



# Effective Health Care

## Probiotics for the Treatment and Prevention of Gastrointestinal Symptoms

### Nomination Summary Document

#### Results of Topic Selection Process & Next Steps

- Probiotics for the treatment and prevention of gastrointestinal symptoms is important, but other topics have higher priority for limited program resources. No further activity on this topic will be undertaken by the Effective Health Care (EHC) Program.

#### Topic Description

**Nominator:** Individual

**Nomination Summary:** The nominator questions whether probiotics are effective in the treatment of gastrointestinal symptoms for patients of all ages. The nominator specifically questions the comparative effectiveness of different delivery methods of probiotics.

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**Population(s):** Individuals with gastrointestinal symptoms, including healthy individuals suffering from occasional symptoms (e.g., bloating, constipation), individuals with a gastrointestinal disease (e.g., Crohn's disease, irritable bowel syndrome), and individuals at risk for developing gastrointestinal upset (e.g., antibiotic-associated diarrhea, healthcare-associated diarrhea)

**Intervention(s):** Probiotics or synbiotics, including food products and supplements

**Comparator(s):** Any intervention (e.g., medication, dietary supplement, exercise) for the treatment or prevention of gastrointestinal symptoms; comparative effectiveness of different strains or delivery forms of probiotics

**Outcome(s):** Any patient health outcomes related to gastrointestinal symptoms, adverse health events

**Key Questions from Nominator:**

1. Do probiotics help with intestinal problems?
2. Are probiotics better than eating certain foods like yogurt that contain the same strain of live cultures?
3. Would long-term use cause any side effects? Do they interact with other medicines?

#### 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/>.)

- In 2011, an AHRQ EPC review titled *Safety of Probiotics to Reduce Risk and Prevent or Treat Disease* was published to address the safety of products containing microorganisms believed to have probiotic properties. This review was jointly sponsored by the National Institutes of Health (NIH) Office of Dietary Supplements, the NIH National Center for Complementary and Alternative Medicine, and the Food and Drug Administration Center for Food Safety and Applied Nutrition. The key questions included in this review address the short- and long-term risks of using probiotics; the characteristics and associations of any identified harms; the evidence that harms differ by product and delivery characteristics; whether harms vary based on dose, timing, mode of administration, patient characteristics, and relationship to efficacy; whether harms lead to hospital administration or lengthened hospitalization; and whether harms relate to the use of concomitant antibiotics, dietary therapies, corticosteroid use, immune suppressants, or other potential confounders.
  - Hempel S, Newberry S, Ruelaz A, Wang Z, Miles JNV, Suttrop MJ, Johnsen B, Shanman R, Slusser W, Fu N, Smith A, Roth E, Polak J, Motala A, Perry T, Shekelle PG. Safety of Probiotics to Reduce Risk and Prevent or Treat Disease. Evidence Report/Technology Assessment No. 200. (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2007-10062-I.) AHRQ Publication No. 11-E007. Rockville, MD: Agency for Healthcare Research and Quality. April 2011. Available at: [www.ahrq.gov/clinic/tp/probiotictp.htm](http://www.ahrq.gov/clinic/tp/probiotictp.htm).
- This nomination is focused on otherwise healthy individuals using probiotics to help treat or prevent gastrointestinal symptoms, including gas, bloating, and bowel problems. The authors of the previous AHRQ review on the safety of probiotics found that the quality of included studies varied, with only a minority of trials adequately reporting randomization methods, concealment of treatment group allocation, and blinding of outcomes assessors. In addition, in the majority of included studies, interventions were poorly documented, lacking detail on the specific probiotic strain that was administered as well as the dose and viability. Given these limitations in available studies of probiotics, it is unlikely that conclusions could be drawn from a review that could have significant impact on health care decision making.