

NETWORK Inflammatory Bowel Disease Group

Winter 2013





## A Message from the Director

The Zane Cohen Centre for Digestive Diseases (ZCC) is a clinical research facility and internationally acclaimed as a leader in the understanding and treatment of gastrointestinal diseases. The Centre's research focus is to determine the causes of hereditary familial cancers and Inflammatory Bowel Diseases (ulcerative colitis and Crohn's disease), with an emphasis on their genetic basis. It is because our investigators are clinicians, the Centre prides itself in being able to quickly and efficiently bring new research findings into the medical setting for more tailored treatment and better patient care.

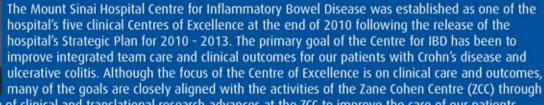
The ZCC is proud of its collaborative team structure consisting of gastroenterologists, surgeons, psychiatrists, psychologists, pathologists, radiologists, molecular geneticists, researchers, genetic counsellors, epidemiologists, pediatricians and IT specialists. We invite you to take advantage of the resources we offer through this newsletter.

> Dr. Zane Cohen Director, Zane Cohen Centre for Digestive Diseases

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## IBD Centre of Excellence Update - Dr. Hillary Steinhart



the application of clinical and translational research advances at the ZCC to improve the care of our patients.

The Centre for IBD has undertaken a number of initiatives to improve the patient experience, enhance quality of care and safety and improve access to care and efficiency of care. On the IBD in-patient unit, the institution of best practices in general surgery, being championed across the province by Dr. Robin McLeod, has resulted in improved patient outcomes. We have also created the role of Patient Navigator on the IBD in-patient unit. The Patient Navigator helps patients and their families through their hospital stay by ensuring that all aspects of their care are organized in a timely fashion and that the transition out of hospital following discharge occurs seamlessly with appropriate continuity of care to the out-patient setting.



## Active Studies at the Zane Cohen Centre

The CCFC Michael J. Howorth GEM Project

Healthy individuals (siblings or children of Crohn's disease patients) who are considered to be at higher risk for developing Crohn's disease are followed over several years and assessed for various factors to determine which contribute to the development of Crohn's disease.

#### The Identification of Genes for Inflammatory Bowel Disease (IBD)

The objective is to identify new genes and biomarkers that may be responsible for causing IBD (Crohn's disease (CD) or Ulcerative colitis (UC)) and understand the role of these. This will lead to a better understanding of why the disease occurs, easier diagnostic tools, better therapies or even a cure. This involves blood sample collection one-time as well as medical data review.

**Tissue (Biopsy) collections, Stool collections & Dietary Information (Food Diaries) for IBD studies**To understand how diet and other biomarkers may affect the gut microbiome (gut bacteria) in IBD (CD or UC), this research involves a one-time blood sample, 4-day food diary, biopsy/stool sample collection as well as medical data review. This may lead to a better understanding of why the disease occurs or how to manage the disease better or possibly a cure.

#### Genetic Analysis of Infliximab-treated IBD Patients

This study hopes to identify which genes are expressed differently between responders and non-responders to Infliximab (IFX) therapy and also to look at differences between IFX-treated UC and CD patients. This research will lead to a better understanding of why some people respond well to IFX and why others may not and possibly help doctors decide if someone should start IFX. This involves blood and biopsy sample collection as well as medical data review during your regularly scheduled visits with your doctor over a period of 30 weeks after your first IFX infusion.

#### Mechanisms of Intestinal Inflammation Following Ileal Resection for Crohn's Disease

This study evaluates microbial and gene expression factors which may be associated with the recurrence of small bowel inflammation following the first ileal/ileocecal or ileocolonic resection surgery for CD. This will have practical implications for evaluating which patients are more likely to rapidly recur as well as provide insight into the pathogenesis of CD. This involves 4-day food diaries, blood and biopsy sample collections as well as medical data review during your regularly scheduled visits with your doctors over a period of 18 months.

#### Characterization of the Intestinal Microbiome in Patients with and without PSC

This research may lead to a better understanding of why Primary Sclerosing Cholangitis (PSC) occurs and what role the gut microbiome and other markers play in PSC and/or IBD. IBD patients with and without PSC (UC or colonic CD) and healthy controls are needed. This involves one-time 4-day food diary, blood and biopsy/stool sample as well as medical data review collection.

The ENABLE Study (Equitability of Insurance Access to Biologics and its Impact on Effectiveness)

The aim of this study is to formally assess the time interval from application for coverage of anti-TNF therapy (including Remicade and Humira) to first dose for privately vs. publicly insured patients with IBD (CD or UC) and to study whether potential delays in access to this therapy will have an effect on health outcomes such as hospitalization or surgery. This involves answering a few demographic questions and medical data review.

**Crohn's Disease Study involving an investigational subcutaneous medication (PF-04236921 – IL-6))**Three doses of medication are studied as compared to placebo. This is a double-blind, placebo-controlled study. There is an open label study that follows this one.

Ulcerative Colitis Study involving an investigational subcutaneous medication (AMG 181-  $\alpha$ 4 $\beta$ 7) This study investigates 4 doses of AMG 181 compared to placebo and is a double-blind, placebo-controlled study. There is an option to enter an open-label study following this one.

Crohn's Disease Study involving an investigational subcutaneous medication (AMG 181-  $\alpha 4\beta 7$ ))

This study investigates 4 doses of AMG 181 compared to placebo and is a double-blind, placebo-controlled study. There is an option to enter an open-label study following this one.

Crohn's Disease Study involving an investigational intravenous/subcutaneous medication (MEDI2070 – IL-23) One dose of MEDI2070 is compared to placebo in subjects who have who have failed, lost response or are intolerant to anti-TNF $\alpha$  therapy. This is a double-blind, placebo-controlled study. There is an option to enter an open-label study following this one.

#### **EVICEL** trial

The purpose of this study is to evaluate the effectiveness of EVICEL, a fibrin sealant, as an adjunct to stapled anastomosis to promote sealing and reduce the incidence of post-operative leaks following a low anterior resection.

For further questions about the studies or to participate, please go to zanecohencentre.ca/ibd/research or contact Joanne Stempak at 416-586-4800 x8399 or jstempak@mtsinai.on.ca.

### News and Events

#### Welcome to our newest team member Dr. Gert Van Assche

This summer we had the great fortune to welcome Dr. Gert Van Assche to our team of gastroenterologists here at Mount Sinai Hospital. Dr. Van Assche is a renowned gastroenterologist and his primary research focus is on novel therapies in fibrogenesis and mucosal immunology in the field of Inflammatory Bowel Disease. Dr. Van Assche received his medical degree from the University of Leuven in 1992. Dr. Van Assche has extensive experience as an advisor and consultant to the pharmaceutical industry in the gastrointestinal field owing to his diverse clinical experience. Gert and his wife and three children are settling in well to life in Toronto.

**Upcoming conferences where our IBD reseach is presented to Canadian & International physicians & researchers**Canadian Digestive Disease Week: March 1-4, 2013, Victoria, British Columbia, Canada
Digestive Disease Week May 18-21, 2013, Orlando, Florida, USA



## Research Study Updates

- Dr. Silverberg's IBD genetics and biomarkers research studies include over 6000 participants collected between 2003-2012. These studies have contributed to finding over 160 single nucleotide polymorphisms (SNPs), which are genetic markers, associated with IBD.
- The role of the microbiome (gut bacteria) is actively being studied by Dr. Silverberg's research group. Preliminary findings show that several groups of organisms are associated with pouch inflammation, with notable decreases in several bacteria with anti-inflammatory potential detected in individuals with inflammation.
- It is important to understand the role of genes and how they act to affect IBD. Dr. Silverberg's research group have preliminary data showing that a number of genes are switched on and off differently in patients who respond to medical therapy compared to those who do not. Likewise, genes are also modulated in a different way in people who remain disease free after surgery.
- The use of complementary and alternative medicine is widely prevalent among IBD patients and is more frequent among those who have experienced adverse effects of conventional medications. From Dr. Nguyen's cross-sectional study, complementary and alternative medicine use does not appear to be associated with reduced overall adherence to medical therapy.
- There is significant variation in reported practices for venous thromboembolism (VTE) prophylaxis (prevention) in IBD patients among gastroenterologists. A more standardized approach to VTE prophylaxis should be implemented to improve health outcomes for IBD inpatients and Dr. Nguyen and his team are researching this area.
- Ambulatory patients have similar prevalence of MRSA, ESBL and VRE compared to non-IBD controls. This finding from Dr. Nguyen's study suggests that the increased MRSA and VRE prevalence observed in hospitalized IBD patients is acquired in-hospital rather than in the outpatient setting.











## Awards and Grants at the Zane Cohen Centre

#### NIDDK/NIH Grant

Dr. Silverberg's NIDDK/NIH grant was recently renewed for another five years. This is a great opportunity for his research group to continue the momentum and add to the achievements of the past 10 years this funding and collaborative effort has accomplished.

## PSC Partners and the International Organization for the Study of IBD (IOIBD)

Dr. Silverberg's group has received funding to investigate and characterize the microbiome in PSC patients (with and without IBD). Funding support has been received from PSC Partners and the International Organization for the Study of IBD (IOIBD).

#### **CCFA Microbiome Consortium**

Dr. Croitoru and Dr. Silverberg are investigators for the Crohn's and Colitis Foundation of America (CCFA) Microbiome Consortium. This is a multi-site study which aims to compare the gut microbiome (bacteria) profile of IBD patients, healthy relatives of IBD patients and healthy people (controls) to study the relation of gut bacteria with host genetic background and gene expression profiles.



The staff of the Zane Cohen Centre thank you for your continued support.

#### We Invite You

To Partner With Us ...
... as we "join the dots more quickly" to bring
new knowledge into practice for
better care for patients and their families.

There are many ways to support our work.

These include gifts of cash, stocks or existing insurance policies.

Legacy gifts to the Zane Cohen Centre can also be designated in a will.

To donate online
www.zanecohencentre.ca/donate
or contact
Patricia Tolkin Eppel, PhD
1-877-586-5112
zcc@mtsinai.on.ca

# MOUNT SINAI HOSPITAL Joseph and Wolf Lebovic Health Complex

Zane Cohen Centre for Digestive Diseases

## **Support Resources**

Treatment of IBD involves more than diagnosis, prescribing medications or undergoing surgery. When confronted with illness, patients seek professional help and advice from their doctor, nurse, social worker and also rely on support from family members, peers and fellow patients.

Our support groups are an excellent resource for patients to gain access to further information on all aspects of their IBD but also provide a safe forum for patents to meet, share information on living with the disease and provide peer support.

For the Daytime support group which starts at 2pm in the 14th floor classroom:

January 30th, 2013 February 27th, 2013 March 27th, 2013

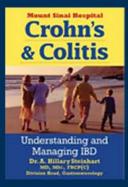
April 24th, 2013 May 29th, 2013

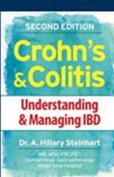
For the Evening support group which starts at 7pm in the 18th floor auditorium:

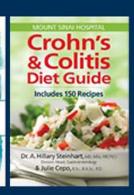
January 28th, 2013 March 18th, 2013 May 27th, 2013

For information about the support groups and speakers, go to http://zanecohencentre.com/ibd/for-patients/ibd-support-network. If you have any questions, please contact Brenda O'Connor at 416-586-4800 x8349 or boconnor@mtsinai.on.ca.

A great addition to your library would be Dr. Steinhart's books:







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