

# Expert Views®

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## facts and fiction: dispelling the myths and misconceptions of probiotics

The complex microbial communities of the gastrointestinal tract—by far the most densely colonized human organ—are now appreciated to play an important role in human health.<sup>1-5</sup> Although not fully characterized, probiotic bacteria are believed to confer health benefits by bolstering the myriad protective, structural, and metabolic functions of the normal intestinal microbiota.<sup>1,6</sup> With the recognition of these potential benefits, there has been increasing interest in probiotic products within the scientific community, with consumers, and in the food industry.<sup>1-5</sup> Despite expanding knowledge, however, many questions about probiotics remain unanswered, and misinformation and misconceptions are common.

The insights of Darren M. Brenner, MD, from the Division of Gastroenterology of the Feinberg School of Medicine in Chicago, Illinois, are featured in this publication. Dr. Brenner's research and clinical interests include lower gastrointestinal (GI) disorders. Dr. Brenner has been awarded multiple teaching awards from the Divisions of Medicine and Surgery at Northwestern and has lectured on both local and national levels. He is a member of the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), and the International Foundation for Functional Gastrointestinal Disorders. He has published multiple peer-reviewed articles on functional GI disorders and currently serves as a reviewer for and is on the editorial boards of several prominent GI journals. In addition, Dr. Brenner has completed multiple reviews on the efficacy of probiotics and has authored the ACG educational piece on the pros and cons of probiotics for GI disorders.

## introduction

Research regarding probiotics has exploded with the volume of medical literature involving these agents increasing over 10-fold in the past decade. Similarly, probiotics are a growing trend in the marketplace, attributable to increasing consumer education and awareness as well as new product introductions. In 2005, only 18% of U.S. adults had heard the term "probiotics," a proportion that had increased to 60% by 2009.<sup>7</sup> In recent years, hundreds of probiotic foods, beverages, and supplements have become available in the U.S. market,<sup>8</sup> with claims offering health benefits in various parts of the body. Despite the growing interest and intensive research in this area, however, there are many common misconceptions about these probiotics among both health care professionals and consumers.

## common probiotic misconceptions

### Misconception #1: all probiotics are the same

**Fact: The health benefits of probiotics are strain-specific.** Probiotics are defined by the Food and Agriculture Organization of the United Nations and World Health Organization as live microorganisms, which when administered in adequate amounts, confer a health benefit on the host.<sup>5</sup> Probiotics are typically naturally occurring microbes, such as those used in foods or isolated from humans or animals, or microbes that have been genetically altered for a specific effect.<sup>9</sup> There are hundreds of commercially available probiotic supplements, with some containing a single strain of a single species and others containing multiple strains of a single species, multiple species, or both.<sup>10</sup> Most probiotic products are available and regulated in the U.S. as foods or dietary supplements, with none currently approved or regulated as drugs.

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Personal Health Care

“It is important to note that most probiotics differ both in their bacterial composition and quantity.”

“The whole point is that not all probiotics are the same. The key is to look at the evidence to support the claimed benefits.”

- Darren Brenner, MD

A probiotic is defined by its genus, species, and strain. The designation of the organism is essential because the effect(s) of a probiotic can only be attributed to the strain or strains tested, and cannot be extrapolated to the group of probiotics as a whole.<sup>3,4</sup> Probiotics within the same genus, or even species, do not necessarily provide the same benefits.

The concept of bacterial strain specificity with respect to probiotic efficacy is analogous to considering differences in various dog breeds. Although all dogs are the same genus and species, different breeds of dogs have different attributes and are suited for different tasks.<sup>11</sup> Similarly, the difference in bacterial strains can be appreciated by considering the disparate effects of various *E. coli* strains. While most *E. coli* bacterial strains are harmless inhabitants of the human digestive system, others such as *E. coli* O157:H7 has not demonstrated a health benefit and, in fact, can cause serious food poisoning.<sup>12</sup> Another (*E. coli* Nissle 1917) has been shown to have a positive GI health benefit.<sup>13,14</sup> These differences may be related to the genetic make-up of bacteria which diverges and becomes more specific at the strain level.

Given the importance of strain specificity, many probiotic products are marketed as different strains of the same species (eg, *Lactobacillus acidophilus* NCFM and La-1; *L. rhamnosus* GR-1 and GG; *Bifidobacterium lactis* HN019 and Bb-12, *Bifidobacterium infantis* 35624 and SD-5845). Health care professionals and consumers alike should appreciate that data from studies conducted on specific strains cannot be used as evidence to support health effects of untested strains.<sup>3</sup>

## Misconception #2: more probiotic is better

**Fact: The optimum dose of a probiotic is the dose that has been shown to have a health benefit in human studies.** The dose of a probiotic is usually expressed as the number of colony forming units (CFUs), which is a way of expressing the number of viable microbes per serving or dose.<sup>11</sup> A recent consumer publication rated marketed probiotic products and yogurts on the basis of how many CFUs they deliver per unit cost, suggesting that products containing higher dosages of probiotics are more effective than lower-dose products.<sup>15</sup> Similarly, some probiotics are marketed as being more effective than those with lower concentrations. Despite this popular belief, however, **probiotic effects should be considered dose-specific**, and it is not possible to make general recommendations about the minimum dose of probiotics that is needed for an effect.<sup>3,16,17</sup>

The dose of a probiotic should be based on human studies showing a health benefit. The required dose of probiotics may vary greatly for different strains and the specific health effect under investigation, with efficacious doses ranging from 50 million to more than 1 trillion CFUs/day.<sup>16</sup> **Table 1** depicts the wide range of doses at which various probiotics are recommended per package labeling.

There is no evidence to support the claim that either preparations with multiple species/strains or higher concentrations of bacteria leads to improved health benefits.<sup>18</sup>

Although using multiple strains may be thought to more closely replicate the normal GI environment,<sup>1,6</sup> few studies have assessed the health effects of single-strain probiotics with those of multispecies or multistrain products. Despite suggestion in the popular media that probiotics containing “more beneficial bacteria” are better, there is no minimum or maximum number of bacteria that must be ingested to obtain a beneficial effect. Thus, more is not necessarily better.<sup>15</sup> To the contrary, the ACG has stated that there is no evidence to support the claim that either preparations with multiple species/strains or higher concentrations of bacteria leads to improved health benefits.<sup>18</sup>

**Table 1.** Labeled directions for various probiotic products

Product Name	Strain	Recommended CFUs
Align®	<i>Bifidobacterium infantis</i> 35624	1 billion once daily <sup>19</sup>
Culturelle® Digestive Health	<i>Lactobacillus rhamnosus</i> GG	10 billion once or twice daily <sup>20</sup>
Florastor®	<i>Saccharomyces boulardii lyo</i>	5 billion twice daily <sup>21</sup>
Phillips® Colon Health®	<i>Lactobacillus gasseri</i> KS-13, <i>Bifidobacterium bifidum</i> G9-1, <i>Bifidobacterium longum</i> MM-2	1.5 billion once daily <sup>22</sup>
Sustenex®	<i>Bacillus coagulans</i> GBI-30, 6086	2 billion once daily <sup>23</sup>

CFUs, colony forming units

### Package directions for use:

**Align®:** Directions: Take one (1) capsule per day. Store at room temperature. For best results store in the original blister package.

**Culturelle® Digestive Health:** Suggested use for adults: Take one (1) capsule per day until discomfort subsides, or as directed by a medical professional. Continued use is suggested. When traveling, take one (1) capsule twice daily throughout the trip. Best results if started two to three days prior to traveling. For children of all ages: Take one (1) capsule daily. Capsule may be opened and mixed into cool drink or food. Do not add to warm or hot foods or beverages. Consult your medical professional for more information.

**Florastor®:** Suggested use: One (1) capsule in the morning, one (1) capsule in the evening.

**Phillips® Colon Health®:** Directions: Adults and children 3 years of age and older: Take one (1) capsule daily with a meal. Children under 3: Consult a doctor.

**Sustenex®:** Directions: Adults 18 and over take one (1) capsule daily with water.

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# the truth about probiotics

Given the growing number of products on the market and the misconceptions regarding these products, various scientific organizations have developed key criteria to help health care professionals and consumers evaluate and guide appropriate selection of these probiotics (**Table 2**).<sup>3,4,10,11,17,24,25</sup> However, not all preparations on the market claiming to be probiotics meet these key minimum criteria.<sup>3,11,17</sup> Strain specificity is recognized by national and international organizations<sup>3,4,10,11,17,24,25</sup> as a key factor in determining the credibility of a probiotic product. Recognizing that different strains of even the same species can be different, probiotics should be identified to the strain level.<sup>4,10,11,17</sup> The labeled strain should have been shown in human studies to provide a health benefit.<sup>11,17</sup>

**Table 2.** Organizations With Published Statements Regarding Probiotic Products<sup>3,4,10,11,17,18,24,25</sup>

<ul style="list-style-type: none"> <li>• American Gastroenterological Association (AGA)</li> <li>• American College of Gastroenterology (ACG)</li> <li>• American Dietetic Association (ADA)</li> <li>• National Center for Complementary and Alternative Medicine (NCCAM)</li> <li>• American Academy of Microbiology (AAM)</li> <li>• International Scientific Association for Probiotics and Prebiotics (ISAPP)</li> <li>• World Gastroenterology Organisation (WGO)</li> <li>• Food and Agriculture Organization of the United Nations/ World Health Organization (FAO/WHO)</li> </ul>
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In addition to containing the specific strain(s) of bacteria that was used in the published research, the product should contain the same level (ie, dose) that was used to demonstrate the health benefit.<sup>11</sup> Given that different probiotics are effective at different doses, more CFUs are not necessarily better.<sup>11</sup> On the contrary, no general recommendations regarding the optimum dose of probiotics can be made at this time.<sup>17</sup> Despite these criteria, some products labeled as “probiotics” do not contain adequate levels of clinically validated strains.<sup>11,17,26-28</sup>

Given the recognized importance of strain specificity and dosage, the labels of probiotic products should indicate key information, at a minimum, to help guide product selection (**Table 3**).<sup>10,11,17</sup> In addition, several organizations such as the AGA, the ACG, and the International Scientific Association for Probiotics and Prebiotics provide educational resources on their Web sites for helping patients/consumers better understand and choose probiotic products appropriately.<sup>10,11,18</sup>

Probiotic Resources For Your Patients <sup>10,11,18</sup>	
American Gastroenterological Association (AGA)	<a href="http://www.gastro.org/patient-center/diet-medications/probiotics">http://www.gastro.org/patient-center/diet-medications/probiotics</a>
American College of Gastroenterology (ACG)	<a href="http://patients.gi.org/topics/probiotics-for-the-treatment-of-adult-gastrointestinal-disorders/">http://patients.gi.org/topics/probiotics-for-the-treatment-of-adult-gastrointestinal-disorders/</a>
International Scientific Association for Probiotics and Prebiotics (ISAPP)	<a href="http://www.isapp.net/docs/Consumer_Guidelines_final.pdf">http://www.isapp.net/docs/Consumer_Guidelines_final.pdf</a>

**Table 3.** Key Information for Probiotic Labeling<sup>10,11,17</sup>

Information	Comments
<b>Genus, Species, and Strain</b>	A listing of only the bacterial genus and species is not sufficient to support strain-specific health claims.
<b>Dosage in CFUs, Suggested Serving Size, and Expiration Date</b>	Packaging should ensure an effective level of live bacteria through the best by or expiration date.
<b>Health Benefits</b>	Claims of health benefits should be based on human studies conducted on the product or specific strains in the product.
<b>Storage Instructions</b>	As living organisms, probiotic products can lose viability if not stored properly. Some products require refrigeration, while others do not.
<b>Corporate Contact Information</b>	The product manufacturer should be able to provide information regarding the content of the product, storage instructions, and health benefits. Several organizations suggest using products manufactured by well-established and trusted companies. <sup>10,11,17</sup>

Finally, although probiotics are generally considered safe, there have been literature reports associating specific strains with severe illness in certain medical settings (eg, intensive care settings, catheter line contamination) and in immunocompromised patients and/or in those with underlying conditions.<sup>9,18,29,30</sup> Thus, it has been suggested that caution be used when recommending probiotic use in these populations.<sup>16</sup>

# conclusions

Despite growing interest and recognition of health benefits associated with probiotics, there are many common misconceptions regarding these products. Despite the common belief that all probiotics are the same, the efficacy of a probiotic depends on the demonstration of health effects of the particular strain or combination of strains—not genus or species—in clinical studies. Thus, strain specificity is a key criteria in determining the credibility and health benefits of a probiotic product.<sup>3,5,10,11,17</sup> Similarly, despite a popular belief that “more is better,” the health effects of probiotics are dose-specific, that is, they are determined by the demonstration of the benefit of the particular strain at a particular dose.<sup>15</sup> The dose of various probiotics demonstrated to have health effects varies widely, and there is no

minimum or maximum dosage or number of bacteria that must be ingested to achieve a beneficial effect. A probiotic with a higher concentration of microbes is not necessarily more beneficial, nor is a product containing multiple strains necessarily better than a single-strain product. To the contrary, no generalizations regarding probiotic dose can be made.

Although choosing among various probiotics can be complicated by misinformation and the growing number of these products, consumers and health care professionals can evaluate products by ensuring that they have been adequately characterized for strain, dose, and stability and that their associated health claim(s) are substantiated with well-controlled strain-specific studies.

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