Study calls for screening for drug-resistant E. coli in capsulized fecal transplants

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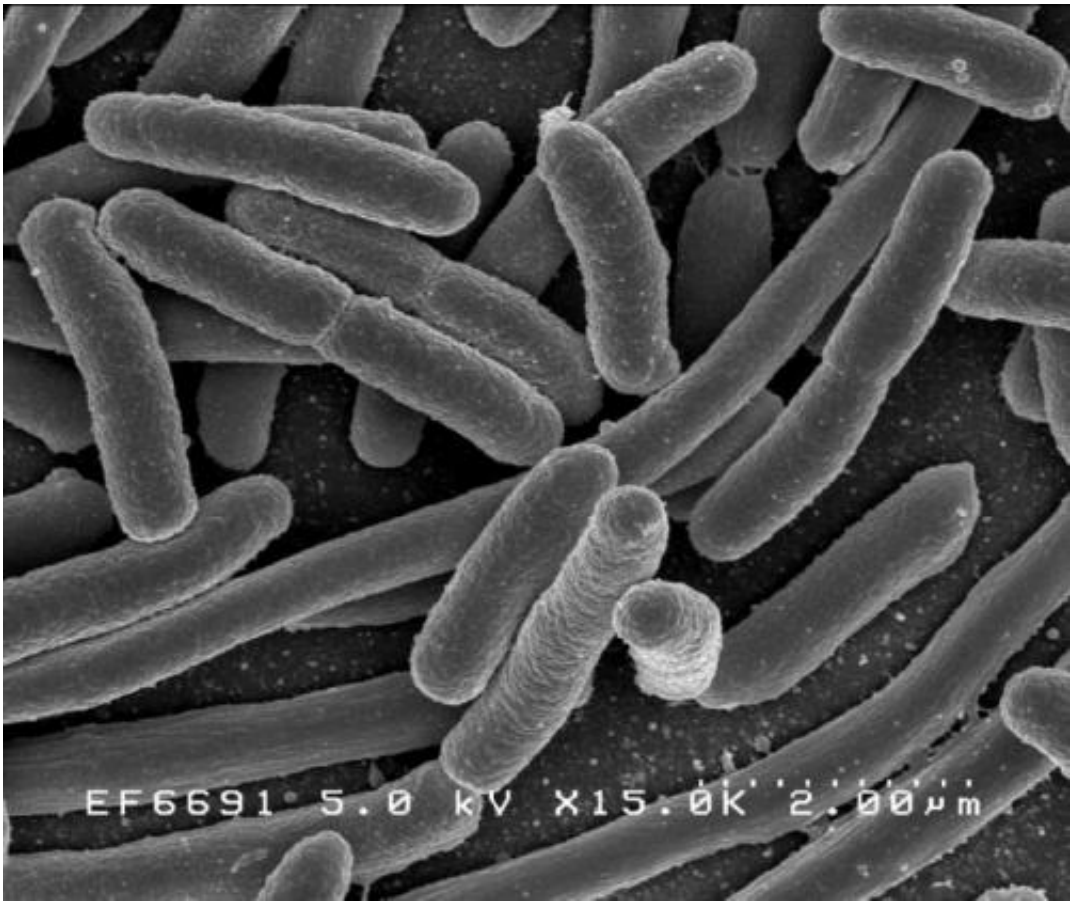

Escherichia coli. Credit: Rocky Mountain Laboratories, NIAID, NIH

Rigorous donor screening for drug resistant *E. coli* in fecal microbiota transplants (FMT) is an essential means of preventing infections among patients, particularly those who are immunocompromised, says a study in

The New England Journal of Medicine by researchers at Massachusetts General Hospital (MGH). The publication describes cases of infection in two patients who received FMT capsules containing drug resistant Extended Spectrum Beta-Lactamase (ESBL) *E. coli*. One patient died and the other was cured of infection.

Originally developed to treat *Clostridiodes difficile* (*C. diff*), capsulized FMT is being studied to treat other conditions, including inflammatory bowel disease, obesity, liver disease, multiple sclerosis and food allergies. In FMT, recipients receive encapsulated, frozen stool that has been donated by healthy volunteers. The capsulized FMT given to each patient cited in the study was created in late 2018 and contained drug resistant *E. coli*. The donor stool had not been specifically tested for the ESBL *E. coli* as screening for this bacterium was not adopted into screening protocols until January 2019.

The first patient was part of a study to determine whether FMT could improve brain function in patients with liver disease. The patient received FMT capsules over a period of three weeks. Seventeen days after the last dose, the patient was found to have ESBL *E. coli* in the bloodstream. The patient received intravenous antibiotics and was cured.

The second patient participated in a research study aimed at improving the intestinal microbiome around the time of a stem cell transplant for leukemia. The study involved administering FMT capsules before and after the patient's stem cell transplant. Five days after the procedure, the patient developed an ESBL *E. coli* infection and despite aggressive treatment, died of complications related to the infection.

Physician investigators overseeing the two trials notified the Food and Drug Administration and institutional oversight boards as soon as it became clear there was possible transmission of a drug resistant organism from the FMT capsules. Both studies were stopped while

researchers tested capsules from all donors. The single donor stool in each of the two cases was the only one that tested positive for ESBL *E. coli* and was identified as the source of the patient infections using genetic testing of the bacteria. The study marks the first time a patient's death has been linked to an infection transmitted by capsulized FMT.

"Patients who are immunocompromised are at higher risk of complications of infection after FMT," said Elizabeth Hohmann, MD, an investigator within the Division of Infectious Diseases at MGH and corresponding author of the paper. "Additionally, in the past, ESBL organisms were uncommon in healthy individuals, such as the donor in this case. They are increasingly common now, and as knowledge of their importance has evolved, so must donor testing."

Investigators recommend continued efforts to improve donor screening to limit transmission of drug resistant organisms. Ongoing research is needed to continue to assess the risks and benefits of FMT, they say.

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