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What Nurses Need to Know About Fecal Microbiota Transplantation: Education, Assessment, and Care for Children and Young Adults[1,2]

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Fecal microbiota transplantation (FMT) is an emerging experimental therapy for treatment of recurrent *Clostridium difficile* infection. In the future, FMT has the potential to be a treatment modality in other diseases that involve gut dysbiosis. As use of FMT is likely to expand, pediatric nurses need a clear understanding of FMT to provide appropriate education, assessment, and care for these patients. Pediatric research and clinical nurses are a resource to help children and parents understand the procedure. Important topics include donor screening, patient assessment before, during, and after treatment; routes of administration and positioning; preparation for discharge and followup evaluation.

FECAL MICROBIOTA TRANSPLANTATION (FMT), also known as stool transplantation, is the infusion of human stool, obtained from a healthy donor, into the gastrointestinal (GI) tract of a diseased patient. Hypothesized to normalize the gut microbiota of the recipient, FMT helps to alleviate disease symptoms by modulating dysbiosis (Khoruts, Dicksved, Jansson, & Sadowsky, 2010; van Nood et al., 2013). Here dysbiosis refers to the microbial imbalance in the intestinal tract. The 17th century Italian anatomist, Fabricius Aquapendente, first described stool transplantation in animals (Borody, Warren, Leis, Surace, Ashman, & Siarakas, 2004). This practice continues to be performed today, for example, "…veterinarians perform fecal transplantation to treat horses with diarrhea by infusing stool from healthy horses into the rectum of the sick animals, and they administer rumen fluid [transfaunation] to cows and alpacas to treat a variety of conditions" (Hanauer, 2012, p. 191).

Since the 1950s, FMT has been used sporadically in human patients with pseudomembranous enterocolitis and *Clostridium difficile* infection (CDI) as it has been shown to alter the gut microbiota of the recipient (Eiseman, Silen, Bascom, & Kauvar, 1958; Khoruts et al., 2010; van Nood et al., 2013). A systematic review of 27 clinical trials and case reports between 1957 and 2009 found that 92% of over 300 patients with recurrent CDI experienced symptom resolution after treatment with FMT (Gough, Shaikh, & Manges, 2011). Similarly, a literature review of 11 clinical trials and case reports between 2010 and 2011 shows a 92% success rate of FMT in 182 patients with fulminant or refractory CDI (Karadsheh & Sule, 2013). Various routes of instillation for FMT are described in these studies and case reports. The most common methods include retention enema, colonoscopy, and administration via nasojejunal (NJ) tube.

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In 1989, Bennet and Brinkman were the first to report the successful use of FMT in a patient with ulcerative colitis (UC), an inflammatory bowel disease (IBD; Bennet & Brinkman, 1989). A similar case series was reported in six adult patients (Borody, Warren, Leis, Surace, & Ashman, 2003). Both these case reports show an improvement in UC symptoms and a reversal of the disease process in patients treated with FMT. Many patients were also able to stop taking medications for their UC. More recently, a small phase I prospective, non-randomized FMT clinical trial was conducted to treat ten children and young adults with UC (Kunde et al., 2013). Clinical results found that 78% of the subjects demonstrated improvement in UC symptoms within 1 week of the treatments and 67% maintained clinical response at 1 month after the final FMT treatment day.

Fecal microbiota transplantation is considered to be an investigational biologic drug (Public Health Service Act of, 1999; Federal Food, Drug, and Cosmetic Act, 1980). Currently, FMT can only be offered in clinical settings to patients with recurrent CDI if an adequate informed consent is obtained from the recipient indicating the experimental nature of the therapy. The use of FMT in other conditions is limited to clinical trials (United States Food and Drug Administration, 2013). Due to the therapeutic potential of FMT, although still poorly understood, researchers across the globe will further explore the biological plausibility, safety, and clinical responses in children and young adults with CDI, IBD (UC and Crohn's disease), anorexia nervosa, constipation, diabetes mellitus, eosinophilic disorders of the GI tract, food allergies, irritable bowel syndrome (IBS), obesity, neurodegenerative and neurodevelopment disorders, and systemic autoimmunity disorders (Borody & Khoruts, 2012; Rogers & Bruce, 2013; Borody, Paramsothy, & Agrawal, 2013). Thus far, FMT has been shown to be safe, effective, and an inexpensive treatment with very few side effects (Bakken et al., 2011; Karadsheh & Sule, 2013). As a result of the positive impact of FMT in patients with recurrent CDI, it is likely to become a regularly used treatment modality in outpatient and acute care settings for children and young adults with disease processes that involve gut dysbiosis. Pediatric nurses have limited available information about providing adequate education, appropriate assessment, and quality care for patients receiving FMT. The purpose of this article is to review the FMT procedure in pediatric patients with CDI and UC and discuss its implications for nursing practice in the clinical and research settings.

Clinical Research Nurses – A Critical Resource

As a result of the Food and Drug Administration (FDA) federal regulations, pediatric clinical research nurses have an essential role in working with children and young adults receiving FMT and collaborating with clinical teams. The main roles and responsibilities of the clinical research nurse include completing regulatory documents, creating a budget and assessing site costs, preparing institutional review board (IRB) submissions, developing an informed consent form, and building tools for data collection and education of patients and families. Clinical research nurses facilitate the identification and screening of potential research subjects, coordinate and schedule visit appointments, perform nursing assessments, educate patients and families and collect data and/or specimens according to the study protocol (Fedor, Cola, & Pierre, 2006).

Initially, FMT may sound unappealing to many children and their families. Preparation of the pediatric research participant and their families is a critical step in the screening phase. For other children and young adults, due to the debilitating symptoms of recurrent CDI and UC, families are desperate for alternative treatment options and may consider performing FMT at home. There may be an increased risk for the transmission of infection in home treatments due to improper or lack of donor screening. The lack of medical supervision may also result in other unknown risks. Clinical research nurses play a key role in informing research participants and parents/guardians about the investigational nature of FMT and any potential risks.

Education of the research participants and family members may be provided through phone, email and IRB-approved study teaching tools. Detailed information about FMT, including all aspects of the process are required to be made available in writing to the research participants, their parents/guardians, and donors. These aspects include donor selection, donor screening and testing, donor stool collection process, participant screening, method and route of administration, side effects, how to report adverse events, intra-procedural and post treatment considerations, compensation and payment for treatment, and other treatment options. Typically, the IRB-approved informed consent incorporates this information and includes the contact information of the study personnel in case the research participant has a question or wants to withdraw from the study.

The clinical research nurse facilitates the authorization of parent/guardian permission for children less than 18 years of age to participate in a research study according to the United States Department of Health and Human Services (2009). Clinical research nurses have an ethical responsibility to evaluate the education provided to the study participants and assess their abilities to make a decision, demonstrate a factual understanding of the information, and appreciate the nature of their decision to participate and its consequences compared to other treatment options (Strauss, 2013). All capable research participants greater than or equal to 18 years of age are required to sign their own informed consent. A signed copy must be given to the participant or their families, as applicable, for their records.

It is also important to include children in decisions about research. Often children are excluded from these discussions with the excuse that they lack the capacity to understand research and/or clinical procedures. However, "children have the right to decide for themselves if they want to participate, and researchers have a responsibility to develop processes to