

Annual Report
Division of Gastroenterology
April 1, 2005 - March 31, 2006

I Highlights

We are delighted to have recruited Dr. Polymnia Galiatsatos to our division. She brings expertise in GI oncology after a fellowship in France.

II Evaluation of the Past Academic Year

a. Faculty

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

b. Clinical Activities

Office visits

Dr. A. Cohen	Monday to Friday	8-4 pm	
Dr. G. Friedman	Monday to Friday	8-4 pm	11 624 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 (started Feb. 2006)	

Endoscopy laboratory

Monday to Friday	8-4 pm	7441 procedures/year
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Cholangiopancreatography (ERCP)

Mondays and Thursdays	1-4 pm	310 procedures/year
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Anemia Clinic

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

Monday to Friday	8-9:00 am	est. 500/yr
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Inflammatory Bowel Disease Clinics

Monday to Friday	8-12 pm	3500 visits/year
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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 Ms. Chantal Coté.

Hepatology clinic

Dr. N. Hilzenrat	Monday to Friday	8-4 pm	3504 visits/year
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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.

c. Honours and Awards

Dr. A. Cohen

Carl Goresky Memorial Award – for outstanding contribution in the field of inflammatory bowel disease; May 2005

Scientific Advisory Committee, McGill IBD Research group
Director, McGill IBD Research Group, JGH Clinical Unit,
Consultant, Inflammatory Bowel Disease, Royal Victoria Hospital
Member, GI Residency Training Program, McGill University
Chair, Dept. of Medicine Practice Plan Management Committee, JGH
Member of Advisory Committee, Dept. of Medicine, Jewish General Hospital
Member of Policy Committee, Dept. of Medicine
Member of Comprehensive Cancer Center Committee, JGH

Dr. G. Friedman

Medical Advisor, Quebec Chapter of Canadian Celiac Foundation
Member, Research Ethics Committee, Jewish General Hospital

Dr. N. Hilzenrat

Senior lecturer, Faculty of Health Sciences, Ben Gurion University, Beer-Sheva, Israel to July 2001
Award for best teacher of the year – GI Division, McGill University, 2005

d. Teaching Activities

Total clinical teaching hours

Dr. S. Blum, Dr. A. Cohen, Dr. G. Friedman, Dr. N. Hilzenrat Dr. A. Szilagyi	Gastroenterology consult service	300 hrs/yr for each physician
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Post-graduate teaching hours

Dr. A. Cohen, Dr. G. Friedman	Training of Interventional Endoscopy fellows	400 hours/year
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GI Pathology Conference Dr. Esther Lamoureux, Dr. L. Alpert	Wednesdays 8-9 am (alternate week)
GI Radiology Conference Dr. M. Rosenbloom	Wednesdays 8-9 am (alternate week)
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: Dr. A. Cohen, Dr. G. Friedman, Dr. N. Hilzenrat and Dr. 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

e. **Service to Academic Community and Other Contributions**

Dr. A. Cohen

- **February 21, 2006**
Speaker, “Colon Cancer Screening”
Family physicians, Westmount Square Clinic, Westmount, Quebec
- **June 22, 2005**
Update on therapeutics in Inflammatory Bowel Disease
Dept. of Pharmacy, SMBD-Jewish General Hospital, Montreal, Quebec
- **May 3, 2005**
Perspectives of Disease of the Gastrointestinal System
Minimed lecture series, SMBD-Jewish General Hospital, Montreal, Quebec

f. **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

Feagan BG, Greenberg GR, Wild G, Fedorak RN, Paré P, McDonald JW, Dubé R, **Cohen A**, Steinhart AH, Landau S, Aguzzi RA, Fox IH, Vandervoort MK: Treatment of Ulcerative Colitis with a Humanized Antibody to the $\alpha_4\beta_7$ Integrin. N Engl J Med, 353:1180-1, 2005

Dr. A. Szilagyi

Szilagyi A, Alenezi B, Lamoureux E, Alpert. Effect of Ursodeoxycholic Acid on Granulomatous Liver Disease due to Sarcoidosis. Digestive Disease and Sciences, Vol. 50:1:196-200, 2005

Szilagyi A, Galiatsatos P, Shrier I, Lamoureux E. Meta-analysis of Outcome of Cytomegalovirus Colitis in Immunocompetent Hosts. Digestive Diseases and Sciences, Vol. 50:4:609-616, 2005

Szilagyi A. Use of Prebiotics for Inflammatory Bowel Disease. Can J Gastroenterol vol 9:8, 2005.

Szilagyi A, Malolepszy, Yesovitch S, Nathwani U, Vinokuroff, Cohen, A, Xue X: Inverse Dose Effect of Pretest Dietary Lactose Intake on Breath Hydrogen Results and Symptoms in Lactase Nonpersistent Subjects. Digestive Diseases and Sciences, Vol. 50:11:2178-2182, 2005

Dr. Nir Hilzenrat:

Hilzenrat N, Lamoureux E, Cohen A, Baron M: Improved Overlap Syndrome with Infliximab. Gastroenterology and Hepatology, 2:88-89:2006

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

g. Research activities:

Dr. Albert Cohen

Epanova in Crohn's Disease (Epic-1) #04-007

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: #04-033 (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): #04-115 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): #04-057

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: #03-091

Identification of the Genes Responsible for Inflammatory Bowel Disease

Apheresis in UC/Sham-controlled (Protocol 512-04-205): #04-083 (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: #02-078 (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): #04-085 (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): #02-093 (closed to recruitment)

A Phase III 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): #04-129

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) #05-105

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) #05-106

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 #05-117

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

Budget: \$45,000

2004 to present

Quebec Genetic Consortium- Identification of the genes responsible for inflammatory bowel disease. This study represents 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

Budget: \$15,000

2003 to present

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

Budget: \$15,000

2004 to present

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 than with induction therapy.

Multi-center International Trial

Site Principal Investigator

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

Budget: \$15,000

2004 to present

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

Budget: \$10,000, London Clinical Trials Group

2002-present

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, Szilagyi 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 prebiotic 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)

Objectives and Priorities

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

COHEN, A.

- 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
- 3) Maximize our efforts for recruitment of a clinician scientist and a clinician teacher.
- 4) Endoscopic ultrasound and recruit a physician trained for this novel procedure. This is undeniably pivotal for optimal integration in a comprehensive cancer center.

Respectfully submitted by:

Dr. Albert Cohen