

ADVANCING CARE, INNOVATION, AND RESEARCH FOR INFLAMMATORY BOWEL DISEASE

Mount Sinai is one of the world's undisputed leaders advancing IBD research globally combined with the largest footprint of IBD patients in the U.S., with over 10,000 people cared for annually. Our goal at this moment is twofold: First to catch those with IBD as early as possible, to treat and target the disease with absolute precision, personalizing therapies to an individual's genetic makeup, quieting the disease throughout their life while optimizing health and wellness. Second, to prevent IBD from developing in the first place. These aims are within our grasp, and we are pursuing them while working to end IBD for all. Our work will catalyze stunning insights and knowledge, moving the entire field forward, towards this ultimate goal.

Under the leadership of **Drs. Marla Dubinsky, Bruce Sands, and Judy Cho**, the team is expanding their work in precision IBD with the launch of a robust Precision IBD Program, focused on precision biology and translating that research to benefit the patient rapidly and precisely. The next cascade of breakthroughs associated with this research will transform how we diagnose, treat, and target the disease. We will keep you apprised of this work as it evolves.

We are pleased to share some highlights of our recent work.

Precision IBD

- Pharmacogenomics (the use of a patient's genetics to guide their therapy) has started to enter the clinic more with the broader use of panels due to input from our esteemed scientists and physicians. This increase in the use of panels in the clinic, developed for both IBD and other common illnesses like depression and cardiovascular disease, in turn produces more data that leads to new and improved markers that can be incorporated into patient care.
- New, non-invasive testing is being studied, using skin taping (placing a tape on the skin and removing it painlessly) to better classify the immune pathway that is the problem in both skin disease (atopic dermatitis and psoriasis) as well as in IBD. If the pathway can be identified, it can be matched to an appropriate medication.
- By leveraging patients' existing technology, such as smartphones and smartwatches, we can study remote monitoring of patients with IBD to predict flare-ups and intervene early.
- Collaboration is the key to incorporating precision tactics that bring together a variety of modalities from many different patient populations, and it has been a focus over the last few years. To promote collaboration and improve reproducibility, the experts at Mount Sinai participate in the panels that make guidelines for biobank development. As an example, we helped draft the European Crohn's and Colitis Organization's statement on Precision in IBD, which seeks to define outcomes and improve data collection around the world.

The Road to Prevention Study Group

This coalition of Mount Sinai researchers has been making important progress toward their shared goal of preventing IBD. Their focus is on primary prevention, which will identify environmental triggers and remove them before they cause disease, and secondary prevention, which would screen high risk individuals and take measures to stop or slow onset. By collecting and generating large scale data to describe a *pre-disease* state, these two projects are making important steps towards secondary and primary prevention.

- **Julie and Bruce Goldsmith Multiplex Program:** Researchers studied 90 Ashkenazi Jewish families in which there are multiple family members with IBD. Gathering data on genetics, blood, and stool markers, including profiling the microbiome, enabled the development of a highly precise risk score for identifying those with IBD. By continuing to follow family members who do not yet have IBD, scientists can validate if this will also identify those at highest risk for developing IBD. They are also applying new methods, such as using ultrasound to assess changes in the bowel wall that may precede the diagnosis of IBD, and mapping environmental exposures using shed baby teeth. Data from a preliminary cohort have found that early-life metal exposures, as revealed in baby teeth, may be a risk factor for later development of IBD.
- **MECONIUM:** This familial study is examining babies of mothers with IBD as well as unaffected individuals by collecting stool, genetic data, and dietary and environmental exposure data. Results have shown that babies of mothers with IBD have altered profiles of bacteria in their stool that persist over time. In pairing data from MECONIUM and the Multiplex Families Study, it was noted that the development of the microbiome in children with a family history of IBD follows a pattern that is somewhat altered from children who have no family history of IBD. Researchers from MECONIUM are now turning to dried blood spots, which are sampled within days of a baby's birth, to assess whether there are changes that could be noted in a blood sample from this early timepoint that might inform an IBD risk assessment.

Henry and Elaine Kaufman IBD Ultrasound Program

Mount Sinai is currently the first center in the U.S. to use ultrasound to detect and monitor inflammation at the point-of-care, in real-time, making treatment decisions based on findings at routine clinic visits within a context of thorough research. If ultrasound yields results in our research, it could be a game-changing tool for high-risk families to follow siblings, eliminating the need for repeated colonoscopies and diagnostic delays, allowing us to intervene early, before complications or even symptoms develop. This could potentially prevent any chronic damage to the intestines and lead to healing that lasts a lifetime.

- We have performed over 3,000 intestinal ultrasounds for IBD patients at Mount Sinai.
- We are the first intestinal ultrasound training center to help other gastroenterologists become experts in the technique, fostering further adoption for patients around the country. This fall, we are hosting the first hands-on training course for 36 gastroenterologists from different leading academic centers in the United States and Canada.
- We have also been vigorously using intestinal ultrasound to perform impactful patient-centric research, presenting our findings on various projects at the Crohn's and Colitis Congress, Digestive Disease Week, European Crohn's and Colitis Congress, and the North American Pediatric Gastroenterology, Hepatology, and Nutrition Annual Meeting.

- A few key findings from our initial research include:
 - Intestinal ultrasound is more accurate than other non-invasive blood and stool biomarkers compared to endoscopy for monitoring postoperative Crohn's disease recurrence.
 - When monitored proactively with intestinal ultrasound, 90 percent of children with IBD achieve healing of their bowel in response to biologic therapy induction.
 - Intestinal ultrasound activity scores are accurate to endoscopy for disease activity assessment at the point-of-care.
 - Patients prefer intestinal ultrasound for disease activity monitoring compared to other testing options.

- We are the only center in the United States to enroll in an international multicenter study to develop a validated ultrasound Crohn's disease activity score based on endoscopy and MRI and have formed the first prospective international multicenter cohort with two leading IBD centers in Australia using ultrasound to monitor disease activity during pregnancy.

IBD Home Program

This pioneering program focuses on psychosocial aspects that can impact the course of the disease. Each facet of IBD Home is built on evidence-based research that is rapidly translated to our work with patients. Recent updates include:

- Our signature programs, GRITT (gaining resilience through transitions) and COMPASS (which ensures early, aggressive, and multifaceted treatment for ulcerative colitis and Crohn's disease) continued virtually throughout the year.
- We added a GRITT order to our electronic health records system, making it easier to refer patients—and have streamlined the process so that wait time for interaction with a provider is less than two business days.
- The GRITT team is now connected to three new innovative IBD clinics in addition to COMPASS, servicing an additional 10-15 patients per month at a minimum.
- We launched clinics in malnutrition, peri-anal disease, and complex IBD/stem cell transplant.
- IBD patients reported a high degree of satisfaction with telehealth services during the COVID-19 pandemic, with 80 percent of patients agreeing with the statement that “The medical care I am receiving is just about perfect.” Communication and access to specialists were also given high marks.
- We started an internship program approved for future psychologists interested in gastro-psychology; one trainee is enrolled and we are seeking support for further trainees.
- We published the results of the IBD Home GRITT Program in *Clinical Gastroenterology and Hepatology* showing that the model improved health care utilization and reduced opioid and prednisone use (attached) and presented results of IBD Home for new diagnoses at Digestive Disease Week, a national meeting (attached).
- Future clinical and research aims:
 - Recruiting a second dietitian to manage our nutrition need volume.
 - Recruiting a second psychologist to manage volume and provide more in-depth care than our two social workers.

- Planning an innovative “medical-trauma-informed” care program, which has never been done in GI. We already are surveying practitioners and have a quality-improvement project related to patients’ perspectives is underway, but we would benefit from a full-time research coordinator to implement a more systematic, rigorous study including both in- and outpatient IBD.
- We are looking to develop a first-of-its-kind questionnaire to identify low resilience and propensity towards disability, enabling us to intervene sooner with people at risk for poor IBD self-management.

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