

Towards Eliminating *Clostridium difficile* Infections (CDI) in Illinois

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OBJECTIVES

- Summarize the impact of *Clostridium difficile* (*C. difficile*) statewide and nationally
- Discuss the importance of facility-specific interventions for meeting state and national agenda to eliminate *C. difficile* infections

TOPICS

- Epidemiology & Diagnosis
- Prevention
 - Hand Hygiene
 - Isolation & Gloving
 - Environmental Cleaning
 - Antibiotic Stewardship
 - Probiotics
- Treatment
 - Oral Antimicrobials; Treatment as Prevention
 - Fecal Bacteriotherapy
 - Surgical Options
- Putting It All Together: ICE CDI!

Infection Control Over the Past Decade

Parameter	Rate		Reference(s)
	Then	Now	
CRBSIs	5.0/1000 catheter days	1.7/1000 catheter days	a,b
VAP	9.5/1000 ventilator days	2.0/1000 ventilator days	a,b
CAUTIs	5.4/1000 catheter days	3.1/1000 catheter days	a,b
<i>C. difficile</i> infection	5.5 cases/ 10,000 discharges	11.2 cases/ 10,000 discharges	c,d

Abbreviations: CRBSIs, catheter-related bloodstream infections; VAP, ventilator-associated pneumonia; CAUTIs, catheter-associated urinary tract infections.

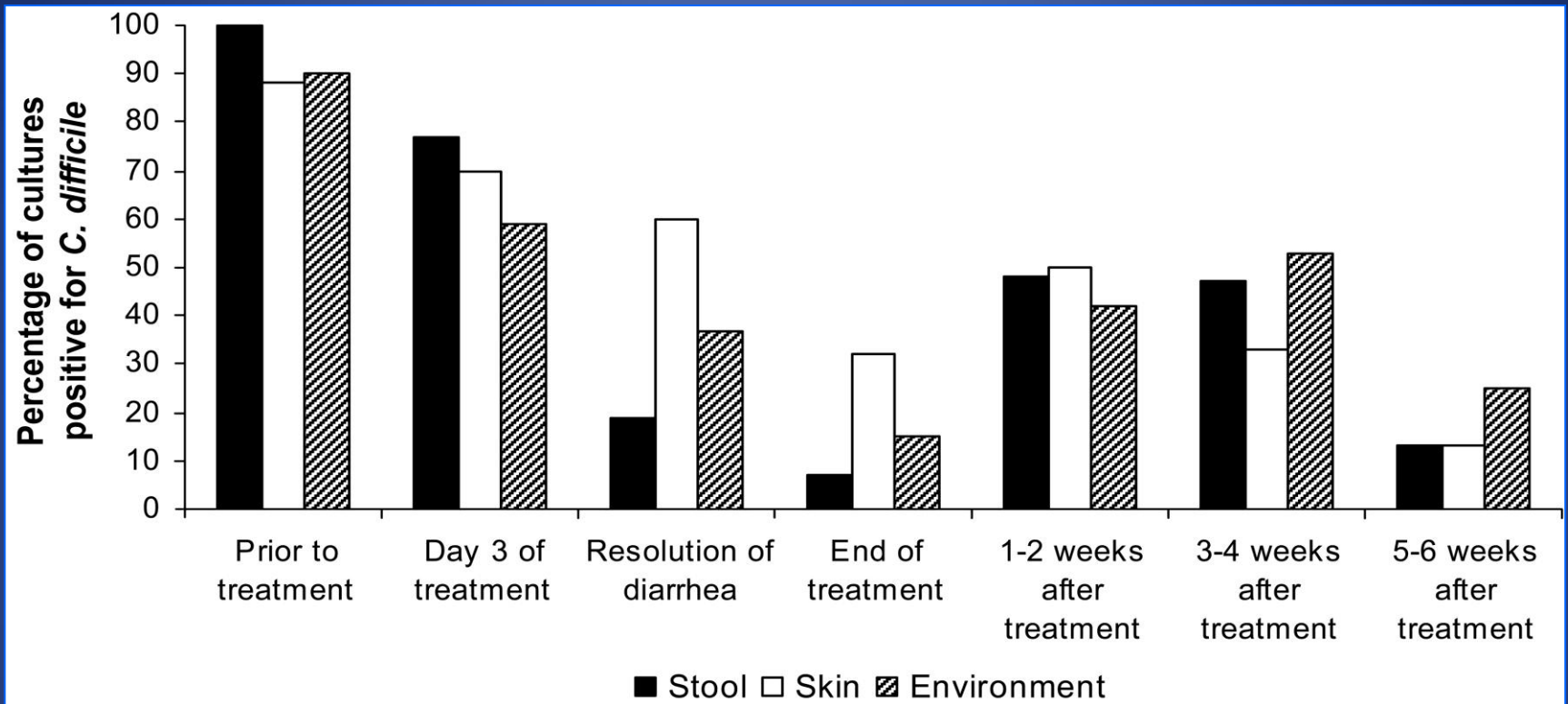
^a *Am J Infect Control* 2000; 28:429–48

^c *Emerg Infect Dis* 2009; 15:122–5

^b *Am J Infect Control* 2009; 37:783–805

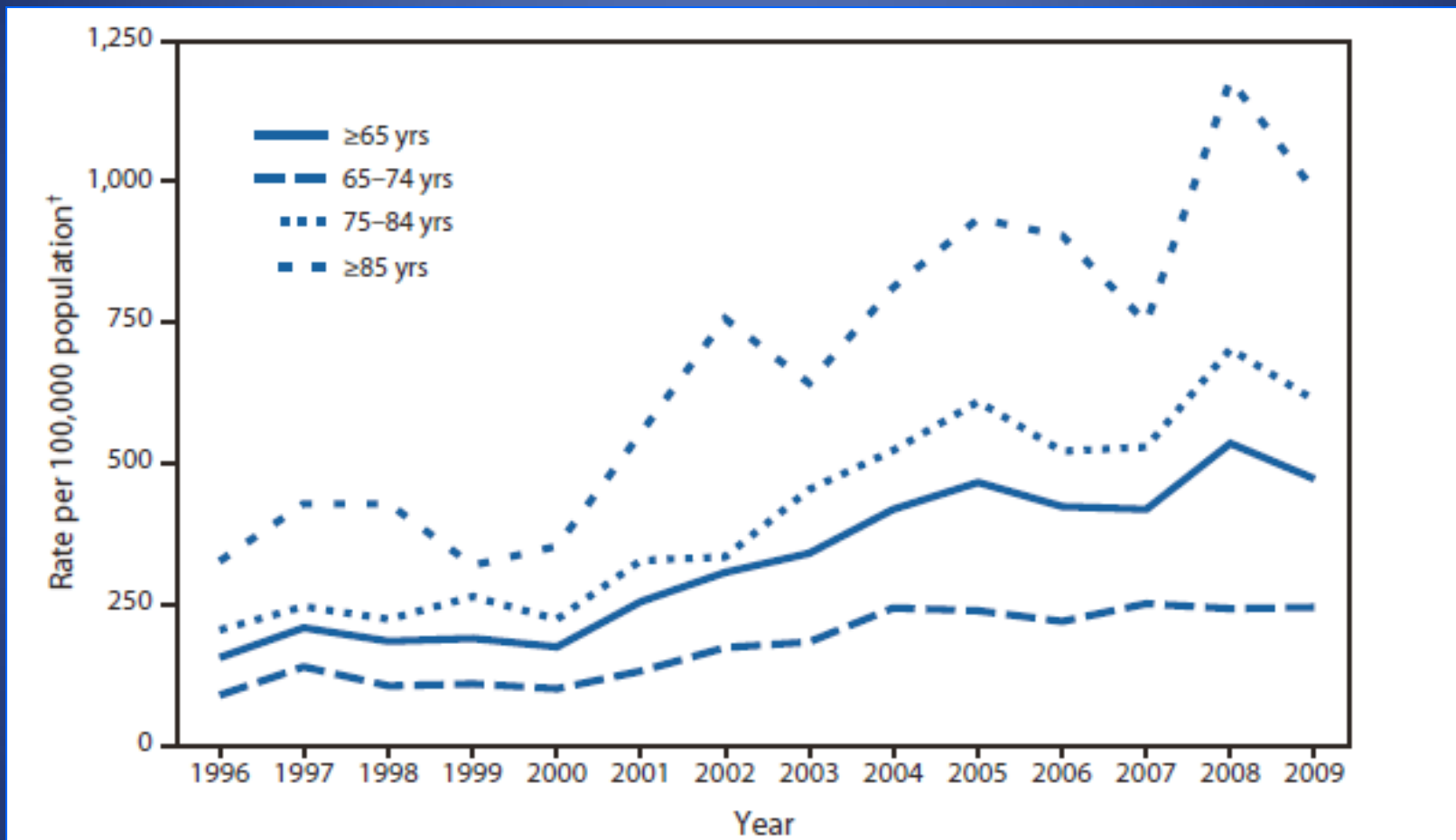
^d <http://hcupnet.ahrq.gov>

Percentage of Stool, Skin and Environmental Cultures Positive for *C. difficile* Among 52 Patients with *C. difficile* Infection



Percentage of stool, skin (chest and abdomen), and environmental (bed rail, bedside table, call button, toilet seat) cultures positive for *Clostridium difficile* among 52 patients with *C. difficile* infection. The limit of detection for stool specimens was $\sim 2 \log_{10}$ CFU/g. The numbers of patients who had samples cultured at each time point were 52 before treatment, 48 on day 3 of treatment, 43 after resolution of diarrhea, 28 at the end of treatment, 22 at 1–2 weeks after treatment, 15 at 3–4 weeks after treatment, and 8 at 5–6 weeks after treatment.

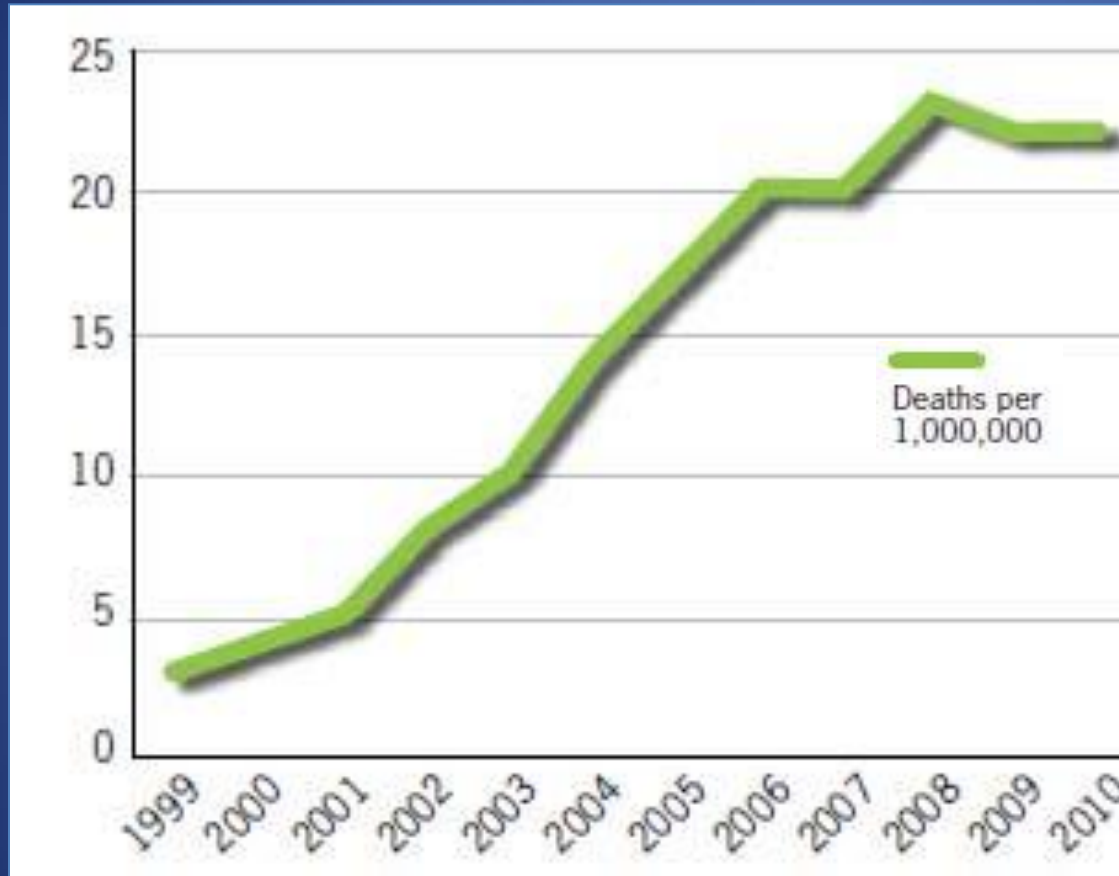
Rates of *Clostridium difficile* Infection Among Hospitalized Patients Aged ≥ 65 Years*, by Age Group – National Hospital Discharge Survey, U.S. 1996-2009



* Includes patients hospitalized with *C. difficile* infections or who acquired *C. difficile* during the hospital stay.

National Impact of *C. difficile*

Deaths Caused by *C. difficile* Infections*



- Deaths related to *C. difficile* increased 400% between 2000 and 2007, partly due to a more virulent strain
- 14,000 deaths are attributed to *C. difficile* each year in the US
- > 90% of deaths related to CDI are in persons \geq 65 years of age

*Age –adjusted rate of *C. difficile* as the primary (underlying) cause of death.
SOURCE: CDC National Center for Health Statistics, 2012

Decreased Cure and Increased Recurrence Rates for *Clostridium difficile* Infection Caused by the Epidemic *C. difficile* BI Strain

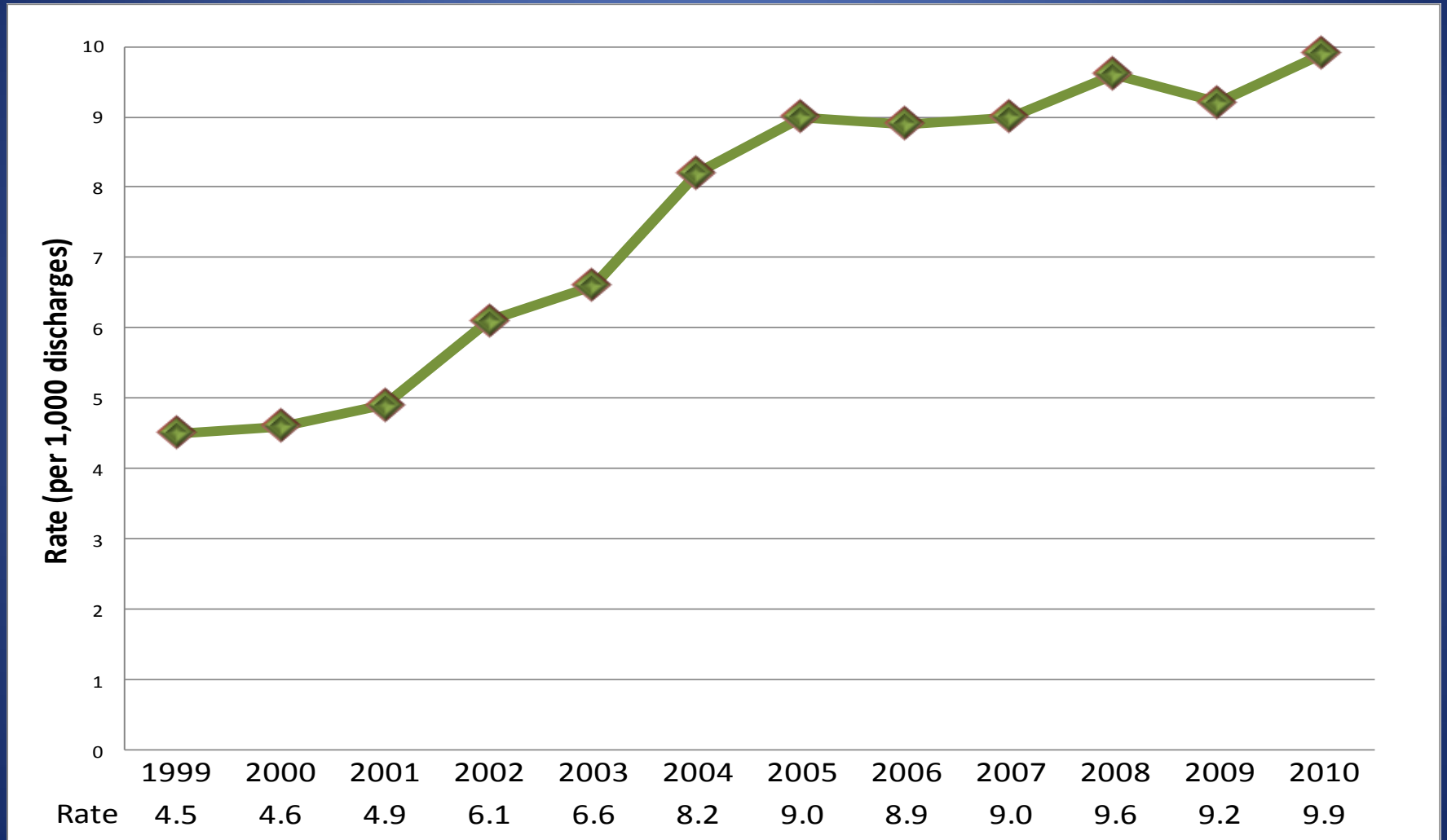
Laurica A. Petrella,¹ Susan P. Sambol,^{1,2} Adam Cheknis,¹ Kristin Nagaro,¹ Yin Kean,³ Pamela S. Sears,³ Farah Babakhani,³ Stuart Johnson,^{1,2} and Dale N. Gerding^{1,2}

By multivariate analysis, BI infection was statistically significant as a risk factor for reduced cure (odds ratio [OR], 0.48; 95% confidence interval [CI], .27–.85; $P = .030$) and for increased recurrence (OR, 1.57; 95% CI, 1.01–2.45; $P = .046$).

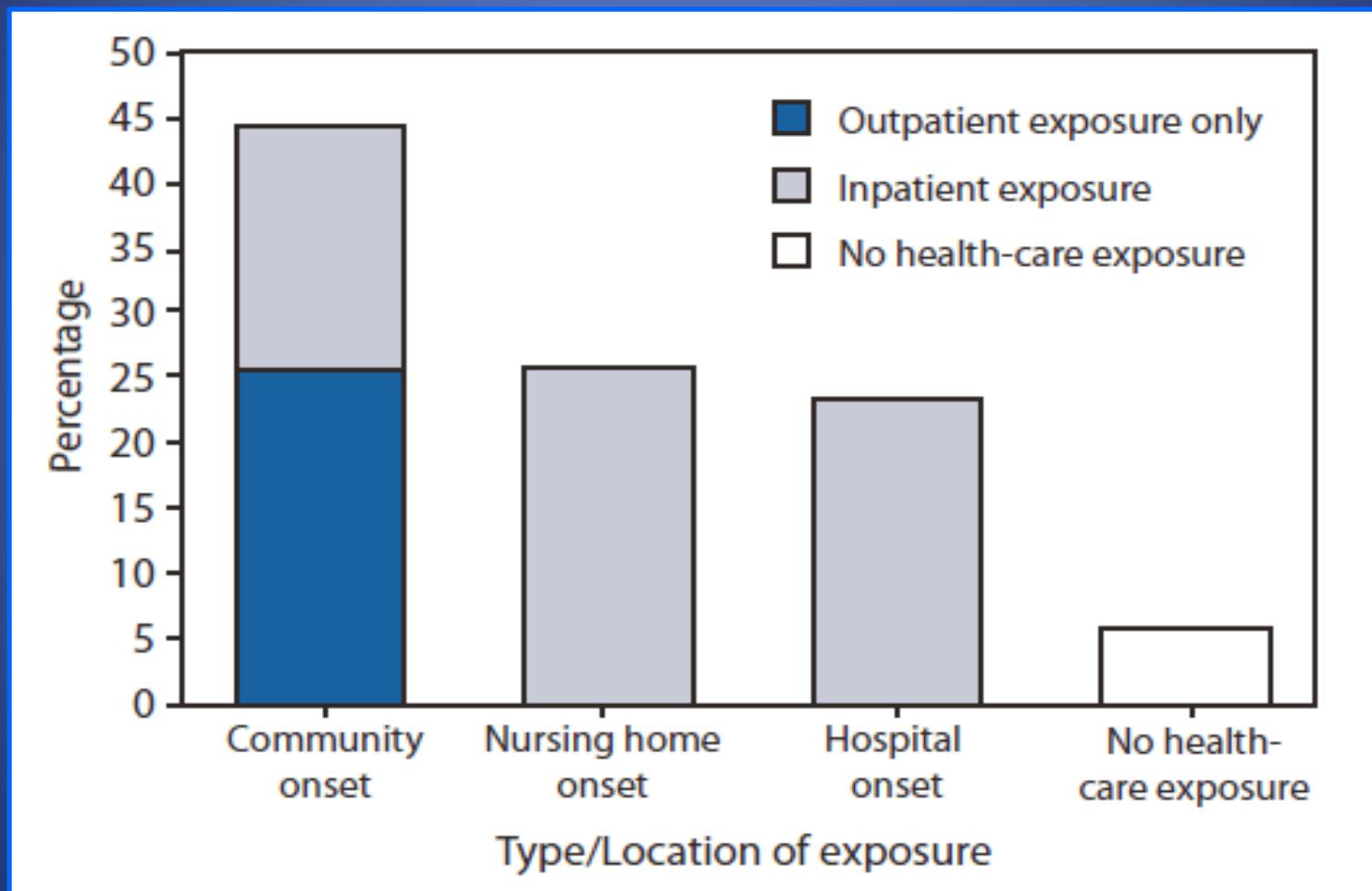
($P = .007$). BI patients had a recurrence rate of 27.4% (51 of 186), compared with a recurrence rate of 16.6% (66 of 397) in non-BI patients ($P = .002$). By multivariate analysis, BI infection was statistically significant as a risk factor for reduced cure (odds ratio [OR], 0.48; 95% confidence interval [CI], .27–.85; $P = .030$) and for increased recurrence (OR, 1.57; 95% CI, 1.01–2.45; $P = .046$).

Conclusions. The clinical cure rate of patients infected with the epidemic BI *C. difficile* strain is lower than the cure rate of those infected with non-BI strains whether treated with fidaxomicin or vancomycin. Similarly, the CDI recurrence rate is increased in patients with the BI strain compared with patients with other *C. difficile* strains.

C. difficile Infections per 1,000 Discharges in Illinois



Percentage of *C. difficile* Infection (CDI) Cases (N = 10,342), by Inpatient or Outpatient Status at Time of Stool Collection and Type/Location of Exposures* — U.S. Emerging Infections Program, 2010



Diagnostic Accuracy of Real-time Polymerase Chain Reaction in Detection of *Clostridium difficile* in the Stool Samples of Patients With Suspected *Clostridium difficile* Infection: A Meta-Analysis

Abhishek Deshpande,¹ Vinay Pasupuleti,² David D.K. Rolston,³ Anil Jain,^{4,5} Narayan Deshpande,⁶ Chaitanya Pant,⁷ and Adrian V. Hernandez⁸

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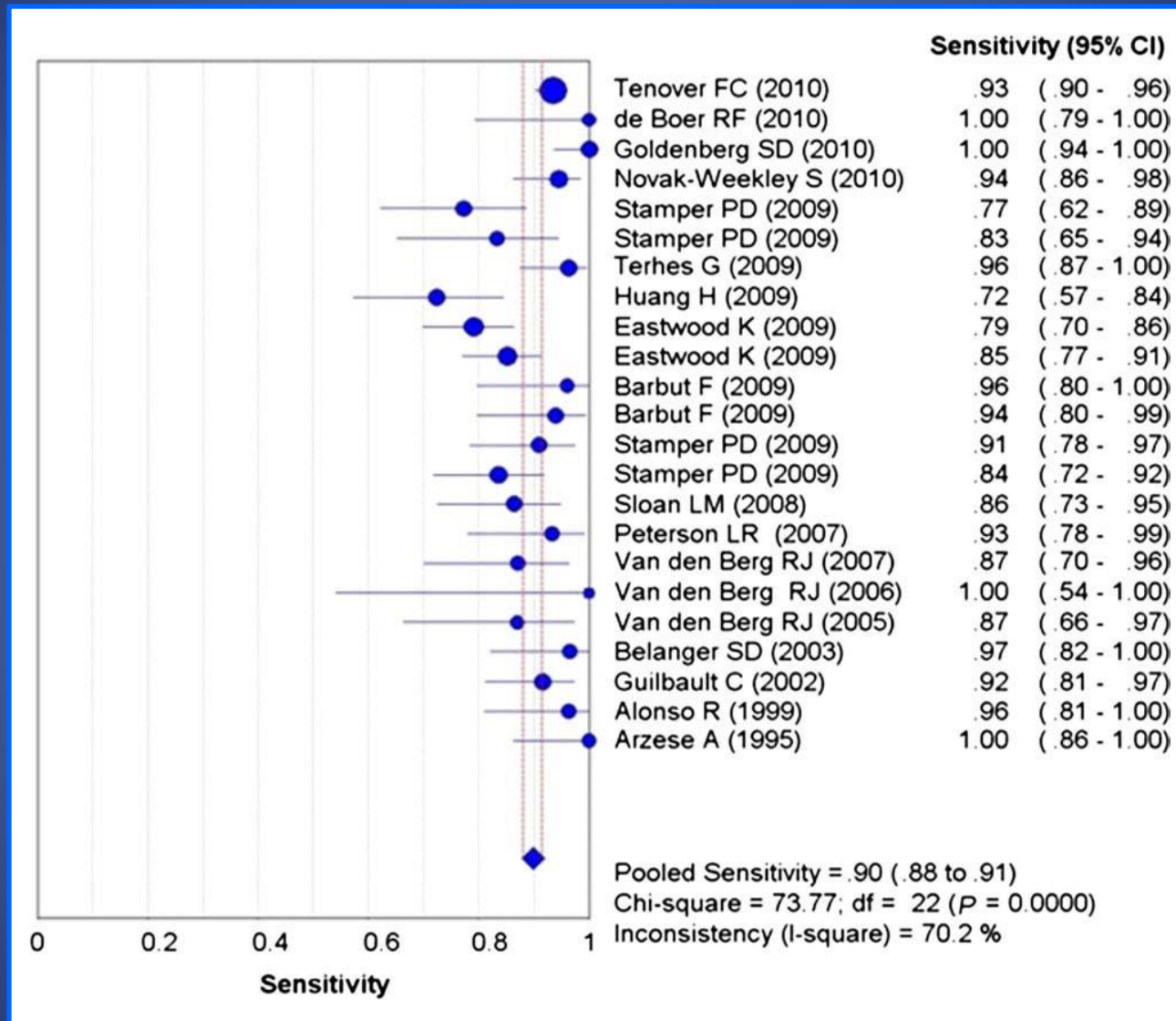
Background. Current detection methods for *Clostridium difficile* infection (CDI) can be time-consuming and have variable sensitivities. Real-time polymerase chain reaction (PCR) may allow earlier and more accurate diagnosis of CDI than other currently available diagnostic tests. A meta-analysis was performed to determine the diagnostic accuracy of real-time PCR.

Methods. We searched MEDLINE (Pubmed/Ovid) and 4 other online electronic databases (1995–2010) to identify diagnostic accuracy studies that compared PCR with cell culture cytotoxicity neutralization assay (CCNA) or anaerobic toxigenic culture (TC) of *C. difficile*. Screening for inclusion, data extraction, and quality assessment were carried out independently by 2 investigators and disagreements resolved. Data were combined by means of a random-effects model, and summary receiver operating characteristic curves and diagnostic odds ratios were calculated.

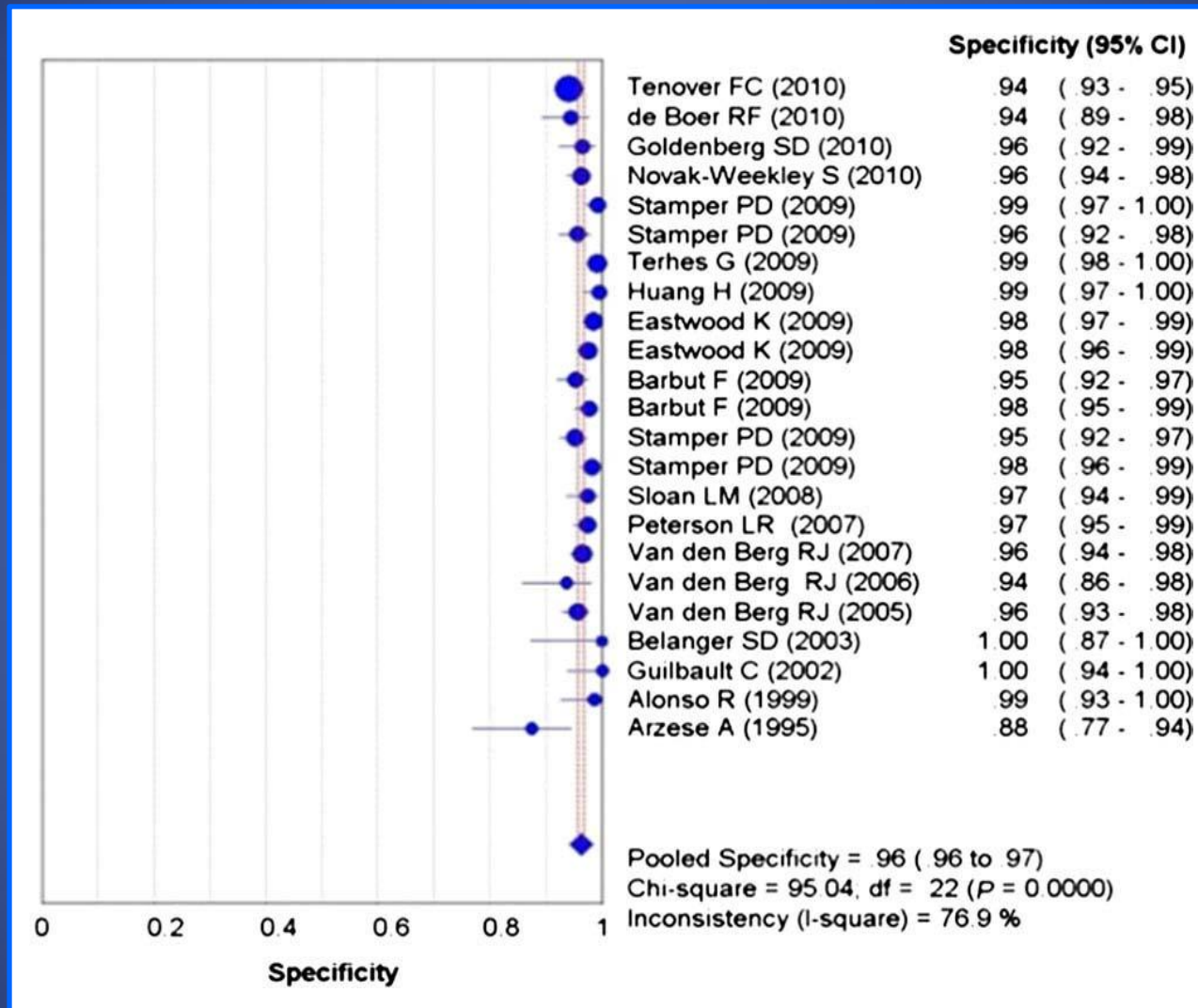
Results. Nineteen studies (7392 samples) met our inclusion criteria. The overall mean sensitivity of PCR was 90% (95% confidence interval [CI]: 88%–91%), specificity 96% (CI: 96%–97%), positive likelihood ratio 26.89 (CI: 20.81–34.74), negative likelihood ratio 0.11 (CI: .08–.15), diagnostic odds ratio 278.23 (CI: 213.56–362.50), and area under the curve 0.98 (CI: .98–.99). Test accuracy depended on the prevalence of *C. difficile* but not on the reference test used. At *C. difficile* prevalence of <10%, 10%–20% and >20% the positive predictive value and the negative predictive value were 71%, 79%, 93% and 99%, 98% and 96%, respectively.

Conclusions. Real-time PCR has a high sensitivity and specificity to confirm CDI. Overall diagnostic accuracy is variable and depends on CDI prevalence.

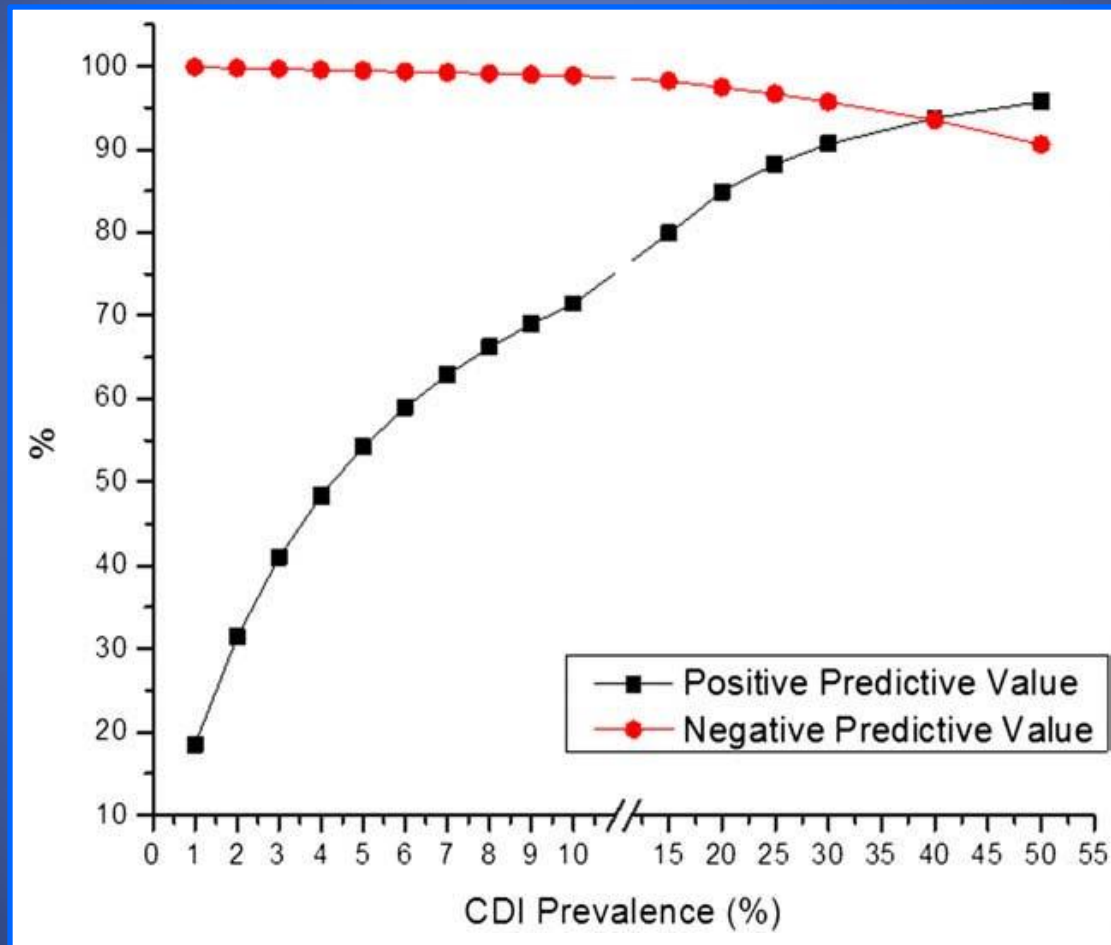
Forest Plot Estimates of Pooled Sensitivity



Forest Plot Estimates of Pooled Specificity



Theoretical Values of PPV and NPV for Increasing CDI Prevalence Calculated Using Pooled Sensitivity (90%) and Specificity (96%)



TOPICS

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INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

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A COMPENDIUM OF STRATEGIES TO PREVENT HEALTHCARE-ASSOCIATED INFECTIONS IN ACUTE CARE HOSPITALS

- 51 **Editorial: Primum Non Nocere** • Nalini Singh, MD, MPH; Patrick J. Brennan, MD; Michael Bell, MD
- 53 **Introduction: Improving Patient Safety Through Infection Control: A New Healthcare Imperative** • Deborah S. Yokoe, MD, MPH; David Classen, MD, MS
- SHEA/IDSA PRACTICE RECOMMENDATIONS**
- 512 **Executive Summary: A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals** • Deborah S. Yokoe, MD, MPH; Leonard A. Mermel, DO, ScM; Deverick J. Anderson, MD, MPH; Kathleen M. Arias, MS, CIC; Helen Burstin, MD; David P. Calfee, MD, MS; Susan E. Coffin, MD, MPH; Erik R. Dubberke, MD; Victoria Fraser, MD; Dale N. Gerding, MD; Frances A. Griffin, RRT, MPA; Peter Gross, MD; Keith S. Kaye, MD; Michael Klompas, MD; Evelyn Lo, MD; Jonas Marschall, MD; Lindsay Nicolle, MD; David A. Pegues, MD; Trish M. Perl, MD; Kelly Podgorny, RN, MS, CPHQ; Sanjay Saint, MD; Cassandra D. Salgado, MD, MS; Robert A. Weinstein, MD; Robert Wise, MD; David Classen, MD, MS
- 522 **Strategies to Prevent Central Line-Associated Bloodstream Infections in Acute Care Hospitals** • Jonas Marschall, MD; Leonard A. Mermel, DO, ScM; David Classen, MD, MS; Kathleen M. Arias, MS, CIC; Kelly Podgorny, RN, MS, CPHQ; Deverick J. Anderson, MD, MPH; Helen Burstin, MD; David P. Calfee, MD, MS; Susan E. Coffin, MD, MPH; Erik R. Dubberke, MD; Victoria Fraser, MD; Dale N. Gerding, MD; Frances A. Griffin, RRT, MPA; Peter Gross, MD; Keith S. Kaye, MD; Michael Klompas, MD; Evelyn Lo, MD; Lindsay Nicolle, MD; David A. Pegues, MD; Trish M. Perl, MD; Sanjay Saint, MD; Cassandra D. Salgado, MD, MS; Robert A. Weinstein, MD; Robert Wise, MD; Deborah S. Yokoe, MD, MPH
- 531 **Strategies to Prevent Ventilator-Associated Pneumonia in Acute Care Hospitals** • Susan E. Coffin, MD, MPH; Michael Klompas, MD; David Classen, MD, MS; Kathleen M. Arias, MS, CIC; Kelly Podgorny, RN, MS, CPHQ; Deverick J. Anderson, MD, MPH; Helen Burstin, MD; David P. Calfee, MD, MS; Erik R. Dubberke, MD; Victoria Fraser, MD; Dale N. Gerding, MD; Frances A. Griffin, RRT, MPA; Peter Gross, MD; Keith S. Kaye, MD; Evelyn Lo, MD; Jonas Marschall, MD; Leonard A. Mermel, DO, ScM; Lindsay Nicolle, MD; David A. Pegues, MD; Trish M. Perl, MD; Sanjay Saint, MD; Cassandra D. Salgado, MD, MS; Robert A. Weinstein, MD; Robert Wise, MD; Deborah S. Yokoe, MD, MPH
- 541 **Strategies to Prevent Catheter-Associated Urinary Tract Infections in Acute Care Hospitals** • Evelyn Lo, MD; Lindsay Nicolle, MD; David Classen, MD, MS; Kathleen M. Arias, MS, CIC; Kelly Podgorny, RN, MS, CPHQ; Deverick J. Anderson, MD, MPH; Helen Burstin, MD; David P. Calfee, MD, MS; Susan E. Coffin, MD, MPH; Erik R. Dubberke, MD; Victoria Fraser, MD; Dale N. Gerding, MD; Frances A. Griffin, RRT, MPA; Peter Gross, MD; Keith S. Kaye, MD; Michael Klompas, MD; Jonas Marschall, MD; Leonard A. Mermel, DO, ScM; David A. Pegues, MD; Trish M. Perl, MD; Sanjay Saint, MD; Cassandra D. Salgado, MD, MS; Robert A. Weinstein, MD; Robert Wise, MD; Deborah S. Yokoe, MD, MPH

CONTENTS CONTINUED INSIDE



THE OFFICIAL JOURNAL OF THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA

THE UNIVERSITY OF CHICAGO PRESS

Device-focused Prevention Guidelines for:

- CLABSI
- VAP
- cUTI
- SSI
- MRSA
- *C. difficile*

Evaluation of the national Cleanyourhands campaign to reduce *Staphylococcus aureus* bacteraemia and *Clostridium difficile* infection in hospitals in England and Wales by improved hand hygiene: four year, prospective, ecological, interrupted time series study

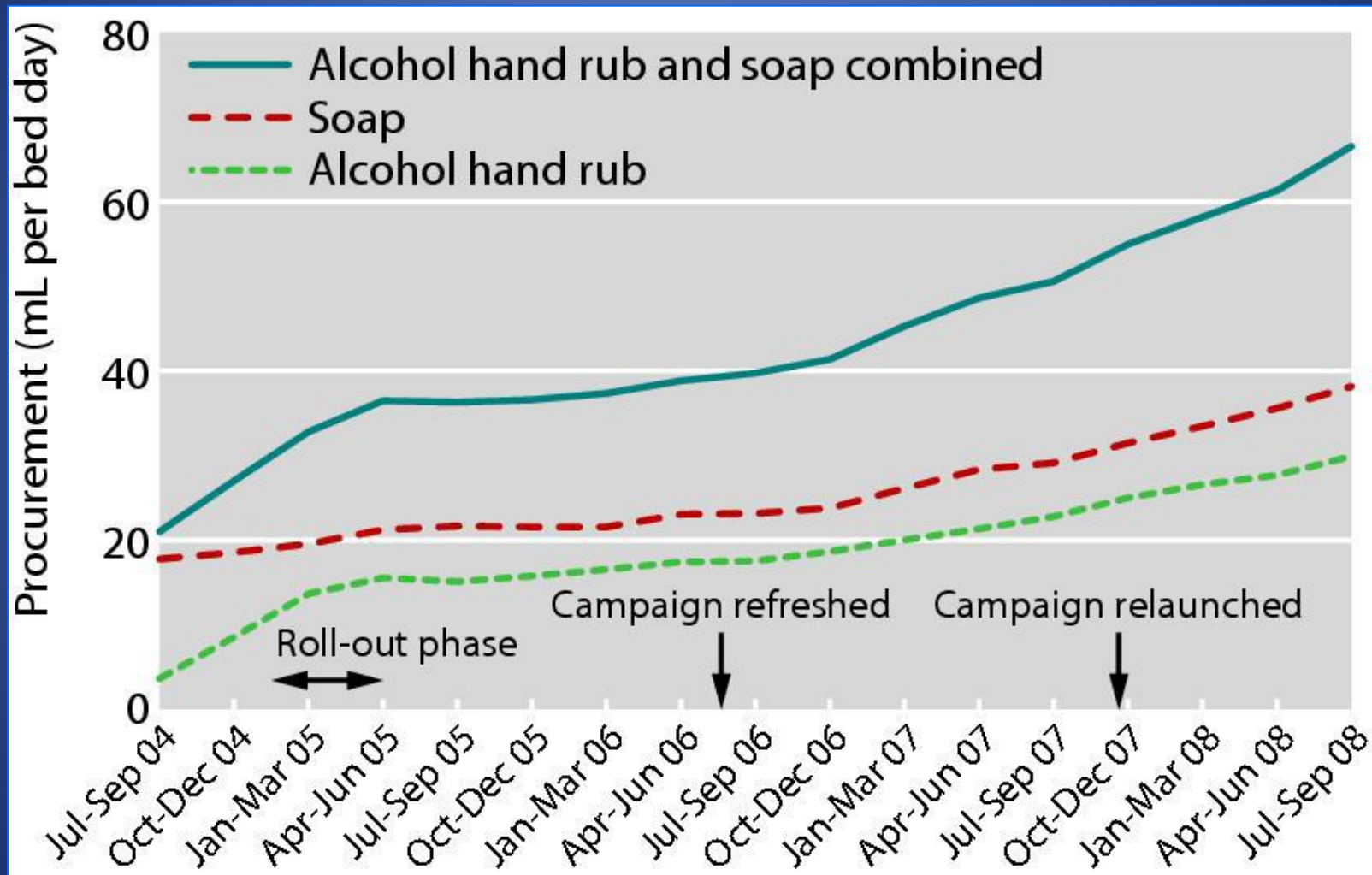


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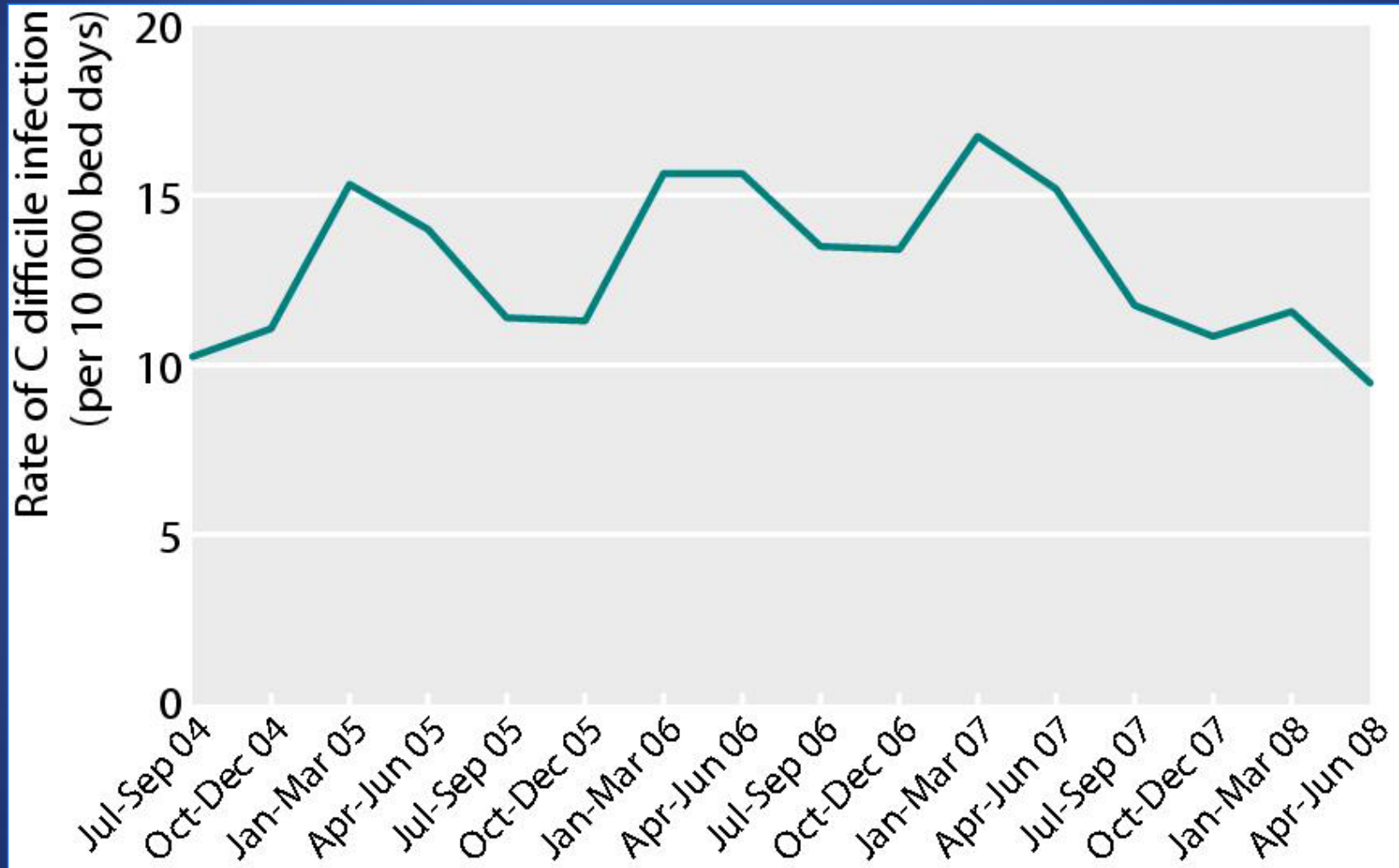
Sheldon Paul Stone *senior lecturer, stroke physician, and general physician for older people*¹, Christopher Fuller *project manager and nursing research fellow*², Joan Savage *research associate*², Barry Cookson *director*³, Andrew Hayward *senior lecturer*², Ben Cooper *mathematical modeller*^{5,10}, Georgia Duckworth *director*⁴, Susan Michie *professor of health psychology*⁶, Miranda Murray *consultant scientist*⁴, Annette Jeanes *consultant nurse in infection control*⁷, J Roberts *emeritus professor of economics of infectious disease*⁸, Louise Teare *consultant microbiologist and infection control doctor*⁹, Andre Charlett *head of department*¹⁰

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Estimated Use of Hand Hygiene Consumables, by Quarter



Estimated Quarterly Rate of *C. difficile* Infection (per 10,000 bed days)



HH – Unintended Consequence Caveat?

Efficacy of Selected Hand Hygiene Agents Used to Remove *Bacillus atrophaeus* (a Surrogate of *Bacillus anthracis*) From Contaminated Hands

David J. Weber, MD, MPH

Emily Sickbert-Bennett, MS

Maria F. Gergen, MT(ASCP)

William A. Rutala, PhD, MPH

ANTHRAX IS CAUSED BY *Bacillus anthracis*, a large gram-positive, aerobic, spore-forming bacillus.^{1,2} *Bacillus anthracis* has nearly a worldwide distribution, exists in the soil in the form of extremely stable spores, and causes infection in farm and wild animals who have grazed on contaminated land or ingested contaminated feed.² Human infection is most commonly acquired by contact with infected animals or with contaminated animal products such as wool, hide, hair, or bone; inhalation of spores; or by ingestion of contaminated meat.² Clinical infection depends on the route of transmission and includes cutaneous anthrax, inhalation or pulmonary anthrax, and gastrointestinal anthrax.

Bacillus anthracis has been recognized as a likely agent for bioterrorism because the spores are highly stable in the environment, virtually all persons are susceptible, infection can occur as a result of inhalation of spores, and considerable morbidity and mortality result from infection.³⁻⁵ During October and November 2001, 22 people

Context The intentional use of *Bacillus anthracis* transmitted via the US mail in October-November 2001 resulted in 22 people developing inhalation or cutaneous anthrax. Glove use with handwashing prior to and after contact with potential contaminated environmental surfaces and cutaneous lesions has been recommended. However, only limited data are available on the susceptibility of *B anthracis* to antiseptics.

Objective To evaluate the efficacy of several hand antiseptics (interventions) and soap and water (control) against *Bacillus atrophaeus*, a surrogate of *B anthracis*.

Design, Setting, and Participants Challenge study conducted among healthy adult volunteers, using the Standard Test Method for Evaluation of the Effectiveness of Health Care Professional Handwash Formulations (American Society for Testing and Materials E 1174-94) to determine the efficacy of various hand hygiene products at wash times of 10, 30, and 60 seconds. Volunteers were excluded if they had eczema, psoriasis, or other chronic skin conditions; nonintact skin; or allergies to any study agent. Study agents were a waterless rub containing 61% ethyl alcohol, a 2% chlorhexidine gluconate preparation, and an antibacterial microfiber towel that releases hypochlorite. A nonantimicrobial soap was used as a control.

Main Outcome Measure Reduction of *B atrophaeus* spores (\log_{10} CFU/mL) on contaminated hands.

Results Washes of 10, 30, and 60 seconds with either soap and water or 2% chlorhexidine gluconate eliminated 1.5 to 2.0 \log_{10} CFUs/mL of *B atrophaeus* spores at wash 3. Mean reductions (95% confidence intervals) with 10-, 30-, and 60-second washes with soap and water were 2.4 (2.2-2.5), 2.3 (2.2-2.4), and 2.1 (1.9-2.4) \log_{10} CFUs/mL, respectively; and with 2% chlorhexidine gluconate, 2.1 (2.0-2.3), 1.8 (1.5-2.0), and 1.7 (1.5-1.9) \log_{10} CFUs/mL, respectively. Handwashing with chlorine-containing towels was increasingly effective as the wipe time increased; reductions at 10, 30, and 60 seconds were 1.3 (1.1-1.5), 1.6 (1.2-2.0), and 2.2 (2.1-2.2) \log_{10} CFUs/mL, respectively. A waterless rub containing 61% ethyl alcohol was ineffective in eliminating *B atrophaeus* spores at all times tested (0 [-0.1 to 0.1], -0.2 [-0.3 to -0.1], and 0 [-0.2 to 0.2] \log_{10} CFUs/mL).

Conclusions In this evaluation of hand hygiene agents, handwashing with soap and water, 2% chlorhexidine gluconate, or chlorine-containing towels reduced the amount of *B atrophaeus* spore contamination, whereas use of a waterless rub containing ethyl alcohol was not effective in removing spores.

JAMA. 2003;289:1274-1277

www.jama.com

Prospective, Controlled Study of Vinyl Glove Use to Interrupt *Clostridium difficile* Nosocomial Transmission

STUART JOHNSON, M.D., DALE N. GERDING, M.D., MARY M. OLSON, R.N., MARY D. WEILER, R.N., RITA A. HUGHES, M.T., CONNIE R. CLABOTS, M.T., LANCE R. PETERSON, M.D. *Minneapolis, Minnesota*

PURPOSE: Despite recognition that *Clostridium difficile* diarrhea/colitis is a nosocomial infection, the manner in which this organism is transmitted is still not clear. Hands of health care workers have been shown to be contaminated with *C. difficile* and suggested as a vehicle of transmission. Therefore, we conducted a controlled trial of the use of disposable vinyl gloves by hospital personnel for all body substance contact (prior to the institution of universal body substance precautions) to study its effect on the incidence of *C. difficile* disease.


PATIENTS AND METHODS: The incidence of nosocomial *C. difficile* diarrhea was monitored by active surveillance for six months before and after an intensive education program regarding glove use on two hospital wards. The interventions included initial and periodic in-services, posters, and placement of boxes of gloves at every patient's bedside. Two comparable wards where no special intervention was instituted served as controls.

RESULTS: A decrease in the incidence of *C. difficile* diarrhea from 7.7 cases/1,000 patient discharges during the six months before intervention to 1.5/1,000 during the six months of intervention on the glove wards was observed ($p = 0.015$). No significant change in incidence was observed on the two control wards during the same period (5.7/

Clostridium difficile is an important cause of colitis and diarrhea in patients exposed to certain antibiotics [1,2]. In addition to the risk of antibiotic exposure, there is a growing consensus that *C. difficile* is acquired nosocomially. The prevalence of asymptomatic *C. difficile* carriage is high in hospitalized populations [2,3] and low in the general adult population [4,5], and numerous hospital outbreaks and case clusters have been reported [3,6-10]. The mode of *C. difficile* transmission, however, is not clear. *C. difficile* has been recovered from the environment and from potential fomites, but most studies show high recovery rates only in the immediate environment of clinical cases or from likely contaminated items such as toilet seats or bedpans [11,12]. The relative importance of fomite or environmental acquisition in the hospital transmission of *C. difficile* remains unknown.

C. difficile has also been recovered from the hands of hospital personnel [13-16]. Transmission of *C. difficile* from patient to patient via the hands of hospital personnel may be an important mode of transmission that could be interrupted by the use of gloves by personnel when handling body substances, particularly feces. To test this hypothesis, we studied the effect of intensive vinyl glove use for all body substance contact as a means to reduce the incidence of *C. difficile*-associated diarrhea and asymptomatic carriage on two hospital wards.



You wouldn't  step in it.

Why do you put
your hands in it?



Wear Gloves!!

C. difficile Diarrhea/1,000 Patients

	6 mo pre	6 mo during	P Value
Glove ward	7.7	1.5	0.02
Control ward	5.7	4.5	NS
Whole hospital	3.2	3.2	NS

Practices for Discontinuing *C. difficile* Infection Precautions in Canadian Health Care Facilities, by Facility Type (n = 662)

	Acute care (n=132), n(%)	Long-term care (n=530), n(%)
<u>Precautions discontinued</u>		
After patient has been asymptomatic for:		
48 hours	37 (28)	145 (27)
72 hours	49 (37)	172 (33)
Other	0 (0)	1 (0.2)
After treatment has been initiated	0 (0)	6 (1)
After treatment has ended and no relapse has been documented within 48 hours	23 (17)	132 (25)
Precautions are continued until discharge	1 (1)	16 (3)
Other policy for discontinuing	22 (17)	58 (11)

The Environment — A Better Product?

Significant impact of terminal room cleaning with bleach on reducing nosocomial *Clostridium difficile*

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Evanston, Illinois

Background: We were alerted to increased rates of *Clostridium difficile*-positive tests at all 3 hospitals in our health care system by MedMined Data Mining Surveillance Service, CareFusion (San Diego, CA). In response, an intervention of terminal room cleaning with dilute bleach was instituted to decrease the amount of *C difficile* environmental spore contamination from patients with *C difficile* infection (CDI).

Methods: The intervention consisted of replacing quaternary ammonium compound as a room cleaning agent with dilute bleach to disinfect rooms of patients with CDI upon discharge. All surfaces, floor to ceiling were wiped with dilute bleach applied with towels to thoroughly wet the surfaces. Daily room cleaning remained unchanged. Patients remained on *C difficile* contact isolation precautions until discharge. To determine the effectiveness of this program, rates of nosocomial CDI for all 3 hospitals were determined using the MedMined Virtual Surveillance Interface for 10 months prior to and 2 years after the cleaning intervention. Statistical significance was determined using Poisson regression analysis.

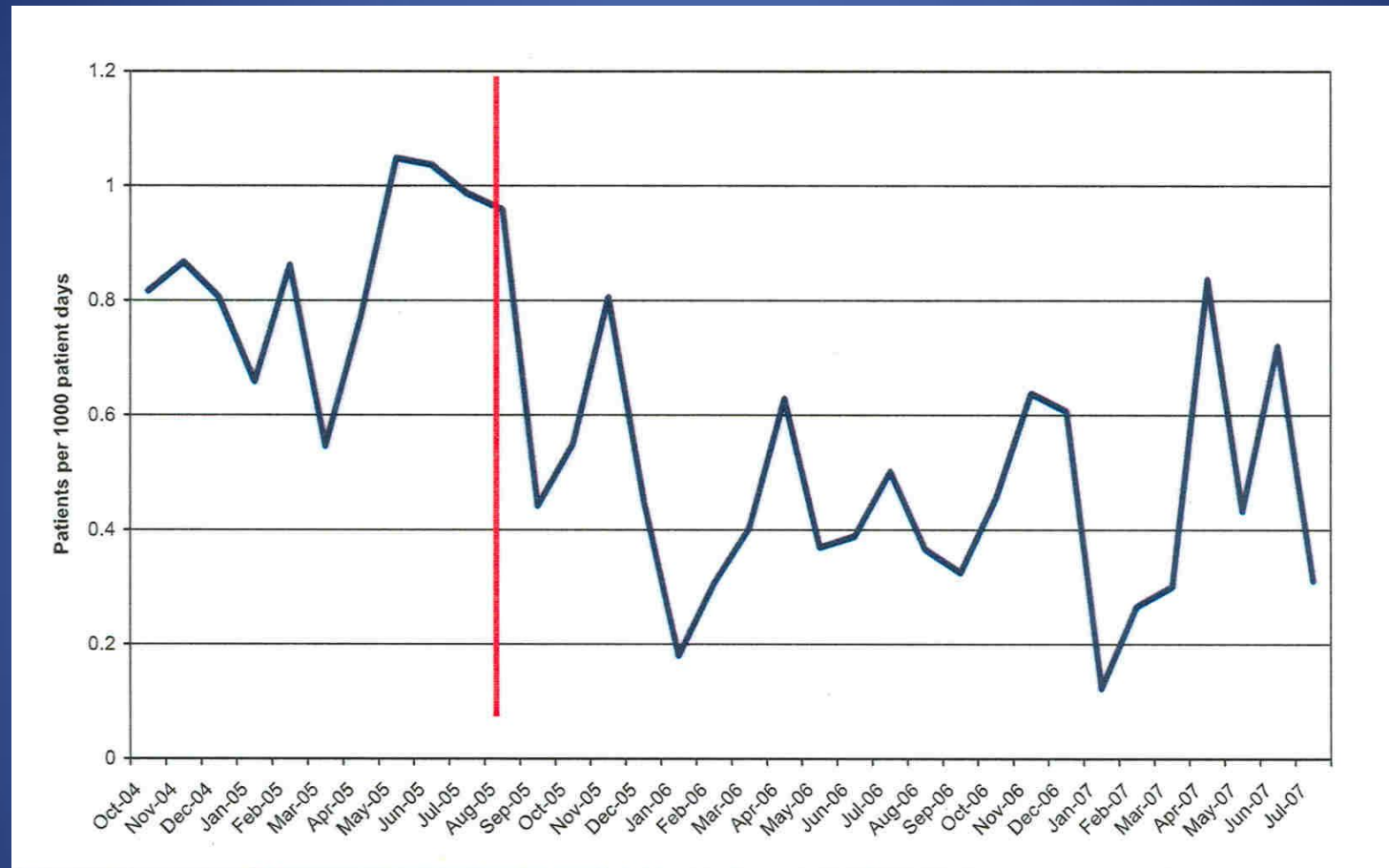
Results: There was a 48% reduction in the prevalence density of *C difficile* after the bleaching intervention (95% confidence interval: 36%-58%, $P < .0001$).

Conclusion: The implementation of a thorough, all-surface terminal bleach cleaning program in the rooms of patients with CDI has made a sustained, significant impact on reducing the rate of nosocomial CDI in our health care system.

Key Words: *Clostridium difficile*, bleach; terminal cleaning.

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Rate of *C. difficile* at Hospital Day 3 or Greater Before and After Bleach Cleaning Intervention



Rates decreased from 0.85 CDI cases/1000 patient-days in the preintervention period to 0.45 ($P < .0001$). Vertical line = Onset of bleach intervention.

Trumping Behavior with Technology

Impact of Hydrogen Peroxide Vapor Room Decontamination on *Clostridium difficile* Environmental Contamination and Transmission in a Healthcare Setting

OBJECTIVE. To determine whether hydrogen peroxide vapor (HPV) decontamination can reduce environmental contamination with and nosocomial transmission of *Clostridium difficile*.

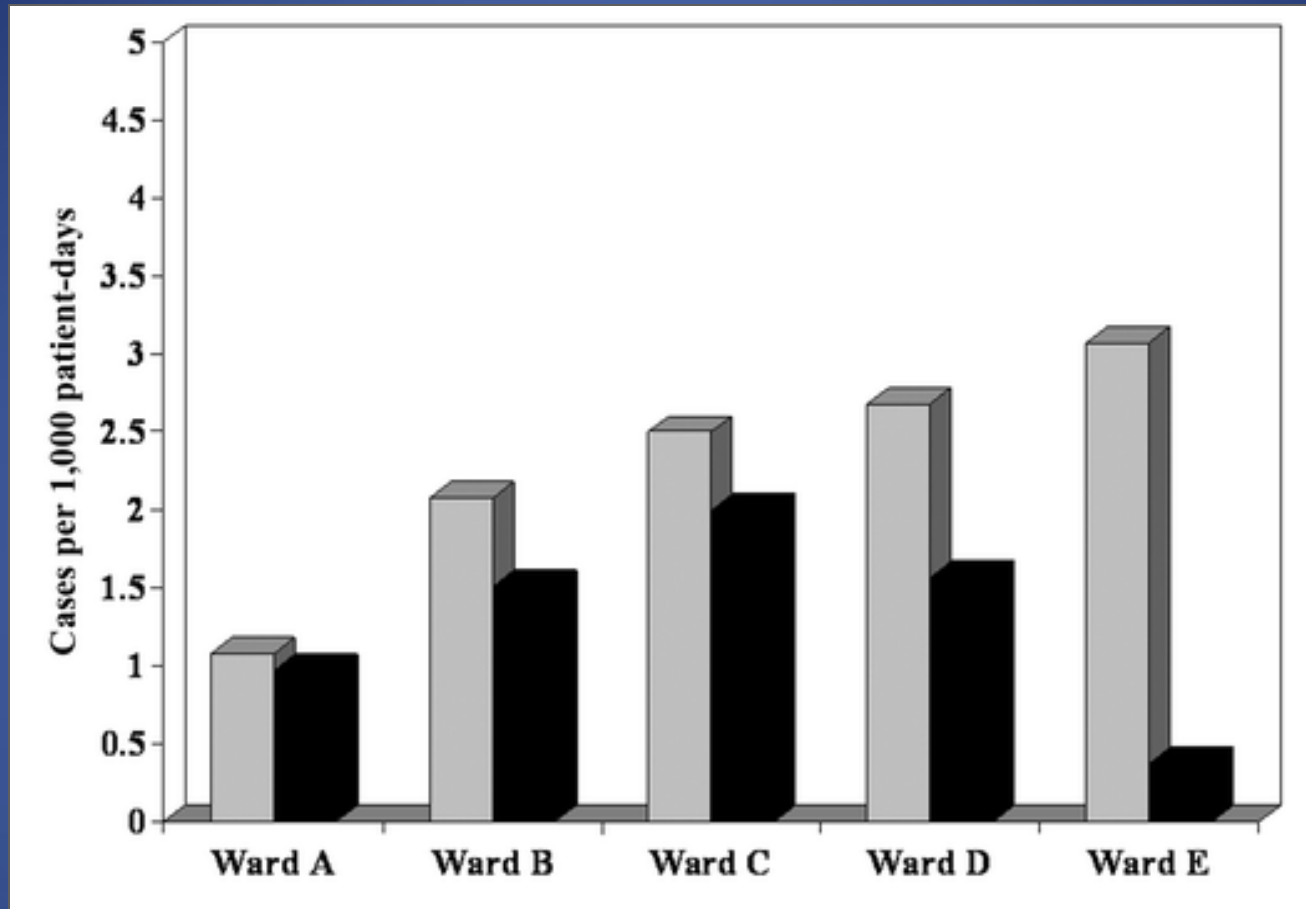
DESIGN. A prospective before-after intervention study.

SETTING. A hospital affected by an epidemic strain of *C. difficile*.

INTERVENTION. Intensive HPV decontamination of 5 high-incidence wards followed by hospital-wide decontamination of rooms vacated by patients with *C. difficile*-associated disease (CDAD). The preintervention period was June 2004 through March 2005, and the intervention period was June 2005 through March 2006.

RESULTS. Eleven (25.6%) of 43 cultures of samples collected by sponge from surfaces before HPV decontamination yielded *C. difficile*, compared with 0 of 37 cultures of samples obtained after HPV decontamination ($P < .001$). On 5 high-incidence wards, the incidence of nosocomial CDAD was significantly lower during the intervention period than during the preintervention period (1.28 vs 2.28 cases per 1,000 patient-days; $P = .047$). The hospital-wide CDAD incidence was lower during the intervention period than during the preintervention period (0.84 vs 1.36 cases per 1,000 patient-days; $P = .26$). In an analysis limited to months in which the epidemic strain was present during both the preintervention and the intervention periods, CDAD incidence was significantly lower during the intervention period than during the preintervention period (0.88 vs 1.89 cases per 1,000 patient-days; $P = .047$).

CONCLUSIONS. HPV decontamination was efficacious in eradicating *C. difficile* from contaminated surfaces. Further studies of the impact of HPV decontamination on nosocomial transmission of *C. difficile* are warranted.



Incidence of nosocomial *Clostridium difficile*-associated disease on 5 wards (A–E) that underwent intensive hydrogen peroxide vapor decontamination, during the preintervention period (gray bars; June 2004 through March 2005) and the intervention period (black bars; June 2005 through March 2006).

Comparison of the Microbiological Efficacy of Hydrogen Peroxide Vapor and Ultraviolet Light Processes for Room Decontamination

Nancy L. Havill, MT;¹ Brent A. Moore, PhD;² John M. Boyce, MD^{1,2}

OBJECTIVE. To compare the microbiological efficacy of hydrogen peroxide vapor (HPV) and ultraviolet radiation (UVC) for room decontamination.

DESIGN. Prospective observational study.

SETTING. 500-bed teaching hospital.

METHODS. HPV and UVC processes were performed in 15 patient rooms. Five high-touch sites were sampled before and after the processes and aerobic colony counts (ACCs) were determined. Carrier disks with $\sim 10^6$ *Clostridium difficile* (CD) spores and biological indicators (BIs) with 10^4 and 10^6 *Geobacillus stearothermophilus* spores were placed in 5 sites before decontamination. After decontamination, CD log reductions were determined and BIs were recorded as growth or no growth.

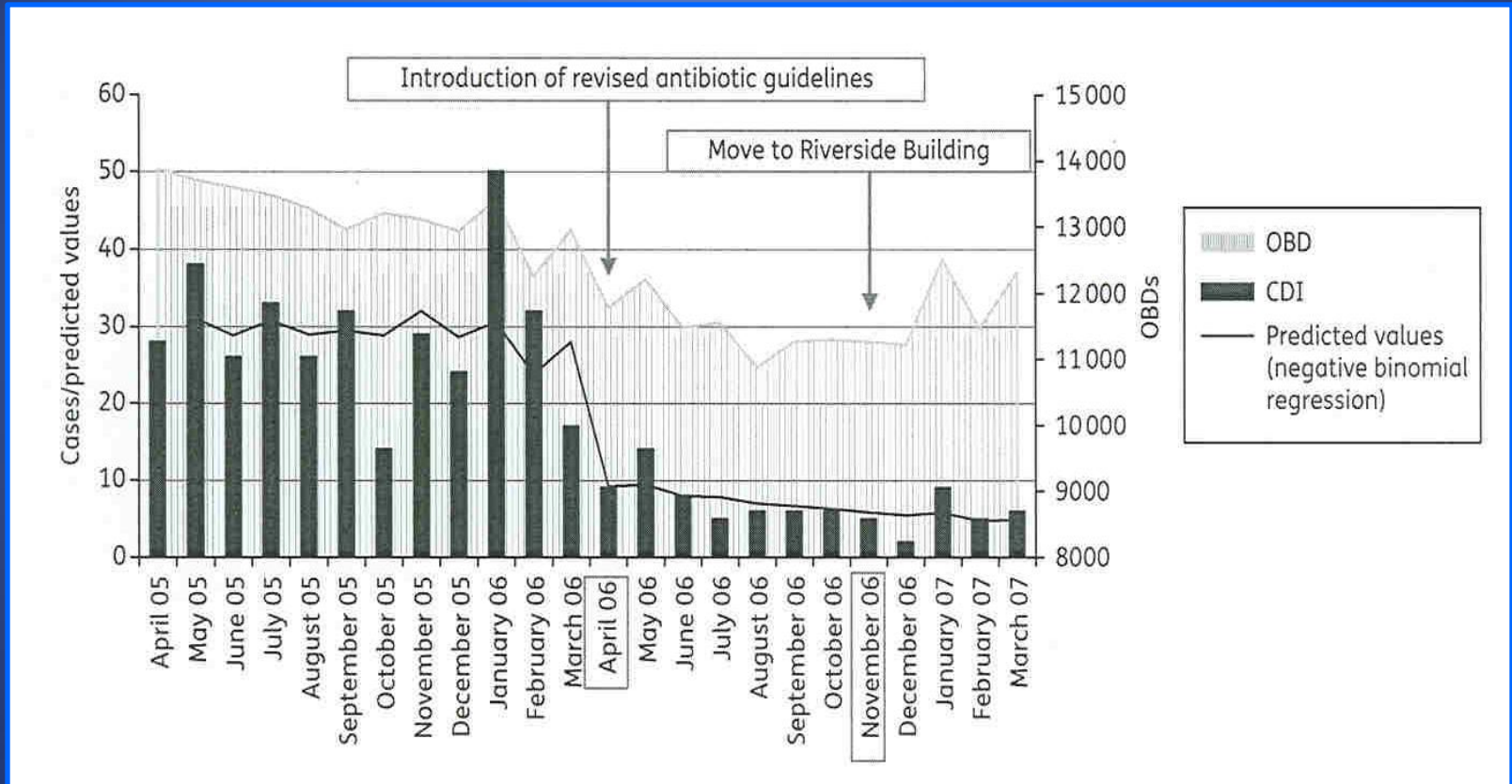
RESULTS. 93% of ACC samples that had growth before HPV did not have growth after HPV, whereas 52% of sites that had growth before UVC did not have growth after UVC ($P < .0001$). The mean CD log reduction was >6 for HPV and ~ 2 for UVC. After HPV 100% of the 10^4 BIs did not grow, and 22% did not grow after UVC, with a range of 7%–53% for the 5 sites. For the 10^6 BIs, 99% did not grow after HPV and 0% did not grow after UVC. Sites out of direct line of sight were significantly more likely to show growth after UVC than after HPV. Mean cycle time was 153 (range, 140–177) min for HPV and 73 (range, 39–100) min for UVC ($P < .0001$).

CONCLUSION. Both HPV and UVC reduce bacterial contamination, including spores, in patient rooms, but HPV is significantly more effective. UVC is significantly less effective for sites that are out of direct line of sight.

Infect Control Hosp Epidemiol 2012;33(5):507-512

ANTIBIOTIC STEWARDSHIP

Monthly Count Data for New Cases of CDI and Number of OBDs Before and After Introduction of Revised Antibiotic Guidelines



OBD = occupied bed days.

Probiotics for the Prevention and Treatment of Antibiotic-Associated Diarrhea

A Systematic Review and Meta-analysis

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THE USE OF ANTIBIOTICS THAT DISTURB the gastrointestinal flora is associated with clinical symptoms such as diarrhea, which occurs in as many as 30% of patients.^{1,2} Symptoms range from mild and self-limiting to severe, particularly in *Clostridium difficile* infections, and antibiotic-associated diarrhea (AAD) is an important reason for nonadherence with antibiotic treatment.³

Probiotics are microorganisms intended to have a health benefit when consumed. Synbiotics refer to preparations in which probiotic organisms and prebiotics (nondigestible food ingredients that may benefit the host by selectively stimulating bacteria in the colon) are combined.

Context Probiotics are live microorganisms intended to confer a health benefit when consumed. One condition for which probiotics have been advocated is the diarrhea that is a common adverse effect of antibiotic use.

Objective To evaluate the evidence for probiotic use in the prevention and treatment of antibiotic-associated diarrhea (AAD).

Data Sources Twelve electronic databases were searched (DARE, Cochrane Library of Systematic Reviews, CENTRAL, PubMed, EMBASE, CINAHL, AMED, MANTIS, TOXLINE, ToxFILE, NTIS, and AGRICOLA) and references of included studies and reviews were screened from database inception to February 2012, without language restriction.

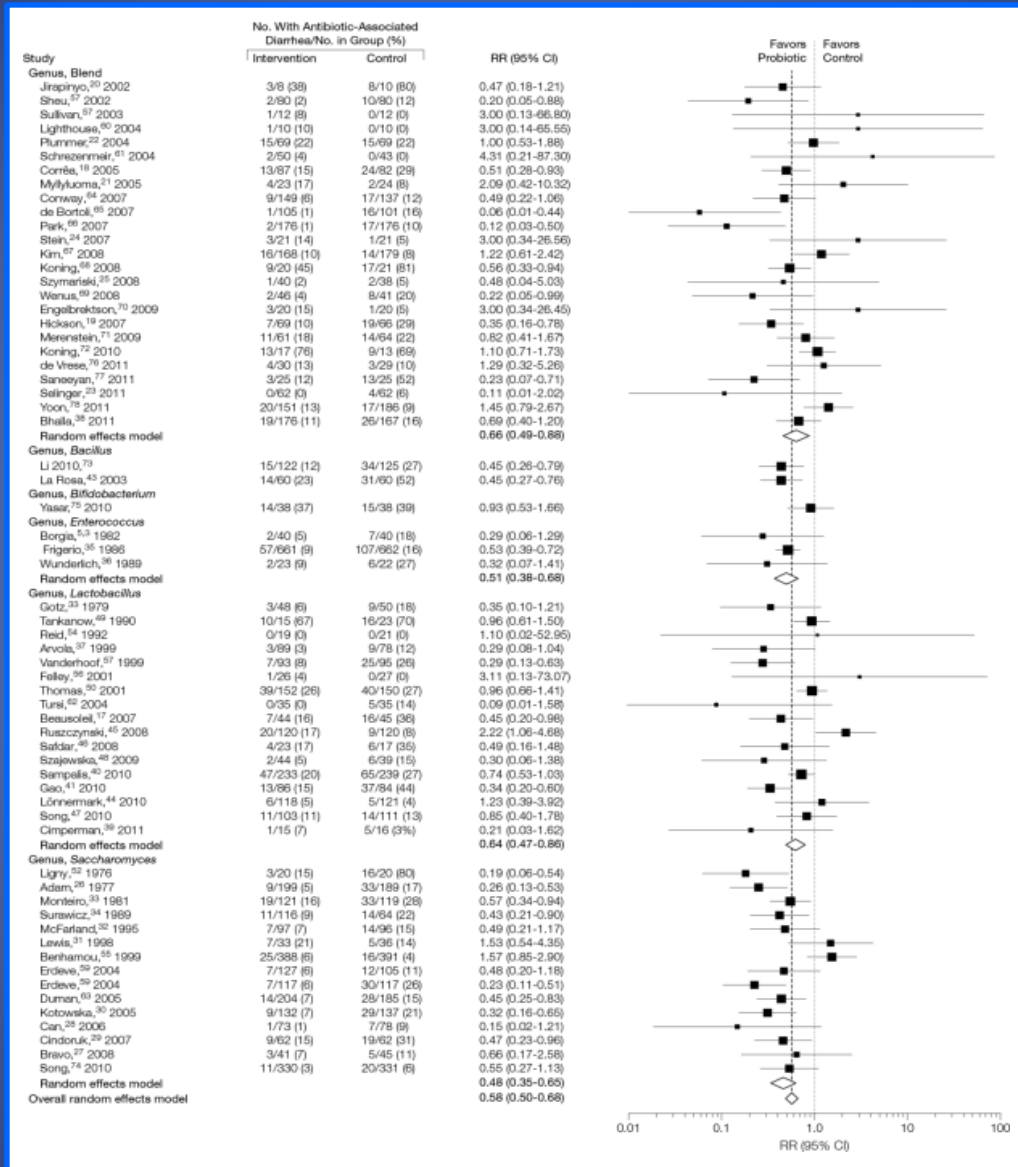
Study Selection Two independent reviewers identified parallel randomized controlled trials (RCTs) of probiotics (*Lactobacillus*, *Bifidobacterium*, *Saccharomyces*, *Streptococcus*, *Enterococcus*, and/or *Bacillus*) for the prevention or treatment of AAD.

Data Extraction Two independent reviewers extracted the data and assessed trial quality.

Results A total of 82 RCTs met inclusion criteria. The majority used *Lactobacillus*-based interventions alone or in combination with other genera; strains were poorly documented. The pooled relative risk in a DerSimonian-Laird random-effects meta-analysis of 63 RCTs, which included 11 811 participants, indicated a statistically significant association of probiotic administration with reduction in AAD (relative risk, 0.58; 95% CI, 0.50 to 0.68; $P < .001$; I^2 , 54%; [risk difference, -0.07; 95% CI, -0.10 to -0.05], [number needed to treat, 13; 95% CI, 10.3 to 19.1]) in trials reporting on the number of patients with AAD. This result was relatively insensitive to numerous subgroup analyses. However, there exists significant heterogeneity in pooled results and the evidence is insufficient to determine whether this association varies systematically by population, antibiotic characteristic, or probiotic preparation.

Conclusions The pooled evidence suggests that probiotics are associated with a reduction in AAD. More research is needed to determine which probiotics are associated with the greatest efficacy and for which patients receiving which specific antibiotics.

Efficacy Results of Probiotic Use by Study



TOPICS

- Epidemiology & Diagnosis
- Prevention
 - Hand Hygiene
 - Isolation & Gloving
 - Environmental Cleaning
 - Antibiotic Stewardship
 - Probiotics
- Treatment
 - Oral Antimicrobials; Treatment as Prevention
 - Fecal Bacteriotherapy
 - Surgical Options
- Putting It All Together: ICE CDI!

Treatment Options

A Comparison of Vancomycin and Metronidazole for the Treatment of *Clostridium difficile*-Associated Diarrhea, Stratified by Disease Severity

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¹University of Illinois at Chicago, Chicago, and ²Saint Francis Hospital, Evanston, Illinois

Background. The incidence and severity of *Clostridium difficile*-associated diarrhea (CDAD) has been increasing, and there have been recent reports of metronidazole treatment failure. Metronidazole is still commonly used as first-line treatment for CDAD but has never been compared with vancomycin in a prospective, randomized, double-blind, placebo-controlled trial. We conducted such a trial, stratifying patients according to disease severity, to investigate whether one agent was superior for treating either mild or severe disease.

Methods. From October 1994 through June 2002, patients with CDAD were stratified according to whether they had mild or severe disease based on clinical criteria and were randomly assigned to receive oral metronidazole (250 mg 4 times per day) or oral vancomycin (125 mg 4 times per day) for 10 days. Both groups received an oral placebo in addition to the study drug. Patients were followed up for 21 days to assess cure, treatment failure, relapse, or intolerance.

Results. One hundred seventy-two patients were enrolled, and 150 of these patients successfully completed the trial. Among the patients with mild CDAD, treatment with metronidazole or vancomycin resulted in clinical cure in 90% and 98% of the patients, respectively ($P = .36$). Among the patients with severe CDAD, treatment with metronidazole or vancomycin resulted in clinical cure in 76% and 97% of the patients, respectively ($P = .02$). Clinical symptoms recurred in 15% of the patients treated with metronidazole and 14% of those treated with vancomycin.

Conclusions. Our findings suggest that metronidazole and vancomycin are equally effective for the treatment of mild CDAD, but vancomycin is superior for treating patients with severe CDAD.

TREATMENT AS PREVENTION?

Rates of Relapse of *C. difficile*-associated Diarrhea, by Disease Severity and Treatment

Disease severity	No. of patients who experienced relapse/no. of patients who were cured (%)			<i>P</i> ^a
	Mtz group	Vm group	Total	
Mild	3/37 (8)	2/39 (5)	5/76 (7)	.67
Severe	6/29 (21)	3/30 (10)	9/59 (15)	.30
All	9/66 (14)	5/69 (7)	14/135 (10)	.27

NOTE. Mtz, metronidazole; Vm, vancomycin.

^a *P* values were calculated using Fisher's exact test.

Fidaxomicin versus Vancomycin for *Clostridium difficile* Infection

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Karl Weiss, M.D., Arnold Lentnek, M.D., Yoav Golan, M.D.,
Sherwood Gorbach, M.D., Pamela Sears, Ph.D., and Youe-Kong Shue, Ph.D.,
for the OPT-80-003 Clinical Study Group*

ABSTRACT

BACKGROUND

Clostridium difficile infection is a serious diarrheal illness associated with substantial morbidity and mortality. Patients generally have a response to oral vancomycin or metronidazole; however, the rate of recurrence is high. This phase 3 clinical trial compared the efficacy and safety of fidaxomicin with those of vancomycin in treating *C. difficile* infection.

METHODS

Adults with acute symptoms of *C. difficile* infection and a positive result on a stool toxin test were eligible for study entry. We randomly assigned patients to receive fidaxomicin (200 mg twice daily) or vancomycin (125 mg four times daily) orally for 10 days. The primary end point was clinical cure (resolution of symptoms and no need for further therapy for *C. difficile* infection as of the second day after the end of the course of therapy). The secondary end points were recurrence of *C. difficile* infection (diarrhea and a positive result on a stool toxin test within 4 weeks after treatment) and global cure (i.e., cure with no recurrence).

RESULTS

A total of 629 patients were enrolled, of whom 548 (87.1%) could be evaluated for the per-protocol analysis. The rates of clinical cure with fidaxomicin were noninferior to those with vancomycin in both the modified intention-to-treat analysis (88.2% with fidaxomicin and 85.8% with vancomycin) and the per-protocol analysis (92.1% and 89.8%, respectively). Significantly fewer patients in the fidaxomicin group than in the vancomycin group had a recurrence of the infection, in both the modified intention-to-treat analysis (15.4% vs. 25.3%, $P=0.005$) and the per-protocol analysis (13.3% vs. 24.0%, $P=0.004$). The lower rate of recurrence was seen in patients with non-North American Pulsed Field type 1 strains. The adverse-event profile was similar for the two therapies.

CONCLUSIONS

The rates of clinical cure after treatment with fidaxomicin were noninferior to those after treatment with vancomycin. Fidaxomicin was associated with a significantly lower rate of recurrence of *C. difficile* infection associated with non-North American Pulsed Field type 1 strains. (Funded by Optimer Pharmaceuticals; ClinicalTrials.gov number, NCT00314951.)

Comparative Effectiveness of *C. difficile* Treatments as Prevention

Context

Several antibiotics are available for treatment of *Clostridium difficile* infections.

Contribution

This comparative effectiveness review of 11 randomized trials involving adults with *C. difficile* found that initial cure rates did not statistically significantly differ for fidaxomicin, vancomycin, and metronidazole. Recurrent disease was common with all agents but was less frequent with fidaxomicin (15%) than with vancomycin (25%).

Caution

There were few studies, and most had small sample sizes. Studies used heterogeneous definitions for cure. Potential harms were inconsistently reported.

Implication

Any of several agents could be used for initial treatment of *C. difficile* infection. Fidaxomicin may be a superior agent for recurrent infection.

— The Editors

More Manipulating the Human Microbiome

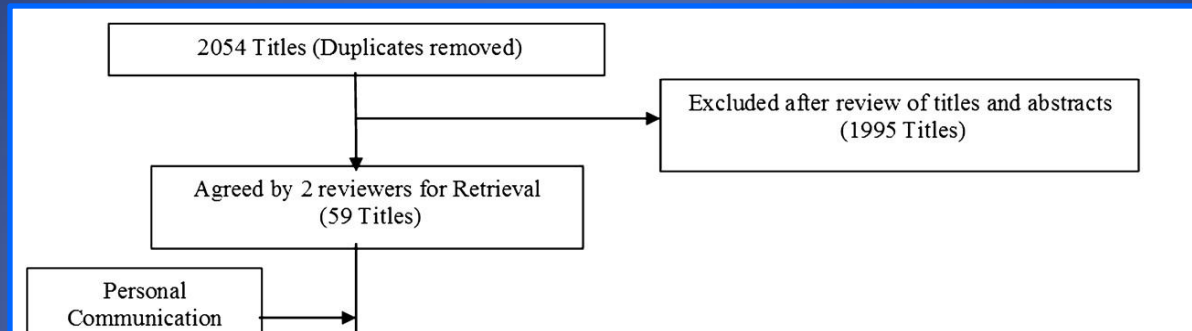
Systematic Review of Intestinal Microbiota Transplantation (Fecal Bacteriotherapy) for Recurrent *Clostridium difficile* Infection

Ethan Gough,¹ Henna Shaikh,² and Ameer R. Manges^{1,3}

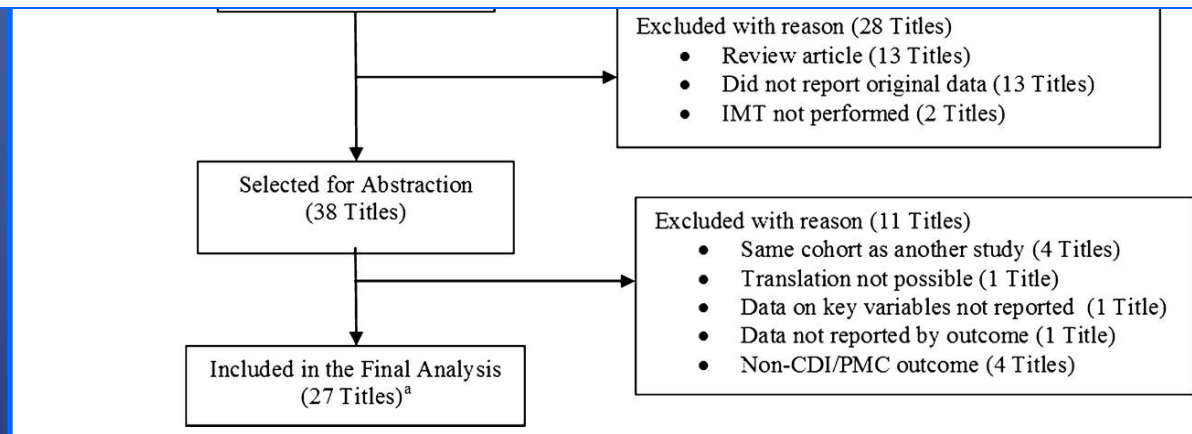
Departments of ¹Epidemiology Biostatistics and Occupational Health, and ²Biology, McGill University, and ³Research Institute of the McGill University Health Centre, Montreal, Quebec, Canada

Clostridium difficile infection (CDI) is a gastrointestinal disease believed to be causally related to perturbations to the intestinal microbiota. When standard treatment has failed, intestinal microbiota transplantation (IMT) is an alternative therapy for patients with CDI. IMT involves infusing intestinal microorganisms (in a suspension of healthy donor stool) into the intestine of a sick patient to restore the microbiota. However, protocols and reported efficacy for IMT vary. We conducted a systematic literature review of IMT treatment for recurrent CDI and pseudomembranous colitis. In 317 patients treated across 27 case series and reports, IMT was highly effective, showing disease resolution in 92% of cases. Effectiveness varied by route of instillation, relationship to stool donor, volume of IMT given, and treatment before infusion. Death and adverse events were uncommon. These findings can guide physicians interested in implementing the procedure until better designed studies are conducted to confirm best practices.

Flow Diagram of Study Selection — 27 Unique Publications Provided 28 Abstractions



In 317 patients treated across 27 case series and reports, IMT was highly effective, showing disease resolution in 92% of cases



Surgical Options

Diverting Loop Ileostomy and Colonic Lavage

An Alternative to Total Abdominal Colectomy for the Treatment of Severe, Complicated Clostridium difficile Associated Disease

Matthew D. Neal, MD,* John C. Alverdy, MD,† Daniel E. Hall, MD,*‡
Richard L. Simmons, MD,* and Brian S. Zuckerbraun, MD*‡

Objective: To determine whether a minimally invasive, colon-preserving approach could serve as an alternative to total colectomy in the treatment of severe, complicated *Clostridium difficile*-associated disease (CDAD).

Background: *C. difficile* is a significant cause of morbidity and mortality worldwide. Most cases will respond to antibiotic therapy, but 3% to 10% of patients progress to a severe, complicated, or “fulminant” state of life-threatening systemic toxicity. Although the advocated surgical treatment of total abdominal colectomy with end ileostomy improves survival in severe, complicated CDAD, outcomes remain poor with associated mortality rates ranging from 35% to 80%.

Methods: All patients who were diagnosed with severe, complicated (“fulminant”) CDAD and were treated at the University of Pittsburgh Medical Center or VA Pittsburgh Healthcare System between June 2009 and January 2011 were treated with this novel approach. The surgical approach involved creation of a loop ileostomy, intraoperative colonic lavage with warmed polyethylene glycol 3350/electrolyte solution via the ileostomy and postoperative antegrade instillation of vancomycin flushes via the ileostomy. The primary end point for the study was resolution of CDAD. The matching number of patients treated with colectomy for CDAD preceding the initiation of this current treatment strategy was analyzed for historical comparison.

Results: Forty-two patients were treated during this time period. There was no significant difference in age, sex, pharmacologic immunosuppression, and Acute Physiology and Chronic Health Evaluation-II scores between our current cohort and historical controls. The operation was accomplished laparoscopically in 35 patients (83%). This treatment strategy resulted in reduced mortality compared to our historical population (19% vs 50%; odds ratio, 0.24; $P = 0.006$). Preservation of the colon was achieved in 39 of 42 patients (93%).

Conclusions: Loop ileostomy and colonic lavage are an alternative to colectomy in the treatment of severe, complicated CDAD resulting in reduced morbidity and preservation of the colon.

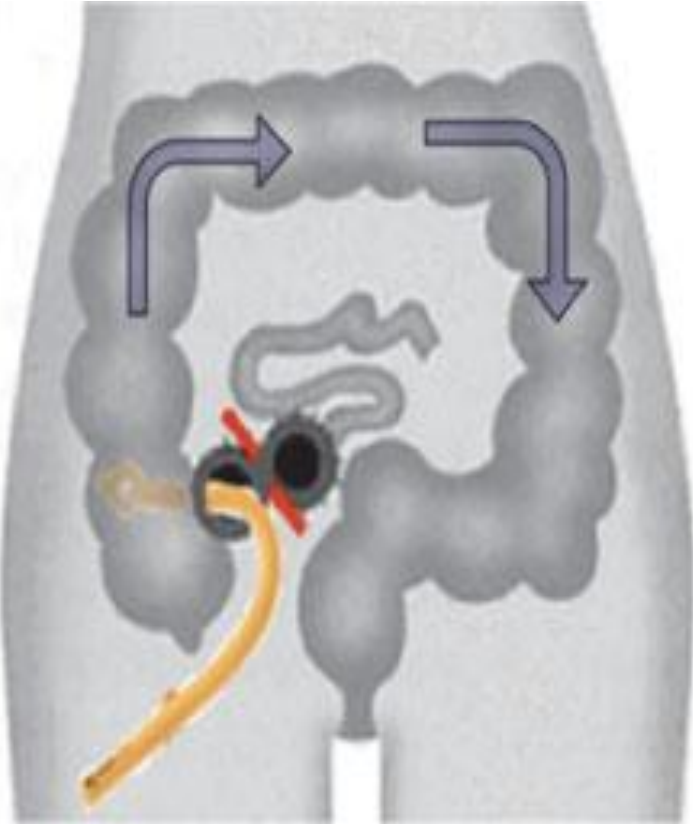
will respond to oral antibiotic therapy, but 3% to 10% of patients with CDAD progress to a severe, complicated, or “fulminant” state of life-threatening systemic toxicity.^{8–10}

The indications for surgical management of patients with CDAD are not clearly defined; however, most advocate surgical intervention in patients with worsening clinical examinations or peritonitis or patients in shock.¹¹ Total abdominal colectomy with end ileostomy has been advocated as the operation of choice and has been demonstrated to marginally improve survival compared to nonoperative management in these critically ill patients.^{10,12} This operation was undertaken even before the etiology of the CDAD was known, primarily because of its superficial similarities to “toxic megacolon” as a late acute manifestation of inflammatory bowel disease.

Colectomy for severe, complicated CDAD has many disadvantages. Most notably, mortality rates in small series continue to range from 35% to 80%.^{8,10,12–15} In addition, laparotomy and subtotal or total abdominal colectomy can result in significant morbidity, and survivors often require permanent ileostomy. Furthermore, there are no universally accepted definitions of severity and physicians cannot predict which patients will progress to fulminant disease.^{7,10,15,16} Although standardized strategies of medical management for mild or moderate disease have long been established, the approaches to the treatment of severe and severe complicated (fulminant) CDAD have remained tentative and fragmented.^{8,17–19}

We now present our experience with an alternative surgical approach to the management of severe, complicated CDAD, which may prove a safer and simpler option. On the basis of the nature of the disease as a bacterial toxin-mediated mucosal inflammatory process with delayed and indirect systemic threats to life, we hypothesized that minimally invasive ileal diversion with intraoperative colonic lavage using a high-volume polyethylene glycol or electrolyte solution will clear *C. difficile* infection, resulting in eradication of CDAD.

Operative Treatment Strategy for Loop Ileostomy and Colonic Lavage for Severe, Complicated *C. difficile*-associated Disease



1. Creation of diverting loop ileostomy.
2. Intraoperative antegrade colonic lavage with 8 liters of warmed PEG3350/electrolyte solution via ileostomy.
3. Postoperative antegrade colonic enemas with vancomycin (500 mg in 500 mL X 10 days) via ileostomy.

Demographics and Outcomes in Patients with Severe, Complicated CDAD Treated with Ileostomy or Colonic Lavage Versus Colectomy

	Ileostomy/Lavage	Colectomy	<i>P</i>
Age, y	65.3 ± 13	62.1 ± 14	0.28
Sex	45% women	45% women	1.0
APACHE-II (mean ± SD)	29.7 ± 5.5	28.5 ± 7.1	0.39
White blood cell count (mean ± SD)	25.4 ± 12.1	27.1 ± 13.2	0.54
Band count (mean ± SD)	21.4 ± 12.2	21.3 ± 12.9	0.97
Albumin (mean ± SD)	2.0 ± 0.8	2.2 ± 0.8	0.26
Intensive care unit	38/42 (90%)	38/42 (90%)	0.64
Intubated	27/42 (64%)	26/42 (62%)	0.82
Vasopressors	31/42 (74%)	32/42 (76%)	0.81
Immunosuppression	19/42 (45%)	17/42 (40%)	0.66
Postoperative death	8/42 (19%)	21/42 (50%)	0.006*

*Odds ratio = 0.24 (0.09–0.63).

TOPICS

- Epidemiology & Diagnosis
- Prevention
 - Hand Hygiene
 - Isolation & Gloving
 - Environmental Cleaning
 - Antibiotic Stewardship
 - Probiotics
- Treatment
 - Oral Antimicrobials; Treatment as Prevention
 - Fecal Bacteriotherapy
 - Surgical Options
- Putting It All Together: ICE CDI!

Proposed Checklist of Hospital Interventions to Decrease the Incidence of Healthcare-Associated *Clostridium difficile* Infection

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BACKGROUND. The incidence and severity of *Clostridium difficile* infection (CDI) are increasing, and previously described interventions for controlling the spread of CDI are not easily generalized to multiple healthcare institutions.

OBJECTIVE. We tested prevention and treatment bundles to decrease the incidence of CDI and the mortality associated with CDI at our hospital.

DESIGN. Observational before-after study of adult patients admitted to a tertiary care, university-affiliated hospital during the period from January 2004 through December 2008.

METHODS. In January 2006, we launched an educational campaign and introduced a prevention bundle—a series of specific processes aimed at preventing the transmission of *C. difficile* among hospitalized patients, including enhanced isolation practices, laboratory notification procedures, and steps coordinating infection control and environmental services activities. In April 2006, we implemented a treatment bundle—a set of hospital-wide treatment practices aimed at minimizing the risk of serious CDI complications. We tracked quarterly incidence rates and case-fatality rates for healthcare-associated CDI cases at our hospital. Our main outcome was the healthcare-associated CDI incidence rate, measured as the number of healthcare-associated cases of CDI per 1,000 patient-days.

RESULTS. We followed patients for a total of 1,047,849 patient-days. The healthcare-associated CDI incidence rates fell from an average of 1.10 cases per 1,000 patient-days before intervention to 0.66 cases per 1,000 patient-days after intervention. This statistically significant decrease amounts to a 40% reduction in incidence after the intervention.

CONCLUSIONS. Our intervention was successful in reducing the incidence of CDI at our hospital. On the basis of our experience, we propose the use of a checklist of hospital interventions to decrease the incidence of healthcare-associated CDI.

Infect Control Hosp Epidemiol 2009; 30:1062-1069







C. difficile Infection Checklist at Brigham and Women's Hospital

Clostridium difficile Infection (CDI) Checklist	
Hospital interventions to decrease the incidence and mortality of healthcare-associated C. difficile infections	
<p>Prevention Checklist</p> <ul style="list-style-type: none"> • When an MD, PA, NP, or RN suspects a patient has CDI: <p>Physician, Physician Assistant, or Nurse Practitioner:</p> <ul style="list-style-type: none"> □ Initiate <i>Contact Precautions Plus</i> □ Order stool <i>C. difficile</i> toxin testing □ Discontinue non-essential antimicrobials □ Discontinue all anti-peristaltic medications <p>Registered Nurse:</p> <ul style="list-style-type: none"> □ Obtain stool sample for <i>C. difficile</i> toxin test □ Place patient in single-patient room □ Place <i>Contact Precautions Plus</i> sign on patient's door □ Ensure that gloves and gowns are easily accessible from patient's room □ Place dedicated stethoscope in patient's room □ Remind staff to wash hands with soap and water following patient contact <p>Microbiology Laboratory Staff Person:</p> <ul style="list-style-type: none"> □ Call relevant patient floor with positive <i>C. difficile</i> toxin test result □ Provide daily list of positive test results for Infection Control <p>Infection Control Practitioner:</p> <ul style="list-style-type: none"> □ Check microbiology results daily for positive <i>C. difficile</i> toxin results □ Call relevant floor to confirm that patient with positive <i>C. difficile</i> toxin results is in a single-patient room and that the <i>Contact Precautions Plus</i> sign is on the patient's door □ Flag the patient's <i>C. difficile</i> status in the hospital's clinical information system or in the patient's paper chart □ Alert housekeeping that the patient is on <i>Contact Precautions Plus</i> <p>Environmental Services Staff Person:</p> <ul style="list-style-type: none"> □ Prior to discharge cleaning, check for <i>Contact Precautions Plus</i> sign on the patient's door □ If <i>Contact Precautions Plus</i> sign is on the door, clean the room with a bleach-based cleaning agent □ Confirm for supervisor that bleach-based cleaning agent was used for discharge cleaning for every patient on <i>Contact Precautions Plus</i> 	<p>Treatment Checklist</p> <ul style="list-style-type: none"> • When an MD, PA, or NP diagnoses mild CDI: <i>All of the following criteria are present: diarrhea (<6 BM/day), no fever, WBC<15,000, no peritoneal signs, and no evidence of sepsis</i> <p>Physician, Physician Assistant, or Nurse Practitioner:</p> <ul style="list-style-type: none"> □ Initiate oral metronidazole at dose 500mg every 8 hours □ If no clinical improvement by 48-72 hours after diagnosis, treat patient as moderate CDI □ Continue therapy for at least 14 days total and at least 10 days after symptoms have abated • When an MD, PA, or NP diagnoses moderate CDI: <i>At least one of the following criteria is present: diarrhea (6-12 BM/day), fever 37.5-38.5°C, WBC 15,000-25,000, or frankly visible stable lower gastrointestinal bleeding</i> <p>Physician, Physician Assistant, or Nurse Practitioner:</p> <ul style="list-style-type: none"> □ Initiate oral vancomycin at dose 250mg every 6 hours □ If no clinical improvement by 48 hours, add IV metronidazole at dose 500mg every 8 hours □ Consider obtaining infectious disease consultation □ Consider obtaining abdominal CT scan □ Continue therapy for at least 14 days total and at least 10 days after symptoms have abated • When an MD, PA, or NP diagnoses severe CDI: <i>At least one of the following criteria is present: diarrhea (>12 BM/day), fever >38.5°C, WBC >25,000, hemodynamic instability, marked & continuous abdominal pain, ileus, absence of bowel sounds, evidence of sepsis, or intensive care unit level of care required</i> <p>Physician, Physician Assistant, or Nurse Practitioner:</p> <ul style="list-style-type: none"> □ Obtain immediate infectious disease consultation □ Obtain immediate general surgery consultation □ Obtain abdominal CT scan □ Initiate oral vancomycin at dose 250mg every 6 hours together with IV metronidazole at dose 500mg every 6 hours □ Following consultation with general surgery regarding its use, consider rectal vancomycin □ Ask general surgery service to assess the need for colectomy
<p>Abbreviations: MD=medical doctor, PA=physician assistant, NP=nurse practitioner, RN=registered nurse, BM=bowel movement, WBC=white blood cell count, CT=computed tomography, IV=intravenous</p>	

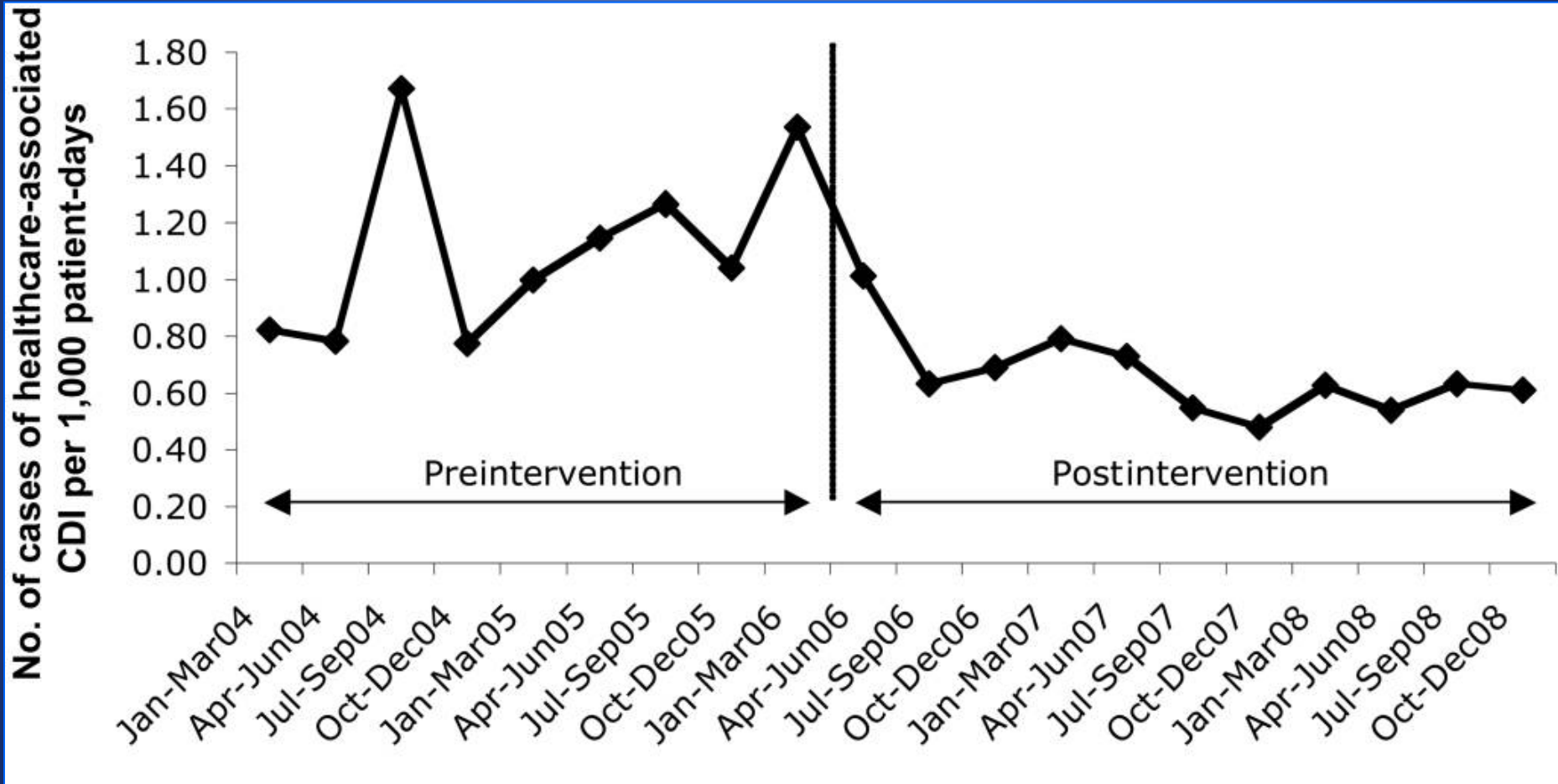
Contact Precautions Plus Sign, as Developed at Brigham and Women's Hospital for Healthcare Workers Caring for Patients with *C. difficile* Infection

CONTACT PRECAUTIONS **PLUS***

*DISPATCH for room cleaning upon patient discharge/transfer

<u>BEFORE entering</u>	<u>BEFORE leaving</u>
 <ol style="list-style-type: none">1. Disinfect hands w. Purell (includes visitors)	 <ol style="list-style-type: none">1. Remove gloves
 <ol style="list-style-type: none">2. Put on gown (if having contact w. patient or patient's environment)	 <ol style="list-style-type: none">2. Remove gown
 <ol style="list-style-type: none">3. Put on gloves	 <ol style="list-style-type: none">3. *WASH HANDS W. SOAP & WATER (includes visitors)

Incidence Rates of Healthcare-associated *C. difficile* Infection Among Patients Hospitalized at Brigham and Women's Hospital (excludes newborns in neonatal ICU)



CDI Key Points from CDC

- *Clostridium difficile* infections (CDIs) increased several fold in the past decade and became more serious, but are nonetheless preventable.
- Of all CDIs, 94% are related to health-care exposures and are potentially preventable by reducing unnecessary antibiotic use and interrupting patient-to-patient transmission of *C. difficile*.
- CDIs were reduced by 20% over approximately 21 months by 71 hospitals participating in prevention programs focused primarily on infection control strategies (e.g. early reliable detection, isolation, and enhanced environmental cleaning).
- Of all health-care–associated CDIs, 75% have their onset outside of hospitals, and 52% of the CDIs treated in hospitals are present on admission; these infections are a potential source for intrahospital transmission.
- More must be done to prevent CDIs by various stakeholders working together to expand prevention strategies, including a greater focus on antibiotic stewardship and extending prevention strategies in settings across the continuum of health-care delivery.

RAW's Take Home Message — Basics Can Work!

- Early Diagnosis Essential
- Prompt Treatment
- Universal Gloving
- Aggressive Environmental Cleaning
- Antimicrobial Stewardship
- Next: Manipulate the Human Microbiome, e.g., Probiotics