



Novel Approaches for Non-Antibiotic Interventions for Clostridium Difficile Stewardship

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Disclosure

Jason Gallagher

Achaogen: Advisory Board; Allergan: Advisory Board, Speaker's Bureau; Astellas Pharma, Inc. : Advisory Board, Speaker's Bureau; Cidara: Consultant; Merck: Advisory Board, Grant Recipient, Speaker's Bureau; Paratek: Advisory Board; Shionogi: Advisory Board; The Medicines Company: Advisory Board; Theravance: Advisory Board

All other planners, presenters, and reviewers of this session report no financial relationships relevant to this activity.

Objectives

- Compare and contrast different rapid diagnostic tests for *Clostridium difficile*.
- Evaluate and mitigate medication risk factors for *Clostridium difficile*.
- Recommend the role of immunomodulatory agents in patient therapy.
- Design an appropriate treatment regimen for a patient with *Clostridium difficile*.

Patient Case

BM is a 73 y/o female called out from the ICU to the GenMed floor after a 3 day stay for AMS and hypotension. After a rather thorough workup, no definitive source was identified and she was transferred to the floor for further evaluation. She has a PMH of osteopenia.

Vitals:

T 98.8°F, HR 68, BP 92/66 mmHg, RR 18, 98% RA

Chem7 and CBC:

135	98	12	100	8.7	11	187
3.6	24	1.2			27	

Medication Upon Transfer:

- Acetaminophen PO prn
- ASA 81 mg PO daily
- Calcium carbonate 500 mg PO QID
- Ciprofloxacin 500 mg PO twice daily
- Influenza vaccine 0.5 mL IM x 1
- Metronidazole 500 mg PO q8h
- Multivitamins PO daily
- Pantoprazole 40 mg PO daily

DOES BM HAVE RISK FACTORS FOR *CLOSTRIDIUM DIFFICILE*?

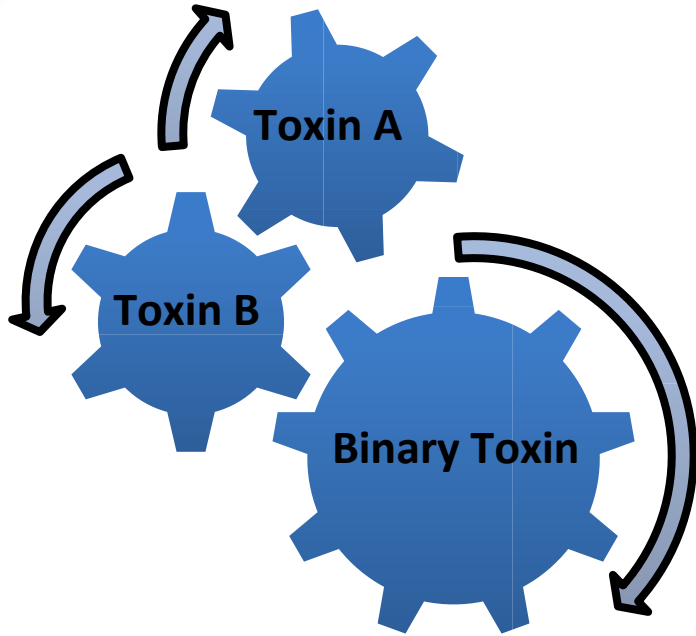
A. Yes

B. No

Background

- *Clostridium difficile* in an anaerobic, spore forming, Gram-positive rod
- Leading cause of health care-associated diarrhea
 - >90% of infections occur in patients with recent (8 weeks) of antibiotic exposure
- Recurrence occurs in ~20% of patients
 - Subsequent courses ↑ difficulty in treating

Toxin Production



- Toxins A/B
 - Intestinal injury
 - Acute inflammation
 - Binary Toxin
 - Increased virulence?
 - Increased recurrence?
- } Hypervirulent strains

CDC “Urgent Threat”

- ~500,000 cases/year
- ~29,000 deaths/year
- \$1-5.4 billion excess medical costs/year



HAZARD LEVEL

URGENT



These are high-consequence antibiotic-resistant threats because of significant risks identified across several criteria. These threats may not be currently widespread but have the potential to become so and require urgent public health attention to identify infections and to limit transmission.

Clostridium difficile (*C. difficile*), Carbapenem-resistant Enterobacteriaceae (CRE), Drug-resistant *Neisseria gonorrhoeae* (cephalosporin resistance)

Hypervirulent Strain

- Epidemic strain (NAP1/BI/027)
 - ↑ spore production
 - ↑ toxin A and B (quantity, duration)
 - 3rd toxin: binary toxin
 - ↑ toxin binding to targets, intestinal epithelial adherence
 - ↑ outbreaks, spreading
 - More difficult to treat

Diagnosis

Recommendation	Quality of Evidence
1. Only test watery stools, diarrhea	Strong recommendation High quality evidence
2. NAAT are superior to and preferred over toxin A+B EIA	Strong recommendation Moderate quality evidence
3. GDH screening can be used in a 2- or 3-step screening algorithm, but sensitivity lower than NAAT	Strong recommendation Moderate quality evidence
4. Avoid repeat testing	Strong recommendation Moderate quality evidence
5. Avoid testing for cure	Strong recommendation Moderate quality evidence

NAAT: nucleic acid amplification test; EIA: enzyme immunoassay; GDH: glutamate dehydrogenase

Clostridium difficile RDT

Organism	Test Name	Technology	Detection time (h)	Batching
<i>C. difficile</i>	Xpert <i>C. difficile</i>	Multiplex PCR	0.5	No
<i>C. difficile</i> BI/NAP1/027	Xpert <i>C. difficile</i> /Epi	Multiplex PCR	0.75	No
<i>C. difficile</i>	Illumigene <i>C. difficile</i>	LAMP	1	Yes
<i>C. difficile</i>	BD GeneOhm Cdiff Assay	PCR	2	Yes
<i>C. difficile</i>	ProGastro Cd Assay	PCR	3	Yes

RDT: rapid diagnostic technologies

Clostridium difficile RDT in Real Life

- *C. difficile* rate can appear to increase
 - PCR more sensitive
 - Spores can be detected even if not actively infected
- Need strict criteria for testing
 - ≥3 loose stools/24 hours
 - No repeat testing within 7 days
 - Do not use for “test of cure”

Treatment

SHEA-IDSA GUIDELINE

Clinical Practice Guidelines for *Clostridium difficile*
Infection in Adults: 2010 Update by the Society for Healthcare
Epidemiology of America (SHEA) and the Infectious Diseases
Society of America (IDSA)



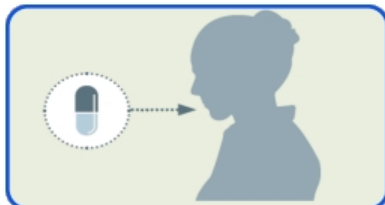
Stuart H. Cohen, MD; Dale N. Gerding, MD; Stuart Johnson, MD; Ciaran P. Kelly, MD; Vivian G. Loo, MD;
L. Clifford McDonald, MD; Jacques Pepin, MD; Mark H. Wilcox, MD

- **Mild/moderate:** metronidazole 500 mg PO q8h
- **Severe:** vancomycin 125 mg PO q6h
- **Severe/complicated:** vancomycin 500 mg PO q6g
+ metronidazole 500 mg IV q8h
- Missing from the guidelines: fidaxomicin, FMT, bezlotoxumab

FMT: fecal microbiota transplantation

Cohen SH et al. *Infect Control Hosp Epidemiol* 2010;31:431-55

Modifiable Risk Factors



Antibiotic Exposure

High risk:

- Fluoroquinolones
- 3rd and 4th generation cephalosporins
- Clindamycin
- Carbapenems



Exposure to *C. difficile* spores

- Spores can remain viable for months
- Contamination ↑ in rooms of pts with active *C. diff*
- Hands easily contaminated



Gastric Acid Suppression

- Data implicates PPI use
- Need more studies: PPI restriction and ↓ *C. diff*

Additional Risk Factors: older age (≥ 65 years), inpatient stay/healthcare exposure, immunosuppression, low anti-toxin A/B antibody []

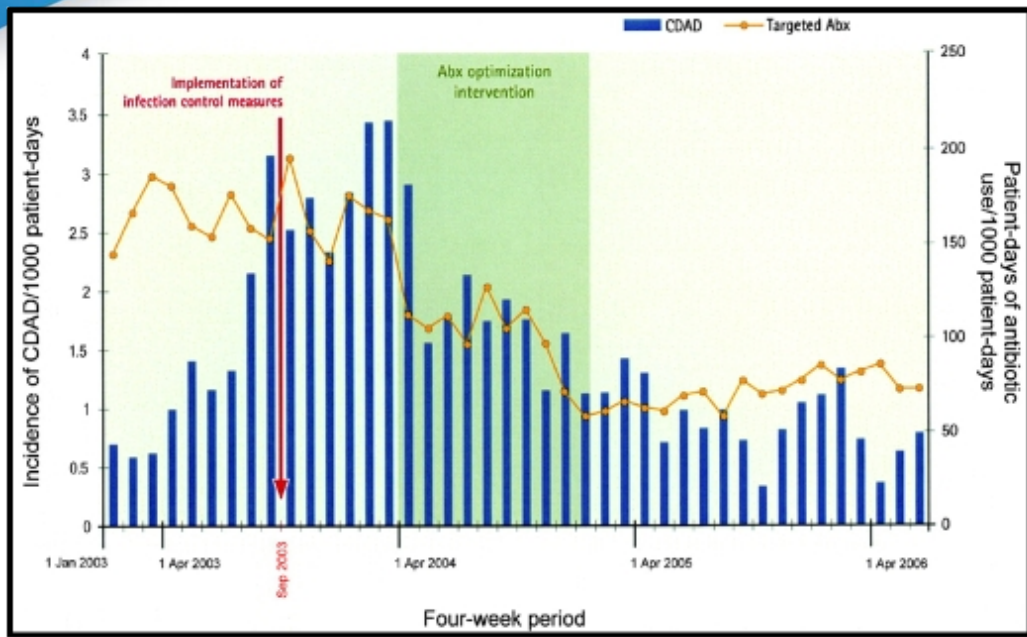
Abx Stewardship – CDI Assessment Tool

Targeted Assessment for Prevention (TAP) Strategy

II. Antibiotic Stewardship for CDI Prevention	Response	Comments (and/or “As Evidenced By”)
1. Does your facility routinely review appropriateness of antibiotics prescribed for treatment of other conditions (e.g., UTI) for patients with new or recent CDI diagnosis?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	
2. Does your facility educate providers about the risk of CDI with antibiotics?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	
3. Does your facility educate patients/family members about the risk of CDI with antibiotics?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	
Does your facility monitor the use of the following antibiotics that are high-risk for CDI:		
4. Fluoroquinolones?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	
5. 3 rd /4 th generation cephalosporins?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	
Does your facility use strategies to reduce the unnecessary use of the following antibiotics that are high-risk for CDI:		
6. Fluoroquinolones?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	
7. 3 rd /4 th generation cephalosporins?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unk	

CDI TAP Facility Assessment Tool V4.0 – Last Updated July 2016

Non-Restrictive AST on CDI Rates

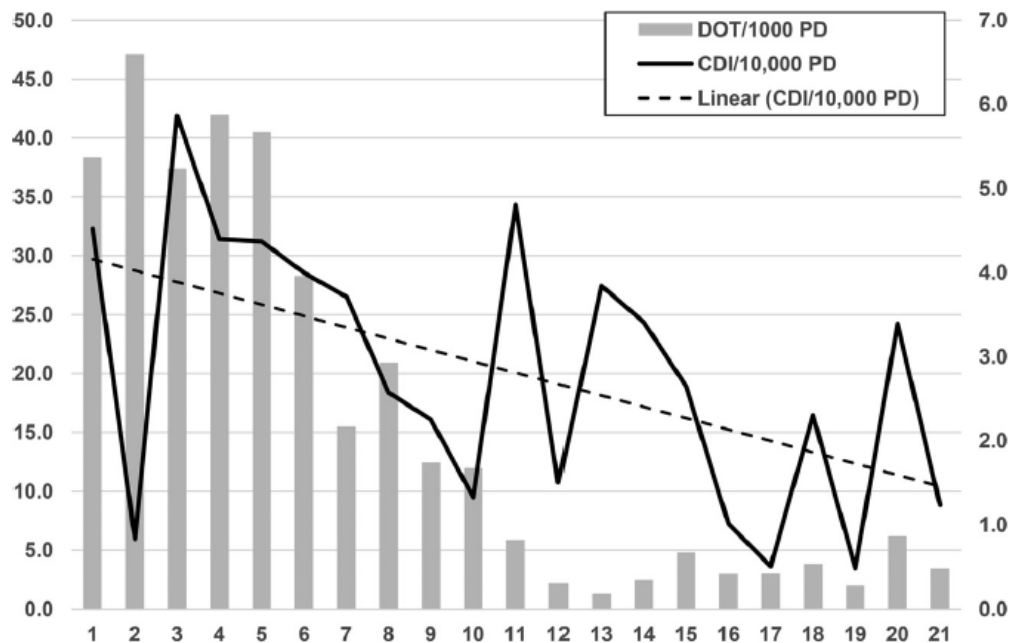


- Local guidelines, physician letter, pocket guide: awareness and alternatives to 2nd /3rd gen cephalosporins, ciprofloxacin, clindamycin, macrolides
- Non-restrictive AST was more effective than infection control measures in ↓ CDI

AST: Antimicrobial Stewardship

Fluoroquinolone Restriction & CDI

- Respiratory FQ restriction
- System-wide education
- Beta-lactam allergy assessment tool
- RPh competency
- Prospective RPh review for all FQ orders
- No CDI interventions



Pre-Intervention	Education	Restriction
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FQ DOT/1,000 PD 41.0 ± 4.4 4.8 ± 3.6

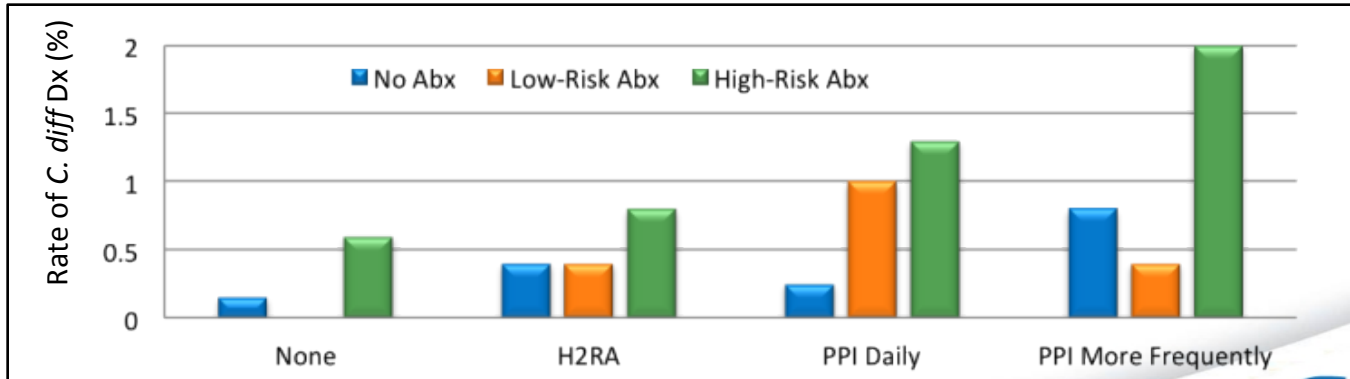
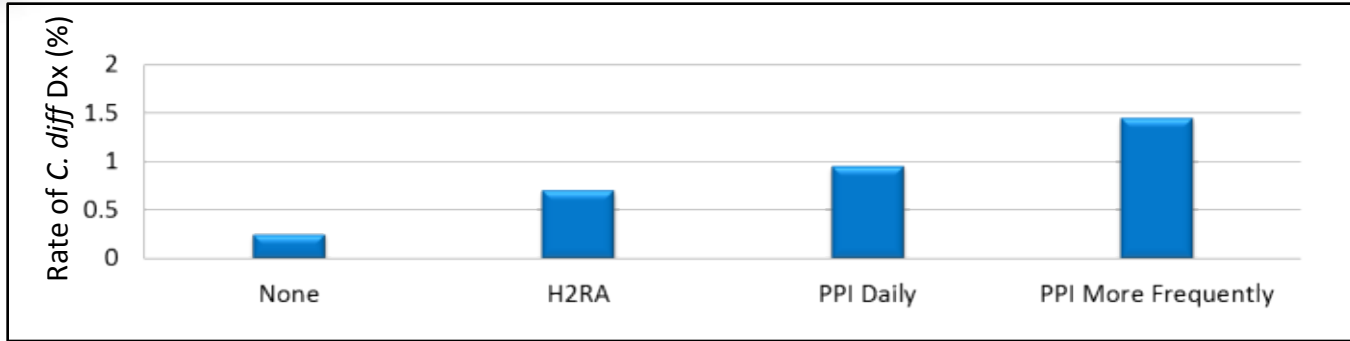
CDI cases/10,000 PD 4.0 ± 2.1 2.2 ± 1.35



C. diff Stewardship – More Data!

Study	Intervention	Outcomes
Carling 2003	<ul style="list-style-type: none"> • Prospective abx monitoring • ↓ inappropriate IV abx • Guidelines, Rx restrictions, individual MD detailing 	<ul style="list-style-type: none"> • 22% ↓ broad IV abx • C. diff incidence 2.2 → 1.4/1,000 pt days
Fowler 2007	<ul style="list-style-type: none"> • ↓ amox/clav use • ↑ benzyl PCN, TMP, amox • Individual MD C. diff/MRSA feedback q8-12 w 	<ul style="list-style-type: none"> • ↓ amox/clav and cepha use • ↑ benzyl PCN use • ↓ C. diff infections with no Δ in MRSA
Muto 2007	<ul style="list-style-type: none"> • Educational material • Active C. diff surveillance • ↑ infection control audits • Restrict clinda, CRO, levo, others 	<ul style="list-style-type: none"> • 41% ↓ abx-associated C. diff • Aggregate C. diff rate 7.2 → 3/1,000 pt discharges
Valiquette 2007	<ul style="list-style-type: none"> • Educational materials • Alternative abx recommendations • Shorter duration of therapy 	<ul style="list-style-type: none"> • 60% ↓ C. diff incidence • 54% ↓ targeted abx use • ↑ use resp-FQs and pip/tazo

PPI Stewardship



Unnecessary PPI Continuation

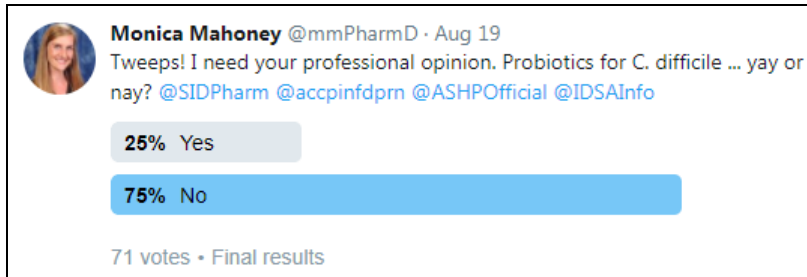
Reference(s)	Population	Unnecessary Start*	Continued Outside of ICU*	Continued at d/c*
Nardino 2000; Parente 2003; Zink 2005	Gen Med	56-75%	-	Up to 55%
Wohlt 2007	MICU/SICU	-	60%	24.4%
Murphy 2008	SICU	4.4%	79.3%	19.2%
Pavlov 2014	MICU/SICU	-	19.1%	-

*Without appropriate indication

Nardino RL et al. *Am J Gastroenterol* 2000;95:3118-22; Parente F et al. *Aliment Pharmacol Ther* 2003;17:1503-6; Zink DA et al. *Aliment Pharmacol Ther* 2005;21:1203-9; Wohlt PD et al. *Ann Pharmacother* 2007;41:1611-6; Murphy CE et al. *Pharmacotherapy* 2008;28:968-76; Pavlov A et al. *Resp Care* 2014;59:1524-9

Probiotics

Reference	Recommendation
IDSA Guidelines. 2010	No
Cochrane Review: <i>Use of Probiotics to Prevent C. difficile Associated with Abx.</i> 2013	Yes
Mexico: <i>Mexican Consensus on Probiotics In Gastroenterology.</i> 2017	Yes
Susan Davis: <i>Pharmacotherapy</i> 2015;35:1016-25	No
Twitter	No



Monica Mahoney @mmPharmD · Aug 19
Tweeps! I need your professional opinion. Probiotics for C. difficile ... yay or nay? @SIDPharm @accpinfdprn @ASHPOfficial @IDSAInfo

25% Yes

75% No

71 votes • Final results

1-2 Punch: ↓ PPIs and ↑ Probiotics

Study	Implementation of Global Strategies to Prevent Hospital-Onset <i>Clostridium difficile</i> Infection: Targeting Proton Pump Inhibitors and Probiotics				
Intervention	<ul style="list-style-type: none">• C. diff educational campaign• PPI prospective audit & feedback: orders not approved if not per protocol• Probiotic bundles added to all abx order sets outside of ICU<ul style="list-style-type: none">• <i>Lactobacillus acidophilus</i>, <i>Bifidobacterium lactis</i>, <i>B. longum</i>				
Results	Variable	FY14	FY15	Difference	p value
	Avg PPI use (doses/1000 pt days)	677	581	-96 (14.2%)	0.0002
	Avg IV PPI use (doses/1000 pt days)	229	158	-71 (31.1%)	0.0008
	Avg probiotic use (doses/1000 pt days)	97	223	126 (129.6%)	0.0006
	# HO-CDI (cases/1000 pt days)	0.49	0.39	-0.1 (20%)	0.04

Kefir

- Fermented milk with yeast and probiotics
 - Gelatinous white/yellow particles called “grains”
 - “Grains” contain bacteria, yeast, casein, and complex sugars
 - “Grains” ferment the milk
 - Strained prior to consumption/packaging
- 15-20 billion CFUs of probiotics per cup, usually:
 - *Bifidobacterium*, *Lactobacillus*, *Lactococcus*, *Leuconostoc*, *Saccaromyces*

Kefir for *Clostridium*?

Antibiotic taper

M 250mg q6h
or
V 125mg q6h

M 750mg q72h
or
V 375mg q72h

M 500mg q72h
or
V 250mg q72h

M 250mg q72h
or
V 125mg q72h

 Weeks 1-2

Weeks 3-4

Weeks 5-6

Weeks 7-8

Weeks 9-15 

150mL TID

150mL TID

150mL TID

150mL TID

150mL TID

Kefir

Key: M: metronidazole, V: vancomycin

Thirsty for More Kefir?

ashp **MIDYEAR** 2017
Clinical Meeting & Exhibition

A Strawberry-Flavored Pearl for *Clostridium difficile* Infection

Kevin W. Garey, PharmD, MS, FASHP
Professor and Chair

Dept. of Pharmacy Practice and Translational Research
University of Houston, College of Pharmacy

ashp 75
CELEBRATING YEARS



Hot Topics in Antimicrobial Stewardship

Tuesday Dec 5, 2017
8am-10am
Chapin Auditorium
Session 238-L01

ashp 75
CELEBRATING YEARS

Probiotics: The Devil is in the Details

- Product matters
 - FDA approved product
 - Probiotic strains/amounts
- Patient selection matters
 - Reports of systemic infection in immunocompromised

DOES BM HAVE RISK FACTORS FOR *CLOSTRIDIUM DIFFICILE*?

- A. Yes
- B. No

Patient Case

BM is a 73 y/o female called out from the ICU to the GenMed floor after a 3 day stay for AMS and hypotension. After a rather thorough workup, no definitive source was identified and she was transferred to the floor for further evaluation. She has a PMH of osteopenia.

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Medication Upon Transfer:

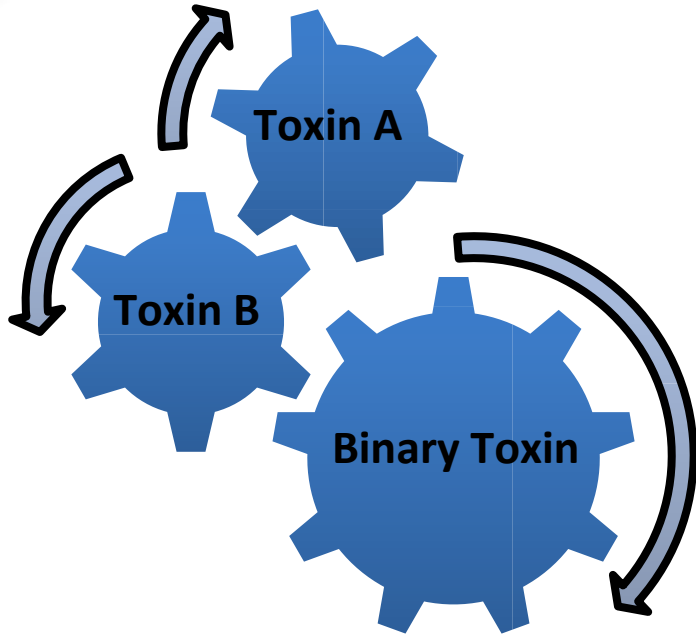
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Poor BM (Patient Case 2)

Fast forward 3 years. BM developed *C. diff* during that initial hospitalization and has had 2 recurrences since then. She is hospitalized again, with foul smelling diarrhea that is suspected to be, once again, *C. diff*. Which of the following stand-alone therapeutic interventions could help treat/prevent recurrent *C. diff*?

- A. Bezlotoxumab
- B. Fecal Microbiota Transplant
- C. Tolevamer
- D. *C. diff* Vaccine

Toxin Production



Toxin binders?

Anti-toxin
antibodies?

- Toxins A/B
 - Intestinal injury
 - Acute inflammation
 - Binary Toxin
 - Increased virulence?
 - Increased recurrence?
- Toxoid vaccines?
- Hypervirulent strains

Tolevamer

- Soluble, high-molecular-weight (≥ 400 kDa) anionic polymer
 - Related to styrenesulfonate (K⁺ binding)
- Non-covalently bonds *C. difficile* toxin A and toxin B
- Not an antibiotic
- No disruption of gut flora

Tolevamer

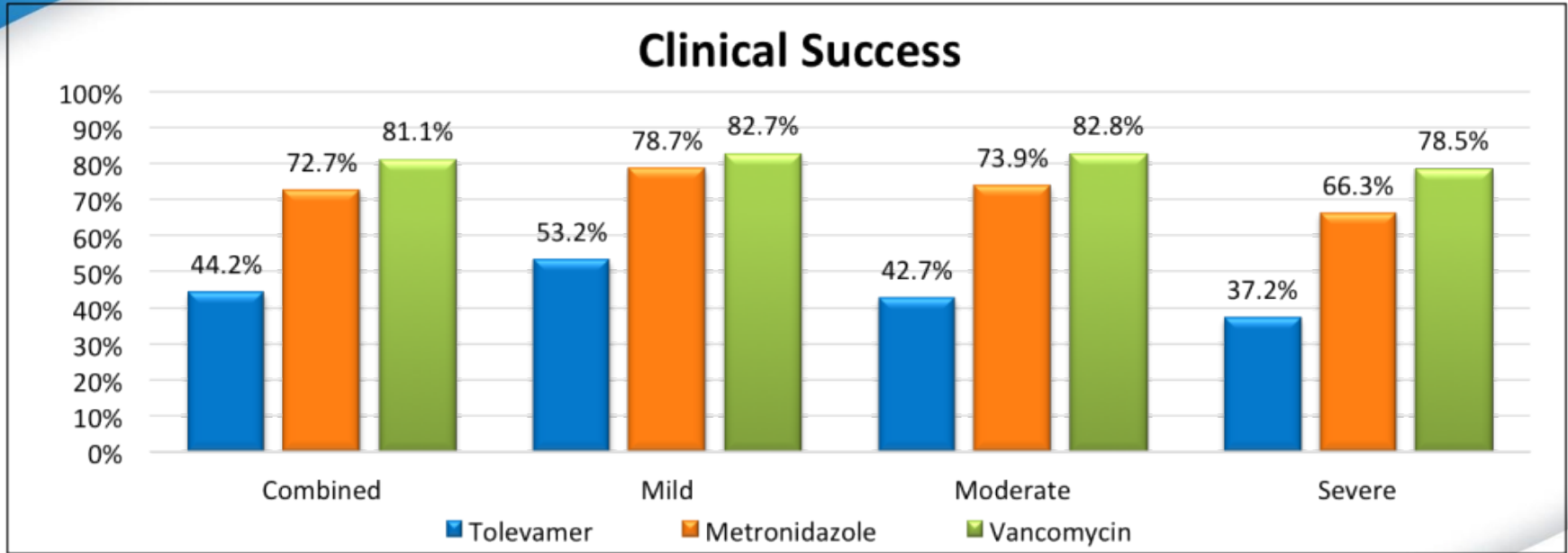
- 2 Phase 3 trials: 2:1:1

Tolevamer:Vancomycin:Metronidazole

- Interventions:

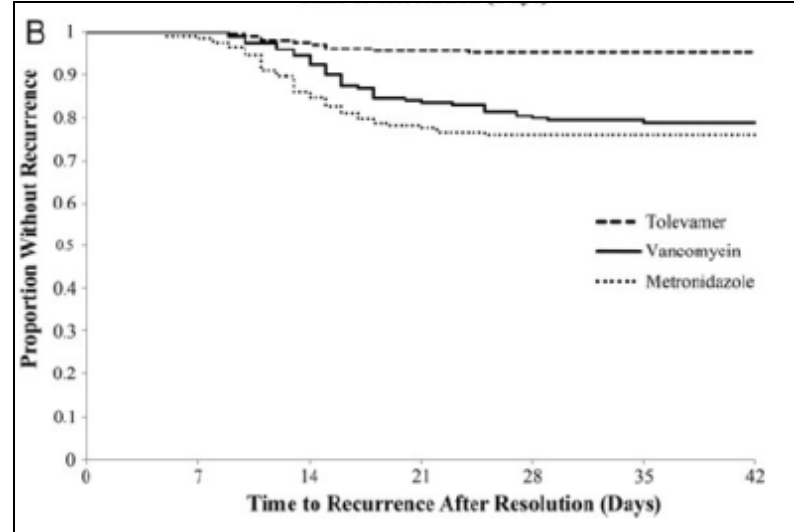
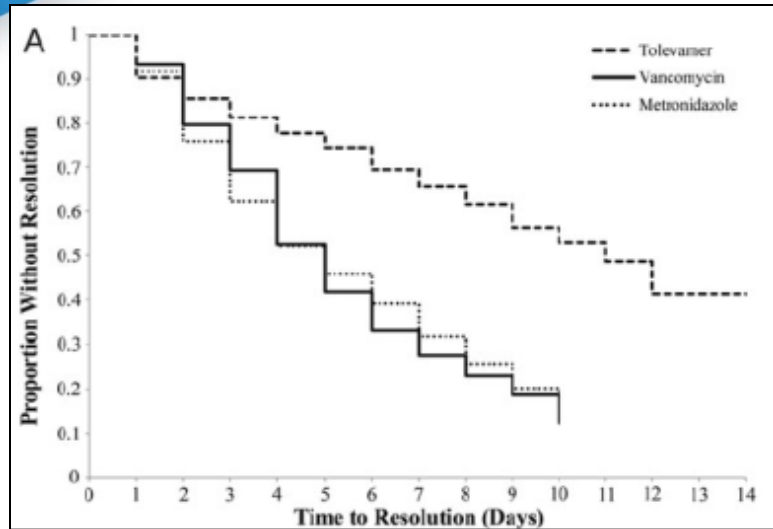
- Tolevamer 9g load (45 mL) x1 then 3g (15 mL) q8h x 14d
- Vancomycin 125mg PO q6h x 10d
- Metronidazole 375mg PO q6h x 10d

Tolevamer



- Statistically inferior to both, metronidazole and vancomycin

Tolevamer

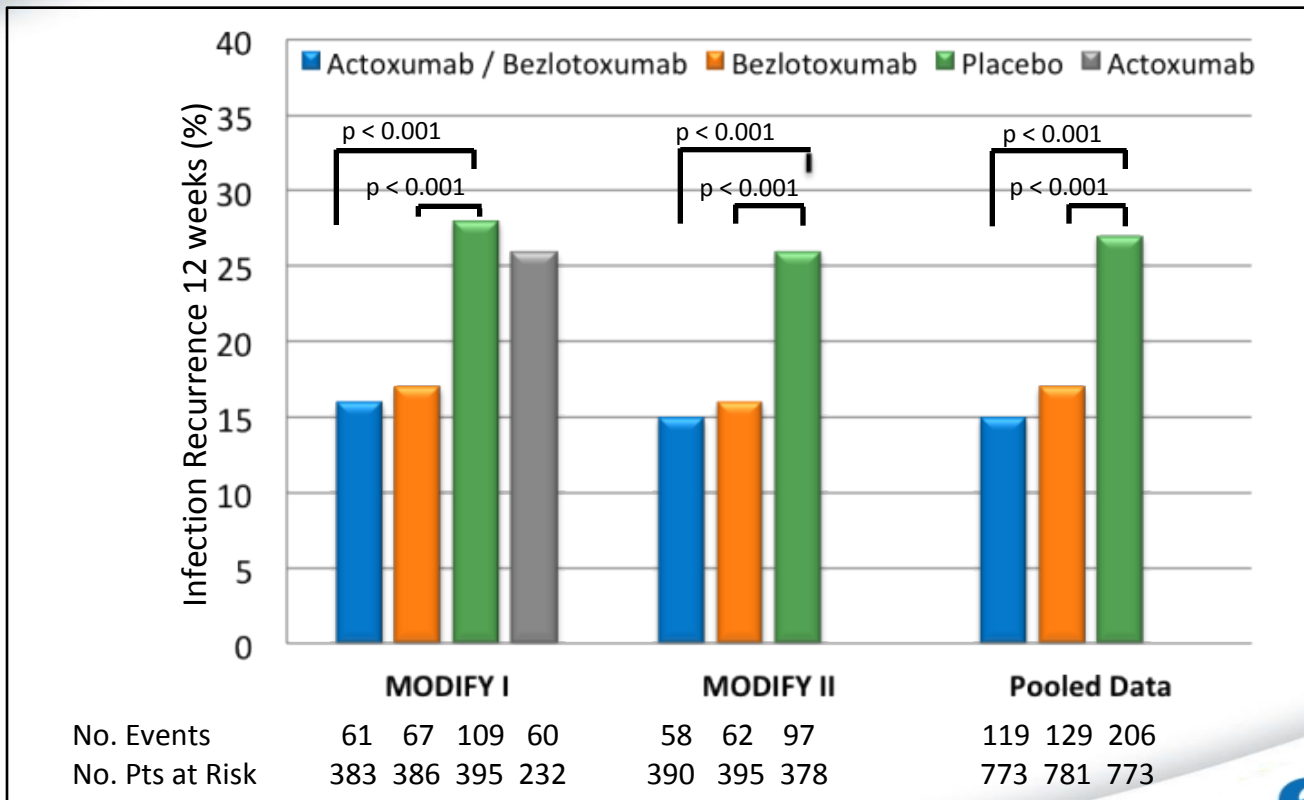


- Unanswered Questions:
 - Studied as primary therapy - Role for adjunctive therapy to prevent recurrence?

Bezlotoxumab

- Fully humanized mAb against toxin B
- Single dose infusion 10 mg/kg IV over 1 hour – **adjunctive therapy only**
 - Metronidazole PO, vancomycin PO (fidaxomicin PO)
- Administer during abx treatment (days 0-14)
- Cost: ~\$4500 per 1,000 mg vial
 - CMS NTAP designation

Bezlotoxumab

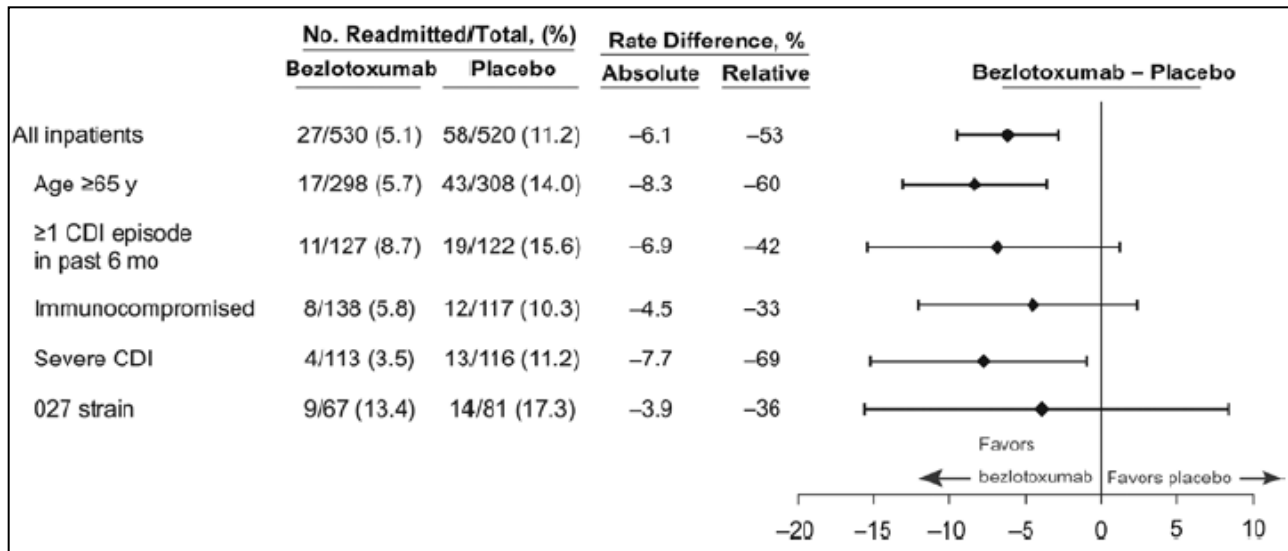


NNT = 10



Bezlotoxumab

Post-Hoc Analysis (MODIFY I + II) – 30 Day Hospital Readmission Rates



NNT = 17



Bezlotoxumab

- Not effective against NAP1/BI/027
- Caution in CHF
- Unanswered Questions:
 - Who to receive? What is “high risk”?
 - Where to receive? Defer to outpatient?
 - Benefit over fidaxomicin or FMT? Still unknown

Toxoid Vaccines – Phase 3 Trials

Manufacturer	Trial	Doses	Patients	Status
Sanofi-Pasteur	<i>Cdiffense.</i> NCT01887912	3 doses: 0.5 mL days 0, 7, 30	15,000 adults ≥ 50 years at risk for CDI •2+ hospital stays •Systemic abx •Anticipated inpatient stay within 2 months	Currently enrolling (8/2013)
Pfizer	<i>Clover.</i> NCT03090191	3 doses	16,000 adults ≥ 50 years at risk for CDI •Systemic abx within 12 weeks •↑ risk of future healthcare contact	Currently enrolling (3/2017)

Good review on Phase 1/2 data: Henderson M et al. *Vaccines* 2017;5:25; doi:10.3390/vaccines5030025

Fecal Microbiota Transplantation (FMT)

- Restoration of gut flora by exogenous transfer of (usually) foreign feces
- Donors:
 - Self vs. related vs. central donor
- Preparation:
 - Fresh vs. frozen vs. synthetic
- Administration:
 - Top-down vs. bottoms-up



Photo courtesy of Maureen Taylor, PA

FDA Approval? (No Poop For You)

- FMT indication may require an FDA IND
 - rCDI failing current therapies?
→ **free flowing FMT**
 - All other indications?
→ **file IND for FMT**

**Enforcement Policy Regarding
Investigational New Drug
Requirements for Use of Fecal
Microbiota for Transplantation to
Treat *Clostridium difficile* Infection
Not Responsive to Standard Therapies**

Draft Guidance for Industry

European Consensus Guidelines

CDI Indication	Recommendation	Level of Evidence
First episode	Insufficient evidence, not recommended	Low quality evidence Weak recommendation
Recurrent	Recommended as treatment for mild and severe rCDI	High quality evidence Strong recommendation
Refractory	Can be considered as an option	Low quality of evidence Strong recommendation

Fecal Fixation: Fecal Microbiota Transplantation for *Clostridium difficile* Infection

Stuart Johnson and Dale N. Gerding

Does Route Matter?

Reference	FMT	Comparator	Outcomes 1 st txt (multiple txt)
Van Nood 2013	Vanco 500mg PO q6h x 4d then FMT NG tube (n=16)	Vanco 500mg PO x 14d q6h (n=13)	81% (94%) vs. 31%
Cammarota 2015	Vanco 125mg PO q6h x3d then FMT colonoscopy (n=20)	Vanco 125mg PO q6h x10d then taper x 3 weeks (n=19)	65% (90%) vs. 26% (63%)
Hota 2017	Vanco 125mg PO q6h x14d then FMT enema (n=16)	Vanco 125mg PO q6h x 14d then taper 4 weeks (n=12)	44% vs. 58%

van Nood et al. *NEJM* 2013;368:407-15; Cammarota G et al. *Aliment Pharmacol Ther* 2015;41:835-43; Hota SS et al. *CID* 2017;64:265-71

Does Preparation Matter?

Reference	Investigator	Comparator	Outcomes 1 st txt (multiple txt)
Youngster 2014	Frozen FMT NG tube (n=10)	Frozen FMT colonoscopy (n=10)	60% (80%) vs. 80% (100%)
Lee 2016	Frozen FMT enema (n=108)	Fresh FMT enema (n=111)	53% (75%, 91%) vs. 51% (91%, 86%)
Kelly 2016	Donor FMT colonoscopy (n=22)	Autologous FMT colonoscopy (n=24)	91% vs. 63%

The Poop Scoop: Colonoscopy > NG tube Frozen ≈ Fresh Donor > Autologous

Youngster I et al. *CID* 2014;58:1515-22; Lee CH et al. *JAMA* 2016;315:142-9;
Kelly CR et al. *Ann Intern Med* 2016;165:609-16

FMT General Process

CDI abx for 3-5 days



Discontinue CDI abx 24-48h prior to FMT

Consider bowel lavage prior to FMT

FMT

Follow-up x 8 weeks



Fecally Challenged?

Non-profits collaborating with FDA to provide frozen, screened FMT material

Open Biome (Medford, MA)

www.openbiome.org



\$485/dose
250 mL



\$485/dose
30 mL



\$635/dose
30 caps

AdvancingBio (Sacramento, CA)

www.advancingbio.org



Stool donations are accepted Tuesdays and Wednesdays from 7 a.m. to 1 p.m.
Closed for lunch between 11 a.m.-11:30 a.m..

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In Summary

- CDI is an increasing burden
- Several new agents target rCDI
- CDC and other organizations provide toolkits for CDI
- Best approach involves multi-faceted antimicrobial stewardship interventions

Another Solid Presentation



Antimicrobial Stewardship Strategies to Reduce Hospital-Acquired *Clostridium difficile* Infections

Erin McCreary, PharmD, BCPS

Jerod Nagel, PharmD

Tristan Timbrook, PharmD, MBA, BCPS

Lucas Schulz, PharmD, BCPS-AQ ID



Tuesday Dec 5, 2017

2:00-3:30 pm

Room W304

Session 256-L01



Because Social Media is All the Rage

 **Monica Mahoney**
@mmPharmD

Got FMT? What do you call it? So far we've got poopsicles 🍦, fecaltini 🍸 & feces pieces 🍌. Others?

Most creative = props from Monica 🙄

got FMT?

7:48 AM - 21 Jul 2017

 **Matt Brown** @mlbrownrx · Jul 21

Replying to @mmPharmD @real_idpharmd and 9 others
Trans"poo"sion 🍌



David Berkowitz @dberkpharmd · Jul 21

Replying to @mmPharmD @real_idpharmd and 9 others
my official title is director of fecal bacteriotherapy

4 4 4



Kurt Wargo @Kurt_Wargo · Jul 21

Replying to @mmPharmD @real_idpharmd and 9 others
Shiitake 🍄



Tim Gauthier @IDstewardship · Jul 21

🍌 Kaka capsules... kakacraipoosickles?

🌐 Translate from Estonian

2 3



Monica Mahoney @mmPharmD · Jul 21

Poop in Polish is "kupa". Kupa Capsules has a better ring to it.

1 3



Tim Gauthier
@IDstewardship

Replying to @mmPharmD @maurentaylor31 and 9 others

Send in the Kupa troopers!



Jacob Morton @JMIDPharmD · Jul 21

Replying to @dberkpharmd @mmPharmD and 9 others
If you work with several people you could be the poop troop!



ashp 75
CELEBRATING YEARS

Key Takeaways

- Key Takeaway #1
 - Discontinue unnecessary antibiotics
- Key Takeaway #2
 - Discontinue non-indicated gastric acid suppressants
- Key Takeaway #3
 - Evaluate institutional/patient need for rCDI therapies
- Key Takeaway #4
 - Consider re**POOP**ulation of gut microbiota

Novel Approaches for Non-Antibiotic Interventions for *Clostridium difficile*

Monica V. Mahoney, Pharm.D., BCPS-AQ ID

Clinical Pharmacy Coordinator, Infectious Diseases

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