Ministry of Health Malaysia

Infection Control Unit
Medical Care Quality Section
Medical Development Division
Ministry of Health, Malaysia

Management of Carbapenem-resistant *Enterobacteriaceae* (CRE) in Healthcare Setting

4th Edition 2019

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Contents

Acronyms and Abbreviations

AMR	Antimicrobial Resistance
AMS	Antimicrobial Stewardship
BMD	Broth Microdilution
CLSI	Clinical Laboratory Standard Institute
CRE	Carbapenem-resistant *Enterobacteriaceae*
ESBL	*Extended Spectrum B-Lactamase*
IMR	Institute for Medical Research
MIC	Minimal Inhibitory Concentration
MRSA	Methicillin Resistant *Staphylococcus aureus*
PCR	Polymerase Chain Reaction
TAT	Turn Around Time
VRE	*Vancomycin Resistant Enterococci*

Chapter 1:
Introduction

1. Introduction
2. Incidence of CRE

1. Introduction

Carbapenem-resistant *Enterobacteriaceae* (CRE) are multidrug-resistant organisms that can cause serious infections and poses a significant public health threat in both high and low-to-middle-income countries.

Enterobacteriaceae are the largest family of gram-negative bacteria causing human infection e.g. *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae* and *Proteus species*. *Enterobacteriaceae* are normal flora of the gastrointestinal tract and not causing any infection. However, they are the most frequent gram-negative bacteria that can cause human infections in the community and in healthcare settings, such as urinary tract infection, abdominal infection and bloodstream infection. In addition, the antimicrobial resistance genes can easily spread between different species and strains within the *Enterobacteriaceae* family.

CRE are Enterobacterales that are resistant to carbapenem antibiotics. Carbapenems e.g. imipenem, meropenem, ertapenem and doripenem are antibiotics used for the treatment of infections caused by gram-negative bacteria that have been resistant to various types of antibiotics. CRE that produce carbapenemases (enzymes that inactivate carbapenems and other β-lactam antibiotics, including penicillins and cephalosporins) are known as carbapenemase-producing CRE (CP-CRE). There are different types of carbapenemases and the most commonly identified include Imipenemase (IMP), New Delhi Metallo-beta-lactamase (NDM), Klebsiella pneumoniae carbapenemase (KPC), Verona Integron-Encoded Metallo-beta-lactamase (VIM) and Oxacillinase-48 (OXA-48). Meanwhile, CRE without carbapenemases are called non-carbapenemase-producing CRE.

A serious implication of the bacteria that produces this carbapenemase is the ability to transmit antibiotic resistant genes among bacteria from other species. The NDM-1 gene has been the leading cause of CRE cases in Malaysia. The identification of bacteria and the control of infection and the control of the use of antibiotics are very important to prevent the spread of the bacteria.

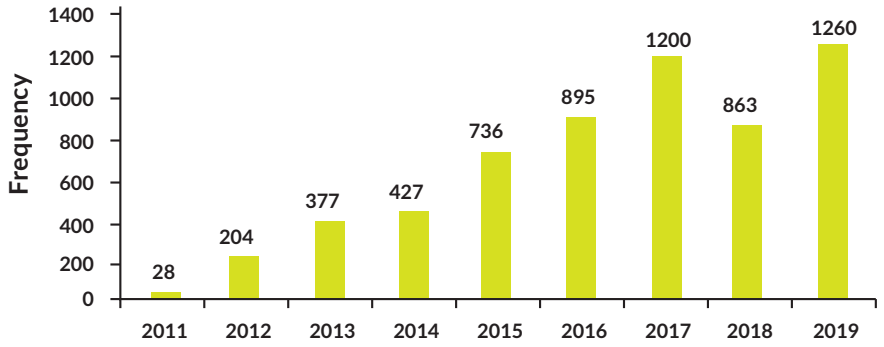
These manuals outline the actions that need to be taken immediately when CRE cases are detected and microbiologically verified. Early detection and intervention is essential to prevent outbreaks.

2. Incidence of Carbapenem-resistant *Enterobacteriaceae* (CRE)

An infection with Carbapenem-resistant *Enterobacteriaceae* (CRE) or Carbapenemase-producing *Enterobacteriaceae* is becoming an important challenge in health-care settings. It has been identified as a global public health threat which requires a coordinated effort involving all stakeholders including healthcare facilities and providers, public health, and community in order to decrease the impact of these organisms.

An increasing number of CRE cases have been identified in Malaysia since 2014. In 2019, a total number of 1260 CRE cases were reported where the most common infection were blood stream infection, pneumonia and urinary tract infection. NDM-1 was the majority of Carbapenemase enzymes identified in clinical isolates in Malaysia. The all cause mortality in CRE infection was 40.4% and CRE attributable death was 13.5%.

Trending of CRE Cases 2011 - 2019



Source: Annual Report 2019, Infection Prevention & Control and Antimicrobial Resistance Containment Program

Chapter 2:
Definitions

1. CRE
2. Confirmed Case
3. Suspect / Contact
4. High Transmission Risk Area
5. Infectivity Period
6. CRE Carrier

1 Carbapenem-resistant *Enterobacteriaceae* (CRE)

The terms refer to bacteria that are members of the family *Enterobacteriaceae* that have been found to have resistance to carbapenem antibiotics by any mechanism.

2 Confirmed Carbapenem-resistant *Enterobacteriaceae* (CRE) Case

A person with a laboratory confirmed CRE isolate (clinical sample or screening sample), who is either colonized or infected with a CRE.

3 Suspect/Contact of Carbapenem-resistant *Enterobacteriaceae* (CRE) Case

An individual who is exposed to a confirmed case (colonized or infected) with CRE during the ***infectivity period*** or has had a contact in an ***area of high transmission risk***.

If undetermined, the period of likely acquisition is at least 2 days before the sample was taken.

For example: A suspect can be defined as patient who shared a room or cubicle with the case ***for ≥ 24 hours*** during the infectivity period of the case at least 2 days before the sample was taken from the confirmed case.

4 High Transmission Risk Area

The decision to identify an area or a ward as a high risk transmission area will be left to local hospital level.

An example: a ward where local transmission has occurred and the following criteria may be used;

1. At least 2 or more confirmed cases of CRE of which at least one case is locally acquired AND
2. There is epidemiological link eg: proximity of cases / sharing of staffs / equipment or from a possible environmental source (e.g. bathroom or toilet facility)

5 Infectivity Period

The time when the laboratory confirmed CRE case could potentially transmit to another patient.

The period should be the date of likely acquisition to the time the case is placed into contact precaution (either isolation) OR discharged or transferred.

If unclear, the period of likely acquisition is at least 2 days before the sample was taken.

6 Carbapenem-resistant *Enterobacteriaceae* (CRE) Carrier

Majority of people who acquired CRE are colonized rather than infected.

The primary site of colonization is lower gastrointestinal tract.

Duration of colonization can be prolonged (> 6 months).

CRE can survive on environmental surface and equipment.

Chapter 3:
CRE Screening & Surveillance

1. Surveillance Strategy
2. Method of Surveillance

1. Surveillance Strategy

1.1 Objective:

The objective of surveillance for CRE is to detect all cases of CRE in order to understand the extent of the problem and to ensure infection control and outbreak management processes are applied whenever necessary.

1.2 Choice of screening specimen:

a. **All laboratory request forms are to be marked CRE screening.**

b. **Rectal swab** (with evidence of faecal matter on the swab)* **or fecal specimen** (when rectal swab is contraindicated e.g Neutropenic patient) **is mandatory.**

c. A peri-anal swab is not acceptable because of low sensitivity and specificity.

d. In addition, the following samples can be considered, but not routinely undertaken:
   - wound swab
   - urine sample
   - tracheal aspirate
   - stomal specimen

   *In order to avoid unnnesseacry screening samples, please discuss with microbiologist or infection control unit regarding appropiate samples.

1.3 Procedure for collecting rectal swab

a. Clean the gluteal area with clean water.

b. Wet the sterile cotton swab with sterile water.

c. Insert wet sterile cotton swab 2-3 cm deep from anal canal and gently rotate 360 degrees 2-3 times.

d. Ensure the swab has fecal material.

e. Place swab into transport media.

1.4 Who to screen?

a. **Patients indicated for screening**:

Routine screening will be conducted on this group of patients:

- Contact(s) of a CRE case.
- Patient transferred from another hospital with high transmission risk (CRE cluster or outbreak).
- A contact of confirmed CRE case who has not screened before in the initial period (e.g due to early discharge).

Note: These group of patient should be isolated.

b. **In outbreak situation, additional screening strategies for HIGH RISK PATIENTS should be considered**:

- Prolonged hospital stay (more than 2 weeks).
- Multiple use of antibiotic agents (the last 3 months) including extended-spectrum penicillins, cephalosporins, fluoroquinolones and carbapenems.
- Indwelling medical device, such as a central venous catheter, hemodialysis catheter, urinary catheter, biliary catheter or wound drain.
- Mechanical ventilation.
- Admission to the intensive care unit.
- Organ or stem-cell transplant.
- Severe illness.
- Haematology patients.

1.5 Screening strategy

a. International guidelines have recommended repeated screening to identify CRE carriage to improve probability of detection. Most patients tend to develop fecal positivity at around 8 days of exposure. The initial screening may be negative due to low burden of bacteria, intermittent shedding and as well as due to antibiotic use.

b. We shoud implement sequential screening for contact who are negative on the first screen i.e. If 1st rectal swab (Day 1) reported as CRE negative, **to repeat 2nd rectal swab (Day 7)**. Refer Diagram 1 and Flow Chart 2.

c. A suspect / contact is considered negative when:
    - ≥1 screening specimen/s reported negative taken >7 days after the last contact with the CRE case.

d. If patient is discharged before 1st or 2nd rectal swab is taken, to tag patient as 'suspect' for CRE (Refer Flow Chart 2).
    - Take rectal swab for CRE screening if this patient is readmitted within 1 year.
        i. If positive, to follow CONFIRMED CASE PROTOCOL
        ii. If negative, to off tag as suspect

    - If this patient is readmitted after 1 year, repeat rectal swab is not needed.

2. Method of surveillance

2.1 Management of a CRE case and its suspects (refer to Flow Chart 1)

2.2. Active Screening (refer to 1.4)

2.3 Point Prevalence Screening

a. Is conducted when a census point in time is chosen to screen a cohort of patients (e.g. all patient on a ward on a particular date) at risk of being infected or colonized with CRE.

b. Can be considered in areas where patients are at higher risk of onward transmission;

    - Copious drainage from wounds
    - Uncontrollable diarrhea / respiratory secretions
    - Indwelling urinary catheters
    - Dementia patients unable to adhere to proper hygiene
    - Patients in acute care settings: burns / malignant hematology patients / ICU

Flow Chart 1: Management of Confirmed CRE Case

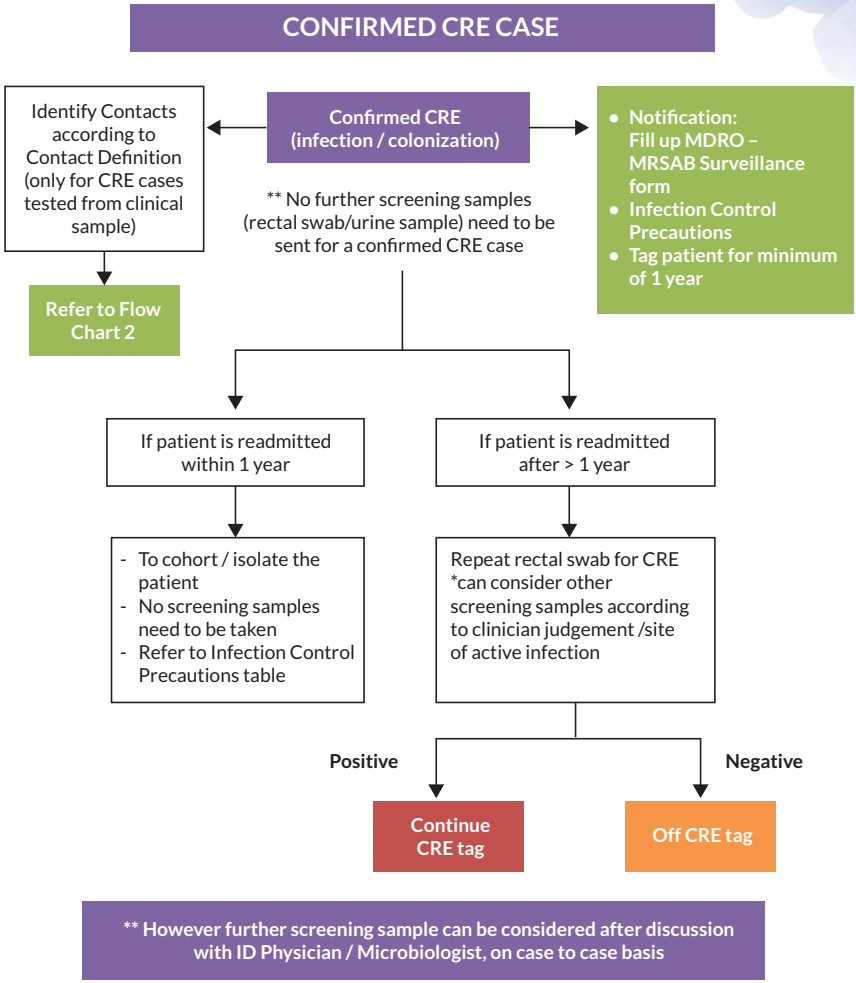
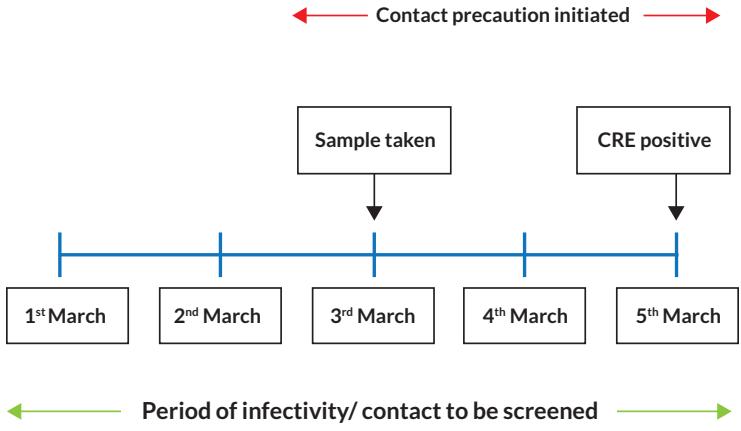


Diagram 1: Determination of contact to be screened based on the period of infectivity of CRE case

CONTACT OF A CONFIRMED CRE CASE

Definition:

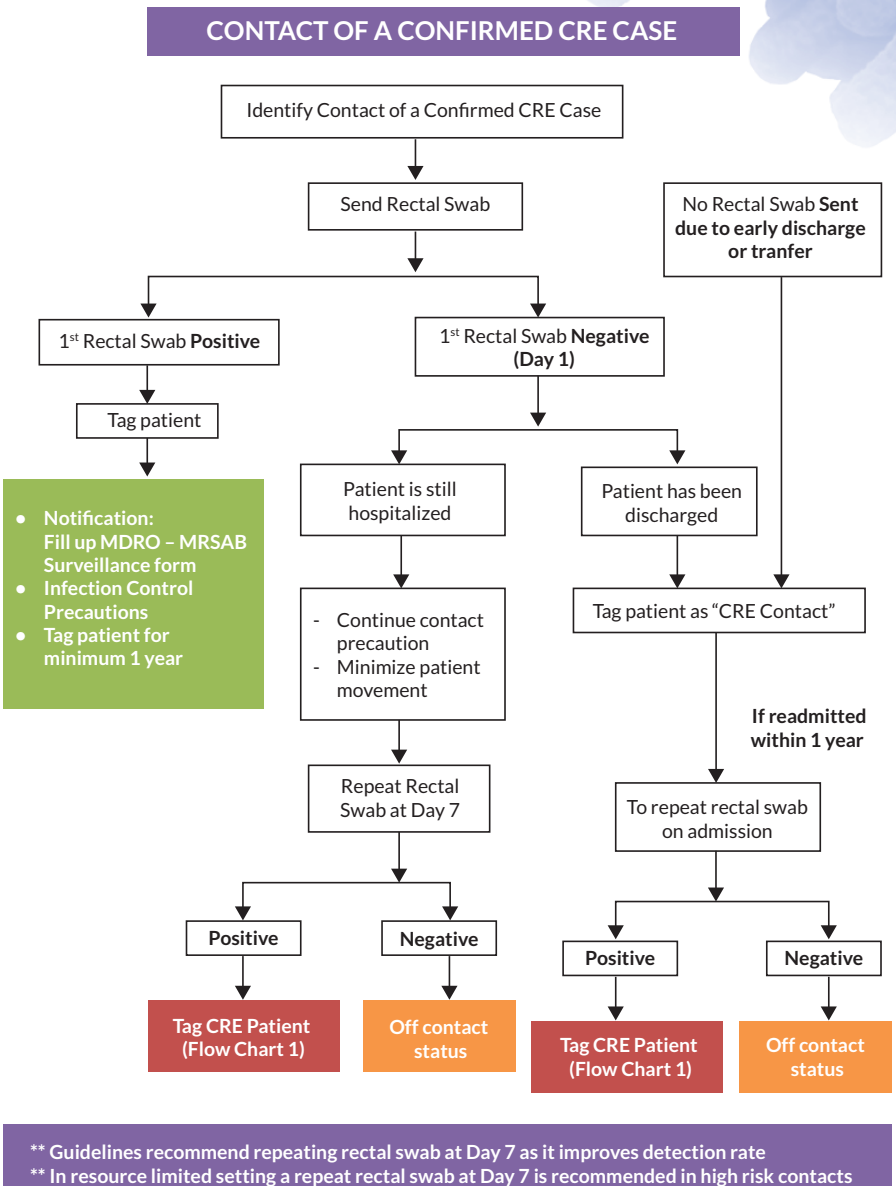
1. Individual who had contact ≥24 hours with the confirmated CRE case
2. Individual who had been in contact ≥24 hours AND at least 2 days before sampling date till index case is isolated / cohorted



Note:

- Contacts needed to be screened are those who have had exposure of ≥24 hours starting from 1st March till 5th March
- Screening sample need to be taken on Day 1= 5th March and if negative, Day 7= 11th March

Flow Chart 2: Management of Contact of Confirmed CRE Case

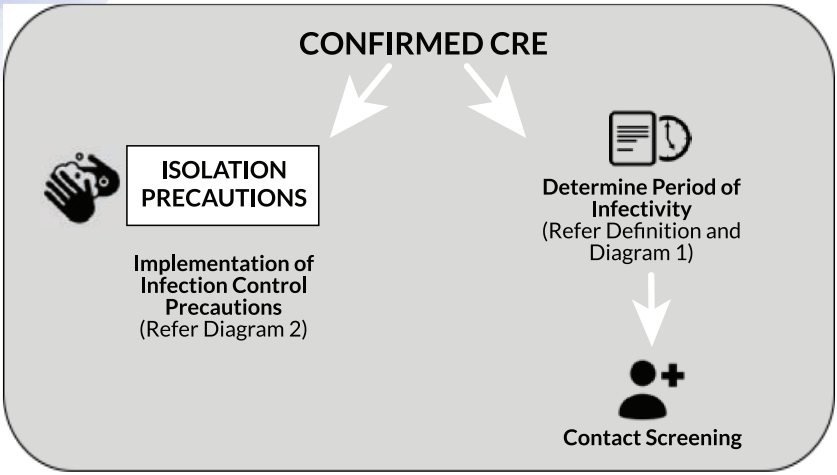


** Guidelines recommend repeating rectal swab at Day 7 as it improves detection rate
** In resource limited setting a repeat rectal swab at Day 7 is recommended in high risk contacts

Chapter 4:
Strategies to Reduce CRE Transmission

1. Management of Confirmed CRE Case
2. Management of CRE Contacts
3. Movement of Patients
4. Cleaning and Disinfection as Part of Contact Precautions

1. Management of Confirmed CRE Case



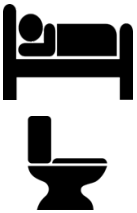
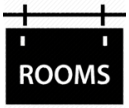
- Treating specialist / medical officer needs to complete and submit the MDRO-MRSAB Surveillance form to Hospital Infection Control Chairman / Hospital Infection Control Unit
(refer MDRO & MRSAB Surveillance Manual.

- Educate staff on CRE and infection control precautions.
- Audit hand hygiene compliance, use of PPE, environmental cleaning or other as required.
- Provide patient information sheet to CRE case & carers regarding diagnosis of CRE and the need to inform other health services of CRE status if admitted to another hospital.
- Not to send / repeat rectal swab for confirmed cases (a case is tagged for minimum 1 year).

Readmission:

- If a case is readmitted within 1 year, rectal swab is not indicated. Case is managed according to CONFIRMED CASE MANAGEMENT protocol.
- If a case is readmitted after 1 year, do repeat rectal swab:
  - If ≥ 2 rectal swab is negative (D0 and D7), to off tag
  - If rectal swab is positive, to consider life-long tag

Diagram 2: Implementation of Infection Control Precautions for Confirmed CRE Case

	Patient placement (in order of preference): • Single room with attached bathroom • Single room without attached bathroom • Cohort in dedicated cubicle / area • General ward with dedicated toilet facilities / commode and isolation tray / trolley beside the bed are strongly recommended
	Clear signage should be visible to alert healthcare workers and visitors of requirement of transmission precautions before entering the room / cubicle
  	When patient is placed in isolaton room: • Gloves and isolation gown must be wear before entering the room • Gloves need to be removed first before isolation gowns • Hand hygiene should be performed after removing each PPE For patients who are nursed in a dedicated cubicle / area or general ward: • Wear gloves and isolation gown / plastic apron only when there is bodily contact (i.e., HCW clothing will have direct contact with the patient) or potentially contaminated environmental surfaces or equipment in close proximity to the patient • Gloves need to be removed first before isolation gowns / plastic apron • Hand hygiene should be performed after removing each PPE Note: Surgical mask and eye protection should be worn for procedures / activities likely to generate splashes/ sprays of blood, body fluids, secretion and excretions.
	Hand hygiene is to be practiced according to WHO 5 moments of hand hygiene
	• Clean and disinfect the environmental surfaces which are frequently touched including toilet with hospital-approved disinfectants daily • Terminal cleaning shall be performed upon patient discharge / transfer

  	Patient care equipment and linen: • Dedicated equipment of non-critical patient care equipments (i.e., stethoscope, blood pressure set, thermometer or bedside commode) • If unavoidable, adequately clean and disinfect them before use on another patient • Contaminated linen should be handled as little as possible to prevent gross microbial contamination of the air. Washing / disinfecting linen should be handled according to hospital protocol
	Place tag on medical record/ BHT/ follow-up cards so that contact precautions are instituted during revisits/ readmissions
	Dedicated nursing staffs (recommended)
	Minimize patient movement (refer Section 3 Patient movement)
	Notify the receiving facilities if patients are to be transferred to other facilities
	Decolonization strategy is not recommended
	Daily Chlorhexidine 2% bath to all affected patients
	Disposable utensils if possible
	Limit visitors
	Non-essential staffs, example medical students, trainee nurses should be restricted/ supervised in patient's care

2. Management of CRE Suspects / Contacts to a Confirmed CRE Case

Diagram 3: Implementation of Infection Control Precautions for CRE Suspects / Contact

	Patient placement • Ideally patient should be placed in a single room with attached bathroom facilities, especially thoses cases that fit high risk of onwards transmission. • However, if this is not possible, to aim functional isolation i.e. to keep patient where he is and to tighten infection control without physical barrier. - Do not transfer patient / minimize patient movement - Dedicated equipments (i.e., stethoscope, blood pressure cuff, thermometer, glucometer). If not possible, to disinfect after use. - Dedicated nursing staff
	Hand hygiene is to be practiced according to WHO 5 moments of hand hygiene
	• Clean and disinfect the environmental surfaces which are frequently touched with hospital-approved disinfectants daily • Terminal cleaning shall be performed upon patient discharge / transfer
	Tag patient as “CRE contact” in medical record/ BHT/ follow up card (physically or electronically)
	Notify the receiving facilities if patients are to be transferred to other facilities
	Daily Chlorhexidine 2% bath to all affected patients

3. Patient Movement

Patient movement for radiological procedure / surgical intervention / haemodialysis

3.1 Notification

- All confirmed CRE case need to be notified to the respective receiving department .

3.2 Patient placement

- The patient should be isolated if possible while waiting for procedure to be done and should not be allowed to mix with other patients.

- If isolation is not possible then patients with CRE should be placed away from other patients (e.g. at the end of the row) and a dedicated toilet (example: handicapped toilet) should be identified.

3.3 Personal Protective Equipment

Staff who accompany the patient during the transportation should:

- Wear isolation gown or apron and gloves when undertaking procedures (i.e., intravenous cannula insertion) or assisting a patient to toilet.

- Remove the isolation gown / apron and gloves and perform hand hygiene before exiting the immediate patient care area.

- Gloves must be changed during patient care.

3.4 Movement of patients

- Patients should be advised to remain in the isolation room if possible.

- Open wound should be covered with impermeable dressing before transport.

3.5 Equipment and instruments / devices

- Equipments (e.g. blood pressure cuff, tourniquet, glucometer) preferably should be dedicated for the one patient's use.
- Such items should be appropriately cleaned, disinfected and stored between admissions.
- Transport trolley or wheelchair should be cleaned with disinfectant after use.
- Patients undergoing endoscopic / surgical procedures should be done as the last case / at dedicated Operation Theatre whenever is applicable.

3.6 Terminal cleaning

- Terminal cleaning of the area should be done after operation or procedure.

Chapter 5:
Outbreak Management

1. Definition of Outbreak
2. Outbreak Management

1. Definition of Outbreak

An outbreak is the occurrence of cases in excess of what would normally be expected in a defined community, geographical area or season.

The decision to identify a clinical area or a ward as an outbreak situation has to be determined at the local level depending on the risk of transmission.

An example: a ward where local transmission has occurred and the following criteria may be used;

a. At least 2 or more confirmed cases of CRE in which at least one case is locally acquired AND there is a plausible epidemiological link eg: proximity of cases / sharing of staff / equipment or from a possible environmental source.
b. Increasing number of unlinked transmission detected in a particular ward / area.

2. Outbreak Management

2.1 General recommendations:

- Timely notifications to Infection Control Unit, Management and relevant departments.
- Collect and provide the data to Infection Infection Control Unit, Management, relevant departments and state.
- Screen CRE contacts (Refer 2.2).
- Strengthen infection control precautions (Refer Diagram 2).
- Education to healthcare workers, patients, relatives / care takers including consessional workers.
- Review compliance audit on hand hygiene practices, standard and transmission based precautions, environmental cleaning and disinfection processes.
- For futher details of outbreak management refer Policies & Procedures on Infection Prevention and Control Third Edition.

2.2 Screening recommendation:

- Ensure all the CRE contacts are identified and screened according to Flow Chart 2.
- If there is ongoing CRE transmission despite adherence to general recommendations above, consider
  - Point prevalence screening of the affected ward or,
  - Extended screening strategy for high risk patients
- Environmental and staff screening is usually not recommended unless persistent transmission despite all above measures implemented.

2.3 Multidisciplinary approach involving administrator of the hospital, infection control unit and respective departments in order to control the outbreak.

- Identify an isolation ward to admit all confirmed CRE cases.
- The suspect / contact should not be admitted together with confirmed CRE cases.

Chapter 6:

Laboratory Detection and Confirmation Methods

Laboratory Diagnosis

The ability of clinical microbiology laboratories to reliably detect Carbapenem resistant *Enterobacterales* (CRE) is an important element of the effort to prevent and contain the spread of these pathogens and an integral part of antimicrobial stewardship.

Centers for Disease Control and Prevention (CDC) define CRE as *Enterobacterales* that are resistant to imipenem, meropenem, doripenem, ertapenem, meropenem/vaborbactam, or imipenem/relebactam by standard susceptibility testing methods (specifically, minimum inhibitory concentrations of ≥4mcg/mL for doripenem, imipenem, meropenem, meropenem/vaborbactam, and imipenem/relebactam or ≥2 mcg/mL for ertapenem) OR by production of a carbapenemase (e.g, NDM, KPC, VIM, IMP, OXA-48) demonstrated using a recognized test (examples: polymerase chain reaction, metallo-β-lactamase test, Carba-NP).

Carbapenem resistance among *Enterobacterales* can be divided into:

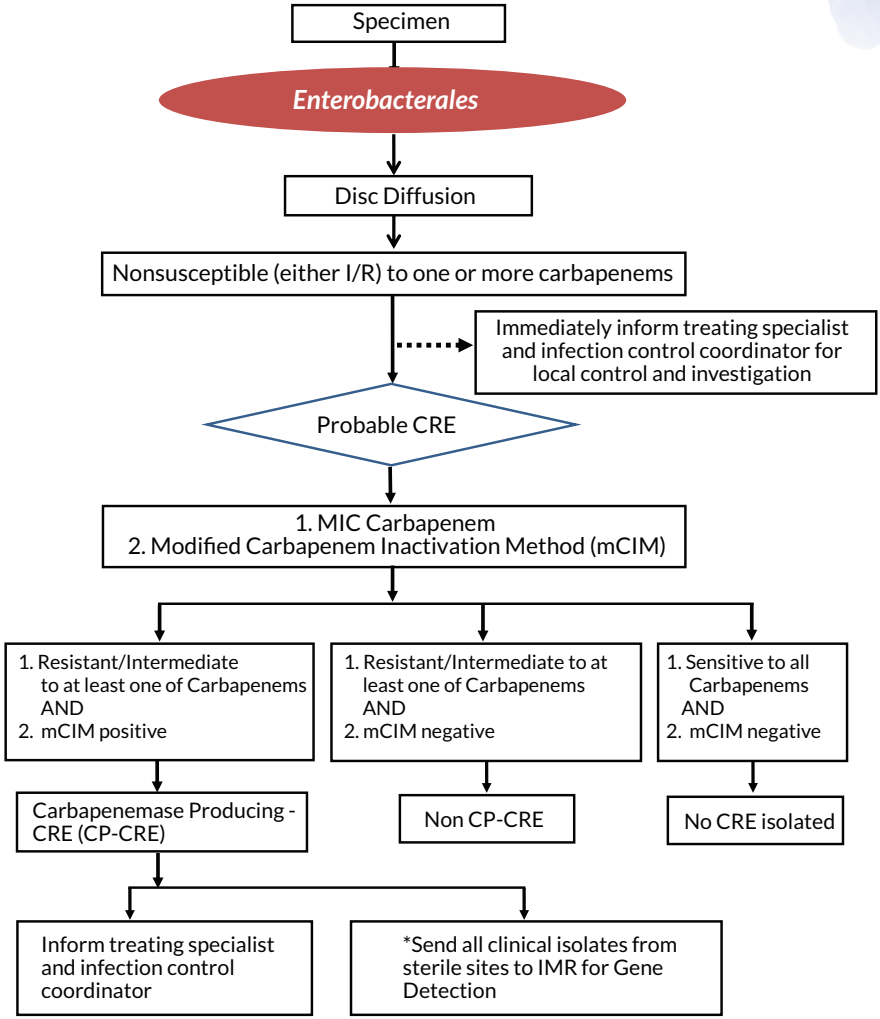
1. Non-carbapenemase-producing CRE (non CP-CRE):
   Some CRE possess a β-lactamase (e.g. hyperproduction AmpC or extended-spectrum β-lactamase (ESBL)), combine with altered membrane permeability, which can render an organism nonsusceptible to carbapenems.

2. Carbapenemase-producing CRE (CP-CRE):
   Some CRE possess a carbapenemase (carbapenemase-producing CRE or CP-CRE) that directly breaks down carbapenems. Carbapenemase genes (e.g NDM, KPC, OXA-48, IMP and VIM) can be spread rapidly between bacteria with potential for widespread transmission of carbapenem resistance. Therefore, CP-CRE is of epidemiological concern and their detection may warrant implementation of more intensive infection control interventions with potential transmission through colonization screening.

For the purpose of this document, CRE surveillance only includes CP-CRE data.

Some Enterobacterales (e.g., Proteus spp., Morganella spp., Providencia spp.) have intrinsic elevated minimum inhibitory concentrations (MICs) to imipenem by mechanism other than production of carbapenamases. Meropenem, ertapenem, and/or doripenem should be tested for these organisms to determine if these organisms meet the CRE definition.

LABORATORY DETECTION OF CARBAPENEM RESISTANT *ENTEROBACTERALES* (CRE)



*In outbreak situation, send 1 in 5 isolates to IMR for carbapenemase gene detection. The accompanying laboratory request form shall indicate **'Carbapenemases Producing – CRE' gene detection.**

Note :

1. All Enterobacterales isolated from CRE screening rectal swab should be screened for CP-CRE, as Enterobacterales isolated from contact maybe different from the index case.

2. The detection of carbapenemase genes can be done by various methods (examples: polymerase chain reaction, rapid molecular, lateral flow test, metallo-β-lactamase test or Carba-NP).

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