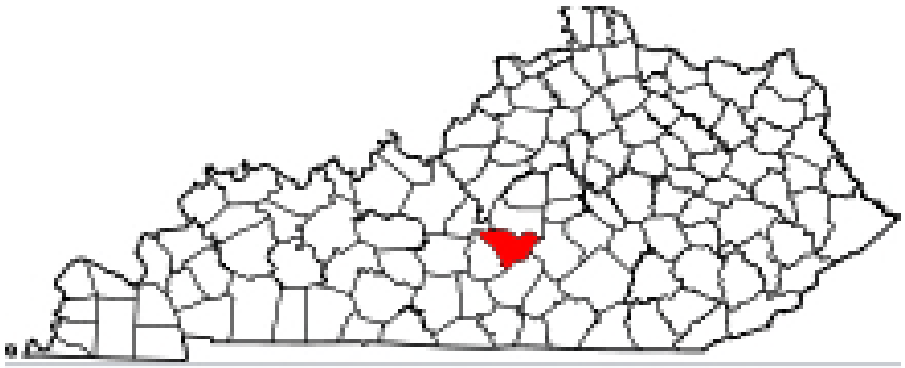
C. Difficile Education and Process Improvement through Infection Prevention, Laboratory, and Pharmacy Collaboration

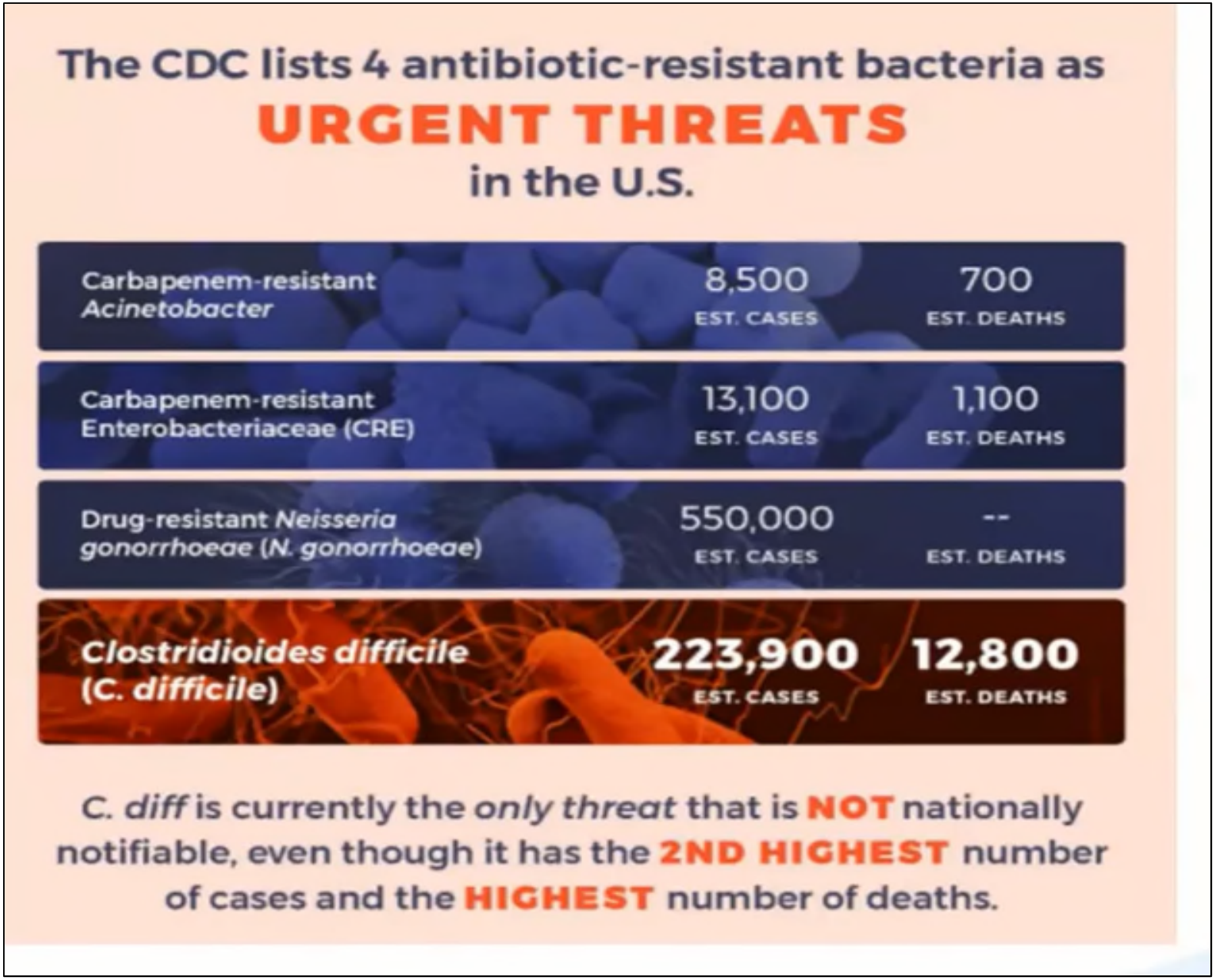
Shannon Davis, RN
Amory Scott, PharmD, BCPS

Taylor Regional Hospital
Campbellsville, Kentucky



Objectives

- Identify opportunities for improvement for increased compliance with current best practices for prevention, diagnosis, and treatment of *C. diff* infections.
- Explain our processes in developing a multi- disciplinary, layered plan to incorporate *C. diff* education and quality improvement interventions.
- Discuss and summarize our evaluation and anticipated sustainability of this plan within the current healthcare climate.


The CDC lists 4 antibiotic-resistant bacteria as
URGENT THREATS
in the U.S.
Carbapenem-resistant Acinetobacter
8,500
EST. CASES
700
EST. DEATHS
Carbapenem-resistant Enterobacteriaceae (CRE)
13,100
EST. CASES
1,100
EST. DEATHS
Drug-resistant Neisseria gonorrhoeae (N. gonorrhoeae)
550,000
EST. CASES
--
EST. DEATHS
Clostridioides difficile (C. difficile)
223,900
EST. CASES
12,800
EST. DEATHS
C. diff is currently the only threat that is NOT nationally notifiable, even though it has the 2ND HIGHEST number of cases and the HIGHEST number of deaths.

C. diff Sprint

QUALITY KENTUCKY
Health Care Quality Improvement Continues

Sprint Coaching Guide

	Taylor Regional Hospital
esentatives:	Shannon Davis
	C diff
aching:	

Action Plan

m	Process Owner	Steps to Accomplish	Resources Needed (generic: education, supplies, etc-detailed descriptions last page)	Potential Barriers	Evaluation of Effectiveness
r that up to diff	Infection Control IT Administration	Develop order Approval from Quality/QA/Medical Staff Education to Staff & Providers Approval from Med Executive	IT Education	Failure to remember to use the order Use of order post 24 hours admission IT focused on rebuilding multiple systems and it slowed the progress. Completed.	The Nurse Driven protocol was written, approved and ready for final steps in approval process. Education is being planned at this time for staff Via-email, storyboard, staff meetings & walk

	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5
	31731	38617	221066	5593	1233
	10/3/2021	5/13/2021	4/28/2021	3/5/2021	3/2/2021
	WING 3	WING 3	WING 3	WING 3	WING 3
iagnoses	UTI	N/V	COPD		AKI
xpected/unexplained stools within 24 hours prior to stool collection	Yes	No	No	Yes	No
ma within 24 hours prior to stool collection	No	No	No	Yes	No
feedings, or IV contrast within 24 hours prior to stool collection	No	No	No	No	No
recent antibiotic (within 30 days)	Unknown	Yes	Yes	Yes	Yes
n/prior to admission	No	No	No	No	Yes
upon admission/in days prior to test date (abdominal pain, fever, increased	Yes	No	No	No	No
fection	No	Unknown	Unknown	No	No
r Cdiff within past 14 days	No	No	No	No	No
r Cdiff within past 30 days	No	No	No	No	No
ecimen formed?	Unknown	No	No	Unknown	Unknown
of stool specimen was documented	No	No	No	No	No
as 5, 6, or 7	Unknown	Unknown	Unknown	Unknown	Unknown
used	Don't use a	Don't use a	Don't use algorithm		Don't use a
	Unknown	Yes	Yes	Unknown	Unknown
refusals, etc?	No	No	No	No	Unknown
was the issue escalated?					
t/contact plus precautions when Cdiff specimen sent	Yes	No	Unknown	Yes	Yes
ted for using soap and water for hand hygiene	Unknown	Unknown	Unknown	Unknown	Unknown
re readily available (for patient) at bedside and working	Yes	Yes	Yes	Yes	Yes
readily available and functioning in the room	Yes	Yes	Yes	Yes	Yes
free of clutter	Unknown	Unknown	Unknown	Unknown	Unknown
r facility policy and procedure	Unknown	Unknown	Unknown	Unknown	Unknown
fic cleaning equipment (ie: toilet brush, etc)	Unknown	Unknown	Unknown	Unknown	Unknown
m routine audits/observations of cleaning processes	Yes	Yes	Yes	Yes	Yes
e for cleaning within room (ex: bleach wipes, etc)	Yes	Yes	Yes	Yes	Yes
oment in patient's room	Yes	Yes	Yes	Yes	Yes

Multi-Layered Process Focus

- Surveillance/ Audits
- Prompt Isolation & Identification
  - Real time notification reflexed from order
  - Nurse-driven protocol
- Prevention
  - Hand Hygiene
  - Dedicated Equipment
  - PPE Compliance
  - Appropriate Notification on transfer
  - Enhanced Contact Precautions compliance

Multi-Layered Process Focus, cont.

- Education
  - Environmental Cleaning
  - Bug of the Month
  - Implemented *C. diff* bundles for inpatient location
- Clinical Responsibility
  - Adherence to best practice
- Diagnostic Stewardship

Surveillance Data

Criteria	**Feb 19 – April 20**	**April 21 – June 20**	**June 21 – August 20**	**Aug 21- Oct 20**	**Oct 21- Dec 20**
C. diff positivity rate	2/50	1/40	1/36	1/24	4/37
Documented 3+ watery stools in 24 hrs	30	31	21	20	28
Received laxative in last 24 hrs	5	3	3	3	2
Test for Cure	4	0	2	0	0
Documented "no diarrhea" or "formed stool"	6	1	2	1	4
Repeat test within a 7-day period	5	1	0	1	4
Presence of other likely cause for diarrhea	4	2	3	0	1

Bug of the Month

BUG of the Month

For Staff Education

MAY 2022

How do antibiotics cause C-diff

Antibiotics cause a disruption in the normal intestinal flora allowing for overgrowth of C diff in the colon

C-diff Bundles are located in ICU, Tele, & Wing 3. Bundles contain everything you need when your patient test positive for C diff. Bundle includes:

- ✓ *Disposable items*
- ✓ *Sign for sanitizer*
- ✓ *Education*
- ✓ *Checklist*

C. diff (Clostridioides difficile) formerly Clostridium difficile

Clostridioides difficile (formally called Clostridium difficile) is gram-positive spore forming anaerobe. *C. diff* is a common bacterium that is found in in 2 – 5% of the general population. *C diff becomes* a serious gastrointestinal infection when individuals have been exposed to antibiotic therapy, have experienced a long-term hospitalization, and/or have had an extended stay in a long-term care facility. However, the risk of acquiring a *C. diff* infection (CDI) has increased in recent years as it is in the community and found in outpatient settings.

Signs & Symptoms

The classic presentation for most all cases of *C. diff* will involve the common denominator of unformed, liquid stool occurring three or more times within 24 hours. Patient may also experience abdominal pain, nauseas, loss of appetite, or fever.

Risk Population

There are significant risk factors for patients who are immunosuppressed, individuals who have been on antibiotic therapy, and the elderly population. About 1 in 5 patients who get *C. diff* will get it again. 1 in 11 people over the age of 65 die within a month of a healthcare –associated *C diff* infection.

Transmission

C. diff is shed in feces. Any surface, device, or material that becomes contaminated with feces could serve as a reservoir for the *C. diff* spores. Spores can also be transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item. *C diff* spores can live for months on surfaces if not disinfected properly. To properly disinfect environmental surfaces and equipment against C diff spores, an EPA Sporicidal should be used. We use sodium hypochlorite (bleach solution) in the form of PDI Bleach wipes. At home a 1:10 Solution of household bleach may be used.

Prevention

- ✓ Use antibiotics as prescribed and only when appropriately indicated.
- ✓ Adhere to Enhanced Contact Precautions by wearing gowns and gloves when caring for patient with suspected or known *C. diff.*

Resources:

https://www.cdc.gov/cdiff/clinicians/faq.html#anchor_1529601728440

BUG of the Month

For Staff Education

C. difficile is the most common cause of Healthcare Associated Diarrhea in industrialized countries. According to a study released by the Centers for Disease Control and Prevention (CDC), nearly half a million Americans suffer from *C. difficile* infections each year.
The estimated annual economic burden of CDI is approximately $4.8 billion.

Questions? Contact
Shannon Davis RN
Infection Prevention
Ext. 5801of
sddavis@trhosp.org

- ✓ It is very important to make efforts not to contaminate the environment, surfaces, equipment, or yourself with the dirty gloves.
- ✓ Wash hands with soap and water after touching the patient or patient's environment.
- ✓ Use Bleach wipe to clean & disinfection equipment and environmental surfaces.
- ✓ Dedicate equipment when possible.

BE ANTIBIOTICS AWARE

Isolation Precautions (For Hospitalized Patients).

In addition to Standard Precautions, Enhanced Contact Precautions should be implemented for inpatients with suspected or known *C. diff.* Gown and gloves should be used when caring for patients with *C. diff.* Patients and their families should be taught about *C diff.* Education can be found on the Patient Instruction section of Meditech. Another source for patient education is the CDC. https://www.cdc.gov/cdiff/pdf/Cdiff-progression-H.pdf

free

Education Opportunity for Nurses to earn 2.1 CNE's

1.Access course at :
https://www.cdc.gov/infectioncontrol/training/strive.html#anchor_CDIFF
2.To receive credit you will need to sign into CDC education link:
https://tceols.cdc.gov/
3.Search Courses: WB4230
4. Print Certificate

Diagnostic Stewardship related to C. diff testing

- ✓ *C. diff* test should only be ordered on patients who have 3 or more liquid stools in 24 hour period. The Laboratory will reject formed stool for testing.
- ✓ If patient has taken laxatives or stool softeners in past 24-48 hours they should be stopped and patient reassessed prior to ordering test for *C. diff* test.

Resources:

https://www.cdc.gov/cdiff/clinicians/faq.html#anchor_1529601728440

Nurse-Driven Protocol

Nurse Driven Protocol for Clostridioides difficile Testing

SUBJECT: ***Clostridioides difficile*** **Stool Testing**

PURPOSE: To allow for early detection of *Clostridioides difficile* infections in patients and provide appropriate treatment.

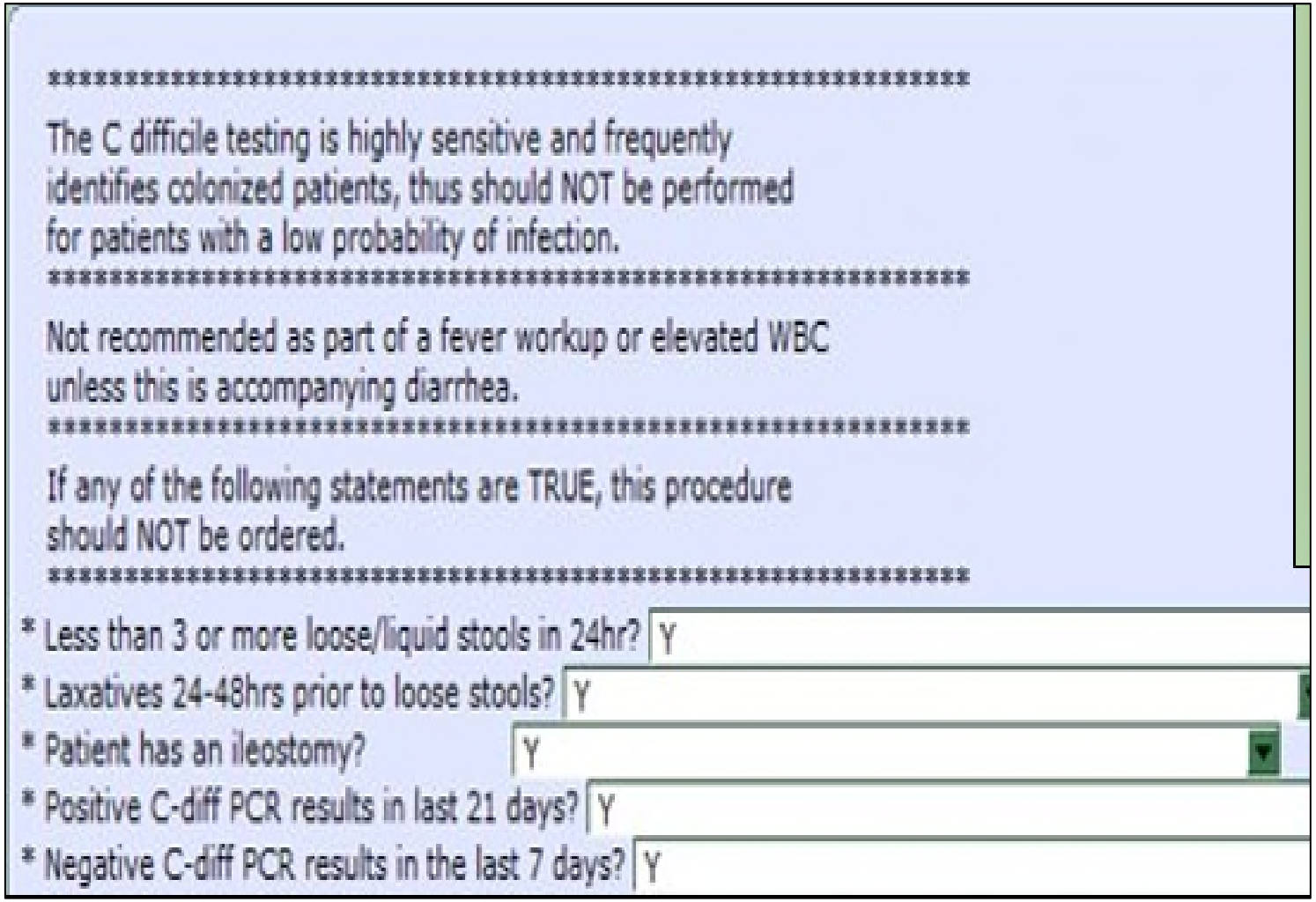
SCOPE: This protocol applies to all inpatient nursing departments and the emergency department within the first 48 hours of admission to Taylor Regional Hospital.

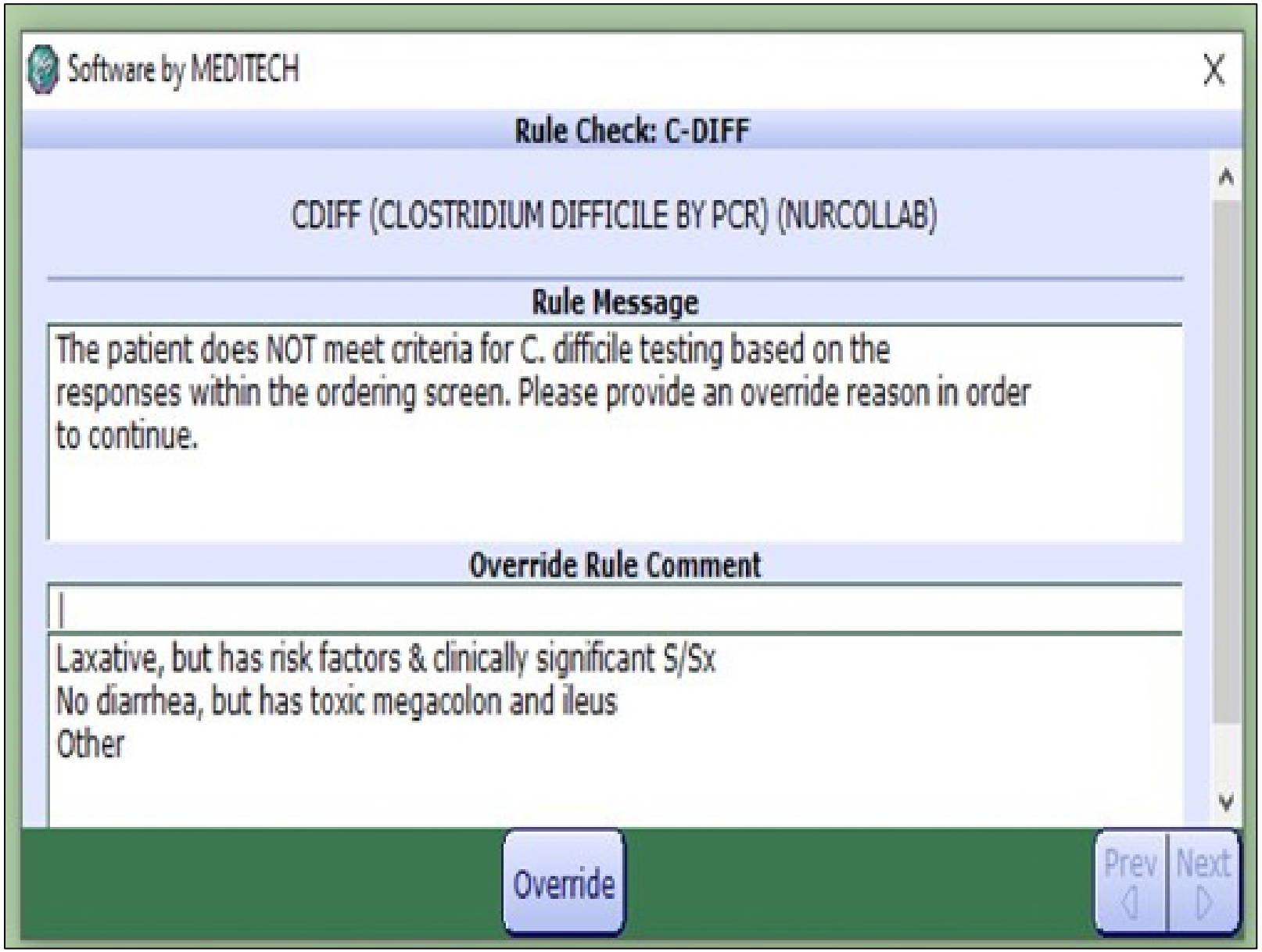
PROCEDURE:

1. Patient meets the following criteria for testing stool for *Clostridioides difficile*:
    a. Patient has 3 or more liquid (takes shape of the container) stools within a 24 hour period.
    b. No other cause for diarrhea noted (such as laxatives, stool softeners, bowel prep, contrast or new tube feedings within the last 48 hrs. Crohn's disease, rotavirus, or recent colorectal surgery).
    c. Stool has not been tested during the current visit.
    d. Patient has not had a positive test for C. difficile in the last 30 days. (Testing convalescent patients and testing for cure are to be avoided.)
2. If the patient meets the above criteria for testing, enhanced contact precautions should be implemented.
3. If the patient meets the above criteria, a reflex standing order will be triggered in EMR or the nurse enters an order to test stool for *Clostridioides difficile* through Electronic Medical Record.
4. A stool specimen is collected and sent to lab per policy.
5. The nurse notifies the patient's provider if result is positive.
6. If the results are negative and the patient has no history of a multi-drug resistant organism within the last 6 months, the nurse contacts the infection prevention department regarding discontinuation of isolation order.

Gastrointestinal Parameters	
Defined Gastrointestinal Parameters	○ Within Defined Limits Abdomen soft, non-tender. No abdominal pain or distention. Bowel sounds present and bowel movements within normal pattern and consistency for patient. Tolerating diet and having no reflux or feeding intolerance.
C.diff Screen	
Contact - C.difficile precautions in place	○ Yes ○ No C.difficile precautions in place, provider notified.
New or progressive diarrhea	○ Yes ○ No Screening phase 1: CDI Case Definition Pt presents with new or progressive diarrhea of unknown cause
Significant increase in diarrhea	○ Yes ○ No Significant increase in baseline diarrhea
Watery, no solid pieces, entirely liquid stool	○ Yes ○ No At least 3 watery, no solid pieces, entirely liquid bowel movements in last 24 hours
Increased Ostomy Output	○ Yes ○ No Significant increase in ostomy output
Possible C.diff infection, risk factors required	○ Yes ○ No Based on above C.diff assessment, patient has unformed diarrhea greater than 3 times in 24 hours.
CDI risk factor	☐ History of C.diff ☐ Antibiotic use recent ☐ Fever >100.4F or 40C ☐ Advanced age >65 ☐ Chemo Treatment ☐ Leukocytosis (WBC>15K) ☐ Recent hospitalization ☐ Proton-pump inhibitor ☐ ABD cramping, discomfort ☐ Transfer patient ☐ Recent GI Surgery Screening phase 2: CDI risk factor a. History of C.Difficile b. Advanced age >65 c. Recent hospitalization or overnight stay in healthcare facility d. Transfer from another healthcare facility (nursing, LTAC) e. Antibiotic use (within previous 8 weeks) f. Antineoplastic Agent use (within previous 8 weeks) g. Proton-pump inhibitor use h. Recent GI Surgery or tube feeding i. Fever >100.4 F or 40.0 C j. Leukocytosis (WBC, usually > 15,000) k. Abdominal cramping, discomfort, or tenderness

Clinical Support Rule




Software by MEDITECH
Rule Check: C-DIFF
CDIFF (CLOSTRIDIUM DIFFICILE BY PCR) (NURCOLLAB)
Rule Message
The patient does NOT meet criteria for C. difficile testing based on the responses within the ordering screen. Please provide an override reason in order to continue.
Override Rule Comment
Laxative, but has risk factors & clinically significant S/Sx
No diarrhea, but has toxic megacolon and ileus
Other
Override
Prev
Next

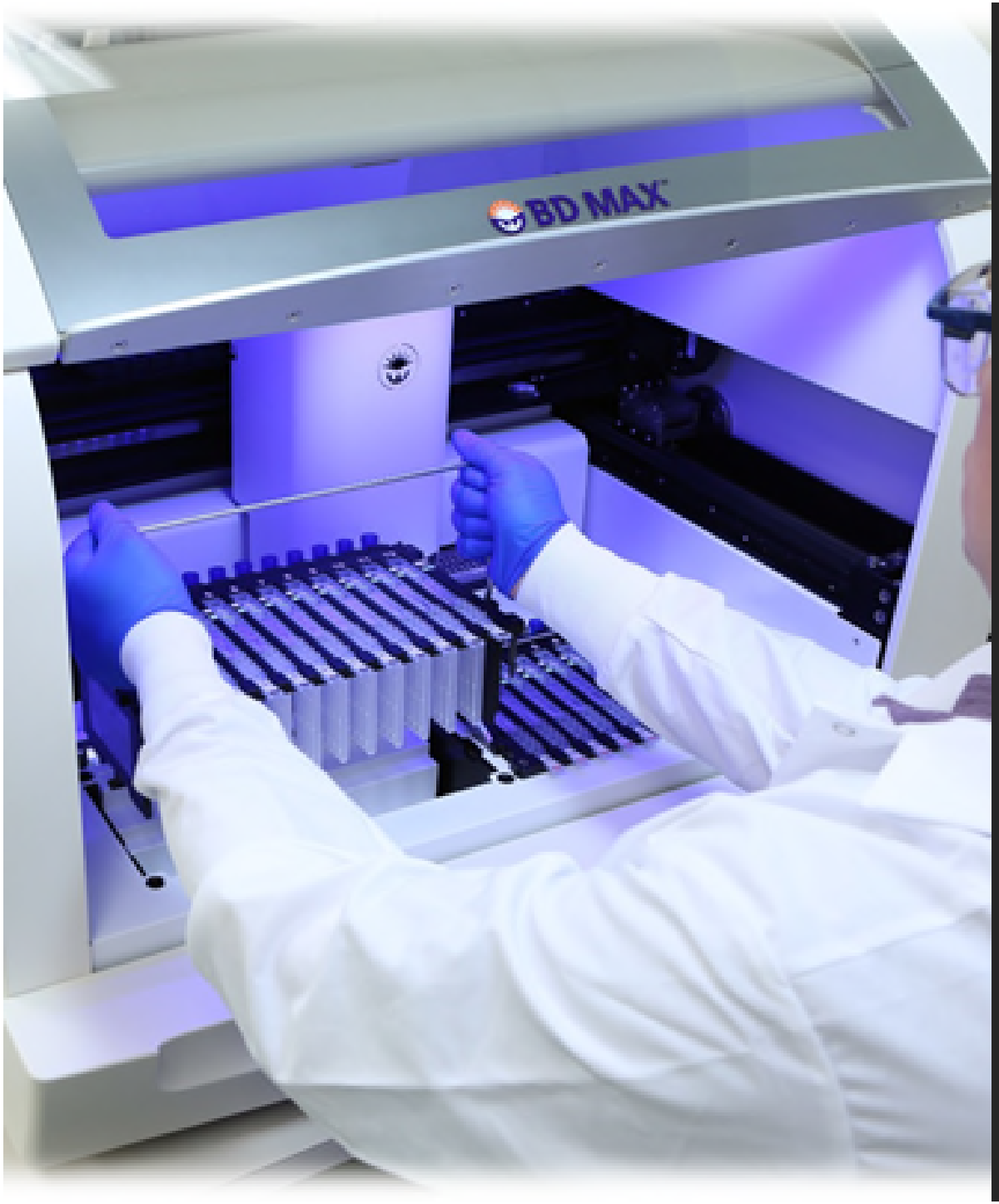
C. diff Bundle

Confirmed C- Diff Readiness Bundle Checklist	
Make sure **Isolation caddy** is in place. Ensure patient has been placed in **Enhanced Contact Precautions.** * patient should be placed in Enhanced Contact precautions when test is ordered Difference in Contact and Enhanced Contact is- 1) wash hands with soap & water 2) disinfect with bleach wipes	
Place Wash with Soap & Water sign on the hand sanitizer	
Use **disposable thermometer** * may send home with patient or discard when patient is discharged	
Use **disposable stethoscope* needs to stay in the room** and discarded when patient is discharged	
Provide Patient & Family **Education on C diff.** Education is Included in bundle but should also be added under Patient Instructions in the EMR ** be sure to involve family in education and document	
Provide Patient & Family Education on importance of hand hygiene with soap and water. Document in teaching record or in the Infection Control portion of Admission Assessment Be sure to involve family	
Document education of C diff illness, hand hygiene, and enhanced isolation in the Teaching Record in the EMR	

Make learning fun

C. Diff Lab Testing

Lab testing at TRH and results interpretation



C. diff PCR

PCR is a molecular based testing platform; we use the BD MAX analyzer.

This tests for the *C. diff* genetic material that could be capable of producing toxins or active infections.

It is a very sensitive test; must only use liquid or very soft stools. Nothing Formed.

A positive can mean current *C. diff* infection or *C. diff* colonization.

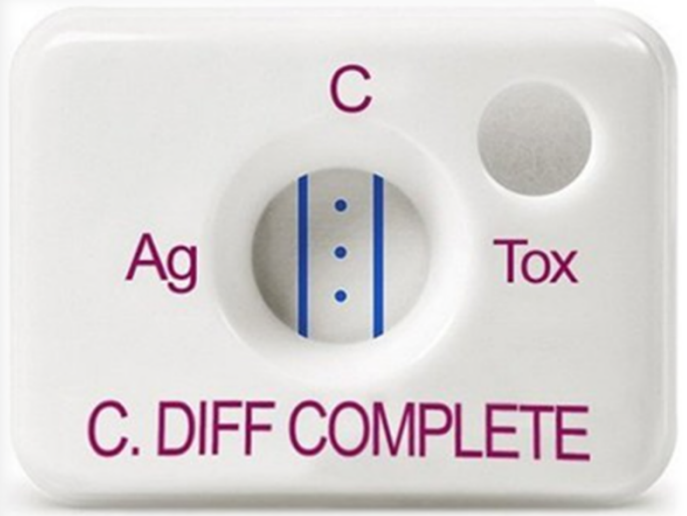
We reflex all positives to a toxin EIA test.

C. Diff toxin EIA kit

Enzyme Immunoassay kit that rapidly detects glutamate dehydronase antigen or *C. diff* bacteria and both Toxins A and B.

If only the AG line is present after testing, that indicates a patient only has *C. Diff* bacteria present or colonized but no toxin producing *C. diff* and does not require treatment.

If the Toxin line is present, that indicates a toxin producing *C. diff* result and patient will need treatment.



C. DIFF TOXIN KIT SPECS:

PERFORMANCE CHARACTERISTICS

The *TOX A/B QUIK CHEK®* test was compared with the tissue culture test at three U.S. hospitals and in-house at TECHLAB®, Inc. Specimens included in the evaluation were submitted to the clinical laboratory for routine testing. The tissue culture test was done according to the in-house procedure. The table below shows a summary of the clinical performance of the *TOX A/B QUIK CHEK®* test. The test exhibited a sensitivity and specificity of 90.2% and 99.7%, respectively. The predictive positive and negative values were 98.6% and 97.9%, respectively, and the correlation was 98.0%.

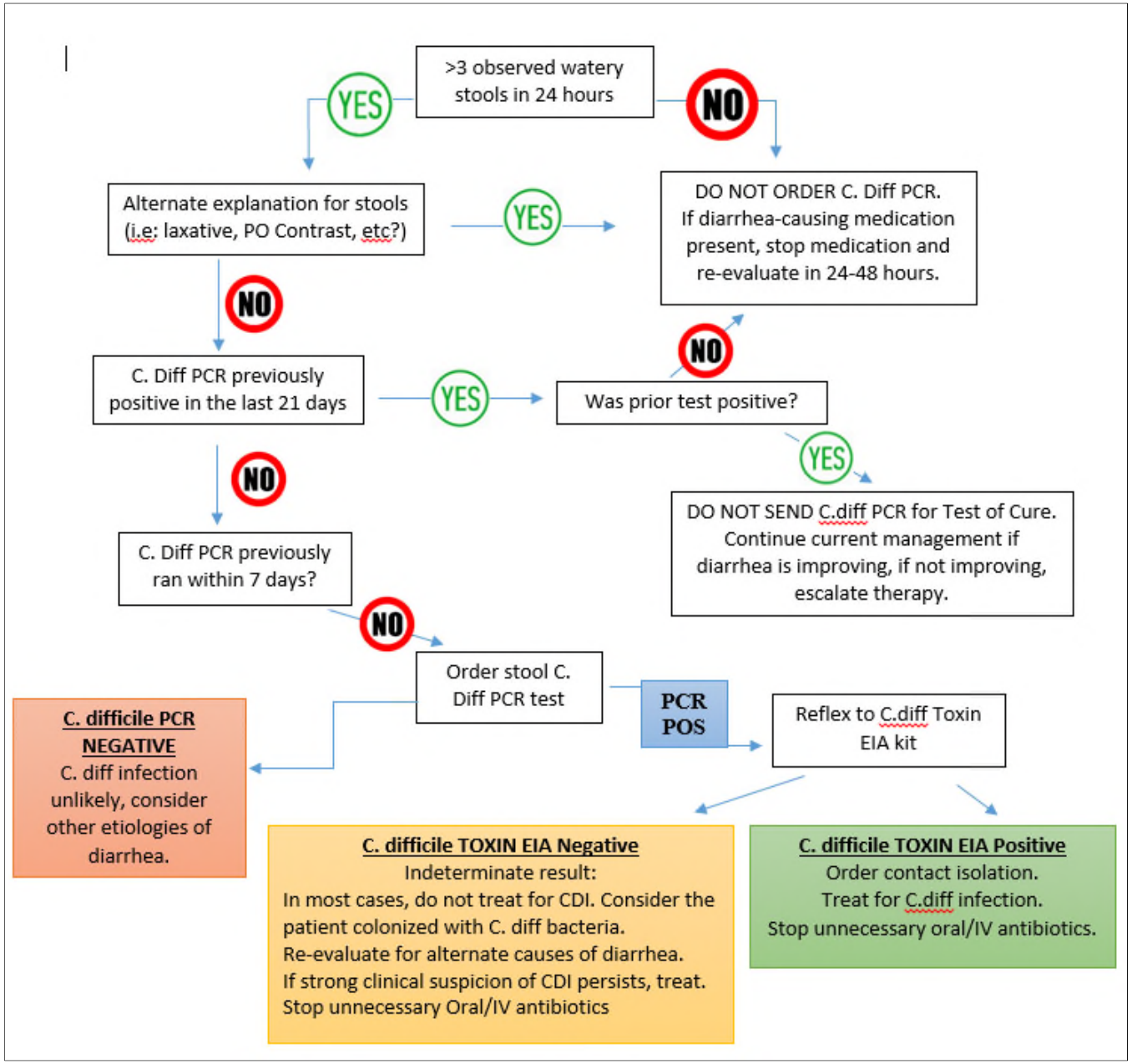
TABLE 1. Correlation of the *TOX A/B QUIK CHEK®* test with tissue culture.

N = 842	Tissue Culture positive	Tissue Culture negative
TOX A/B QUIK CHEK® positive	138	2
TOX A/B QUIK CHEK® negative	15	687

		95% CI
Sensitivity	90.2%	84.1 - 94.2
Specificity	99.7%	98.8 - 99.9
Predictive Positive Value	98.6%	94.4 - 99.8
Predictive Negative Value	97.9%	96.4 - 98.7
Correlation	98.0%	97.8 - 98.2

We use a kit called Tech Lab C. Diff Toxin EIA. There are many different brands of C.diff toxin kits but this specific one we have in house is the best on the market. It's the most expensive kit for testing of toxin but because of its performance for diagnosis, it's valuable.

C. difficile Testing Algorithm: PCR/Reflex Toxin EIA



PCR/Reflex Toxin EIA Key Points:

- Identify new onset of unexplained large-volume, frequent, liquid stools and consider a broad differential diagnosis. This process of medical decision-making is unchanged.

- Avoid unnecessary testing. The first test, the *C. Diff* PCR, is a very sensitive molecular test. *C. diff* PCR+ means the sample carries *C. diff* organisms with the genetic material capable of producing toxin. A positive PCR test could mean current *C. diff* infection OR could mean *C. diff* colonization. Colonization does not need treatment.

- The reflex testing required for all PCR+ samples, the *C. diff*Toxin EIA kits, differentiate between current infection with *C. diff* which warrants treatment and colonization, which does not.

Treatment

2021 Update to SHEA/IDSA Treatment Guidelines

New(er) *C. Diff* therapies

- Fidaxomicin (*Dificid*®)
  - Macrolide antibiotic
  - Narrow spectrum
  - Minimally absorbed
  - Bactericidal (vs. vancomycin – bacteriostatic)
  - $4000 per treatment course
  - Greatest potential benefit: Sustained clinical response/fewer recurrences

CDI recurrence

- Initial response rate vs. recurrence rate
- Multiple recurrences:
  - No difference in treatment agent used
- Risk factors for recurrence

Age > 65
Immunocompromised host
Severe CDI on presentation

- Importance of healthy gut microbiome

IDSA/SHEA 2021 Focused Update Guidelines on Management of *Clostridioides* difficile Infection in Adults.
Am Fam Physician. 2013;87(3):211-212.

New(er) *C. Diff* therapies, cont.

- Bezlotoxumab (*Zinplava*®)
  - Monoclonal antibody – binds Toxin B and neutralizes
  - Place in therapy: patient with CDI in past 6 months
  - Single dose – Adjunct given any time during therapy
  - $2921 per vial
  - Greatest potential benefit: reducing recurrence, especially in high risk/elderly

C. diff Treatment

Table 1. Recommendations for the Treatment of *Clostridioides difficile* Infection in Adults

Clinical Presentation	Recommended and Alternative Treatments	Comments
Initial CDI episode 1	Preferred: Fidaxomicin 200 mg given twice daily for 10 days	Implementation depends upon available resources
	Alternative: Vancomycin 125 mg given 4 times daily by mouth for 10 days	Vancomycin remains an acceptable alternative
	Alternative for nonsevere CDI, if above agents are unavailable: Metronidazole, 500 mg 3 times daily by mouth for 10–14 days	Definition of nonsevere CDI is supported by the following laboratory parameters: White blood cell count of 15 000 cells/μL or lower and a serum creatinine level <1.5 mg/dL
First CDI recurrence 2	Preferred: Fidaxomicin 200 mg given twice daily for 10 days, OR twice daily for 5 days followed by once every other day for 20 days	…
	Alternative: Vancomycin by mouth in a tapered and pulsed regimen	Tapered/pulsed vancomycin regimen example: 125 mg 4 times daily for 10–14 days, 2 times daily for 7 days, once daily for 7 days, and then every 2 to 3 days for 2 to 8 weeks
	Alternative: Vancomycin 125 mg given 4 times daily by mouth for 10 days	Consider a standard course of vancomycin if metronidazole was used for treatment of the first episode
	Adjunctive treatment: Bezlotoxumab 10 mg/kg given intravenously once during administration of SOC antibiotics[a]	Data when combined with fidaxomicin are limited. Caution for use in patients with congestive heart failure[b]

IDSA/SHEA 2021 Focused Update Guidelines on Management of *Clostridioides* difficile Infection in Adults

C. diff Treatment

Table 1. Recommendations for the Treatment of *Clostridioides difficile* Infection in Adults

Clinical Presentation	Recommended and Alternative Treatments	Comments
Second or subsequent CDI recurrence 3	Fidaxomicin 200 mg given twice daily for 10 days, OR twice daily for 5 days followed by once every other day for 20 days	…
	Vancomycin by mouth in a tapered and pulsed regimen	…
	Vancomycin 125 mg 4 times daily by mouth for 10 days followed by rifaximin 400 mg 3 times daily for 20 days	…
	Fecal microbiota transplantation	The opinion of the panel is that appropriate antibiotic treatments for at least 2 recurrences (ie, 3 CDI episodes) should be tried prior to offering fecal microbiota transplantation
	Adjunctive treatment: Bezlotoxumab 10 mg/kg given intravenously once during administration of SOC antibiotics[a]	Data when combined with fidaxomicin are limited. Caution for use in patients with congestive heart failure[a]
Fulminant CDI	Vancomycin 500 mg 4 times daily by mouth or by nasogastric tube. If ileus, consider adding rectal instillation of vancomycin. Intravenously administered metronidazole (500 mg every 8 hours) should be administered together with oral or rectal vancomycin, particularly if ileus is present	Definition of fulminant CDI is supported by: Hypotension or shock, ileus, megacolon

The recommendations are based the 2017 guidelines and these current focused guidelines. Abbreviations: CDI, *Clostridioides difficile* infection; SOC, standard of care.

[a]Bezlotoxumab may also be considered for patients with other risks for CDI recurrence but implementation depends upon available resources and logistics for intravenous administration, particularly for those with an initial CDI episode. Additional risk factors for CDI recurrence include age >65 years, immunocompromised host (per history or use of immunosuppressive therapy), and severe CDI on presentation.

[b]The Food and Drug Administration warns that "in patients with a history of congestive heart failure (CHF), bezlotoxumab should be reserved for use when the benefit outweighs the risk."

IDSA/SHEA 2021 Focused Update Guidelines on Management of *Clostridioides* difficile Infection in Adults

Conclusion

- Discuss and summarize our evaluation and anticipated sustainability of this plan within the current healthcare climate and its future application