Effective Health Care

Fecal Microbiota Transplantation for Treatment of Clostridium difficile Infection

Nomination Summary Document

Results of Topic Selection Process & Next Steps

- The topic, *Fecal Microbiota Transplantation for Treatment of Clostridium difficile Infection*, will go forward as part of an update to or expansion of an existing comparative effectiveness or effectiveness review.
    - Butler M, Bliss D, Drekonja D, Filice G, Rector T, MacDonald R, Wilt T. *Effectiveness of Early Diagnosis, Prevention, and Treatment of Clostridium difficile Infection*. Comparative Effectiveness Review No. 31 (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) AHRQ Publication No. 11(12)-EHC051-EF. Rockville, MD. Agency for Healthcare Research and Quality. December 2011.

Topic Description

Nominator(s): Individual

Nomination Summary: The nominator is interested in the comparative effectiveness of fecal microbiota transplantation as a treatment *for Clostridium difficile* infections compared to the standard antibiotic therapy and possible need for surgical interventions in some refractory cases.

Population(s): Individuals (adults and children) suffering from *Clostridium difficile* infection (CDI).
Intervention(s): Fecal microbiota transplantation (FMT) in addition to or instead of current standard antibiotic therapy and surgical interventions.
Comparator(s): Standard treatment options alone (antibiotics such as metronidazole, vancomycin, and fidaxomicin.)
Outcome(s): Resolution of symptoms of CDI.

Key Questions from Nominator: No key questions were provided in the original nomination. Based on a review of the nomination, the following key question as developed: What is the effectiveness of fecal microbiota transplantation for the treatment of *C. difficile* infection?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)

- *Clostridium difficile* (*C. difficile*) infection (CDI) is one of the most common hospital-acquired infections (HAIs). While most types of HAIs are declining, CDIs remain at historically high levels. Each year, more than a half million people are affected by CDI, and in recent years, CDI has become more frequent, severe and difficult to treat.

- Recurrence of CDI occurs in up to a fifth of those affected by *C. difficile* either because the initial infection never resolved or because they are re-infected with a different strain of the bacteria. After one or more recurrences, rates of further recurrence increase up to 65%. For a first recurrence, the effectiveness of antibiotic therapy is around 60% and further declines with each subsequent recurrence. Fecal microbiota transplantation (FMT) is emerging as an alternative therapy to antibiotic therapy to treat recurrent infections.

- This topic was found to be best suited to move forward as part of an update to or expansion of the existing AHRQ report published in 2011 titled *Effectiveness of Early Diagnosis, Prevention, and Treatment of Clostridium difficile Infection*. Key questions are listed below. Specifically, this nomination relates to an update of Key Question 4.]
    - KQ 1. How do different methods for detection of toxigenic C. difficile to assist with diagnosis of CDI compare in their sensitivity and specificity?
        - Do the differences in performance measures vary with sample characteristics?
    - KQ 2. What are effective prevention strategies?
        - What is the effectiveness of current prevention strategies?
        - What are the harms associated with prevention strategies?
        - How sustainable are prevention practices in health care (outpatient, hospital inpatient, extended care) and community settings?
    - KQ 3. What are the comparative effectiveness and harms of different antibiotic treatments?
        - Does effectiveness vary by disease severity or strain?
        - Does effectiveness vary by patient characteristics: age, gender, comorbidity, hospital- versus community-acquired setting?
        - How do prevention and treatment of CDI affect resistance of other pathogens?
    - KQ 4. What are the effectiveness and harms of nonstandard adjunctive interventions?
        - In patients with relapse/recurrent CDI?