



U-M Inflammatory Bowel Disorder Program
www.med.umich.edu/ibd

U-M Division of Gastroenterology
www.med.umich.edu/gi

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Our IBD Clinical Study Coordinators

Our IBD research group has recently added two new clinical study coordinators, Judi Schmitt and Meg Chaudhary. Judi is replacing Tahira Khan, and will be working on the CCEA-sponsored Symptom Survey and Biomarkers studies in ulcerative colitis. She will also help with completing the Crohn's Leukopheresis study.

Judi graduated from Eastern Michigan with honors in biology, and previously taught biology at Community High in Ann Arbor. She has worked as a bench scientist in the department of Dermatology, a research assistant in the Clinical Trials Office in the Bone Marrow Transplant group, a research associate for Oral & Maxillofacial Surgery in the Dental school as a Laboratory manager and Clinical Research coordinator/Project manager, and most recently as a Clinical Research Coordinator in the Transplant Research program in the Department of Surgery. Judi likes antiquing, traveling, gardening, reading, quilting and going to U-M football games, art fairs, movies and museums.

Meg Chaudhary is replacing Anne Dahlkemper, and will be working on our ASCRS-sponsored UC Utilities study and helping to complete the Crohn's Leukopheresis study. Meg graduated from the University of Pune, India with degrees in Microbiology, and from the State University of New York at Buffalo with a Master of Science Degree. She has worked in bench research on gene expression in the Epstein-Barr virus, protein expression methods, and cancer research. Meg loves to travel far and wide and enjoys hiking with her dog. She also likes to read and express her creative side through ceramics, drawing and crafts.

Tahira Khan, our previous senior study research coordinator, recently moved to Connecticut with her husband, who was transferred there by Pfizer. She has taken a position as a study coordinator with Pfizer. Anne Dahlkemper departed this summer to start Physician's Assistant School in Oregon, where she is at the top of her class. Tahira and Anne greatly improved our ability to recruit subjects and complete clinical trials in IBD.

Our study coordinators can be reached at:



Judi Schmitt
734/615-2457



Meg Chaudhary
734/615-4843

CCFA Fundraising Walk

A University of Michigan Team – the "IBD Busters" participated in the CCFA Michigan chapter fundraising walk in Maybury State Park on September 8th. IBD Nurses Lisa Sylvest and Terry Logan led the team in their matching t-shirts and hats, and raised more than \$1000 for CCFA Programs.



Lisa Sylvest and Patricia Lai led the Michigan IBD Busters team in the CCFA fundraising walk on September 8th.

IBD News

Fall 2007 U-M Division of Gastroenterology

The following clinical IBD studies are actively enrolling at the University of Michigan:

Utilities and Quality of Life in Ulcerative Colitis

This study, sponsored by the American Society of Colorectal Surgeons, investigates how patients make decisions between medical therapy and colectomy, and how they view their quality of life with and without a colon.

Patients are asked to fill out a single detailed survey about their choices between medication and surgery, and details about their health history that might influence their choices. This is a single-visit study.

The goal of this study is to find out how patients rate their quality of life with and without a colon, and what factors affect how they perceive their quality of life. These results should help us better counsel patients trying to decide between further medical therapy and colectomy in ulcerative colitis.

Measurement of Ulcerative Colitis Disease Activity

This series of studies, sponsored by the Crohn's and Colitis Foundation of America, is ongoing at the University of Michigan. You should call one of our study coordinators if you or someone you know are eligible for one of these upcoming studies:

1. Surveys to Assess UC Disease Activity

This is a study that asks patients for their opinions on survey questions to measure disease activity in ulcerative colitis. Patients are asked to rate the survey questions and make suggestions to improve the measurement of disease activity in UC.

2. Biomarkers of UC Disease Activity

This is a study that measures molecules (biomarkers) in stool, urine, or blood of patients to determine if these biomarkers can provide good objective measures of disease activity in UC patients. Part of the goal is to determine how hard it is to actually collect samples of stool, urine, and blood from patients with UC who are not in the hospital.

3. A Simulated Clinical Trial to Measure UC Disease Activity

This is a study that will use the results of studies 1 and 2 to measure disease activity in patients with survey questions, biomarkers, and endoscopy. We will recruit patients who are actively ill, and collect measurements at 0, 4, and 8 weeks. Their gastroenterologists will be allowed to use any therapy needed to make them better by 8 weeks. We will determine the change in disease activity, and determine which measurement items (survey questions, biomarkers, and endoscopy) contribute accurately to the measurement of ulcerative colitis. The goal of this study is to develop three new, more accurate indices of UC disease activity, one of which will only use survey questions, one which will add biomarkers, and one which will add biomarkers and endoscopy. We will determine how much biomarkers and endoscopy add to the measurement of disease activity, and may be able to encourage noninvasive measurement in future clinical trials.



Study Coordinators:
Judi Schmitt 734/615-2457
Meg Chaudhary 734/615-4843

More information on these studies can be found at www.med.umich.edu/engage.



IBD Visiting Professors Series

Beginning this fall, Shire Pharmaceuticals is sponsoring the IBD Visiting Professors Series at the University of Michigan. Invited IBD researchers will present their cutting-edge results and discuss their research at the U-M Gastroenterology Grand Rounds.

For the 2007-2008 year, the IBD Visiting Professors will be:

September 24th
Dr. Corey Seigel
Dartmouth University

November 13th
Dr. Robert Cima
Mayo Clinic

January 8th
Dr. William Sandborn
Mayo Clinic

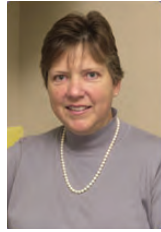
March 11th
Dr. Charles Bernstein
University of Manitoba

April 14th
Dr. Richard Blumberg
Harvard University

May 12th
Dr. Gary Wu
University of Pennsylvania

Gastroenterologists throughout the region are welcome to attend. Contact Patricia Arnold at 734-615-2170 or at reineman@umich.edu if you would like to attend the Grand Rounds.

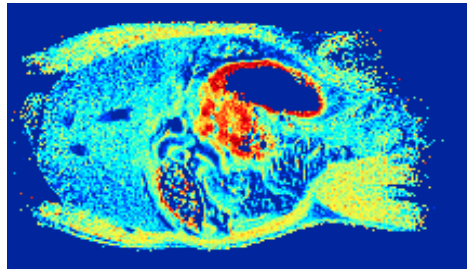
NIH funds Noninvasive Radiation-Free Imaging Research in Crohn's



Dr. Ellen M. Zimmermann recently received a 5-year, \$2.6 million grant from the National Institutes of Health to study the use of non-invasive imaging methods in the assessment of strictures in Crohn's disease. These techniques

include computerized tomography (CT) that specifically looks at the small intestine (CT enterography) and magnetic resonance imaging (MR enterography). Dr. Zimmermann has done preliminary studies in rats with intestinal scarring that is quite similar to Crohn's, and found that a high-tech form of MRI (MT-MRI) is able to identify areas of intestine that are scarred and fibrotic. Either inflammation or chronic scarring can cause narrowing of the small intestine in Crohn's disease. When patients have narrowing of the small intestine, this can lead to pain, nausea, and vomiting. Doctors don't have a way to tell if a narrowing is due to inflammation (which needs to be treated with anti-inflammatory medications) or due to scarring (which usually needs surgery).

These high-tech forms of imaging are in the developmental stages, but they have the potential to quantitate fibrosis of the intestine. These approaches may eventually be able to tell us whether an intestinal narrowing is due to inflammation or scarring in people. Dr. Zimmermann's grant funds further development in animal models, and then application of this technology to scanning patients with Crohn's. This approach has the benefit of not requiring an invasive scope procedure, and not requiring radiation. Clinical studies of patients with intestinal narrowing may help us direct therapy toward anti-inflammatory medications or surgery.



On the Drawing Board

This is a list of clinical studies we are currently designing, considering, trying to get funding for, or filing the paperwork to get institutional permission to do in the future:



- A survey study of people of college age to understand how having IBD affects adjustment to college.
- A study of whether injection of adalimumab next to fistula openings can close fistulas in Crohn's.
- A study of how patients with colitis understand their risk of colon cancer.
- A study of magnetization transfer-MRI to detect intestinal scarring in patients going to surgery for Crohn's.
- A study of whether molecules (biomarkers) in the stool, urine, or blood can predict which IBD patients will be able to taper off steroids faster, and which patients will flare if they taper quickly.
- A study of how bacteria in the lining of the intestine affect recurrence of Crohn's after surgery.
- A study of ultrasound elasticity imaging to detect intestinal scarring in patients going to surgery for Crohn's.

Why Do I Need to Keep Taking Asacol When I Feel Well and My UC is Inactive?



This is a common patient question, and many patients attempt the experiment of discontinuing their 5-ASA medication (these include Asacol, Dipentum, Balsalazide (Colazal), Lialda, Pentasa, and an older, distant relative, sulfasalazine). There are four main reasons to continue these medications when you are feeling well.

First, there is a great deal of evidence that continuing to take the medication at the dose that produced remission is effective in preventing future flares of ulcerative colitis. While stopping the medication is often not a problem in the short-term, eventually symptoms return, usually within a few months. This is part of the fluctuating pattern of IBD – patients often have good periods, but IBD invariably returns with flares unless a maintenance medication is used.

Second, each flare carries the risk that symptoms will not be easily controlled, and will require medications with more side effects, like steroids. Steroids can

cause osteoporosis, diabetes, cataracts, acne, agitation, weight gain in the belly and the face, and fluid retention, among other side effects.

Third, each flare carries a risk that it will not be controllable with medications, and will lead to urgent colectomy, which carries greater risk than a scheduled colectomy. Maintenance medication reduces the risk of colectomy.

Fourth, there is epidemiologic evidence that patients who took at least 2.4 g of 5-ASA per day were less likely to later develop colon cancer (about half the risk of patients who did not take this much regularly).

Approximately 40% of UC patients fail to take their 5-ASA medications regularly. Those that do take them regularly have fewer flares and lower overall medical costs. Most people with IBD need to develop a system to help ensure that they take their medications regularly.

Specializing in Both Ends



Dr. Timothy Nostrant has unusually broad interests for an academic gastroenterologist, with clinical subspecialization in both esophagus and the colon (IBD). Dr. Nostrant is a Professor of Internal Medicine in the Division of Gastroenterology and is the Director of Inpatient Service (Consult and Inpatient Services) at the University of Michigan Medical Center. His areas of clinical interest have revolved predominantly around disorders of bowel motility, including all forms of esophageal, colonic and small bowel dysmotility, and inflammatory bowel disease. His most recent research interests have centered on outcomes research, decision making, and medical management problems in these two clinical areas. Dr. Nostrant is actively pursuing educational interests, particularly in medical

lecturing, medical education research (for which he has received a Masters degree), and clinical trials in inflammatory bowel disease. He has served for 8 years as the Michigan Governor for the American College of Gastroenterology (ACG). He has also served on the Practice Committees for the ACG, as well as the American Gastroenterological Association. He is currently on the Credentials Committee for the ACG. Dr. Nostrant has authored over 100 peer reviewed publications, multiple research reviews, and several audio-visual teaching aids.

Dr. Nostrant is currently developing an audio-visual atlas for Gastroenterology which will serve as a pocket guide for physicians seeking a visual reference during diagnostic evaluations. He is also involved in educational projects for resident training, particularly an interactive internet website and CD-ROM training in Gastroenterology.