

Clostridioides Difficile in Long-Term Care: The Epidemiology, Challenges, and Patient Journey



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There has been a dramatic change in the epidemiology of *Clostridioides difficile* infection (CDI) since the turn of the 21st Century. This increase is noted by the growing incidence, severity, and resistance patterns specifically occurring at a disproportionately higher frequency in geriatric patients residing in long-term care facilities (LTCF). Historically considered a nosocomial infection associated with antibiotic exposure, CDI has now also emerged in the community in populations previously considered low risk. Emerging risk factors, disease recurrence, and disease burden represent continued challenges in the management of CDI. This program and an in depth case discussion of a patient journey will focus on; the current epidemiology of CDI, current challenges facing the care of our geriatric population, the disease burden on our patients and healthcare team, and current guidance for all healthcare professionals to aid in combating and reducing the spread of this severe infection in this special population.

Learning Objectives

Pharmacist

1. Recognize the pathophysiology of human microbiome disruption and its impact in the *Clostridioides difficile* disease process.
2. Define the diagnostic criteria and symptoms of a CDI.
3. Describe the current epidemiology of *Clostridioides difficile* infection (CDI) and the disease burden it has on the patient's overall mental and physical health, as well as its effects on the healthcare team.
4. Identify potential challenges of diagnosing diarrhea in patients in Long-term Care Facilities (LCTF), and the potential processes to reduce the transmission and recurrence of CDI.

Pharmacy Technician

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Nurse

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Pharmacists, Pharmacy Technicians, Nurses

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Pharmacy Technician

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Nurse

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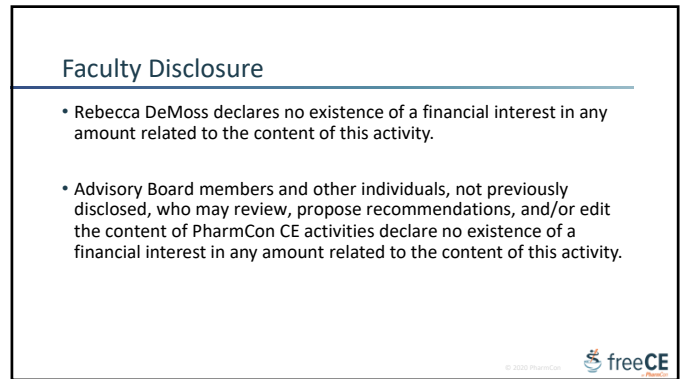
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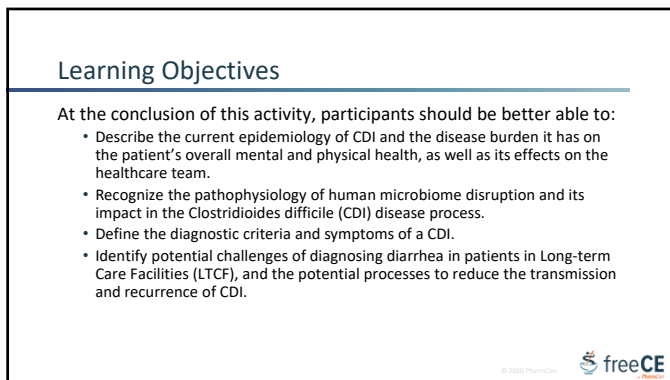
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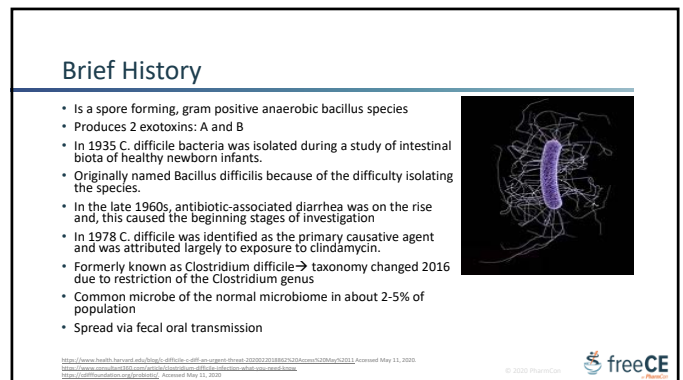
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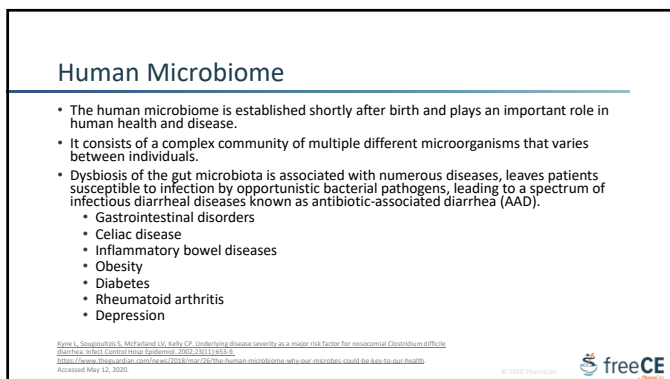
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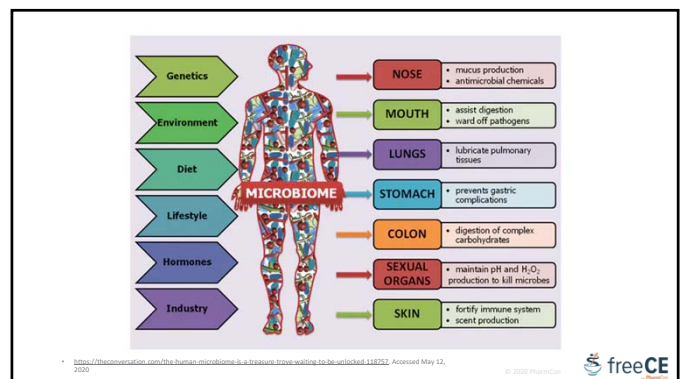
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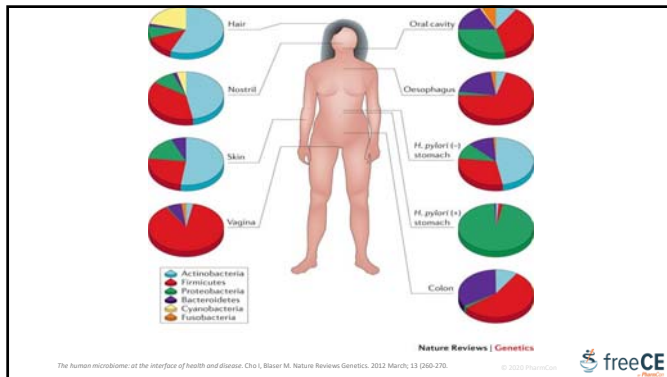
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Human Microbiome

- Multiple pathogens associated with antibiotic-associated diarrhea (AAD)
 - Clostridioides difficile
 - Clostridium perfringens
 - Klebsiella oxytoca
 - Staphylococcus aureus

* Burt L, Songstadon C, McFarland LV, Kelly CP. Underlying disease severity as a major risk factor for nosocomial Clostridium difficile diarrhea. Infect Control Hosp Epidemiol. 2002; 127(11):1033-6. © 2010 PharmCon

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Epidemiology

- In 2013 CDC gave it the most severe label and “urgent threat” to public health label surpassing carbapenem-resistant Enterobacteriaceae (CRE) and drug-resistant Neisseria gonorrhea.
- Mortality has increased
 - 1979-1987 highest percentage of deaths having diarrhea listed as immediate or underlying cause of death
 - 3000/year from 1999-2000
 - 14,000/year 2006-2007
- >90% of deaths occurred in persons >65 years or older
- In 2017, **223,900** people in the US were hospitalized due to CDI and **12,800** died.

https://www.cdc.gov/drugresistance/pdf/health-care/2013-ur-threat-report-508.pdf
https://www.cdc.gov/ncidod/dhqp/pdf/clostridium-difficile-infection-what-you-need-know.pdf
https://www.sciencedirect.com/science/article/pii/S0950268816300000. Accessed May 11, 2020. © 2010 PharmCon

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Epidemiology

Hospitalizations skyrocket
Annual hospitalizations in the United States with Clostridium difficile as a diagnosis.

Source: Agency for Healthcare Research and Quality
By Frank Pompa, USA TODAY

https://usatoday30.usatoday.com/news/health/story/2012-08-16/lethal-bacteria-hospital-infections/57079514/1. Accessed May 14, 2020. © 2010 PharmCon

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Epidemiology

- Approximately 60% of healthy adults are thought to have detectable serum IgG and IgA antibodies to the C. Difficile toxins
- CDI is associated with at least \$1 billion in extra healthcare costs each year

https://www.uspharmcon.com/articles/clostridium-difficile-infection. Accessed May 14, 2020. © 2010 PharmCon

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Epidemiology

Duggan BP, Duggan C, Duggan BP, Luo VL, Muto CA. Antimicrobial-associated risk factors for Clostridium difficile infection. Clin Infect Dis. 2008;46:1033-41.
Duggan BP, Duggan C, Duggan BP, Luo VL, Muto CA. Antimicrobial-associated risk factors for Clostridium difficile infection. Clin Infect Dis. 2008;46:1033-41. © 2010 PharmCon

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Pathophysiology

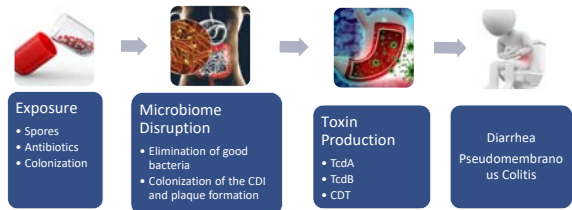
- Spore forming, gram positive anaerobic bacillus species
- Produces 2 toxins: enterotoxin A (TcdA) and cytotoxin B (TcdB)
 - Highly virulent strains have produced third virulence factor-binary toxin (CDT)
- TcdA
 - Increases intestinal permeability and fluid secretion
- TcdB
 - Extreme colonic inflammation
- CDT
 - Role in pathogenesis is not understood yet

Disruption of the Gut Microbiome: Clostridium difficile infection and the Threat of Antibiotic Resistance. Johansen F, Macklin Kate, et al. Genes 2015, 6, 1347-1360
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4500000/>



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Pathophysiology –Progression of Disease



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Pathophysiology

- Disease Spectrum
 - Asymptomatic carrier
 - Approximately 30% of hospitalized patients
 - Prevalence increases to 50% if the patient has a history of previous hospitalization
 - Currently no indication for treatment
 - Mild to moderate diarrhea with ≥ 3 loose stools/ 24 hours
 - Severe profuse diarrhea with severe abdominal cramping
 - Pseudomembranous colitis
 - Toxic megacolon
 - Colonic perforation

Disruption of the Gut Microbiome: Clostridium difficile infection and the Threat of Antibiotic Resistance. Johansen F, Macklin Kate, et al. Genes 2015, 6, 1347-1360
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4500000/>



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Diagnosis

- Transmission
- Testing
- Severity
- Recurrence



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Diagnosis: Transmission

Identification

1. Healthcare facility-onset (HO)
2. Community-onset, healthcare facility-associated (CO-HCFA)
3. Community-associated (CA)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4500000/>



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Diagnosis: Testing

Testing:

- i. Recommended to test patients that have ≥ 3 loose stool in a 24-hour period
- ii. Nucleic acid amplification tests (NAATs) are highly sensitive and somewhat specific for a CDI can be used alone or in a multistep diagnostic algorithm
- iii. Repeat test or performing a test of cure is no longer recommended

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4500000/>



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Diagnostic Criteria: Severity

Severity	Symptoms
Mild	Diarrhea without colitis/symptoms
Moderate	Colitis (fever, abdominal cramps/discomfort)
Severe	Leukocytosis (WBC) > 15,000c/ml; serum albumin <3g/dL; and /or Scr >1.5x normal level
Fulminant	Hypotensive or shock, ileus, megacolon

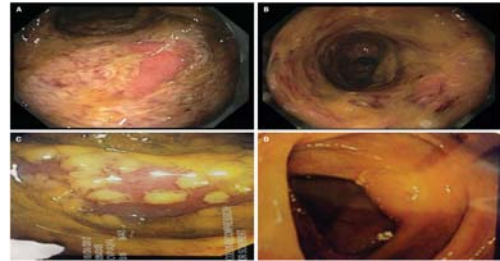
• <https://www.uptodate.com/contents/clostridium-difficile-infection-emerging-therapies-and-current-standards-of-care>

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Diagnostic Criteria and Symptoms



• <https://www.consultant360.com/articles/clostridium-difficile-infection-what-you-need-know>

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Diagnosis: Recurrence

- Initial Episode
 - Non-severe
 - Severe
 - Fulminant
- First Recurrence
 - Within 8 weeks of initial therapy completion
- Second or subsequent recurrence

McDonald L, Gerding D, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children. 2017. Update by the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical Infect Dis. 2018; 66(10):1485-495.

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Clinical Definition	Supportive Clinical Data	Recommended Treatment*	Strength of Recommendation/Quality of Evidence
Initial episode, non-severe	Leukocytosis with a white blood cell count of $\leq 15,000$ cells/mL and a serum creatinine level < 1.5 mg/dL	- VAN 125 mg given 4 times daily for 10 days, OR - FDX 200 mg given twice daily for 10 days - Alternate if above agents are unavailable: metronidazole, 500 mg 3 times per day by mouth for 10 days	Strong/High Strong/High Weak/High
Initial episode, severe*	Leukocytosis with a white blood cell count of $\geq 15,000$ cells/mL, or a serum creatinine level > 1.5 mg/dL	- VAN, 125 mg 4 times per day by mouth for 10 days, OR - FDX 200 mg given twice daily for 10 days	Strong/High Strong/High
Initial episode, fulminant	Hypotension or shock, ileus, megacolon	VAN, 500 mg 4 times per day by mouth or by nasogastric tube. If ileus, consider adding rectal instillation of VAN. Intravenously administered metronidazole (500 mg every 8 hours) should be administered together with oral or rectal VAN, particularly if ileus is present.	Strong/Moderate (oral VAN); Weak/Low (rectal VAN); Strong/Moderate (intravenous metronidazole)
First recurrence	---	- VAN 125 mg given 4 times daily for 10 days if metronidazole was used for the initial episode, OR - Use a prolonged tapered and pulsed VAN regimen if a standard regimen was used for the initial episode (eg. 125 mg 4 times per day for 10-14 days, 2 times per day for a week, once per day for a week, and then every 2 or 3 days for 2-8 weeks), OR - FDX 200 mg given twice daily for 10 days if VAN was used for the initial episode	Weak/Low Weak/Low Weak/Moderate
Second or subsequent recurrence	---	- VAN in a tapered and pulsed regimen, OR - VAN, 125 mg 4 times per day by mouth for 10 days followed by rifaximin 400 mg 3 times daily for 20 days, OR - FDX 200 mg given twice daily for 10 days, OR - Fecal microbiota transplantation*	Weak/Low Weak/Low Weak/Low Strong/Moderate

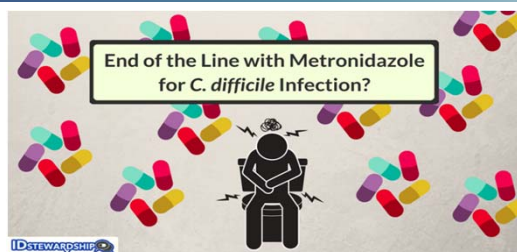
McDonald L, Gerding D, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children. 2017. Update by the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical Infect Dis. 2018; 66(10):1485-495.

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Just Say NO to -> Metronidazole (Flagyl™)



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Fecal Microbiota Transplant

- Very successful
- Ideal route of administration unknown
 - Encapsulated stool
 - Frozen preparations
- Potentially may be used to treat other conditions; ulcerative colitis
- With access limited there has been a growing trend of taking matters into their own hands
 - YouTube videos
 - Home blenders

<https://www.thejournalnewspaper.com/news/2018/may/26/the-human-microbiome-why-our-microbes-should-be-key-to-our-health>
Accessed May 13, 2020. <https://www.cdc.gov/nczod/diseases/zoonotic/difficile/faq.html> Accessed May 13, 2020.
<https://www.uptodate.com/contents/clostridium-difficile-infection-emerging-therapies-and-current-standards-of-care>

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Additional Therapeutic Options

1. Monoclonal Antibody Therapies
 - i. Bezlotoxumab (Zinplava™) approved in 2016

[https://www.esbmjournal.com/article/S2468-2667\(19\)30001-1](https://www.esbmjournal.com/article/S2468-2667(19)30001-1)

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Future Therapies??

1. Vaccine
 - i. Cdiffense (NCT01887912)
 - a. Currently in phase III trial evaluated for prevention of CDI up to 3 years
 - b. Contains formalin-inactivated TcdA and TcdB
 - ii. VLA84
 - iii. NCT02561195
2. New classes of antibiotics...
3. Synthetic stool products
4. Use of probiotics in treatment and/or prevention

[https://www.esbmjournal.com/article/S2468-2667\(19\)30001-1](https://www.esbmjournal.com/article/S2468-2667(19)30001-1)

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Risk Factors

1. Admission to LTCF
2. Age >65
3. Antibiotic use <3 months*
4. >3 comorbidities
 - Acute or chronic kidney disease^
 - Chronic lung disease^
 - Acute respiratory failure ^
 - Chemotherapy
5. Hypoalbuminemia; <3.4g/dL
6. Fluid and electrolyte abnormalities
7. Presence of a NG -tube or G-tube
8. Fecal incontinence
9. Proton pump inhibitors (PPI) and Histamine-2 Receptor Blockers (H2RA)

Clinical Infectious Diseases, Clostridium difficile infection in Long-term Care Facilities: A Call to Action for Antimicrobial Stewardship. Volume 60, Issue suppl_2, May 2015, Pages S72-S76. [https://www.esbmjournal.com/article/S2468-2667\(19\)30001-1](https://www.esbmjournal.com/article/S2468-2667(19)30001-1)

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Antibiotic Exposure and CDI Rates

Frequently	Infrequently	Rarely
Ampicillin	Macrolides	Parenteral Aminoglycosides
Amoxicillin	Sulfonamides	Metronidazole
Cephalosporins	Tetracyclines	Vancomycin
Clindamycin	Trimethoprim	
Fluoroquinolones		
Other broad spectrum Penicillins		

<https://cdmffoundation.org/antibiotics/>, Accessed May 11, 2020

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Antibiotic Exposure: Modifiable Considerations

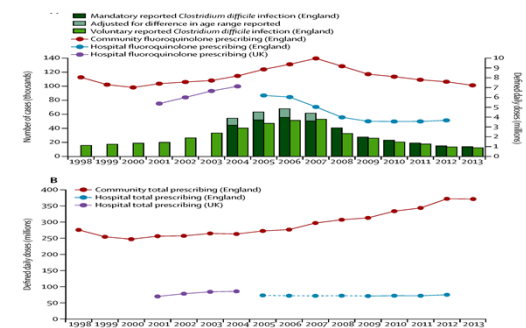
- Use of Antimicrobial Stewardship Programs
- Class of antibiotics
 - Fluoroquinolones have highest odds ratio of 2-12.7
 - Cephalosporins 1.6-5.4
 - Clindamycin 1.8-4.8
- Type of infection
 - Targeted therapeutic options instead of broad spectrum
- Decrease Dosage
- Shorter Duration of Therapy
 - 3 vs 5 days
 - 5 vs 7 days

Devereux RC, Donnelly CL, Davies GP, van Vliet A, Moore CA. Antimicrobial-associated risk factors for Clostridium difficile infection. Clin Infect Dis. 2008;46(suppl_3):S13-S17. [https://www.esbmjournal.com/article/S2468-2667\(19\)30001-1](https://www.esbmjournal.com/article/S2468-2667(19)30001-1)

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Effects of control interventions on Clostridium difficile infection in England: an observational study. Lancet Infect Dis. 2017 April; 17(4):411-421.

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Antibiotic Exposure: IV vs PO Vancomycin

- IV Vancomycin
 - Absorbed systemically and will contribute to microbiome disruption
 - High dose and long therapies increase risk for CDI
- PO Vancomycin
 - NOT systemically absorbed and is concentrated only in the GI tract→ only used in the treatment of CDI

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Proton Pump Inhibitors (PPI) and Histamine-2 Receptor Blockers (H2RA)

- Gastric acid has a protective mechanism by inhibiting bacterial overgrowth and preserving the normal microbiome.
- Acid suppressive therapy (AST) has been associated with increasing the risk of primary CDI
- Recommendation to encourage cessation of AST is overall beneficial not only for CDI but other chronic conditions; (i.e.: osteoporosis)
- If patient requires AST for a valid indication (e.g., mechanical ventilation, severe coagulopathy, recent gastrointestinal bleed), switching to H2RA or trial discontinuation or decrease in dosage may be warranted.

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Long-term Care Facility Setting (LTCF)

- Large to small complex
 - Independent Living, Assisted Living (ALF), Skilled/Long-term Nursing (LTCF), Group homes, Prison systems.
- Average length of stay >25 days
- Average age is >60 y/o
- Patients typically have 3-6 concurrent active diagnoses AND an acute diagnosis with multiple underlying comorbidities
- Most recovering from surgeries
- Some recovering from acute illness
 - Received high dose broad spectrum antibiotics, and get discharged to LTCF **BEFORE** signs/symptoms of CDI

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Challenges in LTCF

- Differential diagnosis of diarrhea
 - Staff may believe other reasons are contributing, instead of getting CDI test
- Shortage of staff
- Proper PPE and education (teach the teacher)
 - Hand hygiene
 - Infection control protocols
 - Appropriate application and removal of PPE in isolation rooms
 - Dedicated area for used/infectious PPE
 - Special detergents recommended for CDI

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Differential Diagnosis of Diarrhea in LTCF

Sorbitol-containing products	Acid-suppressants	NSAIDs	Alendronate
Colchicine	Laxatives	Metformin (ER may be preferred)	Digoxin
Lithium	Itraconazole	Chemotherapy	Magnesium
Mycophenolate	Dicyclomine	Amitriptyline	Hyoscyamine

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Challenges in LTCF

- Response time of diagnosis and isolation
- Unknown CDI status upon admission
- Patient emotional and physical burden
- Costly therapies
 - Fidaxomicin (Dificid™)→ \$600/day
 - Bezlotoxumab (Zinplava™) →\$5,000/day
 - PO Vancomycin (Firmvanq™)→\$10/day*
- Implementation of Antimicrobial Stewardship Program (ASP/AMS)

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Disease Burden: A Patient's Journey

- AG 84 y/o female residing in LTCF
- Admitted in 2013 recovering from sepsis due to Pneumonia, discharged from LTC in 2019
- Comorbidities
 - GERD
 - Osteoporosis
 - Atrial Fibrillation
 - Hypertension
 - Glaucoma
 - Chronic UTI
- Prior to admission medication list
 - Pantoprazole (Protonix™) 40mg BID for GERD
 - Alendronate (Fosamax™) 70mg weekly
 - Carvedilol (Coreg™) 3.125mg BID for heart failure
 - Triamterene/HCTZ (Maxzide™) 37.5mg/25mg 1 tab daily
- Since admission prescribed 27 rounds of different antibiotics
- 10 rounds of oral Vancomycin
- 2 rounds of fidaxomicin (Dificid™)

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Disease Burden: A Patient's Journey

- Predisposition to Pneumonia and chronic UTI
- Family Challenges
 - Family believed patient should be given an antibiotic at every beginning sign of pneumonia or UTI
- Facility Burden
 - Time...
 - Applying PPE
 - Communication with family, provider, patient, director of nursing or administrator, discharging hospital
 - Insurance companies and coverage of necessary medications (Prior authorizations)

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Disease Burden: A Patient's Journey

- Patient Psychosocial challenges and burdens
 - Feeling of isolation
 - Diagnosis of depression or anxiety
 - Fear
 - Recurrence
 - Transmitting the disease to another person
 - Soiling their clothing
 - Judgment/Ridicule
 - Lack of understanding of disease process and expectations
 - Lack of social support post infection or with recurrence of disease
 - Since admission patient has consistent cognitive decline and last round of Dificid nursing staff has seen noticeable change

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Key Takeaways

PREVENTION PREVENTION PREVENTION!!

1. Understanding the population of an LTCF will truly encourage change
2. Implement an ASP to decrease use and misuse of ALL antimicrobials
 - Specifically targeted therapies, dose, frequency, duration, and unnecessary use
3. Appropriate infection control policies and procedures
 - Excellent hand hygiene with SOAP and WATER, alcohol-based hand sanitizers do not penetrate the spores formed and spread
4. Appropriate screening and diagnostic protocols
 - Testing patients who have >3 loose stools in 24 hours
5. Implementation of appropriate transition of care models
 - Encourage antibiotic de-escalation
 - Confirm end of therapy/discontinuation dates
6. Together as a healthcare team we can reduce this deadly disease and its transmission

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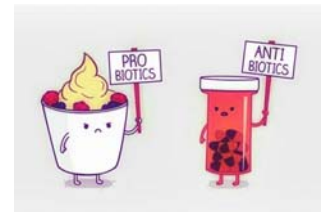
Key Takeaways

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Thank You



<https://cdiffoundation.org/probiotic/>. Accessed May 11, 2020

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Activity Test

Clostridioides Difficile in Long-Term Care: The Epidemiology, Challenges, and Patient Journey

Activity tests must be completed online at www.freeCE.com.

A passing grade of 70 or higher and completion of an online activity evaluation are required to earn credit.

1. Which statement is TRUE regarding the human microbiome?

- a. There is typically only one species of microbes in the human microbiome.
- b. Disruption of the human microbiome can contribute to many different diseases such as depression, obesity, and other GI disorders.
- c. The human microbiome is established during the adult years of life.
- d. Clostridioides difficile is the only pathogen associated with antibiotic-associated diarrhea.

2. Which is NOT included in the diagnostic criteria for CDI?

- a. Species specification
- b. Transmission
- c. Severity
- d. Recurrence

3. PB is a patient in your LTC facility. Over the last few months, PB has experienced recurrent infections treated with antibiotics, including amoxicillin, levofloxacin, azithromycin, and sulfamethoxazole/trimethoprim. Which of PB's antibiotics contributes most to PB's increased risk for CDI?

- a. amoxicillin
- b. levofloxacin
- c. azithromycin
- d. sulfamethoxazole/trimethoprim

4. You are a consultant in a skilled nursing facility (SNF). The director of nursing has asked you to consult on a facility policy to reduce CDI. She asks your opinion on a list of proposed interventions. After review, you advise her that all of the following interventions are appropriate to reduce the spread of CDI, EXCEPT:
- a. Antimicrobial Stewardship Programs
 - b. Infection Control Policies
 - c. Testing all LTC residents every day for CDI spores
 - d. Appropriate personal protective equipment and knowledge of use
5. Which of the following is NOT considered a psychological burden of CDI?
- a. Fear of spreading disease
 - b. Loneliness
 - c. Cognitive decline
 - d. Increased serotonin levels
6. Which is NOT part of the CDI disease progression?
- a. Exposure to antibiotics
 - b. Exposure to *Clostridioides* spores
 - c. Proliferation and growth of the normal human microbiome
 - d. Production of enterotoxins and cytotoxins
7. What is the primary mechanism of transmitting CDI?
- a. Blood transmission
 - b. Fecal-oral transmission
 - c. Airborne
 - d. Droplet
8. In addition to chronic infections, such as UTI's, which comorbidity may increase the risk of contracting a CDI?
- a. Glaucoma
 - b. GERD
 - c. Atrial Fibrillation
 - d. Arthritis

9. Which is NOT considered a differential diagnosis of diarrhea in the LTC population?

- a. Bowel regimen considerations
- b. Current chemotherapy regimens
- c. Sorbitol-containing products
- d. Age

10. Appropriate screening and diagnostic tools include testing LTC patients who have _____ or more loose stools in a 24-hour period.

- a. 1
- b. 2
- c. 3
- d. 4