Growing Pains and Solutions: 
Adding Physician Assistants and 
Physicians to Our IBD Program

Increasing national recognition and the rapid growth of our IBD program in the past year have been very good things, but we have found that demand for IBD appointments has been growing rapidly. Our wait time for new patient visits with busy IBD experts grew to 3 months or more, and we found that we had difficulty in getting established patients back in for visits quickly when needed. We had more than 5,000 IBD patient visits in 2008, and our referring physician survey in the fall of 2008 identified the difficulty in getting rapid appointments as a problem for physicians making referrals. We had a problem that clearly needed to be addressed.

We listened to what our referring physicians told us. We have added four new providers in the past year to keep up with demand and position our IBD program for further growth. Two physicians have been added to our IBD group. Dr. Michael Rice joined our group in 2009, and provides double balloon and capsule endoscopy for our IBD patients. Dr. Akbar Waljee provides IBD care both at the University of Michigan and at the Ann Arbor Veterans’ Affairs Hospital, and he is the first dedicated IBD specialist in the Michigan VA system.

We have also added two physician assistants, Kristen Boardman and Christine Brozo. This has allowed us to substantially shorten our wait times for new visits. These PAs will help cover our growing number of return visits, as we are following more than 3,000 IBD patients. Kristen and Christine will also help in making urgent appointments available 9 days a week. Any existing patient with a severe flare or a new problem can now be seen the same day or the following day in our IBD specialty clinic by requesting an urgent appointment with a PA, who will staff the visit with one of our IBD specialists. If you have an acute problem, you can be seen on any day of the week by one of our IBD specialists, even if your IBD specialist is not available on that day.

We hope that referring physicians and patients will appreciate the increased availability of appointments in our nationally recognized IBD program.
Patient Assistance Programs

With the recent economic times, money is short in many people's lives. When you are living with Crohn's disease or ulcerative colitis, the expense of ongoing treatment can sometimes become overwhelming. It is very important to talk to your physician about any difficulties you are having with taking your medication regularly. Patients who stop their medications are at a much higher risk of flares, hospitalizations, steroid use, and surgeries. There are a number of programs that can help you and your physician keep your medication going during difficult times. Below is a list of medication assistance programs that may be able to help you continue using your maintenance medications.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Source</th>
<th>Phone</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>Centocor</td>
<td>866-489-5957</td>
<td><a href="http://www.remicade.com">www.remicade.com</a></td>
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<tr>
<td>Purinethol</td>
<td>Gate</td>
<td>877-254-1039</td>
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<tr>
<td>Azulfidine</td>
<td>Pfizer</td>
<td>866-706-2400</td>
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<tr>
<td>Asacol</td>
<td>Proctor Gamble</td>
<td>800-448-4878</td>
<td><a href="http://www.asacol.com">www.asacol.com</a></td>
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<tr>
<td>Pentasa</td>
<td>Shire US</td>
<td>866-325-8224</td>
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<tr>
<td>Entocort</td>
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<tr>
<td>Cimzia</td>
<td>UCB</td>
<td>866-4-cimzia</td>
<td><a href="http://www.cimzia.com">www.cimzia.com</a></td>
</tr>
<tr>
<td>Any</td>
<td>Patient Advocate Foundation</td>
<td>800-532-5275</td>
<td><a href="http://www.patientadvocate.org">www.patientadvocate.org</a></td>
</tr>
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New on the Website

Look for regular updates of content on the University of Michigan Crohn's and Colitis Program website,

New this quarter, we have the Crohn's and Colitis Program Patient Information Packet. This is a large (104 page) downloadable pdf document with lots of helpful information about Crohn's disease and ulcerative colitis. Take a look!

We also have a link with the latest information about swine flu, which is generating a lot of questions from patients on immune suppression.

We also have posted the new video webcasts of presentations in our IBD visiting professor series. These are available as webcasts, or video podcasts downloadable from iTunesU to any Ipod. See the newest lecture on the risks of Clostridium difficile infection in IBD patients from David Binion, from the University of Pittsburgh.

We also have archived pdfs of past issues of this newsletter. Check them out!

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:
Looking for Something Better? **Ongoing Clinical Trials in IBD:**

**Golimumab for UC** – This medication is an under the skin injection of an antibody against TNF alpha, much like Remicade. This medication is designed for use in ulcerative colitis, and a clinical trial for patients with active ulcerative colitis is now underway. After an initial randomized study of induction of remission, subjects will be eligible for a maintenance trial, in which they can receive medication for up to 3 years. Please contact Carrie Bergmans at 734-615-2457 for patients with active ulcerative colitis.

**IL12p40** – Interleukin-12p40 is an important ‘ON’ signal for inflammation, and this molecule can be blocked by specific antibodies and reduce inflammation. This medication (ustekinumab, an antibody against IL12p40) has been successful in clinical trials as an intravenous drug and as injections under the skin. A new study will test whether intravenous medication for rapid control of symptoms, followed by under the skin injections for maintenance, will be effective in patients with active Crohn’s disease. Please contact Carrie Bergmans at 734-615-2457 for patients with active Crohn’s disease.

**Is your intestine scarred?** – Being able to tell whether the intestine is becoming scarred and narrowed in Crohn’s disease before an intestinal blockage occurs is a major goal of the research of Dr. Zimmermann and Dr. Higgins. Two studies of different approaches to this problem are getting underway. Dr. Zimmermann’s NIH-funded study uses a special kind of MRI to detect large molecules, like collagen, as they accumulate in scar in the intestines. Dr. Higgins’ study uses a special kind of ultrasound to measure the stiffness of intestines of patients. Both studies will be available for patients with narrowing in their intestines who are planning on surgery. The results of these imaging tests will be compared to the actual microscopic-level scarring found in the sections of the intestine removed at surgery to determine how accurate these non-invasive, radiation-free approaches to measuring scarring are.

**Measurement of ulcerative colitis and Crohn’s disease** – This is how we find out if new drugs actually work. Unfortunately, all of our current measures require endoscopy, so clinical trials in ulcerative colitis require patients to undergo repeated endoscopies. The EMBARK study, sponsored by Genentech, will test whether measurement of blood markers, stool markers, and symptoms is as good as measurement with endoscopy. Subjects with active UC or Crohn’s will be asked to answer questions about symptoms, provide stool and blood samples, and have a free colonoscopy with biopsies. If your doctor is thinking about doing a colonoscopy to evaluate your symptoms, you could have this procedure paid for by this study.

- A study of the symptoms that bother UC and Crohn’s patients during disease flares, followed by patient-guided development of survey items to measure these symptoms.
- A study of whether molecules (biomarkers) in the stool or blood can predict which IBD patients currently in remission will have a flare, and which patients will stay in remission.
- A study of whether molecules (biomarkers) in the blood can predict which Crohn’s disease patients are actively developing scarring of the intestine.
- A survey study of high school students to understand how having IBD affects their decisions about whether and where to go to college, and how they expect to adjust when they get there.

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How to Refer a Patient to an IBD Clinical Trial

They do not need a clinic appointment – Just call one of our IBD Study Coordinators:

Carrie Bergmans
734-615-2457

Jessica FunNell
734-615-4843

Andrace DeVampert
734-764-0507
IBD News You Can Use

The American College of Gastroenterology Meeting was held in San Diego in October. The highlights in IBD Research included:

- **Asacol once per day.** In a head-to-head randomized study, patients taking all of their Asacol tablets at once did just as well as patients who took their capsules at two different times of the day.

- **Bone density screening is being underused.** IBD patients who have taken steroids for at least 3 months, are smokers, have had low-trauma bone fractures, or are over 60 should have bone density testing. In one study, only one third of IBD patients who met criteria had bone density testing. Among the patients tested, 15% had osteoporosis, and 42% had osteopenia.

- **Skin cancer is on the rise.** IBD patients had a 64% increase in non-melanoma skin cancers compared to non-IBD patients. This risk was particularly increased in patients on long-term immune suppressive therapy, including thiopurines (like azathioprine and 6-MP) or biologic therapies (like Remicade or Humira).

- **Perianal fistulas in Crohn’s disease are hard to close.** Despite surgical intervention, only 45% of patients with Crohn’s disease were able to maintain fistula closure at 6 months. The best predictors of fistula return were active inflammation in the rectum, and a narrowing of the anal outlet (which likely increases the pressure on the fistula opening).

Patient Question of the Quarter:

**Why Does My Doctor Worry About Blood Clots in Patients with IBD?**

We are becoming increasingly aware that patients with IBD are at increased risk of blood clots compared to the average person. Blood clots can form in the legs, and move through the heart to the lungs. These clots can block the drainage of blood from the legs, causing swelling, and can block the exchange of air in the lungs, making patients short of breath. Large clots in the lungs that prevent oxygen exchange can be lethal. Rarely, clots can go through the heart to the brain, causing a stroke. People with IBD have a 3-5 fold increase in the rate of clots in the legs or the lungs.

These risks are increased during active inflammation (during an IBD flare). There is also evidence that the risk of clot formation is increased when taking hormones (birth control pills or estrogen replacement), when immobile for long periods of time (car or plane trips, or in a hospital bed), and in smokers. In addition, the clot risk is increased when taking steroids like prednisone. People with IBD who are hospitalized and taking steroids have a clot risk that is 11 times higher than other patients in the hospital.

The risk of blood clots can be reduced in a number of ways. Controlling inflammation in the bowels is the first step. Avoiding smoking, and avoiding hormone replacement therapy when possible, can help. It is a good idea on long trips to take breaks to walk around and move your legs often. When hospitalized with a flare, it is important to stay mobile (especially moving the legs), and to use anti-clotting medication during this high risk period. While injections of anti-clotting medications like heparin or lovenox are not much fun, they are important to reduce risk during hospitalization, when patients have active inflammation, are relatively immobile, and are often treated with steroids.