

CASE STUDY

CLINICALLY STUDIED CULTURELLE® BENEFITS PATIENTS AND MAKES FINANCIAL SENSE



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SUMMARY

Pharmacists at health systems and long-term care facilities can now include on the pharmaceutical protocol the most clinically studied probiotic for patients experiencing:

- Antibiotic associated diarrhea
- Acute-infectious diarrhea
- Traveler's diarrhea

Numerous human clinical trials have shown that supplementation with *Lactobacillus rhamnosus* GG, delivered in many Culturelle® dietary supplement products from i-Health, a division of DSM, significantly benefits the patients with these conditions.

Recently renamed *Lactobacillus rhamnosus* GG,¹ *Lactobacillus rhamnosus* GG is still commonly referred to as *Lactobacillus* GG. Clinical data demonstrates that *Lactobacillus* GG reduces diarrhea resulting from travel to foreign countries,^{2,3} side effects of antibiotics,⁴⁻⁹ and dysbiosis due to viral and bacterial intestinal infections,¹⁰⁻¹² including *Clostridium difficile* infection.¹³⁻¹⁵

This unit-dose hospital pack under the brand of Culturelle® comes with the reassurance for the pharmacist and physician that they are prescribing the most extensively studied probiotic strain since its identification in 1985. The outcome is that the patients feel better quickly, physicians see that the overall digestive system is working better, and pharmacists provide a clinically studied strain. The purchasing officer also recognizes the value and quality of the Culturelle® suite of products. Overall, Culturelle® products may contribute to improved patient care and pharmacy efficiencies.

DATA-DRIVEN DECISION MAKING FOR PHARMACIST & PHYSICIAN

Pharmacists play a crucial role when they are counseling physicians on options for patients experiencing digestive conditions. One of the more common health problems for physicians to address is when they prescribe antibiotics to heal a bacterial infection. The antibiotic often affects the balance of gut microbiota, causing distressing diarrhea. Furthermore, studies have shown that antibiotics can disturb the microbiome for up to one year.^{16, 17}

Clinical research indicates *Lactobacillus rhamnosus* GG reduces diarrhea and minimizes the adverse effects of the antibiotic.⁴⁻⁶ With this medical knowledge, pharmacists can provide the physician with data on why prescribing a probiotic is safe and effective. The findings also support that *Lactobacillus* GG, delivered in many Culturelle® products, helps with nausea, taste disturbances, and bloating, all side effects that can contribute to non-compliance.

When pharmacists and physicians join other colleagues on the Pharmacy and Therapeutics (P&T) committee to add to their

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formulary, they are now including *Lactobacillus* GG in that review because of the evidence and comprehensive way it aids the patient with digestive problems, especially when patients receive antibiotics.

Specifically, when *Lactobacillus* GG, a live microorganism, is administered in adequate amounts, it confers a health benefit on the host. *Lactobacillus* GG promotes the balance of the intestinal microbiota, providing digestive assistance and immune support.¹⁸⁻¹⁹

Lactobacillus rhamnosus GG exerts its effects by:

- Binding to sites in place of pathogens.
- Influencing epithelial barrier function.
- Blocking proinflammatory molecules.
- Releasing antimicrobial substances.

All this activity contributes to the strength of the epithelial barrier, which in turn provides a defense against potential toxins, pathogens, and inflammatory responses.²⁰ With Culturelle® products delivering *Lactobacillus* GG, pharmacists and physicians offer multiple advantages for their patient, including, but not limited to, the following factors:

■ EVIDENCE-BASED AND SAFE PROBIOTIC STRAIN

Probiotic strains differ, and the variances in those strains may be critical in delivering benefits to the patient. Lactobacillus rhamnosus GG is associated with supporting the digestive and immune systems.

Lactobacillus GG contains the most clinically studied probiotic strain in the world. It has been demonstrated in more than 1,000 scientific studies and 200 clinical studies.²¹ The probiotic passes the highest testing standards and limited adverse events in the wide range of clinical studies.¹⁹ *Lactobacillus* GG is also the most clinically studied probiotic in children and infants.²²

Lactobacillus GG significantly reduces common side-effects associated with various antibiotics, ultimately improving compliance and reducing the risk of acquired antibiotic resistance. Reduced risk of upper respiratory infection has also been demonstrated in children.^{23, 24}

“Culturelle® has a 20-year history of providing digestive and immune benefits that support health, including relief from diarrhea,” said Margaret Haldeman, Ph.D., Global Research & Development, Probiotics, i-Health, Inc. “*Lactobacillus rhamnosus* GG’s efficacy and safety have been established in multiple trials in adults, children, and infants.”

ALIGNMENT WITH MEDICAL PROFESSIONALS

Authoritative medical societies, listed below, have endorsed the use of *Lactobacillus rhamnosus* GG to manage acute gastroenteritis.²⁵ They also recognize other benefits such as preventing nosocomial diarrhea,²⁶ treating gastrointestinal conditions,^{8, 9} and relieving pain related to gastrointestinal disorders in children.²⁷

- American Gastroenterological Association (AGA)
- Cochrane Database of Systematic Reviews
- European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)
- European Paediatric Association/ Union of the National European Paediatric Societies and Associations (EPA/UNEPSA)
- Journal of the American Academy of Pediatrics (AAP)
- Journal of the American Medical Association (AMA)
- World Gastroenterology Organization (WGO)

THE DIFFERENCE
CULTURELLE® MAKES
WITH C. DIFF

Although antibiotic therapy is standard for primary *C. difficile* colitis, the frequency of relapse can be as high as 20 percent. If the patient has multiple relapses, involving diarrhea and reappearance of the organism, with its cytotoxin in the stool, they can experience detrimental consequences to their overall health. To counter this negative result, a physician would prescribe *Lactobacillus* GG as it has reduced the relapse rate of *C. difficile* in two clinical trials.^{13,14}

The team at Culturelle® offers a tool whereby each institution can estimate potential cost savings for *Lactobacillus rhamnosus* GG and C. diff. The tool pulls from the number of institutional C. diff infections and calculates the economic burden for the facility. Moreover, it uses published clinical results for the efficacy of *Lactobacillus* GG to reduce C. diff infections, along with an estimate for the number intended to treat with Culturelle® products. The result is a model that estimates the financial benefit of a *Lactobacillus rhamnosus* GG protocol. If you would like a demonstration of the tool, please email margaret.haldeman@dsm.com.

CONCLUSION

The *Lactobacillus rhamnosus* GG strain is the differentiator in the multiple benefits for the patient's immune system. Because of the strong science, pharmacists offer Culturelle® products in their formulary in over 1,000 healthcare facilities across the United States.



**Order from your
wholesaler today!**

Culturelle® has *Lactobacillus rhamnosus* GG, which helps the digestive system work better & supports the immune system by restoring the natural balance of good bacteria in the digestive tract.*

Formulated with naturally sourced *Lactobacillus rhamnosus* GG which is scientifically proven to work in harmony with the human body.*

Able to survive stomach acid and bile

Helps manage relapsing *Clostridium difficile* colitis*

Helps manage antibiotic-associated gastrointestinal side effects*



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Visit CulturelleHCP.com for more info

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* THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

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