



Cystic Fibrosis Research News

Title:

DESIGNING THE GALAXY STUDY: PARTNERING WITH THE CYSTIC FIBROSIS COMMUNITY TO OPTIMIZE ASSESSMENT OF GASTROINTESTINAL SYMPTOMS

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What was your research question?

The GALAXY (Longitudinal Multicenter Study to Determine the Patient-reported Prevalence of GI Symptoms in Persons with CF) Study partnered with the CF community to evaluate existing Patient Reported Outcome Measures (PROMs) in order to develop a standardized clinical outcome measure in the study of gastrointestinal (GI) disease in persons with CF.

Why is this important?

Gastrointestinal (GI) symptoms among persons with CF are very common and has a significant impact on quality of life. Both people with CF and their care providers have identified GI concerns as an area of focus for research, but a lack of clinical outcomes measures has limited progress.

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What did you do?

The GALAXY study team partnered with Community Voice, a group of people with CF older than 16 and their caregivers who are engaged in providing input on research initiatives that benefit the CF community, in order to determine which PROMs most accurately reflected the GI symptoms in people with CF. In addition to partnering with Community Voice, the GALAXY study team also surveyed care team members at accredited CF care centres to determine the comfort level of managing common GI conditions among providers (physicians and advanced practice providers), nurses and dietitians.

What did you find?

Members of Community Voice identified a combination of the Patient Assessment of upper Gastrointestinal disorders-Symptom severity Index (PAGI-SYM), Patient Assessment of Constipation-Symptom severity Index (PAC-SYM) and Patient Assessment of Constipation-Quality of Life (PAC-QOL) as the PROMs that provided the most accurate reflection of GI symptoms in CF. However, based on their feedback on topics that were missing, the Bristol Stool Scale and three stool-specific questions were added. In addition to identifying their preferred PROMs that could be used for clinical or research purposes, they also felt it was reasonable to complete the PROMs weekly and preferred to complete the questions electronically on their phone or smart device rather than in clinic on paper or by email.

Surveys completed by CF care members (208 providers, 149 nurses, 135 dietitians and 17 members who self-classified as other) reported a high level comfort level of managing common GI symptoms such as constipation, reflux and gassiness. However, comfort level was limited to first-line interventions most suitable for mild disease, and in some instances, the diagnostic modalities utilized are not typically advised (such as abdominal x-ray for constipation).

What does this mean and reasons for caution?

By partnering with persons with CF, as well as their caregivers and medical providers, the GALAXY study is designed to uniquely capture the prevalence and severity of GI involvement among persons with CF in a manner that reflects the CF patient experience. Engagement with the CF care teams also clarified areas needing improvement for treatment of GI disease in CF.

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What's next?

The results of GALAXY will inform the development of future interventional trials and serve as a reproducible and objective study endpoint in order to standardize future GI research in CF. The PROMs from GALAXY are currently being used in the PROMISE study and the GALAXY study team is developing three separate interventional studies based on our results.

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