Fecal Transplantation for treating C. Difficile infections

Conclusions from a recent Danish study supports the use of fecal transplantations over antibiotics in critically ill patients with *C. difficile*-associated infectious diarrhea. Results of such transplantation of donor fecal matter into a sickly patient's gut resulted in 9 of 10 patients achieving clinical cure. 64 patients were randomized to receive either transplantation therapy, or fidaxomicin or vancomycin. Of the 24 treated with a single feces transplant, 22 patients were cured. Results were not so promising for patients in the antibiotic arms, with only 3 of 16 patients treated with vancomycin achieving clinical cure, and 10 of 16 patients treated with fidaxomicin achieving clinical cure. Patients with recurring cases of *C. difficile* after using antibiotics received a fecal transplantation, eliciting a cure in 90% of the recurring cases.

In the US, the FDA has set forth standards for the appropriate use of fecal transplantations in patients refractory to the standard of care. The process includes obtaining informed consent from the patient or legally authorized representative, disclosing that fecal transplantation is an investigational treatment, that the feces is not obtained from a stool bank, and that the stool donor has been screened and tested prior to providing the sample. In other words, stool is a regulated article by the FDA, but is exempt from licensing requirements when the treatment is used pursuant to an IND application. Other barriers that face the widespread use of fecal transplantation is patient perception and acceptance of the procedure, and the lack of accessibility to the procedure at some facilities.

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2. FDA. Enforcement Policy Regarding Investigational New Drug Requirments for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies. Draft Guidance for Industry. US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. March 2016. Available at: https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/UCM488223.pdf Accessed: February 08, 2019.

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