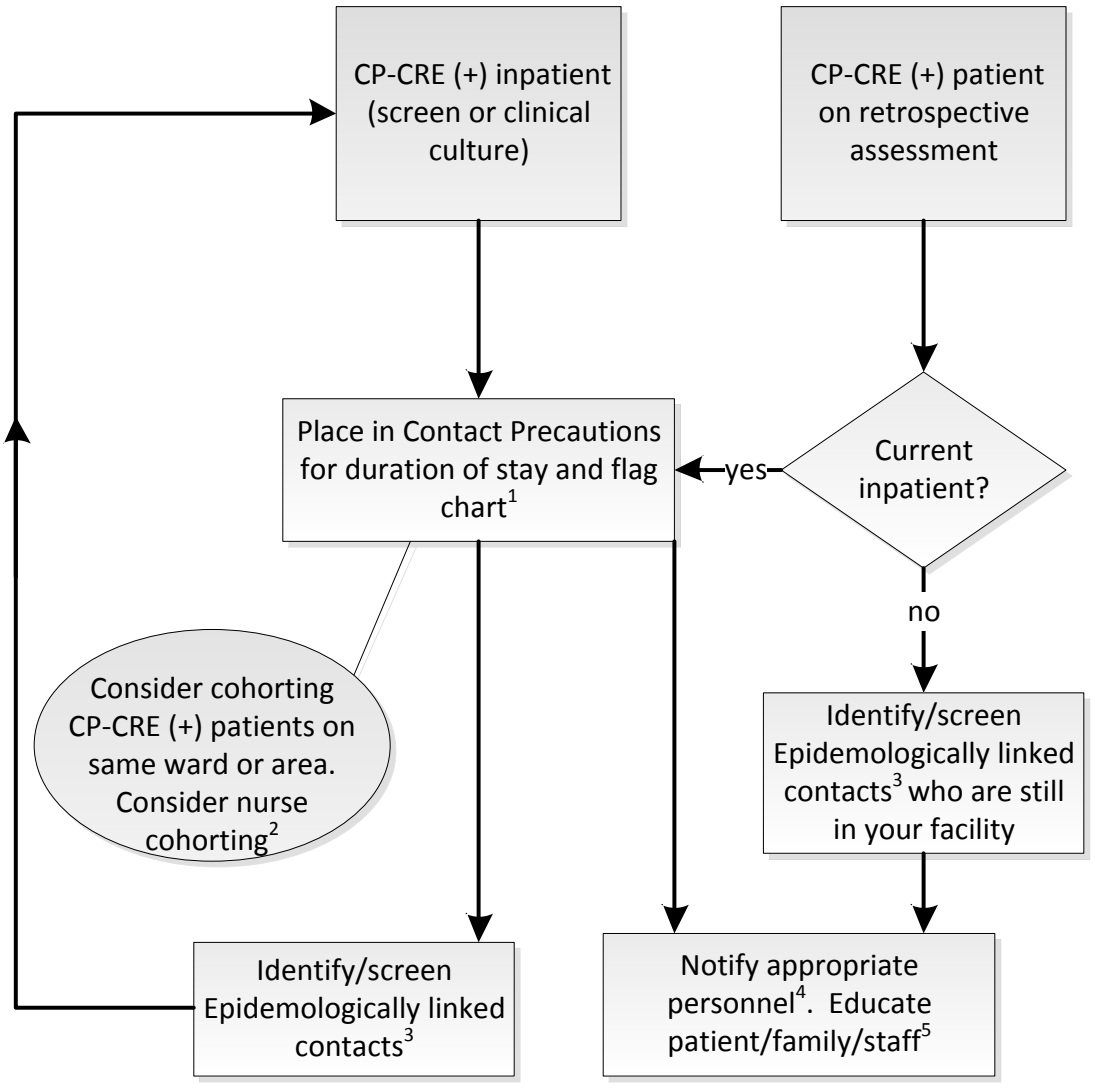
   a. Appropriate educational materials such as the "Should I be tested for CRE?" and the "What you need to know about multidrug-resistant organisms (MDROs)" brochures (available and printable from MDRO Education and Training Resources) should be provided to the patient/resident prior to collecting a specimen.

   b. Obtain specific oral consent for collection of a surveillance specimen for CP-CRE and document this in the Computerized Patient Record System (CPRS). Standard VA consenting practices apply (see VHA Handbook 1004.01 "Informed Consent for Clinical Treatment and Procedures" paragraph 13c(1)b Informed Consent Handbook).

      c. Obtain and process surveillance specimens according to manufacturers recommendations available at http://vaww.mrsa.va.gov/Carbapenem_resistant_Enterobacteriaceae_CRE.asp.

   d. The preferred screening method is an FDA-approved PCR test using material from rectal swabs. If that is not available in your facility, please follow the CDC guideline (Lab Protocol for CRE). There are still no FDA approved screening agar plates available for CP-CRE.

Algorithm 3: Management of Patients with CP-CRE in Acute Care Facilities



Footnotes:

1. When an inpatient is identified with CP-CRE (either by screen or clinical culture), they should be managed in Contact Precautions in a private room if possible. Acute care inpatients colonized or infected with CP-CRE should remain in Contact Precautions for the duration of their stay. Be sure an appropriate Infection Control flag is posted in CPRS (per local facility policy) to notify healthcare workers during future admissions to acute care. A mechanism should be in place to describe how infection control flags for CP-CRE positive patients will be managed and when they will be discontinued. Note: There are currently little data available on when to discontinue Contact Precautions when patients with a prior

history of CP-CRE are readmitted to your facility. As a minimal guideline, the following is recommended: 1) the original site of infection or colonization (if it can be cultured) is negative for CP-CRE and 2) CP-CRE screening for gastrointestinal (GI) carriage (surveillance specimen) is negative. There should be two negative tests for GI carriage collected at least one week apart while off antibiotics.

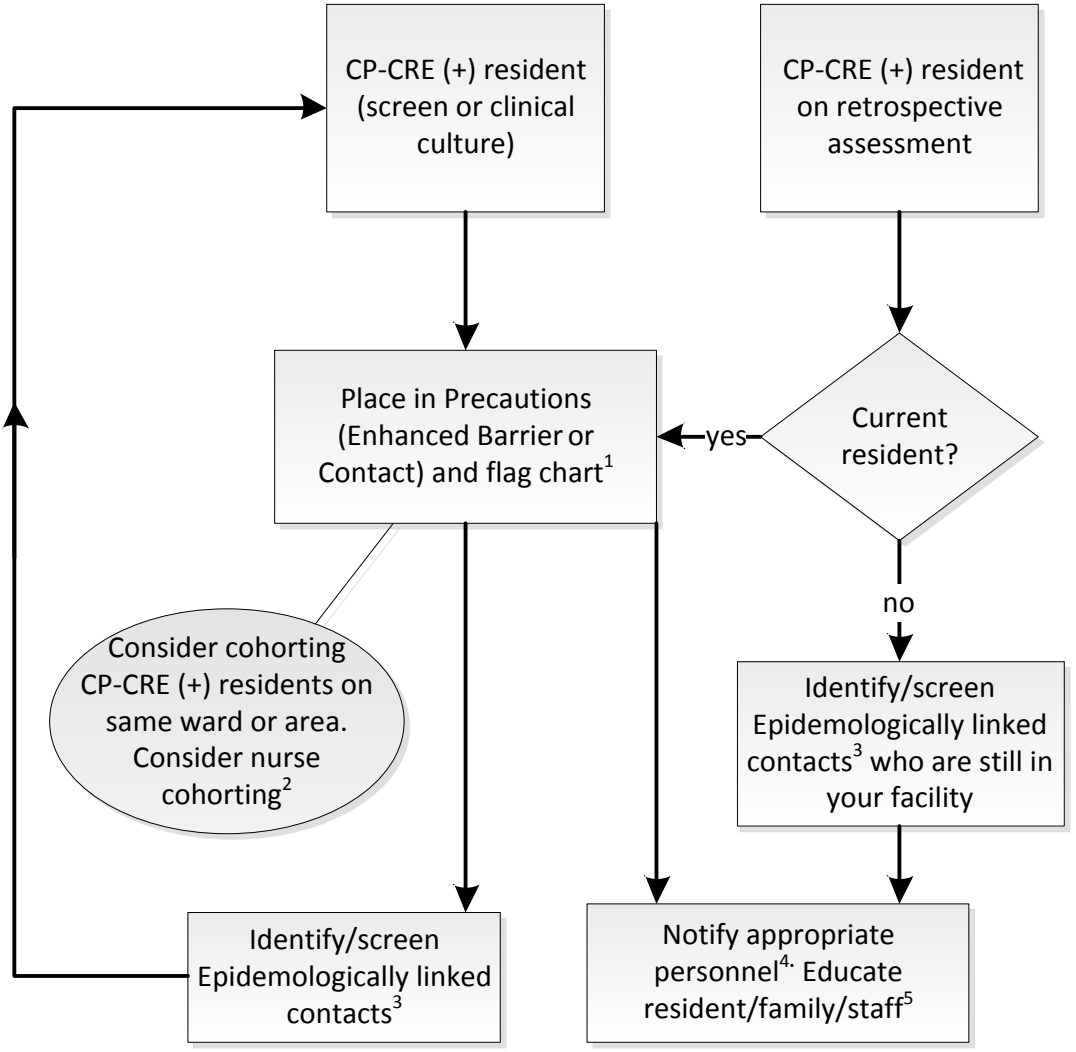
2. Cohorting patients and/or staff is not recommended for single CP-CRE patients (unless in an outbreak situation), but could be considered if there is evidence of intra-facility transmission or if multiple CP-CRE patients are admitted at one time.
3. Once previously unrecognized CP-CRE-positive patients are identified, epidemiologically-linked patients who are still in your facility (e.g., those having contact or sharing a room or bathroom with the CP-CRE-positive patient) should be assessed by IP&C who can then decide if screening for CP-CRE is indicated. Screening might be extended beyond these patients to high acuity patients that shared healthcare providers or were in close proximity to the CP-CRE index patient, particularly if overlap with the CP-CRE index patient was prolonged and if the CP-CRE index patient required a high intensity of nursing care or had stool and/or urine incontinence. Screening should be performed as detailed under Algorithm 2, footnote 3.
4. Mechanisms (in compliance with VHA privacy and confidentiality policies) should be in place to report when CP-CRE-positive patients are or have been in the facility. Hospital administration, the Antibiotic Stewardship Program, and pertinent clinical groups in the facility should be notified when CP-CRE-positive patients are identified. Local facilities should determine the best way and how often to convey this information.
5. The brochure "What you need to know about multidrug-resistant organisms (MDROs)" is available at MDRO Education and Training Resources for educating patient/family about CP-CRE if indicated. It can be printed for the patient/family from the website. It provides basic information for the patient about MDROs including CP-CRE, their significance, implications, methods to stop spread, and answers to questions about what to do when at home. Additional PowerPoint presentations on MDROs are available on the same website for licensed independent practitioners and non-clinical healthcare staff at Education Brochures and CRE Infection Clinician FAQs.

Other Information:

1. When a CP-CRE positive patient is transferred to another healthcare facility, the receiving facility should be notified of the patient's status. See Appendix C for an example of a template of an inter-facility transfer form that can be filled out, printed and sent with the patient.
2. Note: Daily and terminal disinfection of patient rooms/spaces can be done using the same EPA-registered products used for MRSA. The sporicidal agents used for *Clostridium difficile* are not necessary. See Appendix D for a sample checklist for monitoring terminal

cleaning.

Algorithm 4: Management of Residents with CP-CRE in Community Living Centers



Footnotes:

1. When a resident is identified with CP-CRE (either by screen or clinical culture), they should be managed in Enhanced Barrier Precautions in a private bedroom if possible (Contact Precautions may be indicated by Infection Prevention and Control). Be sure an appropriate Infection Control flag is posted in CPRS (per facility policy) to notify healthcare workers during future admissions. A mechanism should be in place to describe how infection control flags for CP-CRE positive patients will be managed and when they will be discontinued. Note: There are currently little data available on when to discontinue

Enhanced Barrier or Contact Precautions for residents with CP-CRE. As a minimal guideline, the following is recommended: 1) the original site of infection or colonization (if it can be cultured) is negative for CP-CRE and 2) CP-CRE screening for gastrointestinal (GI) carriage (surveillance specimen) is negative. There should be two negative tests for GI carriage collected at least one week apart while off antibiotics.

2. Cohorting residents and/or staff is not recommended for single CP-CRE residents (unless in outbreak situation), but could be considered if there is evidence of intra-facility transmission or if multiple residents with CP-CRE are admitted at one time.
3. Once previously unrecognized CP-CRE-positive patients are identified, epidemiologically-linked residents who are still in your facility (e.g., those having contact or sharing a bedroom or bathroom with the CP-CRE-positive resident) should be assessed by IP&C who can then decide if screening for CP-CRE is indicated. Screening should be performed as detailed under Algorithm 2, footnote 3.
4. Mechanisms (in compliance with VHA privacy and confidentiality policies) should be in place to report when CP-CRE-positive residents are or have been in the facility. Hospital administration, the Antibiotic Stewardship Program, and pertinent clinical groups in the facility should be notified when CP-CRE-positive residents are identified. Local facilities should determine the best way and how often to convey this information.
5. The brochure "What you need to know about multidrug-resistant organisms (MDROs)" is available at MDRO Education and Training Resources for educating resident/family about CP-CRE if indicated. It can be printed for the resident/family from the website. It provides basic information for the resident about MDROs including CP-CRE, their significance, implications, methods to stop spread, and answers to questions about what to do when at home. Additional PowerPoint presentations on MDROs are available on the same website for licensed independent practitioners and non-clinical healthcare staff at Education Brochures and CRE Infection Clinician FAQs.

Other Information:

1. When a CP-CRE positive resident is transferred to another healthcare facility, the receiving facility should be notified of the patient's status. See Appendix C for an example of a template of an inter-facility transfer form that can be filled out, printed and sent with the patient.
2. Note: Daily and terminal two-step disinfection of resident rooms/spaces can be done using the same EPA- registered products used for MRSA. The sporicidal agents used for *Clostridium difficile* are not necessary. See Appendix D for a sample checklist for monitoring terminal cleaning.

Appendix A: Recommendations for Verification of an MIC Panel for Imipenem and/or Meropenem when Using CLSI Document M100-S24 (2014)

1. The College of American Pathologists (CAP) has approved a 3 x 5 plan for verification of FDA/CLSI approved breakpoints (see Table 5F in M100-S24). To do so, test 3 replicates of each QC strain for 5 days using individually prepared inocula.
2. The M100-S24 (2014) carbapenem breakpoints for susceptibility to imipenem and meropenem have been lowered from ≤4.0 µg/ml to ≤1.0 µg/ml.
3. Select an MIC panel that has concentrations of imipenem and/or meropenem that go down to at least 1.0 µg/ml
4. To verify that your panel can detect imipenem and/or meropenem susceptible/resistant strains in the expanded dilution range, it is recommended the following QC strains be used:
    a. *Pseudomonas aeruginosa* ATCC 27853 (selected because the acceptable QC ranges will verify MICs of 1 to 4 µg/ml for imipenem and 0.25 to 1 µg/ml for meropenem
    b. *Escherichia coli* ATCC 25922 (selected as the standard *Enterobacteriaceae* QC strain)
    c. *Klebsiella pneumoniae* ATCC BAA-1705 (selected as a carbapenem–resistant strain)
5. Once the expanded MIC panel is verified, regular weekly QC as specified to Table 2A in M100-S24 is sufficient. There is no need to repeat the 3 x 5 process.
6. These recommendations, proposed by the VHA CRE Work Group, are subject to modification based on changing epidemiology of CP-CRE.

Appendix B: Core Prevention Measures for Acute Care and Community Living Centers

1. Hand Hygiene
    - Promote hand hygiene
    - Monitor adherence to hand hygiene and provide feedback to staff
    - Ensure access to hand hygiene stations and supplies
2. Transmission Precautions

    Acute care – Contact Precautions

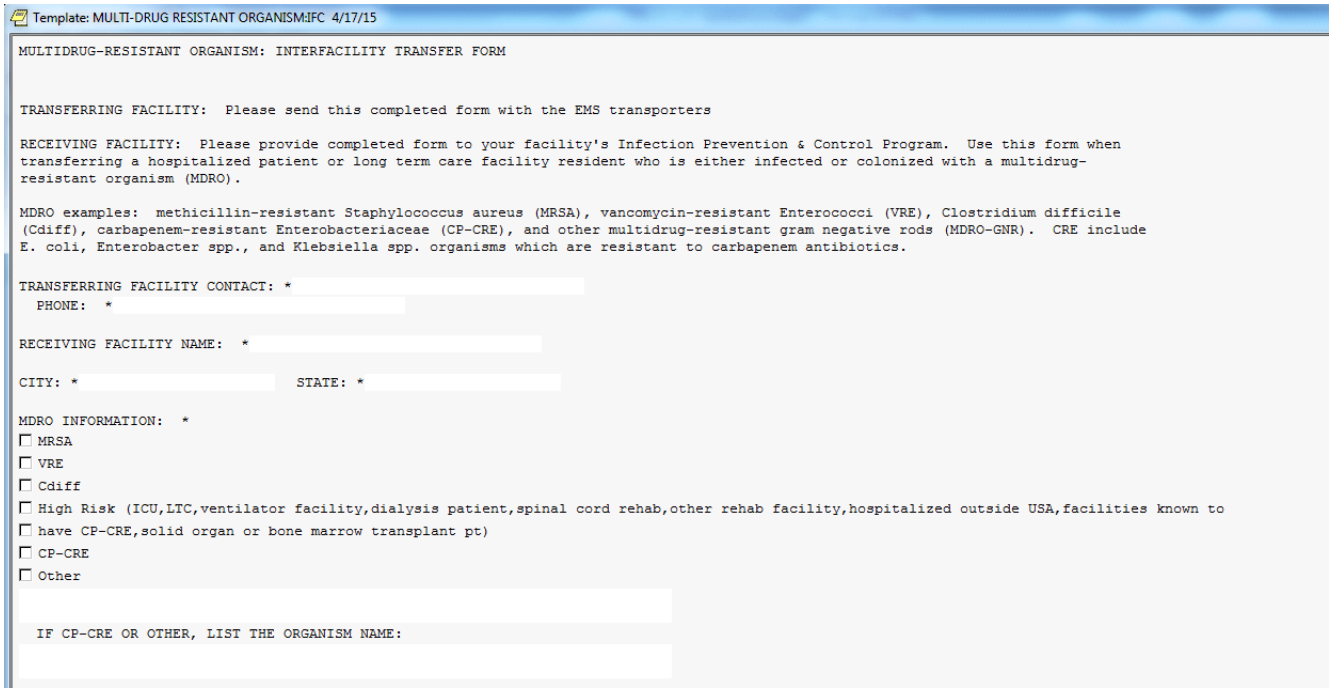
    - Place CP-CRE colonized or infected patients in Contact Precautions for the duration of their acute care stay (see footnote #1, Algorithms 3 and 4)
    - Private room (if available)
    - Post a sign near entry to the patient's room/space indicating the area is being used for Contact Precautions
    - Hand hygiene on entry and exit to patient room/space
    - Gown and glove on entry to patient room/space
    - Patient to leave room only for medically necessary procedures
    - Educate staff, patient, visitors, and family about Contact Precautions
    - Monitor adherence to Contact Precautions and provide feedback to staff

Community living centers – Enhanced Barrier Precautions or Contact Precautions

- Place CP-CRE colonized or infected residents in Enhanced Barrier or Contact Precautions (the latter determined by local Infection Prevention and Control) as detailed in the Revised Guideline for Implementation of the Veterans Health Administration Methicillin-Resistant *Staphylococcus aureus* Prevention Initiative in Community Living Centers (08-10-2016)
- Educate staff, resident, visitors, and family about Enhanced Barrier and/or Contact Precautions

3. Minimize use of invasive devices
4. Promote antimicrobial stewardship
5. Environmental management services
    - Hospital disinfectants for CP-CRE are the same as those used for MRSA.
    - A terminal cleaning checklist is available.

Appendix C: Example of Interfacility Transfer Form



Template: MULTI-DRUG RESISTANT ORGANISM:IFC 4/17/15

MULTIDRUG-RESISTANT ORGANISM: INTERFACILITY TRANSFER FORM

TRANSFERRING FACILITY: Please send this completed form with the EMS transporters

RECEIVING FACILITY: Please provide completed form to your facility's Infection Prevention & Control Program. Use this form when transferring a hospitalized patient or long term care facility resident who is either infected or colonized with a multidrug-resistant organism (MDRO).

MDRO examples: methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococci (VRE), Clostridium difficile (Cdiff), carbapenem-resistant Enterobacteriaceae (CP-CRE), and other multidrug-resistant gram negative rods (MDRO-GNR). CRE include E. coli, Enterobacter spp., and Klebsiella spp. organisms which are resistant to carbapenem antibiotics.

TRANSFERRING FACILITY CONTACT: *

PHONE: *

RECEIVING FACILITY NAME: *

CITY: * STATE: *

MDRO INFORMATION: *

- ☐ MRSA
- ☐ VRE
- ☐ Cdiff
- ☐ High Risk (ICU,LTC,ventilator facility,dialysis patient,spinal cord rehab,other rehab facility,hospitalized outside USA,facilities known to have CP-CRE,solid organ or bone marrow transplant pt)
- ☐ CP-CRE
- ☐ Other

IF CP-CRE OR OTHER, LIST THE ORGANISM NAME:

Appendix D: Environmental Checklist for Monitoring Terminal Cleaning

Date:	
Unit: **Room Number:**	
Initials of EMS Staff:	

Evaluate the following priority sites for each patient room:

High-touch Room Surfaces[1,2]	Cleaned	Not Cleaned	Not Present in Room
Bed rails/controls Tray table (overbed table) Call box/button			
Telephone			
Bedside table Chair			
Pull cord			
Room sink Room light switch Room inner door knob			
Room inner door knob/plate			
Bathroom light switch Bathroom handrails by toilet Bathroom sink Restroom sink			
Toilet Toilet flush handle			

Evaluate the following additional sites if these equipment are present in the room:

High-touch Room Surfaces[2]	Cleaned	Not Cleaned	Not Present in Room
IV pole (grab area)			
IV pump control Multi-module monitor controls Multi-module monitor touch screen Multi-module monitor cables			
Ventilator control panel			

Mark the monitoring method used:

☐Direct observation ☐Fluorescent gel

☒Swab cultures ☐ATP system ☐Agar slide cultures

[1]Selection of detergents and disinfectants should be according to institutional policies and procedures, [2]Sites most frequently contaminated and touched by patients and/or healthcare workers. Form adapted from CDC (see Oregon CRE Toolkit).

Appendix E: Expert Advisory Group Membership

This Guideline was originally developed by an Expert Advisory Group for Carbapenem-Resistant *Enterobacteriaceae*. Members of the group currently include:

Gary A Roselle, M.D., FACP, Director National Infectious Diseases Service, VA Central Office

Martin Evans, M.D., National Infectious Diseases Service, Director of the VHA MRSA/MDRO Prevention Office, VA Central Office

Kenneth Berkowitz, M.D., FCCP, Chief, Ethics Consultation, National Center for Ethics in Health Care

Stephen Brecher, PhD, Director of Microbiology, VA Boston Healthcare System

Marla Clifton, R.N., MSN, CIC, Acting Clinical Programs Coordinator, National Infectious Diseases Service, VA Central Office

Kathleen DeRoos, APRN, MSN, CIC, Healthcare Associated Infections Clinical Programs Coordinator, National Infectious Diseases Service, VA Central Office

Matthew Bidwell Goetz, M.D., Chief of Infectious Diseases, VA Greater Los Angeles Healthcare System

Michael Icardi, M.D., Director Office of Pathology and Laboratory Medicine Service, VA Central Office

Makoto Jones, M.D., Infectious Disease Research, Salt Lake City VA Medical Center

Allison Kelly, M.D., MSOH, Staff Physician/Antimicrobial Stewardship Coordinator, National Infectious Diseases Service, VA Central Office and Cincinnati VA Medical Center

J. Stacey Klutts, M.D., PhD, Medical Director of Clinical Microbiology, Staff Pathologist, Iowa City VA Medical Center

Stephen Kralovic, M.D., MPH, Staff Physician/Medical Epidemiologist, National Infectious Diseases Service VA Central Office and Cincinnati VA Medical Center

Janice Lattus, R.N., MSN, MPH, CIC, CPHQ, Infection Control Nurse, Durham VA Medical Center, Durham, NC.

Karen Lipscomb, R.N., MSN, CIC MDRO Clinical Coordinator, National Infectious Diseases Service, VA Central Office

Monsita McCall, R.N., BSN, MSM, Multi-Drug Resistant Organism Prevention Coordinator, Hampton VAMC

Brian McCauley, DPM, MHSA, National Infectious Diseases Service, VA Central Office

Melinda Neuhauser, PharmD, MPH, National PBM Clinical Pharmacy Program Manager, Infectious Diseases, VHA Pharmacy Benefits Management Services, Hines, Il.

Donna Oblack, PhD, DABMM, Director of Microbiology, Cincinnati Veterans Affairs Medical Center, Cincinnati, OH.

Christopher Pfeiffer, M.D., MHS, Hospital Epidemiologist, Portland VA Medical Center, Portland, OR.

Zydnia Pomales, MT, MPC, Health Science Specialist, VA Caribbean Healthcare System, San Juan, PR.

Sonia Saavedra, M.D., PhD, Chief Infectious Diseases, VA Caribbean Healthcare System, San Juan PR.

Matthew Samore, M.D., Chief, Division of Epidemiology, Salt Lake City, UT.

Judith Whitlock, R.N., MSN, APRN, CIC MRSA/MDRO Education Coordinator, National Infectious Diseases Service, VA Central Office

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