Annual Report

Division of Gastroenterology, Department of Medicine Sir Mortimer B. Davis - Jewish General Hospital April 1, 2006 - March 31, 2007

I. Highlights

The GI division continues to grow both in terms of its faculty as well as in its volume of activity. Our endoscopic procedure volume has increased by 20% from the previous year and our office visits have also increased exponentially by 15% compared to the previous year. These increases result from the recruitment of Dr. Galiatsatos who is specialized in gastrointestinal oncology and also reflects our commitment to respond to the needs of the community and to the hospital staff. We have established a Post Polypectomy Clinic which is a multidisciplinary effort at reducing the incidence of colon cancer in patients who have been identified with colonic polyps. Our clinical research in the field of inflammatory bowel disease and hepatology continues to grow and we are solicited from prestigious international centers for participation in these research activities.

II. Evaluation of the Past Academic Year

1) Teaching Activities

Total clinical teaching hours

Dr. S. Blum, Dr. A. Cohen, Gastroenterology)

Dr. G. Friedman, Dr. N. Hilzenrat consult service) 300 hrs/yr for each

Dr. A. Szilagyi, Dr. P. Galiatsatos physicians

Post-graduate teaching hours

Dr. A. Cohen, Dr. G. Friedman Training of 400 hours/year

Interventional Endoscopy fellows

GI Pathology Conference Wednesdays 8-9 am (alternate week)

Dr. Esther Lamoureux, Dr. L. Alpert

GI Radiology Conference Wednesdays 8-9 am (alternate week)

Dr M Rosenbloom

GI Medical Rounds Fridays 12:30-1:30 pm (every alternate week)

McGill interhospital GI rounds Wednesdays 4-6 pm

MED 1:

McGill Gastrointestinal Physiology Small Group Tutor, Unit IV:

Drs. A. Cohen, G. Friedman, N. Hilzenrat and A. Szilagyi – total number of hours: 16/physician

Total Clinical Teaching hours:

Residents:CTU: 80 hours OPD: 800 Students:CTU: 80 hours OPD: 200

Participation in CME courses

Digestive Disease Week: 28 hours/year

Association des Gastroenterologues du Québec : annual meeting 12hours/year

Update in Liver and Inflammatory Bowel Disease: 14 hours/year

American Congress of Gastroenterology: 12 hours/year

American Association of the study of Liver Diseases: 20 hours/year

2) Research activities

Dr. Albert Cohen

- -Epanova in Crohn's Disease (Epic-1)
- -A One Year, Multi-Center, Randomized, Placebo-Controlled Parallel-Groups Assessment of the Tolerability, Safety and Efficacy of Epanova Soft Gelatin Capsules 4g/day for Maintenance of Remission of Crohn's Disease (CD).
- -ACT Long term Extension phase: (closed to recruitment)
 A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and
 Efficacy of Infliximab in Patients with Ulcerative Colitis Extension phase for 3 years.
- -Leukine Open-label in Crohn's (GM-CSF) Protocol 307340 (BERLEX): An Open-label Trial of Sagramostim (Leukine), a Recombinant Human Granulocyte-Macrophage Colony Stimulating Factor, in Patients with Active Crohn's Disease
- -RESULT- UC (Advanced Biologics)
- -Protocol C0168T62: A Multi-center International Study of the Long-Term Safety of Infliximab (REMICADE) in Ulcerative Colitis; RESULTS UC: REMICADE Safety Under Long-term Study in Ulcerative Colitis.
- -Quebec Genetic Consortium: Identification of the Genes Responsible for Inflammatory Bowel Disease
- -Apheresis in UC/Sham-controlled (Protocol 512-04-205): (closed to recruitment)A Randomized, Prospective, Double-blinded, Placebo-controlled (Sham-controlled) Study to Evaluate the Safety and Effectiveness of the Adacolumn Apheresis System for the Treatment of Moderate to Severe Ulcerative Colitis.
- -Remicade in UC: (closed to recruitment)
 A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients with Ulcerative Colitis
- -Leukine Induction Study in Crohn's (GM-CSF) Protocol 308380(BERLEX): (closed to recruitment)

- -A Phase III Randomized, Double-Blind, Placebo-Controlled Induction Study of Sagramostim (Leukine) in Patients with Active Crohn's Disease
- -Epanova in Crohn's Disease (EPIC-2): (closed to recruitment)
 A Phase 111 Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Multi-Center Study to Assess the Safety and Efficacy of Omega-3 Free Fatty Acids (EPANOVA) for the Maintenance of Symptomatic Remission in Patients with Quiescent Crohn's Disease.
- -Apheresis in UC/Open-label (Protocol 512-04-207)
- -A Prospective, Open-label Study to Evaluate the Adacolumn Apheresis System for the Treatment of Moderate to Severe Ulcerative Colitis.
- -Apheresis in CD/Sham-controlled (Protocol 512-04-206)
- -A Prospective, Randomized, Double-Blinded, Placebo (Sham)-Controlled Study to Evaluate the Safety and Effectiveness of the Adacolumn Apheresis System for the Treatment of Moderate to Severe Crohn's Disease.
- -Apheresis in CD/Open-label (Protocol 512-04-208)
- -A Prospective, Open-Label Study to Evaluate the Adacolumn Apheresis System for the Treatment of Moderate to Severe Crohn's Disease
- -COMMIT Study in Crohn's
- -A Phase III Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Multi-Center Study to Evaluate the Safety and Efficacy of Infliximab in Combination with Methotrexate for the Long-term Treatment of Crohn's Disease (CD)
- -A multi-center randomized double-blind placebo controlled of human anti-TNF monoclonal antibody (Adalimumab) for the induction and maintenance of clinical remission with Crohn's disease. Anti-TNF antibody, infliximab, has had demonstrated efficacy for the induction of remission in Crohn's disease. This new formulation will be given subcutaneously which could reduce costs and difficulties associated with intravenous infusions.

Multicenter National trial

Site Principal Investigator

Co-investigator: Dr. A. Szilagyi, Dr. G. Friedman, Dr. S. Blum, Dr. N. Hilzenrat

-Quebec Genetic Consortium- Identification of the genes responsible for inflammatory bowel disease. This study represents a collaboration between gastroenterologists throughout Quebec, involving all medical faculties in conjunction with the Whitehead Institute and the National Health Institute, Bethesda, MD.

Multicenter International trial

Site Principal Investigator

Co-investigator: Dr. A. Szilagyi, Dr. G. Friedman, Dr. S. Blum, Dr. N. Hilzenrat

-A Phase III randomized multi-centre, double-blind, parallel group, placebo controlled study to evaluate the safety and efficacy and SPD-476 (mesalazine) given twice daily vs SPD-476 given as a single dose (4.8 g/day) in subjects with acute mild to moderate ulcerative colitis. The goal of this study is to evaluate a new formulation of mesalazine with a greater concentration and dosage/tablet as well as a modified pharmacokinetic profile which could allow a simplified mode of administration. This could dramatically improve patient compliance with this class of medication.

Multi-center International Trial

Site Principal Investigator

Co-investigator: Dr. A. Szilagyi, Dr. G. Friedman, Dr. S. Blum, Dr. N. Hilzenrat

-A Phase III randomized multi-centre, double-blind, open-labelled, 12-14 month extension study to evaluate the safety and tolerability of SPD-476 (mesalazine) given once daily vs twice daily for the maintenance of ulcerative colitis in remission. This is a continuation of the previous trial evaluating this modified medication for the maintenance of ulcerative colitis. The issue of patient compliance for maintenance therapy is even more critical then with induction therapy.

Multi-center International Trial

Site Principal Investigator

Co-investigator: Dr. A. Szilagyi, Dr. G. Friedman, Dr. S. Blum, Dr. N. Hilzenrat

-Asacol in Crohn's Disease – A Six Week Randomized Double-Blind, Controlled Trial of Asacol 6.0 g/day Versus Asacol 2.4 g/day for the treatment of Mild to Moderate Crohn's Disease. Dose escalation has been thought to be beneficial in mild to moderate Crohn's disease but previous sulfa based agents limited tolerability at higher doses. Asacol is sulfa free and has not been evaluated at this higher dosage.

Multicenter

Site principal investigator

Co-investigators: Dr. A. Szilagyi, Dr. G. Friedman, Dr. S. Blum

Dr. Nir Hilzenrat

- -Hilzenrat N (P.I) with Idenix Pharmaceuticals, Inc. A randomized, Double Blind Trial of LdT (Telbivudine) versus Lamivudine in Adults with Compensated Chronic Hepatitis B. Protocol: NV-02B-007
- -The effect of information level and coping style on pain and anxiety in needle liver biopsy.
- -Psoriasis and non-alcoholic steatohepatitis-what is the association?
- -Pegasys+Ribavirin for the treatment of naïve subjects with chronic hepatitis C. Supported by: Roche Research Institute.
- -Pegasis + Ribavirin for the treatment of naïve subjects with chronic hepatitis C and normal liver enzymes. Supported by: Roche Research Institute

- -PEG-Intron + Rebetrol for the treatment of subjects with chronic hepatitis C who failed to respond to previous combination therapy (any α -Interferon treatment in combination with Ribavirin). Supported by: Schering-Plough Research Institute)
- -PEG-Intron as maintenance therapy vs an untreated control group in adult subjects with compensated cirrhosis (METAVIR F4) secondary to chronic HCV, who failed to respond to therapy with an α -Interferon plus Ribavirin. Supported by: Schering-Plough Research Institute.
- -PEG-Intron as maintenance therapy vs an untreated control group for prevention of progression of fibrosis in adult subjects with chronic HCV with hepatic fibrosis (METAVIR Fibrosis score of F2 or F3) who failed therapy with PEG-Intron plus Ribetrol (in protocol P02370). Supported by: Schering-Plough Research Institute.
- -Hilzenrat N and Kader T. Chronic hepatitis C liver disease and diabetes- what underlies the association?
- -Hilzenrat N, Cohen A, Friedman G, Szilagyi A, Blum S. Sodium-phosphate with or without magnesium citrate bowel preparation for colonoscopy: randomized, endoscopist-blinded trial.
- -Hilzenrat N, Szylagyi A. The role of AMA and IgM in the natural history of PBC
- -Hilzenrat N and Karagozian R. HCV and extrahepatic cancer what is the association?
- -Hilzenrat N and Karagozian. HCV genotypes and NIDDM what is the association?
- -Hilzenrat N and Kader T. The incidence of diabetes following interferon treatment in patient with HCV.
- -Hilzenrat N, Turbide C, Soulellis D, Deschenes M. Does the rapid decline in biochemical parameters induces by interferon/Ribavirin combination therapy for HCV indicate a sustained virological response?

Dr. Andrew Szilagyi

- -Research on association of diet and probiotics as they relate to colonic disease (IBD carrier)
- -The potential use of lactose as a probiotic agent in the therapy of intestinal diseases.

Dr. Gad Friedman

- -Gastroenterology consultant for Canadian Scleroderma Registry
- -Member of RUGBE (Canadian Registry of Upper Gastrointestinal Bleeding Endoscopy)

3) Clinical Activities

Dr. A. Cohen: Monday to Friday 8-4 pm)

Dr. G. Friedman: Monday to Friday 8-4 pm) 16 528 visits/year

Dr. A. Szilagyi: Monday to Friday 8-4 pm)
Dr. N. Hilzenrat: Monday to Friday 8-4 pm)
Dr. P. Galiatsatos: Monday to Friday 8-4 pm)

Endoscopy laboratory

Monday to Friday: 8-4 pm 10 481 procedures/year

Cholangiopancreatography (ERCP)

Mondays and Thursdays: 1-4 pm 245 procedures/year

Anemia Clinic

Monday, Thursday: 1:30-4 pm 800 procedures/yr

Emergency Endoscopy

Monday to Friday: 8-9 am est. 500/yr

Inflammatory Bowel Disease Clinics

Monday to Friday 8 am-12 pm 3500 visits/year

Clinical trials in inflammatory bowel disease have continued to flourish. We are participating in numerous international clinical trials under the direction of our research nurses, Stefania D'Aleo and Nathalie Desjardins with the assistance of Paula Malolepszy and Marcos Amorim.

Hepatology clinic - Dr. N. Hilzenrat

Monday to Friday 8 am-4 pm 3504 visits/year

Maria Stavrakis and Paul Plaisir are our research nurses in Hepatology. Activities include conduction of clinical trails in Hepatology as well as teaching and monitoring of patients undergoing anti-viral therapy for chronic hepatitis.

In-patient activities revolve around the GI consulting service which is attended by our staff physician on a two week rotating schedule throughout the year. The volume of consultations is approximately 2400/year, the majority of which involve endoscopic procedures.

4) Academic Staff

There has been one new recruit in this past academic year: Dr. Polymnia Galiatsatos, specializing in gastrointestinal oncology.

5) Consulting Activities

6) Honors, Awards and Prizes

None reported

7) Service to Academic Community and other contributions

Dr. A. Cohen

May 9, 2007: Speaker, "Severe Atypical Reflux," Sponsored by Abbott Laboratories, Montreal, Quebec

April 11, 2007: Speaker, "Gastroenterology for family physicians," Sponsored by AstraZeneca, Montreal, Quebec

February 28 – March 4, 2007: AGEQ, Rivièra Maya, Mexico

November 28, 2006: POST ACG-Las Vegas, Musée McCord, Montreal, Quebec

October 12, 2006: Invited Speaker, Information Session on Gastrointestinal Disease, McGill University, Montreal, Sponsored by AstraZeneca

Dr. A. Szilagyi

February 2007: Poster presented at CDDW in Banff, Alberta, Laboratory Tests to diagnose Crohn's disease during Pregnancy

February 2007: Poster presented at CDDW in Banff, Alberta, Fructose malabsoprtion may be gender dependent and fails to show compensation by colonic adaptation

8) Publications

Dr. Albert Cohen

--De Jager PL, Sawcer S, Waliszewska A, Farwell L, Wild G, **Cohen A,** Langelier D, Bitton A, Compston A, Hafler DA, Rioux JD: Evaluating the role of the 620W allele of protein tyrosine phosphatase PTPN22 in Crohn's disease and multiple sclerosis. Eur J Hum Genet. 14:317-21, 2006

Dr. N. Hilzenrat

- **--Hilzenrat N,** Lamoureux E, Cohen A, Baron M: Improved Overlap Syndrome with Infliximab. Gastroenterology and Hepatology, 2:88-89, 2006.
- --Lee S, Bain VG, Peltekian K, Krajden M, Yoshida EM, Deschenes M, Heathcote J, Bailey RJ, Simoyi S, Sherman M, and the Canadian Pegasys Study Group: Anderson F, Feinman V, Green bloom S,

- **Hilzenrat N**, Kaita K, Marotta P, Scully L, Willems B, Witt-Sullivan H, Worobetz L. Treating chronic hepatitis C with peginterferon alfa-2a (40KD) and ribavirin in clinical practice. Aliment Pharmocol Ther, 23:397-408, 2006.
- **--Hilzenrat N,** Yesovitch R, Shrier I, Starakis M, Deschenes M. The effect of information level and coping style on pain and anxiety in needle liver biopsy. Canadian Journal of Gastroenterology 20:597-600, 2006.
- --Nudo C, Wong P, **Hilzenrat N**, Deschenes M. Elderly patients are at greater risk of cytopenia during antiviral therapy for hepatitis C. Canadian Journal of Gastroenterology, 20:589-5922, 2006.

Dr. A. Szilagyi

- --Pharmacological therapy of gastrointestinal vascular malformations. **Szilagyi A,** Ghali MP. Can J Gastroenterol 20, 171-178, 2006.
- --Evaluation of relationships among national colorectal cancer mortality rates, genetic lactase non-persistence status and per capita yearly milk and milk product consumption. **Szilagyi A,** Nathwani U, Vinouroff C, Correa JA, Shier I. Nutrition and Cancer: 55:151-156, 2006.
- --The effect of lactose maldigestion on the relationship between dairy food intake and colorectal cancer. A systematic review. **Szilagyi A,** Nathwani U, Vinokuroff C, Correa JA, Shrier I. Nutrition and Cancer: 55:141-150, 2006.
- --Adaptation to lactose intolerance is not achieved by long term ingestion of a multi species containing probiotic. Malolepszy P, Shier I, **Szilagyi A**. International Journal of Probiotics and Probiotics. 1:113-120, 2006.
- --Acute Symptomatic Gastritis due to Helicobacter heilmannii. Al-Hamoudi WK, Zalpert L, **Szilagyi A.** Helicobacter 11:446-450, 2006.
- --Comparison of a Real-time PCR Assay for lactase genetic polymorphism with standard indirect tests for lactose maldigestion. **Szilagyi** A, Malolepszy P, Hmard E, Xue X, Hilzenrat N, Ponnia M, Macnamara E, Chong G. Manuscript accepted Clinical Gastroenterology and Hepatology 5; 192-196, 2007.

Dr. P. Galiatsatos

- **--Galiatsatos P,** Kasprzak L, Chong G, Jass JR, Foulkes WD. Multiple primary malignancies in a patient with situs ambiguus. Clinical Genetics, 69:528-531, 2006
- **--Galiatsatos P,** Foulkes W. Familial adenomatous polyposis: clinical review. The American Journal of Gastroenterology, 101:385-398, 2006

III. Objectives and Priorities

The main objectives of the division for the coming year are:

- 1) Resolve our critical shortage of space in the face of an exponential rise in the demand for our services. The current space limitations both for office visits but particularly for endoscopic procedures are an insurmountable obstacle to future academic and clinical growth.
- 2) Obtain the necessary equipment for Maximize our efforts for recruitment of a clinician scientist and a clinician teacher.
- 3) Recruit a physician trained in Endoscopic ultrasound. This novel procedure is undeniably pivotal for optimal integration in a comprehensive cancer center.

Respectfully submitted by:

Albert Cohen, MD, FRCPC Chief, Division of Gastroenterology