

Anticipated Impact of Live Biotherapeutic Products on Fecal Microbiota Transplantation Practice

J. SCHARFEN¹, A.M. KIM², L. FREDELL², Y. NERSESOVA², S. SERRA², J.D. LEWIS³, G.D. WU³, L. LAINE⁴, C.R. KELLY¹

¹Brown University, Providence, Rhode Island

²American Gastroenterological Association Institute, Bethesda, Maryland

³University of Pennsylvania, Philadelphia, Pennsylvania

⁴Yale University, New Haven, Connecticut

INTRODUCTION

- FMT is effective for treatment of recurrent C. difficile infection (CDI), but use is limited by access to FMT material.
- Commercial formulations of live microorganisms, known as live biotherapeutic products (LBPs), are being developed for CDI.
- Late-stage clinical trials are underway.

AIM

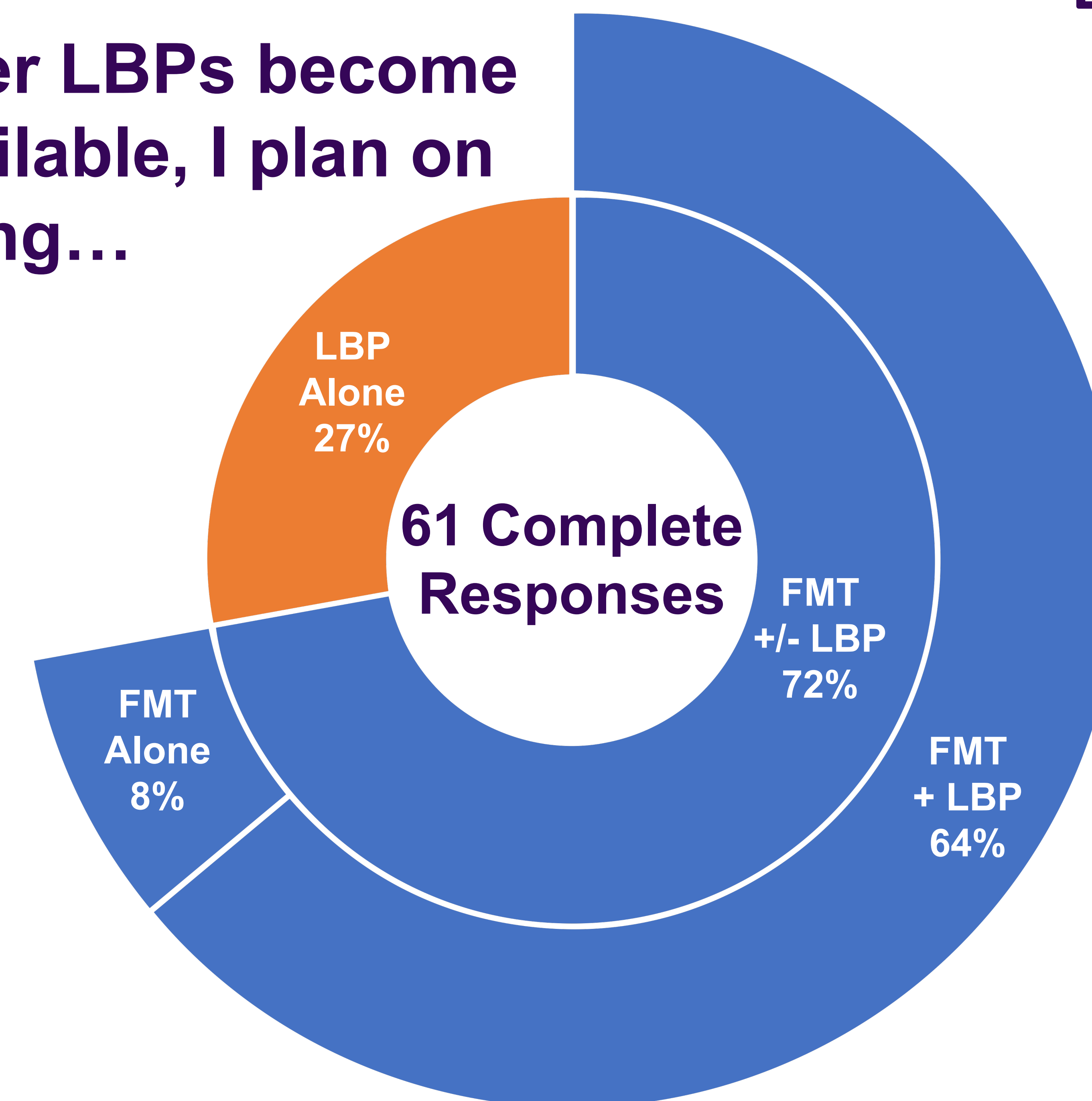
- To understand the impact LBPs may have on the practice of FMT.

METHODS

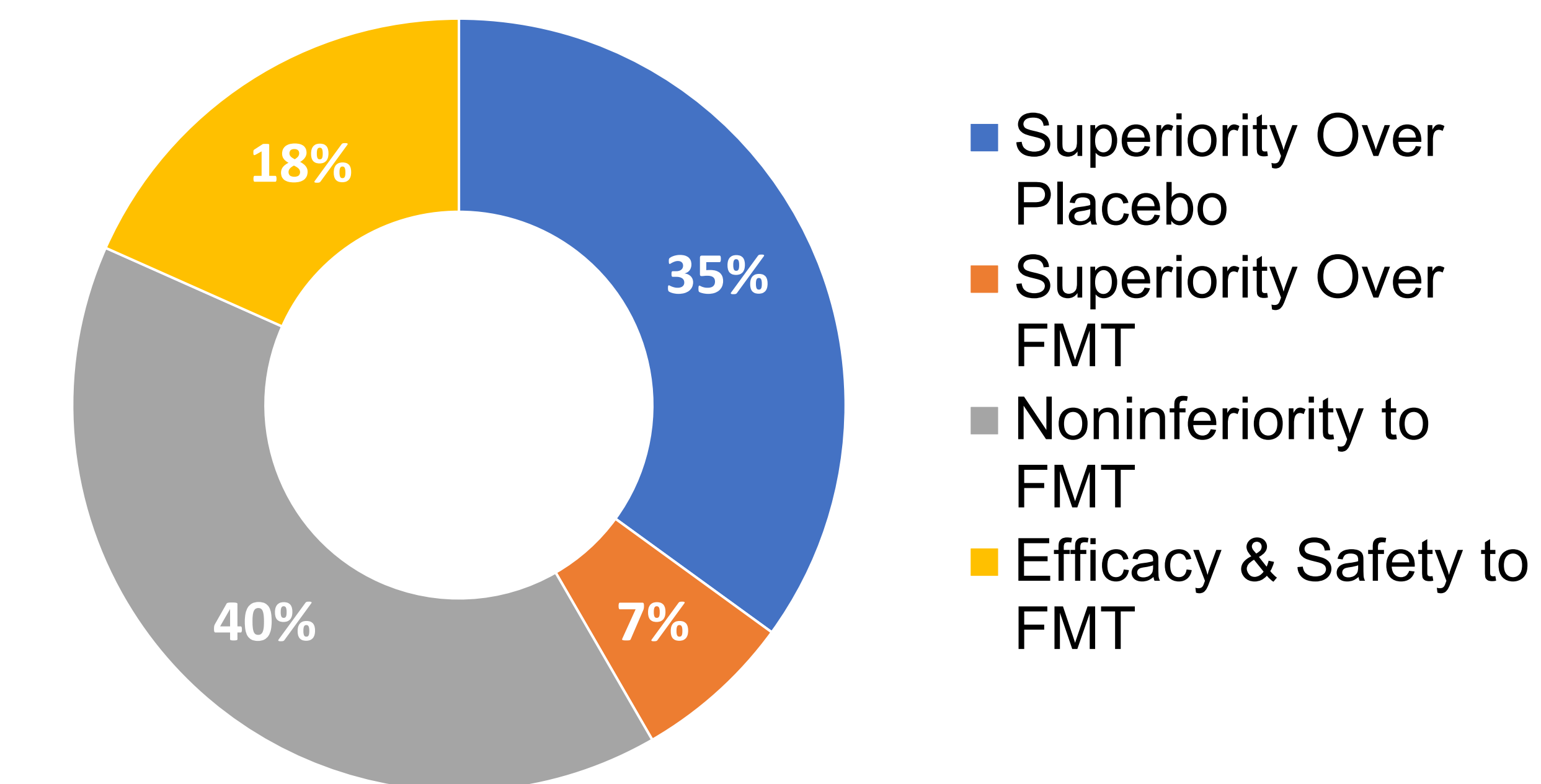
- Survey developed by the FMT National Registry Steering Committee
- Wave 1 emailed on 12/15/2020 to 135 investigators who were currently enrolling participants in or in negotiations to join the FMT registry.
- Wave 2 emailed on 02/09/2021 to 1,050 AGA members who were affiliated with the Immunology, Microbiology & Inflammatory Bowel Diseases and Microbiome & Microbial Therapy sections of the AGA Institute Council.
- Survey closed on 02/25/2021.

RESULTS

After LBPs become available, I plan on using...



Level of evidence needed for me to use LBPs



74% Believe that patients will prefer LBPs over FMT

&

75% Believe that LBPs will be easier to use than FMT

However

62% Believe the LBPs will cost more than FMTs

Concerns

56% That defined consortia may be less effective than whole-stool products

39% That defined consortia may introduce strains not present in a patient's native gut microbiota

61% That the FDA may impose significant restrictions on providers performing conventional FMT

CONCLUSIONS

- LBPs are expected to be approved soon for treatment of CDI by the FDA
- Many practitioners report concerns about cost, efficacy, and unanticipated adverse effects, although most felt patient preference and ease of use would favor LBPs
- A small minority of practitioners plan to continue to use conventional FMT exclusively
- Most respondents felt LBPs had to be at least as effective as FMT to justify their use

ACKNOWLEDGEMENTS

Thank you to the Fecal Microbiota Transplantation National Registry and the American Gastroenterological Association Institute. This research was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under award number R24AI118629.

CONTACT INFORMATION

James Scharfen, Brown University
james_scharfen@brown.edu