

# Probiotics as Therapy in Gastroenterology

## A Study of Physician Opinions and Recommendations

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**Goals:** The objective of this study was to determine how gastroenterologists perceive and use probiotic-based therapies in practice.

**Background:** In the United States, there has been a recent increase in research investigating the therapeutic capacities of probiotics in human disease and an accompanying increase in product availability and marketing. How medical care providers have interpreted the available literature and incorporated it into their practice has not been earlier assessed.

**Study:** A 16-question survey (see Survey, Supplemental Digital Content 1, <http://links.lww.com/JCG/A14>) was distributed to practicing gastroenterologists and physicians with a specific interest in GI disorders within a large metropolitan area.

**Results:** All physicians responded that they believed probiotics to be safe for most patients and 98% responded that probiotics have a role in treating gastrointestinal illnesses or symptoms. Currently 93% of physicians have patients taking probiotics most often for irritable bowel syndrome. Commonly used probiotics included yogurt-based products, *Bifidobacterium infantis* 35624 (Align), and VSL#3. Most surveyed physicians recommended probiotics for irritable bowel syndrome, antibiotic, and *Clostridium difficile*-associated diarrhea because they believed that the literature supports their usage for these conditions. However, physician practice patterns did not consistently correlate with published, expert-panel-generated recommendations for evidence-based probiotic use.

**Conclusions:** This study suggests most gastrointestinal disease specialists recognize a role for and have used probiotics as part of their therapeutic armamentarium; however, the effective implementation of this practice will benefit from additional supporting studies and the eventual development of clinical practice guidelines supported by the major gastroenterology societies.

**Key Words:** probiotic, gastroenterology, opinion, recommendation, survey

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Probiotics are human-associated microorganisms which are consumed either with food or as a supplement with the purpose of improving the health of the host.<sup>1</sup> Use of these supplements has increased in the United States and abroad over the past several years as patients seek natural treatments for gastrointestinal ailments. As these agents can be obtained without a prescription, patients often start taking probiotics without prior medical consultation. The medical community has developed an increased interest in the potential benefits of probiotics, which is amplified by the growing body of literature on probiotics, their increasing commercial availability, and inadequate successes with traditional pharmacotherapies. Together, these factors have led some practitioners of gastroenterology to incorporate the use of these organism-based treatments into their own therapeutic algorithms.

Probiotics have been used in a variety of gastrointestinal illnesses with varying degrees of success and supporting evidence. The proposed mechanisms of action for their benefit are multiple and include suppression or displacement of pathogenic bacteria, enhancement of innate immunity, and promotion of epithelial barrier function.<sup>2,3</sup> They are most often recommended to treat irritable bowel syndrome (IBS), antibiotic-associated diarrhea (AAD), *Clostridium difficile*-associated diarrhea (CDAD), and inflammatory bowel disease including pouchitis in addition to other gastrointestinal and nongastrointestinal illnesses.<sup>4,5</sup> Commonly used protective microorganisms include various species of *Lactobacillus* and *Bifidobacterium* in addition to nonpathogenic *Escherichia coli* Nissle 1917, *Clostridium butyricum*, *Saccharomyces boulardii*, and *Streptococcus salivarius*.

Although there is a global growing interest in the field, little is known about practicing gastroenterologists' perceptions regarding the use and efficacy of probiotics. Information describing how often physicians encounter probiotic usage in their practices and their specific recommendations to their patients has not previously been reported. Knowledge of medical care providers' familiarity and opinions regarding probiotic-based treatments is important as more patients begin to incorporate these supplements into their own medical regimens and as more clinical research investigating probiotic effectiveness become available. Therefore, we designed this survey-based study of physicians who regularly treat gastrointestinal symptoms and diseases to further characterize their knowledge regarding the existing probiotic literature, their perceptions regarding the use of probiotics in a variety of gastrointestinal illnesses, and their recommendations for probiotics usage in their own practice.

## METHODS

### Participants

Survey participation was offered through mail and/or email invitation to practicing gastroenterologists in the

Saint Louis, Missouri metropolitan area. Before close of the study, 41 of the 59 Saint Louis City and County community-based gastroenterologists were successfully reached and all of the 37 gastroenterologists with an academic appointment at either of the 2 medical schools (Washington University in Saint Louis and Saint Louis University) were reached for invitation to participate. An additional 18 participants attending a Washington University gastroenterology continuing medical education symposium who were not part of the aforementioned groups also received an invitation to complete the online survey 1 week before the symposium. These symposium participants included both practicing gastroenterologists and primary care physicians interested in gastrointestinal illnesses and senior gastroenterology trainees. Responses from symposium participants were collected before an 18 minute lecture at the symposium titled "Antibiotics and Probiotics in IBD."

### Questionnaire

To address the proposed questions, a 16 item multiple choice questionnaire was developed by 2 of the researchers (MC and CH, Appendix 1). The brief survey was designed to enable completion within 10 minutes time and was offered through either a hard copy or could be completed using an internet-based survey tool.<sup>6</sup> The online survey tool used has been earlier applied by the researchers and others as a method of assessing physician opinions and practice patterns.<sup>7-9</sup> To compile the data at the survey's completion, all hard copy surveys were entered into the internet survey tool. To maintain anonymity, the physician's name, gender, and age were not requested. The first 2 questions were used to determine participants' gastrointestinal expertise (internal medicine, general, or subspecialty gastroenterology) and their practice setting (private practice or academic hospital based). The remaining questions focused on probiotics. For analysis, senior trainees were grouped as academic based, general gastroenterologists.

The questions were designed to determine physicians' familiarity with common commercially available probiotic preparations including Align (*Bifidobacterium infantis* 35624 Procter and Gamble, Cincinnati, OH), VSL#3 (VSL Pharmaceuticals Inc.), Culturelle (Amerifit Brands, Cromwell, CT), Mutaflor (*E. coli* Nissle 1917 Ardeypharm, Germany), Yogurt-based products, Florastor (*Saccharomyces boulardii* lyo, Biocodex, San Bruno, CA), and Flora-Q (Pharmaderm, Melville, NY). Physicians were questioned regarding their knowledge of the probiotic literature and their perceptions regarding the safety, roles, and efficacy of probiotics for the treatment of various gastrointestinal illnesses. Physicians were surveyed regarding the percentage of patients in their practice who take probiotics and the percentage of those who do so based on their recommendations. They were asked how often they prescribe probiotics and whether they believe probiotics are efficacious for the treatment of specific conditions including irritable bowel syndrome, Crohn's disease, Ulcerative Colitis, pouchitis, radiation enteritis, *C. difficile* diarrhea, and as prophylaxis for antibiotic-associated diarrhea. As a follow-up, physicians were questioned regarding which specific probiotic they prescribe for each of the mentioned diseases. Finally, physicians were surveyed with regards to whether or not they personally had ever taken probiotics.

Several considerations were made in survey design. Survey structure was considered in questionnaire construction using contingency questions to avoid respondents answering questions that did not apply to them. Only

closed ended questions were included, although respondents were allowed to write additional comments regarding their responses to each question. The survey was reviewed independently by 2 expert gastroenterologists with survey study experience in addition to the researchers for content and format of the questionnaire. The simple multiple-choice survey design allowed for easy categorization of participants' responses. Skipped questions were not included in the overall response totals. Although there was not a follow-up survey to determine reasons for nonparticipation, the survey was resent to each invitee once to ensure delivery. The online tool did not allow duplicate responses. The complete questionnaire and associated request for participation were reviewed and approved by the Washington University in Saint Louis School of Medicine's Human Research Protection Office.

### Statistics

The 2-tailed Fisher exact test was used to compare respondent numbers between groups and a  $P$  value  $\leq 0.05$  was considered to be statistically significant.

## RESULTS

### Respondent Characteristics

Of the 96 invitations sent, 56 (58%) physicians completed the survey with a response rate of 65% among academic-based physicians and 53% of community practice physicians ( $P = 0.30$ ). The characteristics of the respondents are summarized in Table 1. Most of the survey participants were practicing gastroenterologists (86%) with an even distribution of physicians practicing in an academic and private practice setting. Twelve responses came from continuing medical education participants including 7 primary care physicians, 1 community gastrointestinal surgeon, and 4 senior fellows. Eighty-four percent of surveys were completed online.

### Physician Familiarity With Probiotics

All respondents deemed probiotics to be safe and nearly all (98%) believed that probiotics have a role for treating gastrointestinal illnesses or symptoms. However, some physicians (6%) noted concerns regarding usage of probiotics in immunocompromised patients and in those suffering from severe pancreatitis (2%). All of the private practitioners surveyed described themselves as at least somewhat familiar with the literature involving probiotics compared with 85% of respondents practicing in an academic setting. Table 2 highlights the respondents' familiarity with the individual probiotic preparations. *B. infantis* 35624

TABLE 1. Respondent Characteristics

	(%)
Practice type	
Gastroenterology	86
General gastroenterology	61
Subspecialty	25
Family practice/internal medicine	12
Gastrointestinal surgery	2
Practice setting	
Academic medicine	50
Private practice	50

**TABLE 2.** Physicians' Familiarity With Commercially Available Probiotic Preparations

Probiotic Preparations	Private Practice Respondents (%)	Academic Medicine Respondents (%)
Align: <i>B. infantis</i>	89	89
VSL#3	68	69
Culturelle: <i>Lactobacillus rhamnosus</i> GG	61	42
Mutaflor: <i>E. coli</i> Nissle 1917	4	12
Yogurt based: danactive/yakult/ lifeway/etc	93	85
Florastor: <i>Saccharomyces boulardii</i>	71	39
Flora-Q: mixture of 4 Bacteria	82	42

(Align) and the yogurt-based probiotic supplement preparations were the most commonly recognized formulations. However, a majority of individuals were also familiar with *Lactobacillus rhamnosus* GG (Culturelle) and the probiotic mixture VSL#3, compounds that have been commonly studied in clinical trials. Mutaflor, a nonpathogenic *E. coli* preparation recognized more widely in Europe, was known by very few respondents in the queried metropolitan area. Overall private practitioners more often confirmed familiarity with commercially available probiotics preparations than academic practitioners.

**Patients' Use of Probiotics**

Ninety-three percent of respondents noted at least some of their patient population takes probiotics. Over half (52%) of the private practitioners responded that at least 10% of their patients take probiotics compared with 30% of respondents practicing in an academic setting. Of the private practitioners, 61% believed that the majority of their patients take probiotics based on their recommendations compared with 46% of the academic medicine respondents.

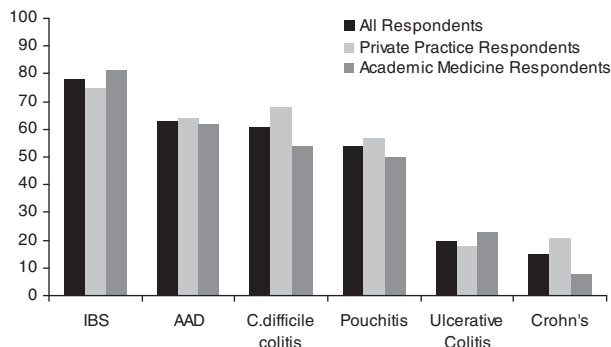
The frequency of probiotic usage by patients, based on physician recommendation or by personal choice, for specific gastrointestinal conditions is summarized in

**TABLE 3.** Conditions for Which Patients Use Probiotics

Diagnosis	(%) Among All Physicians	(%) Patients of Private Practitioners	(%) Patients of Academic Practitioners
IBS	98	96	100
<i>C. difficile</i> -associated diarrhea	74	89	55*
Pouchitis	38	43	32
Crohn's disease	34	39	27
Ulcerative colitis	30	29	32
General wellness	26	25	27
Radiation enteritis	10	14	5

Note: On the basis of 50 total respondents, 28 private practitioners, and 22 in an academic setting.

\*Denotes statistically significant difference between groups.



**FIGURE 1.** Conditions for which physicians believe literature supports probiotic usage.

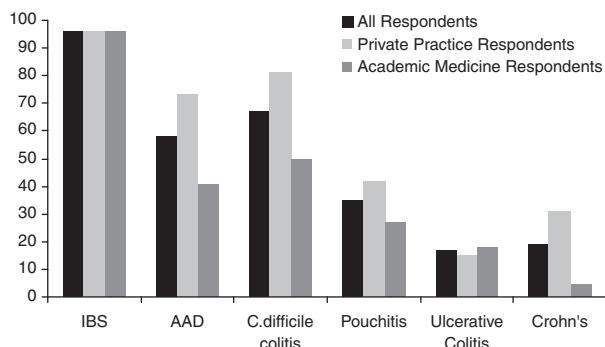
Table 3. Almost all physicians surveyed had patients taking probiotics for irritable bowel syndrome. For most of the other conditions, the percent of patients taking probiotics was similar, regardless whether they received treatment in an academic versus a community-based setting. However in this survey, patients seen by private practitioners more commonly took probiotics for *C. difficile*-associated diarrhea when compared with patients of their academic counterparts, 89% versus 55% ( $P=0.009$ )

**Physicians' Approach to Using Probiotics**

Ninety-eight percent of all practitioners responded that they believe probiotics have a role in the treatment of gastrointestinal illness. However, several practitioners also commented that although probiotic therapy may have a role in their treatment algorithms, there still remains a paucity of convincing data to support such usage. Both private and academic practitioners had similarly positive responses regarding the efficacy of probiotics. Although 82% of the surveyed physicians responded that they were at least "sometimes" effective and 7% responded that they were "always" effective, 11% of physicians had never recommended probiotics in their practice.

Figure 1 illustrates the respondents' opinions regarding the literature supporting probiotic therapy for different gastrointestinal illnesses. Irritable bowel syndrome, antibiotic-associated diarrhea, *C. difficile* colitis, and pouchitis were the conditions in which probiotic usage was believed to be best supported by currently available literature. No physicians affirmatively recognized the literature supporting a role for probiotics in radiation enteritis. Nine percent of physicians responded that they were unfamiliar with the literature on probiotics.

In total 96% of private practice and 85% of academic-based respondents had recommended probiotics. Figure 2 illustrates the probiotic recommendation habits of surveyed physicians. IBS was overwhelmingly the most common condition for which probiotics were recommended by both groups. More private practitioners than academic physicians had recommended probiotics for AAD (73% vs. 41%,  $P=0.04$ ), and Crohn's Disease (31% vs. 4.5%  $P=0.03$ ). Although not statistically significant, the trend was similar for CDAD (81% vs. 50%,  $P=0.07$ ) and pouchitis (42% vs. 27%  $P=ns$ ). The overall responses from the 13% of respondents whose principle specialty was primary care closely approximated the responses from gastroenterologist in private practice for *C. difficile*.



**FIGURE 2.** Conditions for which physicians recommended probiotics in practice.

Table 4 details the most commonly recommended probiotics for each condition. Overall, the most frequently recommended probiotic among the polled group, both private practitioners and academic gastroenterologists, was the proprietary *B. infantis* 35624 species Align. This was true for all conditions listed except for pouchitis in which the combination probiotic VSL#3 was the more frequently recommended among both groups.

The final survey question asked each physician whether they themselves had ever taken a probiotic preparation for a gastrointestinal disorder or symptom. Sixty-one percent of private practitioners compared with 15% of academic-based practitioners had used probiotics in the past ( $P = 0.001$ ).

**DISCUSSION**

Until recently, marketing of probiotics to the U.S. lay public was uncommon and probiotics were rarely recommended by gastroenterologists or the subject of significant discussion at major scientific meetings.<sup>1,10</sup> Although the evidence showing efficacy for probiotics in human disease has been mixed, increased awareness from some high-impact studies and direct to consumer marketing has led to increased interest in the usage of probiotics for gastrointestinal diseases and general wellness. Physicians now regularly encounter patients who use probiotic supplementation as a tool to restore order to their diseased or overly symptomatic digestive tract and for maintaining general health and gastrointestinal homeostasis. However, little has been done to address and quantify how the physicians who

specialize in gastrointestinal diseases have themselves interpreted this increased general interest and the current published data to adopt the use of probiotics into their own practices. Our study, including both private practice and academic hospital-affiliated physicians practicing within a single metropolitan area, now reports several findings to address this topic.

All physicians responded that they believe probiotics to be safe and almost all felt they had a role in treating certain GI illnesses. Some individuals, however, commented that probiotics should be used with caution in certain cases referencing recent literature indicating probiotic supplementation has at least occasionally been associated with adverse outcomes in immunocompromised patients, sepsis, and severe pancreatitis.<sup>11,12</sup>

Similar to prescription medications, significant differences exist in strain, packaging, and dosages of available probiotic preparations. To discern how practitioners accounted for these differences, we asked respondents which individual probiotic formulations they had recommended for the various conditions earlier mentioned. The vast majority of respondents described themselves as at least somewhat familiar with the associated literature and available products, the most recognizable of which were *B. infantis* (Align) and yogurt-based products (Table 2). The wide recognition of these particular preparations may be based on nationwide advertising campaigns for the yogurt-based products. In addition, this particular metropolitan area was a test and initial launch market for *B. infantis* (Align). Although this was important for the time of the survey, *B. infantis* (Align) is now marketed nationwide. Overall these findings suggest that the polled physicians, regardless of practice setting, recognized probiotics as a therapeutic entity and were aware of some of the more common commercially available options.

CDAD and IBS were the 2 most common conditions for which physicians noted that their patients had taken or were taking probiotic supplementation at 74% and 98%, respectively (Table 3). The use of probiotics in CDAD may reflect the increasing frequency of this diagnosis and the physicians' attempts to curtail rates of its development or recurrence.<sup>13</sup> In IBS the high frequency of probiotic use likely reflects several factors including the commonality with which this condition is seen, patients' relative frustration with the incomplete efficacy of other available treatments, and the generally applicable marketing claims of commercially available probiotics such as "improved digestive health" and "maintaining a natural defense against

**TABLE 4.** Most Commonly Recommended Probiotics by Condition

Condition #All/ Private/Academic	IBS 45/25/20	<i>C. difficile</i> 35/24/11	AAD 29/19/10	Pouchitis 22/12/10	Crohn's 13/12/1	Ulcerative Colitis 13/9/4
All physicians (%)	Align (91) Yogurt (44) Flora-Q (38)	Align (51) Florastor (49) Flora-Q (29) Yogurt (26)	Align (59) Yogurt (45) Florastor (48) Flora-Q (28)	VSL#3 (59) Align (50) Flora-Q (18)	Align (54) Flora-Q (46) Yogurt (31)	Align (54) VSL#3 (30) Yogurt (23)
Private practice (%)	Align (96) Flora-Q (56) Yogurt (52)	Align (58) Florastor (50) Flora-Q (33) Yogurt (25)	Align (79) Yogurt (47) Florastor (47) Flora-Q (32)	VSL#3 (67) Align (58) Flora-Q (25)	Align (58) Flora-Q (50) Yogurt (33)	Align (78) Flora-Q (22) Yogurt (22)
Academic (%)	Align (85) Yogurt (35) Florastor (20)	Flora-Q (45) Align (36) Yogurt (27)	Florastor (50) Yogurt (40) Align (20)	VSL#3 (50) Align (40) Flora-Q (10)	VSL#3 (100)	VSL#3 (75) Yogurt (25)

**TABLE 5.** Strength of Evidence Supporting Probiotic Use

Condition	Recommended Probiotics	Strength of Evidence
Pouchitis (prevent and maintain remission)	VSL#3	A
Antibiotic-associated diarrhea	LGG, <i>S. boulardii</i>	A
<i>C. difficile</i> -associated diarrhea	<i>S. boulardii</i> , LGG	B
IBS	<i>B. infantis</i>	B
Ulcerative colitis	<i>E. coli</i> Nissle, VSL#3	C
Crohn's disease	<i>E. coli</i> Nissle, <i>S. boulardii</i> , LGG	C

Adapted from reference 5: Floch MH, et al. *J Clin Gastroenterol*. 2008; 42:S104-S108.

A: recommendation refers to strong, positive, well-conducted, controlled studies in the primary literature.

B: recommendation is based on positive, controlled studies but the presence of some negative studies.

C: recommendation is based on some positive studies, but clearly inadequate amount of work to establish the certainty of "A" or "B."

constipation, diarrhea, urgency, gas and bloating."<sup>14,15</sup> However, although some evidence suggests efficacy for a specific Bifidobacteria species in IBS,<sup>16,17</sup> other probiotic strains have failed to meet IBS study endpoints.<sup>18,19</sup>

Physicians were asked in this survey, whether they believed existing literature supported probiotic usage for certain conditions and then whether they ever recommended probiotics for those same conditions (Figs. 1, 2). Physicians were most impressed with the literature for probiotics in IBS (78%), but more than 50% of respondents also believed data supporting their use in antibiotic-associated diarrhea, pouchitis, and CDAD. This survey did not differentiate between primary and recurrent CDAD. It is notable that for both CDAD and Crohn's disease, the percent of physicians who had recommended probiotics was higher than the percent who believed the literature supported its use. When physicians were asked which probiotic preparations they recommended for the various conditions, it was clear that the most commonly recommended probiotic for all conditions except for pouchitis, was the *B. infantis* strain marketed as Align despite current literature only evaluating this probiotic strain for the treatment of irritable bowel syndrome.<sup>17</sup>

An unanticipated finding of this study was the possible differences in probiotic use practice patterns between academic based and private practitioners. Overall, the responses indicated that private practitioners were more likely to report themselves as familiar with the literature related to probiotics and the various available probiotic preparations (Table 2) (combined greater reported recognition of probiotic preparations  $P < 0.001$ ). They also reported that more, although not significantly so, of their patients took probiotics, which was usually based on their recommendation. Most of the difference is made up by the discrepancies of practice patterns with antibiotic-associated diarrhea, CDAD, pouchitis, and Crohn's disease. Interestingly, *B. infantis* (Align) was also the most frequently recommended probiotic for all conditions except pouchitis for the private practitioners, whereas the academic counterparts had more varied recommendations. Finally, of the physicians who had taken probiotics themselves for a GI symptom or illness, 81% were in community-based private practice.

Additional perspective is gained by comparing the opinions expressed by physicians in this study to the current

published recommendations on probiotic use. Table 5 summarizes the recommendations of an assembled panel of experts who reviewed available literature and assigned a strength of evidence score for the conditions covered in this study.<sup>5</sup> Although these recommendations have not been formally endorsed by the major US gastrointestinal societies, they represent the best "graded" composite viewpoint published to date in our viewpoint. From this group's assessment, the best clinical data for probiotics are in AAD and pouchitis. However, just over half of polled physicians believed that the literature supported probiotics for these conditions. Where the expert panel gave *B. infantis* (Align) a grade "B" and other probiotics a grade "C" for IBS, nearly 80% of practicing physicians believed the literature for this indication and over 90% were recommending probiotics to their patients with IBS. Interestingly, the commercially marketed probiotic that most physicians recommended for IBS, *B. infantis* (Align), was also frequently recommended for other conditions despite a lack of published trials of using this probiotic for these indications. This practice may reflect practitioners' familiarity with *B. infantis* (Align) in treating IBS, but also its ease of access for patients, relative affordability (\$30/mo), and perhaps effective marketing in the community. Few practicing physicians were recommending probiotics in the setting of Crohn's or Ulcerative Colitis, likely reflecting the negligible supporting evidence for probiotics in these conditions.<sup>5,20</sup> It is notable that subsequent to this survey; 3 additional studies, 2 of which were placebo controlled, did find efficacy for VSL#3 in UC within their respective study populations.<sup>21-23</sup> However, overall the findings of this survey suggest that some physicians may overestimate their understanding of the current literature on probiotics. And furthermore, whereas practice patterns for probiotics recommendations sometimes follow published literature and expert panel-based guidelines, frequently the studied probiotic preparation was not the physician-recommended preparation.

The limitations of this study include those inherent to any survey study.<sup>24</sup> Sampling bias of respondents may have skewed results as individuals who were not familiar with probiotics may not have returned the survey. However, the overall response rate of nearly 60% is higher than often encountered in anonymous voluntary questionnaire studies.<sup>8,9</sup> The relatively limited number of respondents may have limited identification or influenced observed differences. To lessen limitations associated with the instrument design of a multiple choice format, the option for a write-in response or commentary was available on all questions. Finally, this was not a nationwide study of all gastroenterologists, but rather an assessment of large metropolitan area and practicing norms that may differ regionally. However, the surveyed physicians included private practitioners serving both rural and urban patient populations and physicians from 2 different academic medical centers.

This is the first study to directly assess practicing physicians' perceptions on the efficacy, use, and practice patterns for recommending probiotics in the treatment of gastrointestinal disorders. This survey shows that most practitioners specializing in gastroenterology in a large, metropolitan area describe themselves as familiar with data regarding probiotics and believe them to be safe and efficacious in treating some gastrointestinal illnesses. As a result, a large percentage of surveyed physicians feel comfortable and recommended probiotics to selected patients within their practices. IBS and CDAD were the most common

conditions for which probiotics were recommended by those polled. Many physicians use the same probiotic preparations to treat different conditions even without supporting evidence for that strain in each condition. In light of these findings, and mounting evidence suggesting that specific probiotic strains work best for specific conditions, further controlled trials, and optimistically major GI society driven development of consensus practice guidelines, will help guide the practicing physician in making rational probiotic strain selection for the appropriate and tested conditions.

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