



## PRACTICE ISSUE

Probiotic supplementation recommendations for healthy term infants 0-12 months with infantile colic, gastroesophageal reflux, or chronic functional constipation

### Best Practice Issue (state as a question, PICO):

What are probiotic supplementation recommendations for healthy term infants 0-12 months related to infantile colic, gastro esophageal reflux and chronic functional constipation?

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Date of Final Approval:

### Site:

River East

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To be Reviewed:

### Purpose: (goals, scope, intended users, settings, and patient/client groups)

Increased parental use of probiotics, the addition of probiotics to formula, and recent research on potential use of probiotics, have led to this review. Is there evidence to support recommending probiotic supplementation for healthy term infants 0-12 months with infantile colic, gastroesophageal reflux (GER), or chronic functional constipation?

### Definitions:

**Probiotic:** Live microorganisms, possibly from an oral supplement or a food product, when administered in a sufficient quantity, alter the microflora of the host and have the potential for beneficial health effects.

**Prebiotic:** Non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon, and thus improve host health

**Infantile colic:** A condition occurring in infants younger than four months of age which includes all of the following: paroxysms of irritability, fussiness, or crying that start and stop without obvious cause; episodes lasting three hours or more per day and occurring at least three days per week for at least three weeks; and no failure to thrive

**Chronic functional constipation:** A group of disorders associated with persistent, difficult, infrequent, or seemingly incomplete defecation without evidence of a structural or biochemical explanation.

**Gastroesophageal reflux (GER):** Common condition of infancy which most often manifests itself as episodes of regurgitation (the passage of refluxed gastric content into the oral pharynx) or vomiting.

**Lactobacillus reuteri (L reuteri):** Probiotic strain from the *Lactobacillus* genus commonly used in research investigating infantile colic, chronic constipation and GER. The active probiotic in the supplement BioGaia which is most widely available probiotic supplement for infants.

### Recommendations:

In otherwise healthy term infants, the following is recommended for probiotic use with regards to colic, chronic constipation, and gastroesophageal reflux (GER):

**Colic:** There is not enough evidence to support a standard recommendation. However, emerging evidence suggests that probiotic supplementation with five drops of *L. reuteri* (BioGaia) daily may provide some benefits in infants that are exclusively breastfed where the mother is also following a dairy-free diet (defined as the avoidance of all food products that contain milk derivatives).

Supplementation with BioGaia is an option for families should they have the financial abilities to purchase the

product, but due to a lack of evidence, this treatment does not need to be promoted to all caregivers of infants with colic.

There is not enough evidence to suggest a benefit with the use of probiotic-supplemented infant formula in formula fed infants with colic.

- **Constipation:** Although some of the research is promising, there is not enough evidence available to support that probiotics are effective in treating chronic functional constipation in children, or to recommend specific probiotics.
- **GER:** No recommendation can be made at this time. Very few studies investigating this condition have been completed to date.

## Evidence Review: (Please list type and grade of evidence reviewed)

### 1) Probiotics

#### a) Background

By definition, a probiotic is live microorganisms, which when administered in a sufficient quantity, alter the microflora of the host and have the potential for beneficial health effects. Probiotics can be ingested through oral supplements or food products. For a certain bacterial strain to be called probiotic, it must meet five criteria: the bacteria must be of human origin (meaning that it will survive in a human body), have a demonstrated safety profile, will survive transit through the gastrointestinal tract (will not be killed or digested by stomach acid or digestive enzymes), will colonize in the large intestine upon its arrival, and will provide a research-proven health benefit to the host.

Regarding nomenclature of probiotics, the bacteria will be written out by genus, species and strain, and one species or strain of probiotic cannot be assumed to have the same effects as another. For example, *Lactobacillus* (genus) *reuteri* (species) DSM 17938 (strain) is the probiotic ingredient of BioGaia. A different species or strain of *Lactobacillus* may not have the same effects (1).

#### b) Mechanisms of action

Probiotics can affect a variety of systems in the body. Not all probiotics have the same mechanisms of action in the body; the ways that probiotics function are thought to be strain specific (4). Two main mechanisms of action are the inhibition of pathogenic colonization and strengthening the immune system. Probiotics can inhibit pathogenic colonization by forming a protective barrier and competitively excluding unhealthy bacteria, which prevents pathogens from entering the body through the gastrointestinal tract (1). Up to seventy percent of immune cells are located within the gastrointestinal tract. Especially in infants, the immune system may need to be activated by the gut microflora to function properly. Probiotics can promote the development of a stronger immune system by influencing and stabilizing the gut microflora, enhancing resistance to potential pathogens and modulating immune function parameters (3).

#### c) Introduction into an infant's system

Traditionally, it was thought that infants were born sterile, but observations in recent years, have suggested that the fetus may be influenced by the mother's gut microflora before birth via the placenta (3). Birth route also plays a role in the intestinal flora of newborn infants; infants born vaginally mainly acquire microbes originating from the mother, and infants born by caesarean section acquire intestinal flora primarily from the environment (1, 3). Skin to skin contact following birth by any route also ensures some transmission of bacteria from mother to infant. The type of bacteria transmitted from the mother depends, therefore, on the bacteria within her gastrointestinal system (3).

#### d) Sources (breast milk/infant formula)

Breast milk contains a number of bacteria; the most frequent are *Staphylococcus*, *Lactococcus*, *Enterococcus*, and *Lactobacillus*. Some of the *Lactobacillus* bacteria are of interest as they are potentially probiotic. The benefits of breastfeeding are widely known and documented. Newborn infants who were breastfed have a more beneficial intestinal flora compared to those fed infant formula (6). It is possible that some of the beneficial effects of breastfeeding could be related to the presence of these beneficial bacteria.

There are varieties of infant formula available which contain added probiotics. Nestle GoodStart Probiotic and Parent's Choice Probiotic, containing *B. lactis*, are two probiotic formulas available in Canada. Studies examining the effect of infant formula on gastrointestinal and respiratory infections, constipation and colic have yielded contradictory results (7). Probiotic supplementation of an extensively hydrolyzed whey formula, such as GoodStart, may accelerate symptom improvement in infants with atopic dermatitis (8). Health Canada's document, Nutrition for Healthy Term Infants: Recommendations from Birth to Six Months, states "Live microorganisms may be added to infant formula if the

microorganism has been assessed as safe for infant use. The addition of live microorganisms to infant formula is intended to mimic the effects of breast milk on the infant's gastrointestinal system. However more evidence is needed to substantiate clinical benefits from infant formula supplemented with live microorganisms" (9).

#### e) *Benefits*

The way probiotics function in the body is generally strain-specific, meaning each strain could have a different effect on the body, if any effect at all (4). Interest and research in this area is increasing, and there are varying strengths of evidence to support benefits of probiotics in several human systems, many within the gastrointestinal system. There is **good evidence** to support that probiotics:

- administered in addition to rehydration therapy result in clear reductions in duration and severity of infectious diarrhea in infants and children
- are associated with a reduction in antibiotic associated diarrhea in both children and adults

There is interest with regards to probiotics and pediatric allergies, upper respiratory tract infections, and other areas (1).

#### f) *BioGaia*

BioGaia is a health care company which develops, markets and sells probiotic products. They have three products available in Canada, including probiotic drops and tablets for infants (BioGaia ProTectis drops), which is the only probiotic product marketed in Canada for infants. According to the BioGaia website, the recommended dose is 5 drops daily, providing a minimum of 100 million live *Lactobacillus reuteri protectis*, and this daily dose should not be exceeded. These drops are available in Canada without a prescription (10). Information about the cost of BioGaia is available in the cost/storage section of the paper on page 5.

## 2) Colic

#### a) *Background and prevalence*

Affecting up to 30% of infants under the age of four months, colic is a condition occurring in infants younger than four months of age which includes all of the following: paroxysms of irritability, fussiness, or crying that start and stop without obvious cause; episodes lasting three hours or more per day and occurring at least three days per week for at least three weeks; and no failure to thrive. The incidence of colic in breastfed and bottle-fed infants is similar (11). Colic is one of the most common reasons parents seek medical advice for their baby in the first few months of life. Parents and caregivers of infants with colic have a number of difficulties, including stress, exhaustion, anxiety, loss of working days and increased visits to a medical professional (16). Some studies report links between colic and maternal depression and child abuse (11, 15).

A number of possible etiologies have been proposed, but generally the cause of colic is unknown. Current literature suggests causative mechanisms such as behavioural, food allergy and hypersensitivity, immaturity of gut function and dysmotility, a possible link between maternal smoking and colic, and the composition of the infant's intestinal microbiota (3,11,14,15,18). Breast milk oversupply may also mimic signs of colic and should be ruled out prior to colic diagnosis. Diagnosis of colic is by exclusion (11,19).

#### b) *Treatment*

General feeding and management advice and providing parental reassurance should be the primary intervention offered to parents (19). Despite a lack of known etiologies, dietary interventions are often attempted to treat infantile colic. Elimination of cow's milk protein, either in the breastfeeding mother's diet, or by switching to an extensively hydrolyzed (not partially hydrolyzed) formula in formula fed infants have demonstrated a reduction in colic in a small number of infants (17). If a breastfeeding mother attempts a cow milk-free diet, it should be done for one to two weeks and with the assistance from a registered dietitian, to ensure that all sources of cow milk protein are eliminated from the mother's diet and adequately substituted (9). The use of soy-based formulas may reduce the symptoms of colic in some bottle-fed infants. However, the use of soy formulas in colic is not recommended because soy protein is often allergenic in infants (17). Soy-based infant formula should be used only in infants who have galactosemia or who cannot consume dairy-based products for cultural or religious reasons (9). While lactose elimination could be trialed, current evidence does not support the use of lactase in the treatment of colic as congenital lactase deficiency is rare (17). The document [Nutrition for Healthy Term Infants: Recommendations from Birth to Six Months](#) states, "Lactose-free, cow milk-based infant formula is also unsuitable for infants with confirmed cow milk protein allergy and is ineffective in the dietary management of infant colic" (9). Other oral treatments including oral sucrose, gripe water, herbal drinks and homeopathic remedies are not recommended due to ineffectiveness, and/or concerns about the safety of these treatments (19). One such treatment is the use of simethicone. Simethicone is an anti-foaming agent that reduces the surface tension of mucus thereby allowing entrapped air bubbles to combine into larger bubbles that can be expelled more easily from the gastrointestinal tract. Products that contain simethicone include Ovol® and Infacol® drops. Results from a systematic review found that simethicone has not been shown to be any more effective than a placebo in treating infant colic (20).

### c) Probiotic supplementation evidence and recommendations

A small amount of studies investigating the effect of probiotic supplements on colic have been conducted in recent years. The results from these studies have been mixed, but some promising studies are emerging. According to PEN, "Results from a randomized study suggests that the use of *Lactobacillus reuteri* probiotic drops may be of some benefit in decreasing symptoms of colic in breastfed infants. More research is needed before dietitians can routinely recommend the use of probiotic drops to treat infant colic. While probiotics have a good safety profile and there are generally no adverse side-effects from their use, the Canadian Pediatric Society states that there is insufficient evidence to recommend for or against the use of probiotics or prebiotics in the management of infant colic" (21). In a study of 83 breastfed infants under three months of age, for 28 days, 41 infants were randomized to receive *L. reuteri* and 42 were randomized to receive simethicone. All mothers were also asked to follow a cow's milk-free diet. At the end of the study, median crying time was less in the probiotic group (51 minutes/day) than the simethicone group (145 minutes/day) and the researchers found that 95% of the patients in the probiotic group responded to the treatment, versus only 7% of the patients in the simethicone group. While this study had limitations, the authors concluded *L. reuteri* has a potential role as a therapeutic approach to infantile colic (18). A systematic review and meta-analysis, involving a total of 1825 infants in twelve trials, examined the outcome of infant crying in infants three months or younger, randomized to receive either oral probiotics versus placebo or no treatment or standard treatment. These twelve eligible trials intervened with three different probiotic strains; *L. rhamnosus LGG*, *Bifidobacterium spp*, and *L. reuteri*. Seven of the reviewed trials were prevention trials, and five were management trials. Of the 12 trials, 6 suggested probiotics reduced crying and 6 did not. Three of the five management trials concluded probiotics effectively treat colic in breastfed infants. Meta-analysis of the three trials using *L. reuteri* as the intervention found that in breastfed infants with colic crying time was reduced (65 minutes less per day) after 21 days of treatment, but noted that all three studies had potential biases. This systematic review and meta-analysis concluded that the use of *L. reuteri* in breastfed term infants with colic is promising, but there is still insufficient evidence to support the general use of probiotics in all infants with colic and in the prevention of colic in healthy term infants (14). A randomized clinical trial involving 589 infants was completed prophylactically, where infants received *L. reuteri* or a placebo within the first week of life, and for 90 days afterwards. At three months of age, the mean duration of crying time was significantly different between the *L. reuteri* and placebo groups (38 vs. 71 minutes, respectively). The authors concluded that prophylactic use of *L. reuteri* during the first 3 months of life reduced the onset of colic, and other functional gastrointestinal disorders, and reduced private and public cost for the management of this condition (16). While research is promising, and no adverse effects have been reported, not enough evidence exists to make a general recommendation for probiotics for the treatment of colic. It is, however, an option for parents who have the financial means for the BioGaia treatment.

## 3) Chronic functional constipation

### a) Background and prevalence

Constipation is a common pediatric condition, affecting between 7% and 30% of children in both western and non-western countries, generally with no organic cause (12). Constipation may manifest in children as less frequent, hard, or painful bowel movements. Bowel movements can vary based on the child's age and feeding method. Infants who breastfeed are rarely constipated. Bowel movements of formula-fed infants vary depending on the type of formula they are fed. An infant who is constipated will typically have bowel movements that are hard or pellet-like, may cry while trying to move their bowels, and have fewer bowel movements than their previous normal. The prevalence of infant constipation increases during the transition from exclusive breast or formula feeding to cow's milk, or during the introduction to solid foods (22).

### b) Treatment

If an infant is less than 4 months and constipated or if there are concerning signs and symptoms accompanying the constipation (severe pain or rectal bleeding), a health care professional should be consulted regarding treatment. Infants who are consuming solid food should be encouraged to eat high fibre foods and increase fluid intake (22).

### c) Probiotic supplementation evidence and recommendations

Limited evidence was available looking at the results and recommendations of probiotic supplementation as a treatment for chronic functional constipation. Two studies were identified. In a study of 44 infants over the age of 6 months, diagnosed with chronic constipation, 22 received supplementation with *L. reuteri* for 8 weeks. At the end of the study period, the authors concluded that the infants receiving *L. reuteri* had statistically significant increased bowel frequency when compared to the control group, but no improvement in stool consistency and episodes of inconsolable crying (12). The second study investigated whether oral supplementation with *L. reuteri* can reduce the onset of constipation (among other indicators) in infants younger than 3 months. Two hundred and thirty eight infants were randomized to receive the intervention. After 1 month of intervention and at the end of the 3-month intervention, infants receiving *L. reuteri*

displayed a significantly increased evacuation frequency when compared to the control group (16).

Although some of the research is promising, there is not enough evidence available to support that probiotics are effective in treating chronic functional constipation in children or to recommend specific probiotics. Trials have been conducted, mostly on small groups of children, but the results are mixed. More well designed, human trials examining the effects of specific probiotic strains and dosages on constipation in children are required. Current research results are conflicting as various probiotic strains and dosages have been examined (23).

#### 4) Gastro esophageal reflux (GER)

##### a) Background and prevalence

Functional GER is a common condition of infancy and infants with this condition most often experience regurgitation (the passage of refluxed gastric content into the oral pharynx) or vomiting (expulsion of the refluxed gastric content from the mouth). Nearly 50% of all healthy infants aged 3 months and younger regurgitate at least once a day. Most infants with GER are healthy and the condition is normally outgrown by the end of the first year of life (13,16).

##### b) Treatment with lifestyle changes

Most infants with GER can be managed conservatively with parental education and reassurance regarding the natural course of GER in infants (24). Concerning symptoms of reflux disease include regurgitation associated with poor weight gain, aspiration, inconsolable or severe crying, persistent food refusal and respiratory problems (25). Other treatment strategies include changes in feeding position, and positions after feeding, thickened feedings, formula changes, and medications (24,25).

##### c) Probiotic supplementation evidence and recommendations

Limited evidence was available looking at the results and recommendations of probiotic supplementation as a treatment for GER. Two studies were identified. In a study of 34 infants with functional GER, 19 infants were randomized to receive probiotics, and at the end of the one month intervention period, the authors concluded that gastric distention was reduced, gastric emptying was accelerated and *L. reuteri* DSM 17938 reduced the frequency of regurgitation (13). A second study of 589 infants, where 276 infants were randomized to receive five drops of *L. reuteri* a day, found that after one month of intervention, there was no significant difference in regurgitation episodes compared with those given the placebo, but at the end of the three month intervention, regurgitation frequency significantly decreased compared with the infants who received the placebo (16). Neither study reported any adverse effects. Due to limited research investigating probiotic supplementation and the treatment of GER episodes, supplementation cannot be recommended for the treatment of GER at this time.

#### 5) Cost/storage of probiotics:

There are only a few probiotic food products available for infants. Probiotic supplemented infant formula is available, but not all brands of infant formula carry probiotic products. The below table outlines available brands of probiotic supplemented infant formula and their percent higher cost when compared to average cost of the standard powdered infant formula of the same brand. All probiotic infant formulas on the market in Canada contain the probiotic strain *Bifidobacterium lactis*. This table is for information purposes only and should not be interpreted as a product endorsement.

Brand	Percent higher cost compared to average cost of standard formula of same brand
Nestle GoodStart Probiotic	114%
Parent's Choice Probiotic (Walmart store brand)	127%
President's Choice Probiotic (Superstore store brand)	133%

BioGaia is the only probiotic supplement available for infants in Canada. This product is available in drops and in tablet form. The drops are widely available for sale at most large pharmacies. The cost for one bottle of drops (which would provide the supplement for one month) was found to vary between \$23.99 and \$33.89. BioGaia product tablets are not widely available. Costing was completed September 15-22, 2014 in several grocery stores and pharmacies in the River East community area, or by phone to certain pharmacies. Cost and availability may vary between community areas.

There are refrigerated food products containing probiotics, as well as freeze-dried supplements intended for adult populations. The freeze-dried supplements do not have to be refrigerated, but as a cautionary measure some manufacturers recommended that they be refrigerated to assist in maintaining the viable counts. The shelf-life for

refrigerated food products containing probiotics ranges from three to six weeks (5). BioGaia supplements should be stored in the refrigerator.

## 6) Safety

The majority of scientific studies completed to date have described a good tolerance to probiotic preparations and the absence of significant adverse effects (2). Most commercially available probiotic strains are considered to be safe; however, the safety of one strain cannot be extrapolated to another. All known cases of bacteremia and fungemia related to administration of probiotics have occurred in individuals who were critically ill or severely immunocompromised. Possible examples of health statuses associated with cases of bacteria and fungemia in the literature include: premature infants with short gut syndrome who were fed via gastrostomy or jejunostomy, a child with cerebral palsy who was suffering from antibiotic-associated diarrhea and had a gastrojejunostomy tube, and contamination of vascular catheters. In cases where the bacteremia or fungemia has been fatal, fatalities were usually related to underlying disease rather than directly to probiotic sepsis (26). No reports of sepsis have occurred in healthy individuals. The *Lactobacillus* and *Bifidobacterium* species used in the food industry and in clinical trials are safe for the general adult and pediatric populations (1,7,10,12,14,15,16,18).

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**Practice Implications:**

Communicate information to health care professionals who work with infants 0-12 months of age.

**Recommendation for implementation:**

The authors of this Evidence Review have provided the information for health care practitioners to use as part of individual assessment, treatment planning and education only.

**These recommendations are being reviewed by:**

Name and Credentials	Date Review Complete
Public Health Dietitian Practice Council	January 6, 2015
Primary Care Dietitian Practice Council	February 27, 2015
PPH Nutrition Promotion Team	April 20, 2015
FNS Nutrition Advisory Subcommittee	