



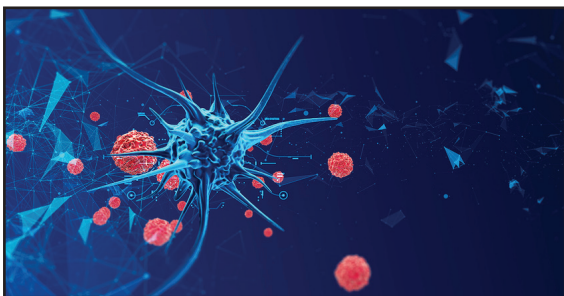
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"Part 1: CRE Infections: A Public Health Issue"

July 2018



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Carbapenem Resistant Enterobacteriaceae (CRE) infections are becoming more common and are a tremendous burden to patients and the healthcare system. The social, economic and personal costs related to them are overwhelming. Many researchers have demonstrated various interventions that decrease infection rates. A multi-faceted approach that includes staff education, minimizing patient risk factors and easy to understand institutional guidelines are needed to prevent these infections. This is an active area of research with advancements to patient care published frequently. **In this lesson (Part 1), we review the definition of CRE infections, the risk factors associated with acquiring CRE infections, identification of CRE infections, and general treatment.**

In the next lesson (Part 2), we review specific therapies, and we relate how CRE infections can be prevented.

This lesson is intended for pharmacists & technicians in all practice settings. **The program ID # for this lesson is 0798-0000-18-223-H01-P for pharmacists, and 0798-0000-18-223-H01-T for technicians.**

Participants completing this lesson by June 30, 2021 may receive full credit. Release date for this lesson is July 1, 2018. This is knowledge-based continuing pharmacy education. You must answer the questions on the quiz (70% correct required) and return the answers. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

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The objectives of this lesson are such that upon completion participants will be able to:

For Pharmacists:

1. Define CRE infections.
2. List the risk factors associated with acquiring CRE infections.
3. Discuss the methods of identifying CRE infections.
4. Relate general treatment of CRE infections.

For Technicians:

1. Define CRE infections..
2. List the risk factors associated with acquiring CRE infections.
3. Discuss the methods of identifying CRE infections.
4. Relate general treatment of CRE infections.

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INTRODUCTION

Over the past several years we have addressed a number of challenging infectious diseases. One of these was Carbapenem Resistant Enterobacteriaceae (CRE), and it is a good time to review this specific bacterial infection because these have been occurring in hospitals more frequently over the past several years. Additionally, community pharmacy is often involved with counseling of patients and caregivers.

By using a sample case we will discuss:

1. WHAT IS CRE?
2. WHAT ARE THE RISK FACTORS FOR ACQUISITION OF CRE INFECTIONS?
3. HOW ARE CRE INFECTIONS IDENTIFIED?
4. HOW ARE CRE INFECTIONS TREATED?
5. HOW ARE CRE INFECTIONS PREVENTED?

In this lesson (Part 1), we review the definition of CRE infections, the risk factors associated with acquiring CRE infections, identification of CRE infections, and general treatment.

In the next lesson (Part 2), we review the specific therapies, and we relate how CRE infections can be prevented.

The past several years brought formidable challenges to clinicians in the area of drug resistant bacteria and preventable infectious diseases. The World Health Organization (WHO) recognizes antimicrobial drug resistance as a major public health risk, endangering decades of medical advances.⁽¹⁾ The overuse of antimicrobials in clinical medicine and animal husbandry over several decades has led to the rise in microorganisms that are resistant to common medicines. There are two primary factors that promote the rise of resistant microorganisms: overuse of antimicrobials, and the spread of resistant organisms between individuals, communities and countries.

The focus of this lesson will be on Carbapenem-resistant Enterobacteriaceae (CRE) because it is an emerging public health issue in the United States and worldwide. This challenge requires concerted efforts from pharmacists, microbiologists, infection control practitioners and infectious disease clinicians. Via a patient-related scenario, we will relate this important area of contemporary pharmacy practice.

HERE IS THE CASE SCENARIO:

A 70-year-old woman with diabetes and recent cardiac bypass surgery with decreased mobility due to deconditioning is admitted from a long-term acute care hospital to your hospital overnight. She presents with new confusion, dysuria, fever and tachycardia. White Blood cell count is elevated to 25,000 cell/mm³. Chest X-ray is normal. Blood and urine cultures are sent. Patient reports flank pain.

Urinalysis:

Leukocyte esterase: 3+

WBC – too numerous to count

Bacteria – 3+

Squamous epithelial cells: none

The patient was diagnosed with a complicated urinary tract infection and was started on ceftriaxone 1g IV daily. The next day the urine culture is reported as positive for 100,000 colony-

forming units/ml of lactose fermenting gram-negative bacilli. Twelve hours later, the organism is identified as *K.pneumoniae*.

The next day, the susceptibilities are reported as follows:

Drug	MIC(mcg/mL)	Interpretation
Ampicillin	>32	Resistant
Ampicillin/Sulbactam	32/16	Resistant
Aztreonam	8	Resistant
Cefazolin	8	Resistant
Cefotetan	16	Resistant
Ceftazidime	16	Resistant
Cefepime	16	Resistant
Ceftriaxone	8	Resistant
Ciprofloxacin	4	Resistant
Ertapenem	2	Resistant
Imipenem	2	Intermediate
Meropenem	4	Resistant
Gentamicin	1	Susceptible
Tobramycin	0.5	Susceptible
tigecycline	0.125	Susceptible

The lab calls you concerned about Carbapenem-resistant Enterobacteriaceae (CRE). They will be performing additional molecular testing to confirm the production of a carbapenemase. The therapy was changed to colistin and tigecycline. The patient is placed in an isolation room.

What is a CRE infection?

Carbapenem-resistant Enterobacteriaceae (CRE) is a family of bacteria that produce an enzyme that inactivates carbapenems and other beta-lactams. The Enterobacteriaceae family includes a large group of gram-negative bacteria that normally inhabit the gastrointestinal tract in both humans and animals. (See Table 1) CRE is most commonly isolated from *E. coli* or *Klebsiella* species. The CDC currently defines CRE as an Enterobacteriaceae spp that is resistant to imipenem, meropenem, doripenem or ertapenem or documentation that the isolate possesses a carbapenemase. There are multiple types of carbapenemases known as, KPC (*Klebsiella pneumoniae* carbapenemase), NDM (New Delhi Metallo-beta-lactamase), IMP (Imipenemases), VIM (Verona Integron-Mediated Metallo-beta-lactamase), and OXA-48.

Infections caused by CRE are dangerous and represent a serious threat to hospitalized patients. CRE infections are often difficult to treat, spread quickly within an institution, and are associated with high mortality rates.(2) Enterobacteriaceae species are a common cause of community-acquired urinary tract infections. These organisms can also cause a range of healthcare-associated infections including urinary and bloodstream infections in patients with indwelling catheters, pneumonia in patients who are mechanically ventilated, and rarely skin and soft tissue and central nervous system infections.(3) Healthcare associated Enterobacteriaceae infections (*E. coli*, *Klebsiella* and *Enterobacter* species) are reported to the Center for Disease Control National Healthcare Safety Network (NHSN) surveillance system. (4)

Antimicrobial resistance within the Enterobacteriaceae family has increased over the last several decades, leading to increased reliance on the antimicrobial class of carbapenems (imipenem,

meropenem, doripenem and ertapenem). Carbapenem-resistant Enterobacteriaceae infections were uncommon in the United States before the year 2000.

The mechanism of resistance is quite complex and can be mediated by several mechanisms. Klebsiella pneumoniae carbapenemase (KPC), an enzyme encoded by a highly transmissible gene, was first identified in the year 2000. (3) KPCs are endemic in the United States, Greece, Israel, Italy, Puerto Rico, China and South America. KPC is the most common carbapenemase found in the United States. (2) It utilizes serine at the active site to hydrolyze beta-lactams. In addition to KPC, additional carbapenemases have emerged outside of the United States, namely New Delhi metallo-beta-lactamase (NDM-1). NDM-1 differs from KPC because it utilizes zinc at the active site to facilitate hydrolysis of beta-lactams. This key difference renders KPCs easier to treat with beta-lactamase inhibitors. (25) Both KPC and NDM-1 have been identified in the United States and can easily spread in healthcare settings. The spread of NDM-1 into the United States has begun with cases of travel or hospitalizations in India. (3) In 2013, the CDC published a report stating that 3.9% of short-stay acute-care hospitalizations and 17.8% of long-term acute-care hospitalizations indicated at least one CRE health-care associated infection in 2012. (4) CRE has been isolated in 42 states and the proportion of Enterobacteriaceae that are CRE has increased fourfold over the past 10 years. In 2013, an outbreak of NDM-1 *E. coli* was identified at a tertiary care hospital associated with contaminated duodenoscopes. The complicated design of the duodenoscopes make cleaning difficult, thus they remain contaminated. Forty-four patients were found to have CRE from the duodenoscopes.

The hospital changed the endoscope reprocessing from an automated high-level disinfection to gas sterilization, which halted the outbreak. (15)

Risk Factors

The risk factors for acquisition of CRE infections include: exposure to health care in general and exposure to antimicrobials. When patients with CRE infections were compared to non-CRE (i.e. patients with Carbapenem-susceptible infections), CRE infections were independently associated with recent organ or stem-cell transplant, recent mechanical ventilation, exposure to antimicrobials and longer length of stay. Long-term acute care hospitals (LTACHs) are considered to be a reservoir for CRE. A surveillance study of Chicago area LTACHs indicated 30% of the patients were colonized with KPC-producing Enterobacteriaceae compared to 3% of short-stay hospital patients. (16) Increased carbapenem use and differences between infection control practices between healthcare settings and travel patterns have led to a dramatic increase in CRE.

The risk factor for CRE acquisition in the patient in this case is likely due to residing in a long-term acute care hospital.

How are CRE infections identified?

The Center for Disease Control and Prevention (CDC) defines CRE as an Enterobacteriaceae species that are non-susceptible to 1 of the following carbapenems: (doripenem, imipenem or meropenem, or ertapenem) OR documentation that the isolate possesses a carbapenemase. Detection of the carbapenemases can be difficult because some isolates have MICs (minimum inhibitory concentration) that fall just below the breakpoint for susceptibility. (2) It is important to distinguish the difference between an organism that produces a carbapenemase (enzymes that breaks down all carbapenems) and an organism that offers other combinations of resistance mechanisms (i.e. other beta-lactamases combined with porin mutations) that render

carbapenems resistant. Some Enterobacteriaceae (*Proteus spp*, *Morganella spp*, *Providencia spp*) have intrinsic resistance to imipenem as evidenced by elevated MICs. In order to determine if they are carbapenemase producing CRE, these species must also have resistance to meropenem, doripenem or ertapenem.(2)

In 2010, the Clinical and Laboratory Standards Institute (CLSI) updated the breakpoints for Enterobacteriaceae. The new breakpoints are lower than the original breakpoints, allowing for easier identification of Enterobacteriaceae that are intermediate or resistant to carbapenems. Since most carbapenemases in the United States are found among *Klebsiella* and *E. coli*, some laboratories might choose to apply the CRE definition only to these specific Enterobacteriaceae. (2) Laboratories may conduct additional phenotypic or genotypic testing for carbapenemases. (17) Several commercial tests are available for rapid detection of carbapenem-resistance producing Enterobacteriaceae. The tests include either molecular tests that detect the resistance mechanism (i.e. presence of the gene (OXA, NDM, KPC and VIM)) or phenotypic tests that detect in vitro activity of carbapenemase enzymes. In addition to the MIC tests, the acceptable tests for detecting carbapenemases include: polymerase chain reaction, modified-Hodge-test, Carba NP, or metallo-beta-lactamase testing. (See Table 3) Additionally, carbapenemase testing may be performed for infection control purposes, and isolates may be sent through the state public health laboratories or to the CDC for further characterization.

In the case, the isolate meets the criteria for CRE because of the meropenem and ertapenem resistance. The microbiology department will conduct additional molecular tests to confirm the presence of a carbapenemase and send the isolate to the public health authorities.

Table 1: Common Genera of Enterobacteriaceae

Escherichia	Klebsiella	Providencia	Serratia
Enterobacter	Proteus	Salmonella	Shigella

Source: Dept of Health, State of Washington.

Table 2: Interpretive Criteria for Carbapenems and Enterobacteriaceae

Agent	Previous Breakpoints (mcg/ml)			Current Breakpoints (mcg/ml)		
	Susceptible	Intermediate	Resistant	Susceptible	Intermediate	Resistant
Doripenem	-	-	-	< 1	2	> 4
Ertapenem	< 2	4	> 8	< 0.5	1	> 2
Imipenem	< 4	8	> 16	< 1	2	> 4
Meropenem	< 4	8	> 16	< 1	2	> 4

Adapted from References: 2 and 6.

Table 3: Laboratory tests for the detection of CRE

Test	Method	Regulatory Status
Carba NP	Color indicator of imipenem hydrolysis	FDA approved
Film Array®	Detects presence of KPC gene	FDA approved
Verigene Gram-negative	Detects presence of KPC, IMP, VIM, NDM and OXA-48	FDA approved
GeneXpert	Detects presence of KPC, IMP, VIM, NDM and OXA-48 from rectal swabs	FDA approved

How are CRE infections treated?

The antibiotic options are limited for CRE infections because the presence of carbapenemases renders resistance to all penicillins, cephalosporins and carbapenems. Beta-lactamase inhibitors such as tazobactam (formulated with piperacillin), sulbactam (formulated with ampicillin) and clavulanate (formulated with ticarcillin) are not stable against the carbapenemases, therefore, cannot be used for treatment. See Table 4.(3,5) The newer beta-lactamase inhibitors, avibactam, relebactam and vaborbactam, will inhibit KPC enzymes but not metallo-beta-lactamases, VIM, IMP and NDM-1. Unfortunately, the gene encoding for carbapenemases are usually found on plasmids or other mobile genetic elements. These genetic elements allow for the organism to acquire genes conferring resistance to other classes of antibiotics, thus most isolates are also resistant to non-penicillin antibiotics including: trimethoprim-sulfamethoxazole, fluoroquinolones and aminoglycosides. Additional susceptibilities should be requested from the microbiology lab for polymixins, aztreonam, tigecycline, and fosfomycin (urinary tract infections.) Selection of antimicrobial therapy should be tailored to susceptibility results.(3) Due to complexity of treating these infections, consultation with an infectious disease clinician is highly recommended.

Table 4: Stability of various beta-lactam and beta-lactamase inhibitors against beta-lactamases in gram-negative organisms.**Enterobacteriaceae beta-lactamases**

Drug/Compounds	AmpC	ESBL	KPC	OXA-48	IMP/ VIM/ NDM
Inhibitors: Clavulanate	No activity	Activity	No activity	No activity	No activity
Sulbactam	No activity	Activity	No activity	No activity	No activity
Tazobactam	No activity	Activity	No activity	No activity	No activity
Avibactam	Activity	Activity	Activity	Activity	No activity
Vaborbactam	Activity	Activity	Activity	No activity	No activity
Relebactam	Activity	Activity	Activity	Unknown	No activity
Drugs: Imipenem/Meropenem	Activity	Activity	No activity	No activity	No activity
Aztreonam	No activity	No Activity	No activity	No activity	Activity

AmpC: cephalosporinase encoded on chromosomes of many Enterobacteriaceae; ESBL: extended spectrum beta-lactamases; KPC: Klebsiella pneumoniae carbapenemase; OXA: oxacillinases which hydrolyze a variety of beta-lactams; IMP/VIM/NDM: Imipenemase, Verona-integron Metallo-beta-lactamase and New-Delhi Metallo-beta-lactamase. Adapted from Reference 25.

In the next lesson we discuss the specific therapeutic options and also prevention of CRE infections.

Additional information:

<http://www.cdc.gov/hai/organisms/cre/>

The case discussed represents a typical presentation and course of a patient with a complicated urinary tract infection. Treatment and management of the patient is based on available clinical data at the time of this lesson and the personal opinion of the author.

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This lesson furnishes 1.25 (0.125 CEUs) contact hours of credit.

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0798-0000-18-223-H01-T (for Technicians).

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QUIZ---"Part 1: CRE (Carbapenem Resistant Enterobacteriaceae) Infections: A Public Health Issue"

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does this lesson meet the learning objectives? (Circle your choice).

- Define CRE infections.

Yes-Meets Objectives

No-Does Not Meet Objectives

- List the risk factors associated with acquiring CRE infections.

Yes-Meets Objectives

No-Does Not Meet Objectives

- Discuss methods of identifying CRE infections.

Yes-Meets Objectives

No-Does Not Meet Objectives

- Relate general treatment of CRE infections.

Yes-Meets Objectives

No-Does Not Meet Objectives

2. Was the program independent & non-commercial? YES NO

3. Relevance of topic Low Relevance Very Relevant

1 2 3 4 5 6 7

4. What did you like **MOST** about this lesson? _____

5. What did you like **LEAST** about this lesson? _____

6. How would you improve this lesson? _____

MARK CORECT ANSWER(S)--- "Part 1: CRE (Carbapenem Resistant Enterobacteriaceae) Infections: A Public Health Issue"

1. **Enterobacteriaceae is a family of bacteria that commonly cause which types of infections in the hospital environment?**
 - a. Urinary tract infections.
 - b. Catheter – related bloodstream infections.
 - c. Central nervous infections.
 - d. A and B.
 - e. None of the above.
2. **The CDC defines Carbapenem Resistant Enterobacteriaceae as:**
 - a. Pseudomonas species that are resistant to meropenem and imipenem.
 - b. E.coli that is resistant to amikacin.
 - c. Klebsiella species that is resistant to imipenem.
 - d. Enterobacter species that is resistant to meropenem or imipenem.
 - e. C and D.
3. **At time of publishing this lesson, how many states have reported CRE infections?**
 - a. 10 states.
 - b. 21 states.
 - c. 42 states.
 - d. 50 states.
 - e. None of the above.
4. **Which influences may facilitate an increase in development of resistant microbes?**
 - a. Aging population.
 - b. Excess use of anti-infective agents.
 - c. Longer patient hospitalization stays.
 - d. Increase of resistant organisms.
 - e. B and D.
5. **Commercial tests for rapid detection of CRE infections include:**
 - a. Molecular tests.
 - b. Tests that detect presence of the gene (OXA, NDM, KPC and VIM).
 - c. Phenotypic tests.
 - d. Tests that detect in vitro activity of carbapenemase enzymes.
 - e. All of these.
6. **The Film Array® test:**
 - a. Is a color indicator of imipenem hydrolysis.
 - b. Detects presence of certain genes from rectal swabs.
 - c. Detects presence of KPC gene.
 - d. Detects presence of KPC, IMP, VIM, NDM and OXA-8.
 - e. None of these.
7. **The following is (are) considered to be a "reservoir for CRE."**
 - A. LTACHs.
 - b. Short term hospital-stay patients.
 - c. Increased carbapenem use.
 - d. Travel patterns.
 - e. A, C and D.
8. **Which of these is (are) genera of Enterobacteriaceae?**
 - a. Proteus.
 - b. Serratia.
 - c. Escherichia.
 - d. Salmonella.
 - e. All of these.
9. **The most common antibiotic treatment possibilities are limited for CRE infections because the presence of carbapenemases render resistance to all penicillins, cephalosporins and carbepenems.**
 - a. True.
 - b. False.
10. **Selection of antimicrobial therapy for CRE infections should be:**
 - a. Accompanied by trial and error.
 - b. Facilitated via consultation with infectious disease clinicians (doctor and pharmacist).
 - c. Finalized after expensive interviews with family members.
 - d. Tailored to susceptibility testing results.
 - e. B and D.