

# Gastroenterology & Endoscopy News

## In the News

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## For Better Clinical Trials, Engage Patients

Sandra Zelinsky is an expert patient. Diagnosed with Crohn's disease at age 19, and breast cancer in 2019 at 36, Ms. Zelinsky has been living with life-altering illnesses for more than a quarter-century. Not long after she received her diagnosis of breast cancer, her Crohn's destabilized and she was admitted for surgery. Following a serious infection after surgery and ongoing complications with the healing process, Ms. Zelinsky sold her business, and she and her husband moved from a small rural town in British Columbia back to her hometown of Calgary, Alberta.

During her recovery, she received an email inviting her to take part in a course called "Patients and Community Engagement Research" (PaCER) at the University of Calgary. The course led her to research and patient advocacy. Today Ms. Zelinsky is a researcher, with published studies and national and international conferences on her curriculum vitae.

"Things just kind of snowballed," Ms. Zelinsky said of her transition from patient to patient engagement researcher. "I couldn't have planned it if I tried."

Ms. Zelinsky presented a study at this year's Crohn's & Colitis Congress in Austin, Texas, titled "IBD Partnerships: Understanding Patients vs. Clinicians' Perspectives of IBD Treatment Options to Improve Shared Decision-Making" (abstract P002).



The pilot study consisted of 21 patients, split into three focus groups. Led by Ms. Zelinsky, the groups worked together to articulate and rank their priorities regarding biologic therapy. The study was externally validated by several gastroenterologists.

The three groups were divided according to where they lived, where they were treated, and how informed they were about IBD research and advocacy. The first group consisted of patients from rural areas being treated by community physicians; the second of patients from urban areas receiving treatment at tertiary care centers; and the third of “very informed patients” familiar with advocacy and research, also from urban areas.

In a novel study design, the groups worked in a series, with the data from the first group analyzed by the second group, and the data from the first two groups analyzed by the third group, Ms. Zelinsky said. Each group generated discussion topics, sorted and themed their concerns, and ultimately defined and ranked their priorities when choosing a biologic therapy. The voting on priorities was anonymous to mitigate group bias.

The data in this study consisted of thoughts and ideas generated by patient discussion.

“I had patients write down one question, comment or concern per sticky note, and we put those sticky notes on the wall,” Ms. Zelinsky said. “Then they had to work through the process of dividing those notes into groups and naming those categories. So, it’s their work, not my work; their lens, not mine.”

### **Risk Reduction a Priority for Patients**



The findings indicated that IBD patients value risk reduction over efficacy when evaluating biologic treatments, in contrast to the “previously demonstrated” priorities of clinicians. They will inform the development of the nationwide patient and clinician surveys that will comprise the next phase of the research, and its final discussion phase.

The project is being conducted by IMAGINE SPOR in collaboration with the University of Calgary, with funding from Takeda’s Canadian division. IMAGINE stands for Inflammation, Microbiome, and Alimentation: Gastro-Intestinal and Neuropsychiatric Effects, and SPOR for Strategy for Patient-Oriented Research.

IMAGINE is a chronic disease research network within SPOR, with a focus on the impact of diet and microbiome in IBD and irritable bowel syndrome. It is currently conducting a trial that seeks to recruit 8,000 patients to study how genetics, diet and mental health each affect the gut microbiome in IBD and IBS, and the overall effect on the course of disease. The study is called MAGIC (Mind And Gut Interactions Cohort). In addition, IMAGINE is recruiting for 13 smaller studies.

Kristin Carman, PhD, MA, the director of Public and Patient Engagement for the Patient-Centered Outcomes Research Institute (PCORI), said her group’s approach is rooted in designing studies to address real-world problems with multiple stakeholders.

“The key is diversity, and diversity means identifying the communities and perspectives who are going to have to be at the table to contribute to effective problem solving for a given research project,” Dr. Carman said. “If we’re testing a treatment that’s going to eat up a lot of time for the clinician, for example, we need a clinician’s voice at the table.”

Disseminating research findings to the people who will benefit is another fundamental concern of PCORI, Dr. Carman said. “You need to know, when the results come out on the other side, that there’s going to be someone who will be interested in implementing them, whether it’s the patient, the clinician or the payor,” she said.

PCORI publishes guidance and funding for those looking to do co-produced research, and hosts an annual meeting each year, with 2020 scheduled for September in Arlington, Va.

“We showcase a lot of work that we’re doing, and we bring our stakeholder communities together to share approaches and methodologies, to network, and to find great ideas,” Dr. Carman said. “PCORI is one of the largest funders of comparative effectiveness research, and what makes us unique is the depth and breadth of stakeholder involvement, as well as our fascinating laboratory of engaged research.”

PCORI's online database contains more than 2,400 citations of research funded by the organization, with links to full articles where available. PCORI has funded 20 trials in IBD since 2016, Dr. Carman said.

## Encountering Doubters

Both Ms. Zelinsky and Dr. Carman said they have faced skepticism about getting patients involved in research.

"I presented at a quality-of-life conference in Berlin in 2014, and during the question-and-answer session after my presentation, a doctor essentially said he didn't see why patients should get involved," Ms. Zelinsky said. "In my head, I was trying to understand this visceral reaction. It's my health, my health care. Why wouldn't I want to be involved?"

Dr. Carman said PCORI responds to skepticism by providing guidance and oversight while letting principal investigators work out the details for themselves. "The way PCORI implemented engagement was to say, 'We're not going to tell you how to do your study,'" she said. "We are going to require that you engage with stakeholders at every stage of the life cycle, but other than that, we want to give projects that have won funding from us the opportunity to innovate."

Paul Moayyedi, MD, PhD, MPH, the joint coordinating editor of the Upper GI and Pancreatic Disease Cochrane Review Group, and IMAGINE's principal investigator, cautioned that clinicians who do conduct patient-oriented research must be vigilant to avoid "tokenism"—or conducting nominally patient-oriented studies—while doing things the same way they always have.

"Sometimes you're leading the way, sometimes you're a contributor, but it's important to really listen to patients every step of the way," Dr. Moayyedi said. "It's also important, when choosing patients, to gather as broad of a set of perspectives as possible in the disease area you're studying. Don't choose someone from your own clinic, for example, or someone who's narrowly focused on a cause or pet treatment, like someone who's super into acupuncture, for example."

Dr. Moayyedi said he expects patient-oriented research to become an "obvious" idea in the future.

"Doctors in the 18th and 19th centuries believed in bloodletting," he said. "Hopefully, in the next 50 to 100 years, we'll look back and wonder why patient-oriented research took so long to arrive."

—Ajai Raj

