

C. difficile vaccine proves safe, 100 percent effective in animal models

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An experimental vaccine protected 100 percent of animal models against the highly infectious and virulent bacterium, *Clostridium difficile*, which causes an intestinal disease that kills approximately 30,000 Americans annually. The research is published ahead of print in *Infection and Immunity*.

In the study, the vaccine protected the mice and non-human primates against the purified toxins produced by *C. difficile*, as well as from an orogastric spore infection, a laboratory model that mimics the human disease, after only two immunizations.

"Animals that received two immunizations did not get sick or show signs of *C. difficile*-associated disease," says corresponding author Michele Kutzler, of Drexel University College of Medicine, Philadelphia.

"While our research was conducted in animal models, the results are very translatable to the clinic," says Kutzler. "In some cases, patients who acquire *C. difficile* can develop serious complications including severe diarrhea, toxic megacolon, bowel perforation, multi-organ failure, and death. Once fully developed, our DNA vaccine could prevent the deadly effects of *C. difficile* infection when administered to hospital patients at risk of acquiring *C. difficile*."

The protection following just two immunizations is especially important since the time window in humans between colonization with *C. difficile* and the onset of disease symptoms can be a mere 10-14 days, says

Kutzler.

The vaccine protects against the bacterial toxins by mustering anti-toxin neutralizing antibodies, says Kutzler.

The cost of fighting the half million *C. difficile* infections that occur annually in the US is estimated to be nearly \$10 billion, most of which could be saved by a successful preventive vaccine, says Kutzler.

Morbidity and mortality have risen over the last decade, likely due to increased prevalence of relapsing disease, and hypervirulent strains, she adds.

Treating the disease is especially difficult, as the bacterial spores persist in the hospital environment, where most infections occur. There is no standard, effective treatment for recurrent disease, but a small number of experimental fecal transplants for *C. difficile* have had a very high success rate, with no adverse reactions.

"Since our [vaccine](#) was safe, effective after only two immunizations, and performed exceptionally well, we feel that this success warrants further studies using human patients," says Kutzler.

More information: *Infection and Immunity*. [DOI: 10.1128/IAI.01950-14](#)

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