

## Study shows oral spores of harmless *C. difficile* prevent repeat infection

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This photograph depicts *Clostridium difficile* colonies after 48hrs growth on a blood agar plate; Magnified 4.8X. *C. difficile*, an anaerobic gram-positive rod, is the most frequently identified cause of antibiotic-associated diarrhea (AAD). It accounts for approximately 15–25% of all episodes of AAD. Credit: CDC

In what is a major step towards the prevention of recurring bouts of *Clostridium difficile* (*Cdiff*) infection, an international team led by Dale Gerding, MD, Hines Veterans Administration (VA) research physician and professor of Medicine at Loyola University Chicago Stritch School of Medicine, has shown that giving spores of non-toxic *Cdiff* by mouth

is effective in stopping repeated bouts of *Cdiff* infection which occurs in 25-30 percent of patients who suffer an initial episode of diarrhea or colitis. The study is published in the May 5 issue of the *Journal of American Medical Association (JAMA)*.

"The results of this study are very gratifying because the preclinical laboratory and patient studies were all done through our VA research program supported by the Department of Veterans Affairs Research Service," says Gerding. "Results of this study confirm findings of earlier studies that showed that if we can establish non-toxic *Cdiff* as a resident of the gut of the patient, that we can protect the patient from infection by the toxic strains of *Cdiff*." Viropharma and Shire pharmaceutical companies supported the clinical trials.

These results warrant additional study to confirm that treatment with non-toxic *Cdiff* spores can reduce recurrent *Cdiff* infection and prevent a first episode of *Cdiff* infection in those who are taking any antibiotics and are at high risk of infection, he added.

Gerding and an international team of infectious disease researchers, including those at Loyola University Medical Center (LUMC), randomly assigned 168 adult patients with *Cdiff* infection who had been treated for their infection with antibiotics to receive doses of 10 thousand or 10 million spores per day of non-toxic *Cdiff* in liquid form for 7 or 14 days, or to receive an identical placebo. Of those assigned any dose of non-toxic *Cdiff*, 11 percent experienced a repeat of infection within 42 days compared with 30 percent of those given a placebo, a statistically significant reduction. For the most favorable dose tested, 10 million spores a day for 7 days, the recurrence of *Cdiff* infection was reduced to 5 percent.

Hospital-acquired infections (HAI) including *Cdiff*, which causes severe diarrhea and inflammation of the lower bowel or colon, continues to

escalate in frequency and severity in the U.S. According to the Centers for Disease Control and Prevention (CDC), almost 500,000 *Cdiff* infections occurred in the U.S. in 2011, with 83,000 recurrences and 29,000 deaths within 30 days of diagnosis.

Older adults taking antibiotics and who receive care at medical institutions are most vulnerable.

Cheryl O'Riordan, who has had repeated bouts of *Cdiff* [infection](#), said having *Cdiff* made her visit the bathroom on an average of 10 times per day. "Before receiving effective treatment, I was unable to leave the house," says the active cyclist, skier and hiker. O'Riordan went into remission after being treated successfully at LUMC. "I am back cycling more than 3 miles every day and have several major adventure trips planned."

Gerding, who has published more than 135 studies on *Cdiff* is considered one of the leading international experts on *Cdiff*.

Stuart Johnson, MD, infectious disease specialist at LUMC, is also the director of research at Hines VA hospital. Together Gerding and Johnson have partnered on *Cdiff* research for almost three decades, involving many LUMC patients.

"The study offers real hope for those debilitated by recurring bouts of *Cdiff*," says Johnson, who cares for O'Riordan at LUMC in Maywood. "This study represents a novel and potentially highly effective bacteriotherapy approach to restoring colonization resistance against toxic strains of *Cdiff* in these patients," he adds.

**More information:** *JAMA*, doi:10.1001/jama.2015.3725

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