



DIGEST



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Our mission is to advance the biopsychosocial understanding and care of patients with functional GI & motility disorders through research, training and education.

SPOTLIGHT ON CENTER'S BIOMETRY CORE

Article by Carolyn Morris, MPH, *Biometry Biostatistician*, and Jane Leserman, PhD, *Biometry Medical Sociologist*

The biometry core, part of the UNC Center for Functional GI and Motility Disorders, works with the Center researchers and clinicians to put their research ideas into a methodologically sound plan for action. The biometry core officially began as a mechanism to review research projects and address methodological issues when our research needs expanded. This was being done informally, but with the Center funding, the core started regular meetings to review research studies by any Center investigator. The purpose of the biometry core is to provide a resource for reviewing the methodology of any research that is being supported by the Center and to suggest improvements with regard to research design, measurement, data analysis, written proposals and papers. These weekly biometry meetings place investigators and the biometry core in the same room to collaboratively discuss all aspects of the research question, often accompanied by a Skype visitor or two from as far away as Singapore. The biometry group is composed of a team that can evaluate research from multiple perspectives and multiple disciplines. To this end, we have biostatisticians, a medical sociologist, a psychologist, and gastroenterologists, each with unique skill sets and perspectives. All fellows within the Center are welcome attendees:

- **Shrikant Bangdiwala, PhD**, is the head biostatistician of the biometry core. A broader explanation on Dr. Bangdiwala and his work can be found on page 20.
- **Carolyn Morris, MPH**, is our assistant "hands-on" biostatistician. She has been with the Center for 9 years. She applies her biostatistical knowledge in



The Biometry Core. Pictured L-R: Spencer Dorn, MD, MPH, Jane Leserman, PhD, Christina Davis, Douglas Drossman, MD, Teresa Hopper, PhD, Carolyn Morris, MPH, Yuming J.B. Hu, PhD, and Jennifer Franklin, MACP, PhD. (Photo by Nicolette DeGroot)

many aspects of analysis from calculating simple descriptive statistics to more complex inferential statistics such as multivariate models. After analysis, she interprets the findings, creates tables and graphs, and effectively communicates the results.

- **Yuming Hu, PhD**, research associate and data manager, has been working with Dr. Drossman since 1992 and with our Center since its inception. Known to everyone as J.B., Dr. Hu works in all aspects of clinical trials from grant idea brain-storming and questionnaire development to the collection, computerization, pre-analysis processing and post-analysis custody of research data. Believing in success from strong team work, J.B. enjoys working with research coordinators, statisticians, and fellow researchers.



The Biometry Core meets weekly. (Photo by Nicolette DeGroot)

- **Jane Leserman, MD**, is a medical sociologist and a professor in the Departments of Psychiatry and Medicine at UNC. She has worked with Dr. Drossman for over 20 years. As an active member of the biometry core, Jane uses her expertise in research design, measurement and data analysis, to address methodological issues that arise in designing new research proposals. Her presence on the team has improved the methodological rigor and quality of these research studies. As part of the biometry team,

BIOMETRY continued on page 20

SAVE THE DATE - IFFGD HOSTED SYMPOSIUM

Nancy Norton
IFFGD President



IFFGD will host the 9th International Symposium on Functional Gastrointestinal Disorders on April 8–10, 2011 at the Pfister Hotel, Milwaukee, WI. The meeting is jointly sponsored by the University of Wisconsin School of Medicine and Public Health, Office of Continuing Professional Development in Medicine and Public Health, Madison, WI and the International Foundation for Functional Gastrointestinal Disorders (IFFGD).

This biennial meeting draws an international audience and addresses issues of interest to multiple health care disciplines, from basic science to clinical care. Consider attending if you are a gastroenterologist, pediatrician, primary care physician, physiologist, basic scientist, epidemiologist, mental health professional, nurse clinician, physician assistant, trainee, or involved in other allied health fields.

- Learn about advances in the pathophysiology of the functional gastrointestinal and motility disorders.
- Develop clinical skills in the diagnosis and care of patients with functional GI disorders.
- Network and share information and experiences with other conference participants.

Learn more about this unique biennial meeting and the many reasons to attend. View a video about the Symposium at: www.iffgd.org/site/news-events/events/professional-symposia.

For further information contact: Terese Bailey, University of Wisconsin, 608-240-2141, tmbailey@ocpd.wisc.edu.

Over the past decade, the UNC Center for Functional GI and Motility Disorders has enjoyed significant grant support from a number of private foundations and corporations. These grants have ranged from sponsorships of specific events (symposia or CME courses) to unrestricted grants in support of fellowships and the Center's education and training effort. The following are among the Center's valued sponsors:

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DIGEST is a quarterly publication of the UNC Center for Functional GI & Motility Disorders, a center of excellence within the Division of Gastroenterology and Hepatology, School of Medicine, University of North Carolina at Chapel Hill.

The Center's co-directors are **Douglas A. Drossman, MD**, Professor of Medicine and Psychiatry, and **William E. Whitehead, PhD**, Professor of Medicine and Gynecology.

For more information about the Center, please visit our website at

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FACULTY PROFILE

Christine Dalton, PA-C
Physician Assistant

What is your title?

Certified Physician's Assistant – Clinical Instructor

Give an example of what you do in a typical day?

I spend much of the day answering phone calls and emails from patients. I also see patients in the functional gastrointestinal clinic (both alone and with Dr. Drossman), and work with our research assistants and study patients.

Currently you are involved in a few gastroenterology studies. What are the studies trying to find out and have you had much success?

- Trials of new medications for functional GI disorders (FGID).
- Usefulness of Medications in patients with FGID that are on the market for different indications.
- Studies assessing gastric motility in patients with nausea and vomiting, and abdominal pain.
- We are having very good results in our studies and are hopeful that our findings will become available to help more patients with FGID.

I understand you are a Physician's Assistant and not a GI doctor. What is the importance of having a Physician's Assistant working alongside GI physicians and researchers?

PA school is a 2 year program that is essentially the two middle years of medical school. After graduation, PAs always work with a supervising physician. The supervising physician is responsible for the further training and professional behavior of the PA.

PAs may work closely with the MD or more independently based on the confidence of the supervising physician.

PAs generally have more time to talk with patients on the phone or in the clinic and are more accessible.

Where did you receive your education and credentials?

Physician's Assistant Program at Wake Forest School of Medicine in Winston Salem.

When did you start working with Dr Drossman at UNC-Chapel Hill?

February 1996

Did you always want to work in GI?

Initially, when I graduated in 1983, there were very few jobs for PAs. I was very fortunate to be hired by a well known GI researcher and clinician at Wake Forest/Baptist Hospital. During that time I met Dr. Drossman when UNC and Wake Forest were collaborating on a research study together.

Did you have any relevant medical experience before your career at UNC?

I worked for 10 years with the GI group at Wake Forest/Baptist hospital -- worked with Upper GI motility disorders (e.g. trouble swallowing and chest pain) and acid reflux. I also saw patients and did research studies. 📞



Christine Dalton, PA-C seen here delivers her talk entitled *What Should you Expect from a Visit to a Functional GI Disorders Clinic?* at Patient Symposium 2010.
(Photo by Nicolette DeGroot)

CLINIC CORNER

PATIENT CARE RESEARCH SUMMARY

Spencer Dorn, MD, MPH
Assistant Professor of Medicine



I am interested in improving care for patients with functional gastrointestinal disorders (FGIDs), especially irritable bowel syndrome (IBS). When I tell others of this interest they typically appear baffled. They ask me why I would be interested in such a challenging group of conditions. How can I handle seeing such “difficult” clinical problems? I admit that FGIDs sometimes frustrate me, too. After all, while FGIDs are quite common (they affect at least 10% of the population), they are poorly characterized, frequently associated with psychosocial stressors, and lack highly effective treatment options. Although a focused evaluation along with ample reassurance and education are sufficient for some patients, a sizeable proportion continues to suffer ongoing symptoms and an impaired quality of life. They may continue to seek health care from gastroenterologists who, at a loss as to what to do next, typically respond by suggesting additional diagnostic tests. Unfortunately this does not alleviate patient suffering; rather by leaving the same questions unanswered it only adds to patient dissatisfaction, exacerbates physician aggravation, and contributes to already exorbitant health care costs.

While the difficulties associated with FGID care cannot be denied, these also make the task of improving care a tremendous opportunity. However, the solution will not be simple. Rather, I believe we need to reorganize care around a new model. My vision of what this should look like has been largely shaped by my clinical experiences at the UNC Center for Functional GI Disorders. There, our multidisciplinary, integrative, patient-centered approach often improves health status and stems the tide of excess health care utilization. However, I am also a student of the healthcare system and I recognize that this model will not be adopted in most practices. Instead, I believe that we need to focus on strategies that are highly feasible and directly appeal to physicians and patients alike. This belief is a driving force behind my research.

Accordingly, we are currently designing and beta testing individual components of an IBS disease management program. First, we seek to improve care within the clinic by collecting essential patient reported information (e.g., health status, quality of life, concerns) at the point-of-care. These data will be automatically transformed into concise 1-page reports that will be given to providers and patients at the clinic visit, thereby enhancing patient-provider communication. Additionally, the data will be stored longitudinally and later analyzed to identify factors that predict favorable and unfavorable clinical responses. The goal is to create a program that may eventually be transported to various practices to facilitate effective communication in even the most time-pressed of settings.

Care for IBS also extends outside of the clinic visit. In a recent systematic review we found that self-management is critically important in IBS. However, most practitioners are unable to support these activities. Accordingly, we plan to develop an integrated, online self-management program that will move beyond the constraints of the clinic to support patients with IBS whenever and wherever they need it. The program will be modeled on the Comprehensive Health Enhancement Support System (CHESS), which has been used as a prototype for dozens of effective internet based interventions.

Upon completion of these pilot programs, the individual components of a highly feasible IBS disease management program would be fully ready to be integrated into an IBS disease management program. The next step would be to assess this program in a clinical trial and, if beneficial, widely disseminate to practices and patients. 🌐



NARCOTIC BOWEL SYNDROME

Douglas Drossman, MD
Center Co-Director & Professor of Medicine

WHAT IS NARCOTIC BOWEL SYNDROME?

The Narcotic Bowel Syndrome (NBS) is a newly recognized condition characterized

by abdominal pain that may have begun after taking narcotics for any type of medical problem and which worsens over time with the continued use of the narcotics. Often, narcotics are not recognized as the cause of the patient's symptoms. It occurs in less than 10% of patients who take high dose narcotics and the reasons as to why some people get this syndrome is unknown. Patients with NBS are often referred to gastroenterologists because their severe abdominal pain is not responsive to narcotics and in fact becomes worse. NBS is different from Opioid bowel dysfunction which relates to the common and predictable effects of narcotics that can include nausea, vomiting, constipation, and bloating.

The abdominal pain of NBS is chronic or intermittent, often crampy in nature, poorly localized, and often accompanied by the usual opioid effects of nausea, vomiting, bloating, constipation, and abdominal distension. NBS can develop in patients with no medical problems who are treated with narcotics for acute pain such as after surgery, or trauma, or it may be seen when treating patients with chronic non-malignant painful conditions like inflammatory bowel disease, or even patients with functional GI pain who are inappropriately prescribed narcotics.

Although helpful initially, over time the pain relief from the narcotics dissipates and increased dosages are needed to relieve the pain. In the US this condition seems more prevalent due to increasing number of prescriptions for narcotics given for all sorts of painful conditions. In fact, 80% of worldwide prescribed narcotics is consumed by Americans. Because of this we expect NBS to continue to become more common.

HOW DO NARCOTICS AFFECT MY GI TRACT?

It is well known that narcotics act directly on the GI tract, although the mechanisms are multiple and not completely understood. Two major effects on the GI tract that are recognized include delayed motility associated with opioid bowel and altered pain sensation (NBS). With regard to the delayed motility narcotics slows down the emptying of the stomach,

and the motility and passage of food contents through the small intestine, thus producing bloating, nausea distension and vomiting. It also slows the passage of stool through the colon and causes constipation because there is less water in the stool, which means the stool is hard and difficult to pass.

The second major effect is altered pain sensitivity. Research has shown that while brief use of higher dosages of narcotics cause pain relief, in some individuals chronic use paradoxically causes increased pain. The increased pain perception and sensitivity in the GI tract relates to affects of narcotics on specific regions of the brain and spinal cord. In the brain long term narcotic use, may impair the brain's ability to reduce the intensity of incoming pain signals. There are also special cells in the spinal cord called glial cells located around the nerves that appear to react to narcotics by producing inflammation. This inflammation releases toxic chemicals called cytokines that increase the pain sensation going from the spinal cord to the brain. In summary, chronic narcotic use can predictably cause constipation, vomiting, nausea, distension, and other effects on motility and in some individuals it can produce increasing pain which we call NBS.

HOW IS NARCOTIC BOWEL SYNDROME DIAGNOSED?

The diagnosis is based on a careful clinical history and detailed physical exam to rule out other serious disease. Laboratory tests, including blood tests, are usually normal. However, abdominal X-rays often reveal large amount of stool and may show signs suggestive of a partial intestinal obstruction.

Diagnostic Criteria for NBS

Chronic or frequently recurring abdominal pain that is treated with acute high-dose or chronic narcotics and all of the following:

The pain worsens or incompletely resolves with continued or escalating dosages of narcotics

There is marked worsening of pain when the narcotic dose wanes and improvement when narcotics are re-instituted (soar and crash)

There is a progression of the frequency, duration, and intensity of pain episodes

The nature and intensity of the pain is not explained by a current or previous GI diagnosis*

**A patient may have a structural diagnosis (e.g., inflammatory bowel disease, chronic pancreatitis), but the character or activity of the disease process is not sufficient to explain the pain.*



NARCOTIC BOWEL *continued from previous page*

Diagnosis of the Narcotic Bowel Syndrome may be suspected when chronic or worsening abdominal pain, together with other symptoms, is related to escalating dosages of narcotics that seem not to be helpful any more.

HOW IS NARCOTIC BOWEL SYNDROME TREATED?

The basis for treatment involves removal of the narcotic as a treatment for pain: detoxification. Detoxification begins first by adding a new medication to help manage abdominal pain prior to the narcotic withdrawal. The most commonly used are antidepressants, either of the tricyclic (TCA – desipramine, amitriptyline, nortriptyline) or serotonin norepinephrine reuptake inhibitor (SNRI – duloxetine, venlafaxine, milnacipran) class. These medications are used in lower dosages than for treating major depression because they are acting on a different area of the brain – that associated with pain regulation.

After a period of treatment with an antidepressant, gradual withdrawal of narcotics is started; this is often done in the hospital setting. Other medications, which help to manage withdrawal effects, are also begun. These may include clonidine which blocks some of the withdrawal effects, anti-anxiety agents like lorazepam which is a benzodiazepine, or quetiapine which helps with sleep, reduces anxiety and enhances pain control.

The most common withdrawal effects to be treated are crampy abdominal pain, anxiety, restlessness, nausea, vomiting, diarrhea and aching of the muscles. Some patients also benefit from talking to a psychologist. Another important part of the treatment is the continued relationship with the doctor. Frequent follow up visits after narcotic withdrawal should be arranged. Despite the possibility of discomfort during the withdrawal period, importantly, once off the narcotics, most patients feel better and narcotics are no longer needed.

RESULTS OF DETOXIFICATION WITH NARCOTIC BOWEL SYNDROME

We recently evaluated 30 patients with NBS who were detoxified on the UNC inpatient service. These were young to middle aged predominantly female patients (average 39 years, 87% female). They had a history of severe abdominal pain (reported as greater than labor or post-operative pain) and many hospitalizations and doctor visits (14.7 visits in 6 months and 6.8 hospitalizations in 2 years) for the pain, and over 80% were unable

to work due to the pain. On average they had been on narcotics for over 5 years and were taking over 80 mg. IV morphine equivalent daily. About $\frac{3}{4}$ were already on an antidepressant and about $\frac{1}{2}$ were on a benzodiazepine anti-anxiety agent just before detoxification began. These patients had a variety of medical conditions including IBS, Crohn's disease, fibromyalgia, postoperative and orthopedic pain, and all were similar by the fact that they developed abdominal pain when on high dose narcotics. They reported many (averaging 17) symptoms rated as moderate to severe in intensity. The most common ones were nausea, fatigue, early satiety, weakness, sleep difficulties and as expected a variety of painful complaints. Psychologically they had very poor coping skills, had poor daily functioning ability, over half reported some abuse history and 30% were clinically anxious or depressed.

All patients underwent detoxification according to our recommended protocol which lasted on average 12 days. Notably 87% were successfully detoxified, and the rest (4 patients) were sent out of the hospital with a prescription for tramadol, which we consider to be a narcotic. Almost all were sent out on antidepressants and anti-anxiety agents and 2/3 were on clonidine. The most notable finding was their dramatic response to the detoxification. There was a significant ($p < 0.03$) reduction in abdominal pain, and non-abdominal ($p < 0.01$) pain, each by over 30%. In addition there was improvement in daily coping ability. Those with less depression were more likely to respond. Unfortunately over half (54.6%) were found to be back on narcotics after 6 weeks on average. These results indicate that patients with NBS can be successfully detoxified with improvement in pain symptoms and coping but there may be enabling factors that lead patients to go back on narcotics. We believe that a concerted effort is needed to educate patients, physicians, regulatory agencies and the general public about NBS in order to reduce or control the use of narcotics for chronic non-malignant pain. 🧠

SUGGESTED READING

- (1) Grunkemeier DMS, Cassara JE, Dalton CB, Drossman DA. The narcotic bowel syndrome: Clinical features, pathophysiology, and management. *Clin Gastroenterol Hepatol*. 2007;5:1126-39.
- (2) Grover M, Drossman DA. Psychotropic agents in functional gastrointestinal disorders. *Current Opinion in Pharmacology*. 2008;8:715-23.
- (3) Drossman DA. Beyond tricyclics: New ideas for treating patients with painful and refractory functional GI symptoms. *Am J Gastroenterol*. 2009;104:2897-902.



CLINICAL PSYCHOLOGY TRAINING IN FUNCTIONAL GI DISORDERS

Stephan Weinland, PhD
Associate Professor of Medicine

The role of clinical psychology in the treatment of functional GI disorders has been

well established in research literature but has yet to be clearly and effectively integrated into gastroenterology practice. One potential roadblock to successful integration is a lack of trained practitioners who have experience working with this patient population. Often times, clinical psychologists specializing in behavioral medicine may have general experience in working with GI concerns but have little formal training on biological aspects of working with these disorders or formal training in how to best integrate into a multidisciplinary GI clinical team.

The UNC Center for FGID provides a unique opportunity to train clinical psychologists in how to implement strategies for working with both functional and organic GI conditions. To our knowledge, this is the only training site in the country that

offers a training experience for psychologists to work with adults in functional GI disorders. An increasing number of clinical psychology interns are training with our center. A rotation offered by the UNC Clinical Psychology Internship Program offers clinical psychology resident interns the ability to select a functional GI disorders rotation consisting of specific training in consultation/liaison psychology in the UNC gastroenterology clinic.

Training involves a combination of didactic and in vivo experiences that provide psychologists with a firm understanding of both the biology and psychology surrounding brain gut dysfunction. Students progress from reading about clinical presentation of a variety of GI conditions, to watching clinicians conduct assessments and therapy, to conducting video

tape supervised sessions and finally progressing to individual therapy and assessment sessions on their own. Additionally, psychologists learn strategies for integrating with a medical team and ways to provide the most effective and beneficial assistance to both physicians and patients.

Practitioners engaging in this training present with basic clinical skills developed over many years of training before seeing any patients in our clinic. Psychologists leave this experience with a firm understanding of how to help patients manage and cope with both a full range of GI concerns. Patients meeting with resident intern practitioners may have concerns about meeting with a resident therapist,

however these students are nearing the final step in their training and have often been practicing clinical psychology for a number of years prior to working with us. In addition, all clinical interactions are fully supervised by a licensed clinician who ensures the standard of care is on par with that provided by fully licensed clinicians.

For the 2010-2011 academic year the UNC Center for FGID is hosting four clinical psychology interns,

and one California licensed clinical psychologist who is receiving additional training in working with functional GI disorders. Our two current psychology interns are David Fingerhut and Cristin Runfol.

Cristin Runfol, M.S. is completing a minor rotation in the Functional Gastroenterology & Motility Disorders Clinic. She will obtain her Ph.D. in Clinical Psychology from Palo Alto University in 2011. As she is undergoing a specialization in eating disorders, she hopes to use the information she learned about the biopsychosocial aspects of functional GI disorders in her care with eating disorder patients, who often present with GI distress.

David Fingerhut, M.S. is a Behavioral Medicine Clinical Psychology Intern with UNC's Department



Pictured L-R: Jennifer Franklin, MACP, PhD, Stephan Weinland, PhD, David Fingerhut, MS and Cristin Runfol, MS. (Photo by Nicolette DeGroot)

VISITING FELLOW

Jennifer Spanier-Stiasny, DO
St. John Macomb-Oakland Hospital, Madison Heights, Michigan



While an undergraduate, I spent a summer engaged in research at Northwestern Memorial Hospital in Chicago. I worked on a systematic review of alternative therapies in irritable bowel syndrome. This was not only my first exposure to functional disorders, but also my first glimpse into the field of gastroenterology. I was fortunate to have an excellent mentor that stimulated my interest in functional disorders and gastroenterology as a whole.

It is fascinating to think how something so commonly encountered as IBS may also pose some of the greatest perceived challenges for gastroenterologists. Having read Dr. Douglas Drossman's work, it was my desire to go to UNC's renowned functional GI and motility center to see what makes this place such an enlightening experience. After having been here I can truly say that its success further flourishes with the help of all those involved. This includes Jennifer Layton who patiently attends to patients in the scheduling process. Sarah Barrett helps visiting fellows acclimate to UNC and feel a part of the center's family. Chris Dalton, PA and Dr. Stephan Weinland play vital roles in contributing to the center's multifaceted approach to patient care aside from involvement in research.

The skills I learned here at UNC go beyond expanding my armamentarium of medications which now include a range of psychotropics. I am now more cognizant of

Being at the center during early November was an optimal time to be at UNC as it was during the weekend of Research Day and the Patient Symposium. It was fun to take in the latest studies and especially hear Dr. Drossman's captivating lecture, *Abuse, Trauma, and GI Symptoms: is There a Link?* I have also been fascinated by the concept of biofeedback so it was exciting to discuss Dr. Steve Heymen's past and future work with him and then later see biofeedback in action with Dr. Mary Scholz.



Jennifer Spanier-Stiasny, DO, Douglas Drossman, MD and Jennifer Franklin, MACP, PhD (Photo by Nicolette DeGroot)

Towards the end of my stay, we made an exciting discovery. A new patient in her early 20's was placed on memantine (Namenda) by a pain management specialist. She had a known history of functional abdominal pain that improved with memantine. This medication is FDA approved for treatment of moderate to severe Alzheimer's dementia. It apparently has been used off label by some for neuropathic pain. Memantine binds N-methyl-D-aspartate receptors and may slow calcium influx and nerve damage (NMDA receptor antagonist). The NR2B subunit of the NMDA receptor may play a critical role in the modulation of anterior cingulate cortex sensitization and visceral pain. Along with the center, I hope to further investigate memantine's utility in functional abdominal pain and narcotic bowel syndrome.

Overall, my experience at UNC has been highly stimulating. I am grateful for my time spent at the center. I look forward to sharing my experiences here with my home institution. Dr. Drossman is a truly inspiring mentor. On behalf of all visiting gastroenterology fellows, thank you! 🙏



Douglas Drossman, MD and Jennifer Spanier-Stiasny, DO
 (Photo by Nicolette DeGroot)

picking up on nonverbal cues and selectively choosing superior word choices that will better enable patients to divulge a greater breadth of information.



CENTER VISITOR

Liming Zhu, MD

*Department of Gastroenterology, Beijing Union Medical College Hospital
Beijing, China*

I am most pleased to write this article for your newsletter. I have worked for 15 years in Peking Union Medical College Hospital, one of the most prestigious hospitals in China. My specialty relates to the functional gastrointestinal disorders and within that specialty had read the articles of Professor Doug Drossman at the UNC center for Functional GI and Motility Disorders and in particular information on Rome III. In fact I had taken part in the translation of the Roma III book into Chinese. Because of these



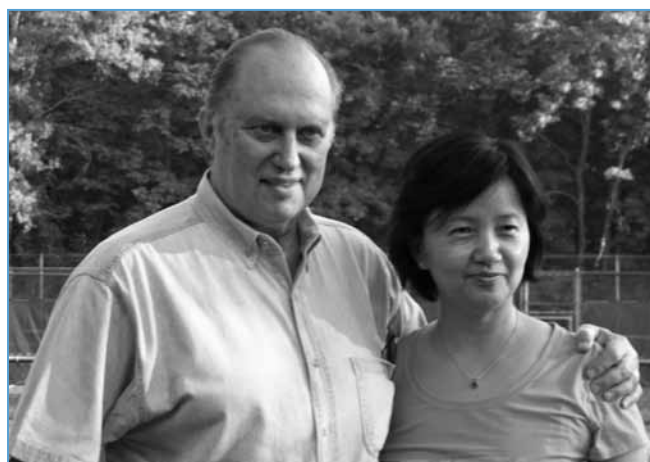
Kathe Davis and Liming Zhu, MD

associations and my interest, I looked forward to visiting the UNC center. I left Beijing and stayed in Chapel Hill from July 3, 2010 to October 5, 2010. I was struck by how peaceful and beautiful this university town was. I was warmly greeted by the Center staff when I arrived.

My main interest was to observe the clinical activities in the functional GI clinic with Dr. Drossman, Chris Dalton, Steve Weinland and others. I also attended GI procedures, the inpatient consult service and also participated in teaching sessions, and did individual studying, attending research meetings, seminars, and symposia. What struck me was the level of patient centered care with great attention not only to the symptoms but also the patient's thoughts, feelings and individual experiences. I learned also how their illness

influenced their family life and their feelings about their own sense of self. The clinicians carefully reviewed the patient's medical record, conducted a patient centered interview to understand the unique impact of the illness on the individual, performed a complete physical examination and discussed the results with the team. Finally they developed a comprehensive biopsychosocial understanding of the illness as a group and then negotiated treatment options with patient. The way this information was processed and discussed was a remarkable learning experience for me as a visiting scholar as well as for the other students, fellows and visiting professors in attendance. Furthermore, I had the opportunity to discuss these cases one on one with Dr. Drossman who I found to be a pleasure to work with. I truly learned how to treat the whole person rather than focus solely on the disease. I also had the opportunity to attend the research (Biometry) conferences of Dr. Drossman's group and also the research meetings of Dr. Whitehead's group. I learned a great deal about research methodology and also about new medical entities such as IBD-IBS, Narcotic bowel syndrome, the use of central agents like antidepressants in combination and all of this considerably updated my medical knowledge.

In general I spent a remarkable informative and enjoyable 3 months at UNC and am thankful to all the clinicians, investigators and staff who helped me in my learning. ☺



Douglas Drossman, MD and Liming Zhu, MD
(Photo by Nicolette DeGroot)

CENTER VISITOR

PERSONAL REFLECTIONS ABOUT CHAPEL HILL

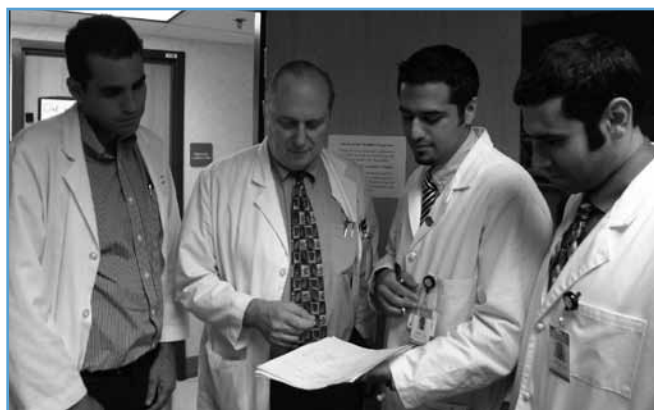
Roy Dekel, MD

Department of Gastroenterology, Tel Aviv Medical Center, Ichilov Hospital, Israel



Well I wasn't really sure what was going to happen during my visit in Chapel Hill. Of course I knew it's a leading center in functional GI disorders but still I had no idea who and what I was actually going to meet when I get there.

Well I thought to myself, worst come to worst, people say North Carolina is a pretty place and I will have a chance to do some sightseeing.



(Pictured L-R: Roy Dekel, MD, Douglas Drossman, MD, Kunwardeep Sohal, MD and Shehzad Sheikh, MD, PhD)
(Photo by Nicolette DeGroot)

The first day arrived and I was going to see my first patient with the IBS fellow. She was a nice 60 year-old patient with about a 40 years history of functional GI problems that made her life miserable. On top of that she also had some major psychological issues with severe anxiety, depression and a history of abuse. She had already been to many GI doctors as well as psychiatrists and didn't get any help from them. After the fellow and I finished taking her history I was pretty sure there is not much more that could be done to help her. Forty five minutes later, after we went back to see her with Dr Drossman I realized how wrong I was.

Treatment of functional GI patients in the UNC functional GI center is really exceptional. Patients are not treated as a defective organs that we have to fix but as people with a life story, fears, concerns and wishes. Empathy is not just a slogan but a real and powerful medical tool. Every patient gets the maximal attention and a real interest in their story and his problems. These things are not easy to achieve. In fact the vast majority of GI doctors are not even interested in trying to achieve them. It requires patience, devotion and

a strong spirit that is ready to deal with failures and is willing to delay immediate satisfactions in order to get a real big one down the road. Most of all it requires that you really care (in the personal as well as the professional sense) about your patients.

Obviously, talking and listening are not enough. The unique use of medications, as done here, also impressed me and is really ground breaking in the field of GI. After I had the chance to see their effect I will definitely consider introducing of atypical anti- psychotics into our daily practice. This is a major treatment breakthrough that unfortunately hasn't gotten enough credit and exposure in the GI literature.

I had the chance to join and observe not only Dr Drossman but also Dr Madanick, Dr Dorn, Dr Weinland and Chris Dalton during their clinic and found out that everybody are committed to that special spirit and way of work as well as being extremely professional. I had also the chance to get some useful views and opinions from Dr Whitehead and Dr Heyman and attended biofeedback sessions with Mary Sholtz. Undoubtedly their work in the pelvic floor area is excellent, and I am currently trying to implement some of the things I have learned in our biofeedback clinic.

Moreover on a more personal level, everybody I had the pleasure to contact with during my visit was always nice and helpful in every way.

I would like to take that opportunity to thank everybody for their help in making my visit such an interesting and fruitful experience and I truly hope that it would not be the last one. 🌟



Douglas Drossman, MD and Roy Dekel, MD
(Photo by Nicolette DeGroot)

<http://www.med.unc.edu/ibs>



RESEARCH SUBJECTS NEEDED

CAUSES OF SYMPTOMS STUDIES

Genetic and Environmental Factors that Cause or Influence IBS

This study involves measuring the relationship between genes, the environment, and various psychological and health factors in men and women with IBS. Individuals who participate will spend one overnight visit in the Clinical and Translational Research Center at UNC Hospital. No additional visits required.

Participation

- Must be 18 years or older
- Must be diagnosed with IBS by a physician.
- Participants completing the study will receive \$250.
- For more information on how to sign up please visit: www.uncmedresearch.com/ibsstudy or call toll free 866-227-0067

Principal Investigator
William E. Whitehead, PhD

Research Nurse
Lenore Keck, RN
(919) 966.8329
akeck@med.unc.edu

Healthy Controls Needed for Research Study

We are conducting a research study investigating a broad range of factors that may cause or influence IBS. We are looking for control (comparison) subjects without IBS or any other gastrointestinal (stomach or bowel) symptoms to participate.

Participation

- Must be 18 years or older.
- Must have not experienced any gastrointestinal symptoms within the last 3 months.
- Must fill out various health questionnaires & physiological testing
- Involves one 4 hour visit to the Clinical and Translational Research Center at UNC Hospital.
- Participants completing the study will receive \$50.
- For more information on how to sign up please visit: www.uncmedresearch.com/ibsstudy or call toll free 866-227-0067

Principal Investigator
William E. Whitehead, PhD

Research Nurse
Lenore Keck, RN
(919) 966.8329
akeck@med.unc.edu

Online Study - Qualitative Analysis of Episodes of IBS

We are looking for patients with IBS to complete an online survey which allows them to answer open-ended questions regarding their personal symptom experience. By examining these reports, we hope to gain a better understanding of how patient symptoms change over the course of an episode and to identify any patterns in symptom experience.

Participation

- Must be currently experiencing symptoms of IBS.
- Must be able to understand and communicate using written English.
- No compensation is offered for this brief survey.
- To take online survey, log on to: http://www.med.unc.edu/medicine/fgidc/qualitative_analysis.htm and click the link.

Principal Investigator
Stephan R. Weinland, PhD

Research Assistant
Megan Houpe
(919) 843.4422
megan_houpe@med.unc.edu

Food and abdominal pain in adolescents and young adults

Many adolescents and young adults who suffer from chronic abdominal pain report food sensitivities which may result in avoidance of certain foods. A research study at UNC investigates which foods patients avoid and what kind of symptoms these cause. If you participate you will be asked to complete three daily food diaries over the phone as well as a questionnaire on eating and symptoms. No visits to UNC are required.

Participation

- Ages 15-17.
- Diagnosed with recurrent abdominal pain or Irritable Bowel Syndrome by a physician.
- You can take part in the study whether or not you avoid eating certain foods.
- You will receive \$40 for completing the study.

Principal Investigator
Miranda van Tilburg, PhD

Research Assistant
Megan Squires
(919) 843.9755
megan_squires@med.unc.edu



TREATMENT STUDIES

RESEARCH SUBJECTS NEEDED

Narcotic Bowel Study	<p>We plan to characterize the nature of the Narcotic Bowel Syndrome population and their response to treatment (i.e., detoxification). This will be an observational study. If you have chronic abdominal pain from any medical condition that is treated with high-dose narcotics, you could be eligible to participate in this study.</p> <p>Participation</p> <ul style="list-style-type: none"> Research assistants will contact patients during treatment at pre-detoxification, post-detoxification, and three and six month follow-up. At each time, the patient will complete questionnaires relating to treatment including symptoms, demographic information and psychological effects. 	<p>Principal Investigator Douglas A. Drossman, MD</p> <p>Research Assistant Christina Davis (919) 966.0729 christina_davis@med.unc.edu</p>
Men and Women with IBS and Chronic Functional Abdominal Pain	<p>The purpose of this study is to try to improve functional bowel disorder symptoms with a combination of Seroquel and anti-depressant medication. Seroquel is an FDA-approved medication that is currently on the market and used in the GI clinic.</p> <p>Participation</p> <ul style="list-style-type: none"> Must be at least 18 years of age. Must have been diagnosed with functional bowel disorder within the past 6 months. Must be on an anti-depressant medication for at least the past four weeks. Study entails seven visits at UNC hospital over a 12 week period, Seroquel treatment once a day for 8 weeks, and \$350 compensation for completion. Some visits involve a brief physical and lab work, which are free to the patient. 	<p>Principal Investigators Douglas A. Drossman, MD Stephen Weinland, PhD Christine Dalton, PA-C</p> <p>Research Assistant Megan Houpe (919) 843.4422 megan_houpe@med.unc.edu</p>
Men and Women with IBS with Diarrhea	<p>Participation</p> <ul style="list-style-type: none"> Men and women who have been diagnosed with Diarrhea predominant Irritable bowel syndrome by a physician Must have had a colonoscopy in the previous 5 years or be willing to undergo a colonoscopy/flexible sigmoidoscopy depending on age Requires approximately 6 visits to UNC over 12 weeks Patients will be compensated for their participation 	<p>Principal Investigator Douglas A. Drossman, MD</p> <p>Research Coordinator Teresa Hopper (919) 966.8328 teresa_hopper@med.unc.edu</p>
Need men and women between the ages of 18-65 with a diagnosis of IBS by Rome III criteria with a subtype of diarrhea	<p>Participation</p> <ul style="list-style-type: none"> Has your physician diagnosed you with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)? The UNC Center for Functional GI and Motility Disorders is conducting a research study to evaluate an investigational drug To be eligible, you must be between the ages of 18-65, diagnosed with IBS-D, had colonoscopy within 5 years. 	<p>Principal Investigator Douglas A. Drossman, MD</p> <p>Research Coordinator Teresa Hopper (919) 966.8328 teresa_hopper@med.unc.edu</p>

RESEARCH DAY 2010

On November 5-6, 2010, the Center hosted its sixth annual Research Day. The program focused on six areas of on-going research: (1) Self-Management Therapies, (2) New Techniques for Diagnosis, (3) Pain Management, (4) Post-Infectious IBS, (5) Genetic Studies of IBS, and (6) Pelvic Floor Disorders. The format included presentations in these areas by visiting scientists, followed by overviews of on-going studies involving UNC faculty and investigators. The event was supported through educational grants from Takeda and Ironwood Pharmaceuticals.

KEYNOTE LECTURE

****Speaker Kurt Kronke was unable to attend Research Day 2010. Douglas Drossman filled in for Kronke with a new Keynote speech.****

- Douglas Drossman, MD (UNC-CH)
Abuse, Trauma and GI Symptoms: Is there a Link?

SELF-MANAGEMENT THERAPIES

- Alben Halpert, MD (Boston University)
State of the Art: Expressive Writing - Promising Self-Management Therapy in IBS
- Susan Gaylord, PhD (UNC-CH)
Treatment of IBS with Mindfulness-Based Stress Reduction
- Rona L. Levy, MSW, PhD, MPH, FACG, AGAF (University of Washington)
CBT for Children with Functional Abdominal Pain: Possible New Delivery Formats
- Spencer Dorn, MD, MPH (UNC-CH)
Multi-Component Point of Care Program to Improve FGID

NEW TECHNIQUES FOR DIAGNOSIS

- Olafur Palsson, PsyD (UNC-CH)
Predicting Diarrhea from Triggers and Warning Sensations: A Diary Study
- Stephan Weinland, PhD (UNC-CH)
Characterizing IBS Symptoms using Ecological Momentary Assessment
- Miranda van Tilburg, PhD (UNC-CH)
Parental Misconceptions of Fecal Incontinence in Children
- Spencer Dorn, MD, MPH (UNC-CH)
Development of a Scale to Measure Patient Satisfaction with Care
- Millie Long, MD, MPH (UNC-CH)
Is Narcotic Use Related to Disease Activity in Patients with IBD-IBS Overlap?

PAIN MANAGEMENT

- Douglas Drossman, MD (UNC-CH)
Results from the UNC Narcotic Bowel Syndrome Study

- William Whitehead, PhD (UNC-CH)
Lubiprostone Effects on Pain
- Olafur Palsson, PsyD (UNC-CH)
Developing a Questionnaire to Identify Pain-Sensitive GI Subjects
- William Whitehead, PhD (UNC-CH)
Treatment of Levator Ani (Rectal Pain) with Biofeedback
- Steve Heymen, PhD (UNC-CH)
CNS Down Regulation of Pain Sensitivity in IBS
- Stephan Weinland, PhD (UNC-CH)
What is the Impact of IBS on the Patient's Partner?

POST INFECTIOUS IBS

- Motoyori Kanazawa, MD, PhD (Tohoku University, Sendai, Miyagi, Japan)
Physiological Features of Post-Infectious IBS
- Miranda VanTilburg, PhD (UNC-CH)
Partnership with the Department of Health and Human Services to Recruit Post-Infectious IBS Patients

GENETIC STUDIES OF IBS

- William Maixner, PhD, DDS (UNC-CH)
State of the Science: Pain Genetics
- Miranda van Tilburg, PhD (UNC-CH)
Possible Mitochondrial DNA Abnormalities in IBS
- William E. Whitehead, PhD (UNC-CH)
Heterogeneity of IBS Investigated with Structural Equation Modeling

PELVIC FLOOR DISORDERS

- Arnold Wald, MD (University of Wisconsin)
State of the Art: Managing Fecal Incontinence
- Catherine Matthews, MD (UNC-CH)
Surgical Innovations for the Management of Fecal Incontinence
- Steve Heymen, PhD (UNC-CH)
Conservative Treatment of Fecal Incontinence
- Barbara Robinson, MD (UNC-CH)
Influence of Stool Consistency and Urgency on Occurrence of Fecal Incontinence
- Steve Heymen, PhD (UNC-CH)
Simplified Test for the Diagnosis of Disordered Defecation (3-D Study)

PATIENT SYMPOSIUM 2010

The Center held its biennial Patient Symposium on Sunday, November 7, 2010 at the Siena Hotel in Chapel Hill. The program highlighted new perspectives and treatments in the field of functional GI disorders. Attendees listened to fourteen presentations and participated in breakout sessions which provided them opportunities for questions and answers with the symposium faculty. Special guest speakers included Arnold Wald, MD from the University of Wisconsin, Alben Halpert, MD from Boston University, and Nancy Norton, President of the IFFGD. The Patient Symposium was made possible through educational grants from the following sponsors: Procter & Gamble, Takeda Pharmaceuticals, Prometheus Therapeutics & Diagnostics, and Ironwood Pharmaceuticals.

UNDERSTANDING FUNCTIONAL GI DISORDERS

- Douglas Drossman, MD (UNC-CH)
Overview of IBS and Other Functional GI Disorders
- Ryan Madanick, MD (UNC-CH)
Chest Pain and Swallowing Difficulties
- Spencer Dorn, MD, MPH (UNC-CH)
Nausea, Vomiting, and Functional Dyspepsia
- Arnold Wald, MD (University of Wisconsin)
Pelvic Floor Disorders, Constipation, Incontinence & Rectal Pain

WORKING TOGETHER

- Nancy Norton (IFFGD President)
The Patient Perspective
- Alben Halpert, MD (Boston University)
Doctor-Patient Relationship
- Stephan Weinland, PhD (UNC-CH)
The Role of the Psychologist
- Christine Dalton, PA-C (UNC-CH)
What Should you Expect from a Visit to a Functional GI Disorders Clinic?
- Miranda van Tilburg, PhD (UNC-CH)
Working with Children: Self-Management Tips for Parents



MANAGEMENT

- Stephan Weinland, PhD (UNC-CH)
Psychological Treatments (CBT, Hypnosis, Stress Management)
- Steve Heymen, PhD (UNC-CH)
Biofeedback for Pelvic Floor Disorders
- Douglas Drossman, MD (UNC-CH)
Medical Treatment
- Spencer Dorn, MD, MPH (UNC-CH)
Dietary Approaches & Probiotics
- Teresa Hopper, PhD (UNC-CH)
Going into a Treatment Trial

BREAKOUT SESSIONS

- *Ask us about Functional GI Disorders and their Management*
Douglas Drossman, MD; Spencer Dorn, MD, MPH; Ademola Aderaju, MD
- *Diarrhea, Constipation and Rectal Pain*
Arnold Wald, MD; William E. Whitehead, PhD; Steve Heymen, PhD
- *Your Relationship with your Doctor*
Nancy Norton, Alben Halpert, MD; Christine Dalton, PA-C
- *Psychological Treatments for Adults and Children*
Stephan Weinland, PhD; Miranda van Tilburg, PhD

PHOTO MONTAGE LEGEND. **Photo 1:** L-R: Teresa Hopper, Stephan Weinland, Steve Heymen, and Spencer Dorn at a panel discussion. **Photo 2:** A patient speaks to Stephan Weinland during a Breakout Session. **Photo 3:** Renée Pickle volunteers at Patient Symposium. **Photo 4:** Nancy Norton, Alben Halpert and Miranda van Tilburg at a panel discussion. **Photo 5:** Staff and volunteers work the registration table. *Top row: Mokie Rooker, Renée Pickle, and Erin Slater. Bottom row: Ceciel Rooker and Sarah Barrett.*

(Photography and photo montage by Nicolette DeGroot)

ACG 2010

The ACG Annual Scientific Meeting and Postgraduate Course
October 10-15, 2010 | San Antonio, Texas

The UNC FGIMD Center was represented at the 2010 American College of Gastroenterology (ACG) Annual Scientific Meeting and Postgraduate Course. ACG presented William Whitehead with a Master's Award, Douglas Drossman gave the Keynote speech and

taught a course, while members of the FGIMD Center presented posters. This year's program delivered the latest clinical updates in gastroenterology and hepatology, and discussed what is on the horizon that impacts GI practice.

ACG 2010 MASTERS RECIPIENT



William E. Whitehead, PhD Receives American College of Gastroenterology Master's Award

The American College of Gastroenterology is the oldest of the professional societies representing gastroenterology, and its primary focus is clinical practice, clinical research, and teaching. Each year the college recognizes a handful of members as Masters of the American College of Gastroenterology for their sustained contributions to the profession in one or more of these areas. In October of this year the college elected Dr. William Whitehead and 4 other members to this elite group.

Dr. Whitehead's election represents a milestone for the college – he is the first non-physician member in the society's history to become a master. His selection was based on a long history of clinical research. He is a career investigator who has been continuously funded by NIH since 1977, and he has received research support from NIDDK, NIDCR, NICHD, NIA, NINR, and NIMH. His 35 R01 grants have included studies of (1) the causes and treatment of fecal incontinence in special populations such as spina bifida and the elderly, (3) the causes and treatment of constipation, (3) treatment of rumination syndrome in developmentally disabled children, (4) the role of visceral perception in IBS, (5) comorbidity of IBS with other disorders, and (6) psychological and behavioral treatment of IBS. He has published 280 journal articles, books, and book chapters and more than 250 abstracts on these topics. He is also a member of the NIH Behavioral Medicine Review Committee, the Data and Safety Monitoring Board of the NIDDK Gastroparesis Research Network, the Scientific



William Whitehead with wife,
Jan Busby-Whitehead



Advisory Board of the NIDDK Managing Abdominal and Pelvic Pain (MAPP) Research Network, and the NIDDK Campaign for Public Awareness of Fecal and Urinary Incontinence.

His honors include Fellow of the American College of Gastroenterology, Fellow of the American Gastroenterological Association, Janssen Award for Clinical Research, International Foundation for Functional Gastrointestinal Disorders Award for Research Excellence, and Functional Brain-Gut Research Award for Clinical Research. He is Professor of Medicine (Gastroenterology and Hepatology Division) and Adjunct Professor of Obstetrics and Gynecology (Urogynecology Division) at the University of North Carolina at Chapel Hill. He is also Co-Director of the UNC Center for Functional Gastrointestinal and Motility Disorders. Dr. Whitehead was trained as a clinical psychologist (University of Chicago, 1973). He has spent his career working with gastroenterologists to develop behavioral medicine treatments for patients with motility and functional gastrointestinal disorders.



ACG 2010 KEYNOTE LECTURE



Douglas A. Drossman, MD as Keynote speaker at ACG 2010

Douglas A. Drossman presented his research on Monday, October 18, 2010 at the American College of Gastroenterology conference, held in San Antonio, Texas.

Drossman presented The American Journal of Gastroenterology Lecture entitled *Abuse, Trauma, and GI Illness - What is the Link?* A video and a full article can be found at www.med.unc.edu/ibs.

Also at ACG, Drossman taught a course in the *What's New in GI Pharmacology Course* entitled *Pharmacologic Treatment of Chronic Functional Abdominal Pain: What's New?*, which summarized the current pharmacologic treatment options for chronic functional abdominal pain with correlation to pathogenesis.



ACG 2010 POSTER PRESENTATIONS

Inpatient Consultations of Patients with Functional GI Disorders (FGIDs) at a Tertiary Care Center: The Value of Diagnostic Testing

Justin Crocker, MD, Spencer Dorn, MD, Carolyn Morris, MPH, JB Hu, PhD, Douglas Drossman, MD

Purpose: While patients with FGIDs are managed as outpatients, a proportion are hospitalized for diagnostic evaluation and treatment. We sought to determine: (1) the prevalence and clinical features of inpatients with FGID diagnoses seen on the gastroenterology (GI) consultation service; and (2) the value of diagnostic testing.

Methods: We used a claims roster to identify all non-liver related in-patient GI consultations performed over one year in a tertiary care teaching hospital. Electronic medical records before and during hospitalization and after discharge were reviewed, and the reasons for consultation were determined. For patients with an FGID-related reason for consult, data were abstracted on patients and their hospitalization-related characteristics.

Results: 102 (6.7%) of 1,514 consultations were admitted with symptoms ultimately attributed to an FGID. Among the patients with FGIDs the most common diagnoses were: functional nausea + vomiting (29% of FGIDs), functional abdominal pain (27%), and irritable bowel syndrome (IBS) (22%). The FGID patients were predominantly middle-aged (43.9 +/- 15.9 years), Caucasian (69%), women (80%) with health insurance (92% insured). Prior to admission, 44% had visited the UNC Emergency Department (range 0-127) and 43% had been hospitalized at least once for a GI related condition (range 0-16). Also, 34% had a prior FGID diagnosis, 55% had a co-existing psychiatric disorder, and 41% had another functional somatic syndrome (e.g., fibromyalgia). Over 2/3rds (69%) had at least one prior abdominal/pelvic surgery, 71% had a prior CT, MRI or ultrasound and 60% had undergone at least one colonoscopy and/or EGD. The average inpatient length of stay was 5.5 + 8.6 days. For these 102 patients, during hospitalization, a total of 38 CTs, 23 ultrasounds, 36 EGDs, and 18 colonoscopies were performed (mean per patient 0.5+0.7 imaging test and 1.5+1.6 endoscopies). Of all the tests performed on patients with a pre-existing FGID diagnosis, only one colonoscopy provided an additional diagnosis (left-sided ischemic colitis). This was in a middle-aged woman with a cardiomyopathy who had an acute worsening of her chronic abdominal pain (over 5 years). Colonoscopy two months later showed marked improvement.

Conclusion: Patients with FGIDs seen by the GI consult service at a teaching hospital had frequent prior healthcare visits and also had many diagnostic studies that continued during their current hospitalization. However, the utility of repeated testing is questionable for existing FGID symptoms; only if objective clinical features change should repeat testing be considered.

[Supported by NIH R24 DK067674.]



DROSSMAN RECEIVES DOCTOR HONORIS CAUSA FROM UNIV. OF ROMANIA

Douglas A. Drossman received an honorary doctorate degree from the University of Medicine and Pharmacy Iuliu Hatieganu, to recognize his achievements in the field of gastroenterology, and of his continuous support to the development of knowledge on functional gastrointestinal disorders in Romania. The ceremony was held on Friday, October 29th, 2010 at the university in Cluj-Napoca.



CCFA 2010 PRESENTATION ABSTRACT

The feasibility of guided imagery treatment for abdominal discomfort in pediatric patients with quiescent inflammatory bowel disease

Emilee Colella, BA, Sandra Kim, MD, Megan Squires, BA, Miranda A.L. van Tilburg, PhD

Background: Pediatric patients with quiescent inflammatory bowel diseases (IBD) commonly experience abdominal discomfort similar to patients with functional gastrointestinal disorders such as Irritable Bowel Syndrome (IBS). Guided imagery is a highly effective therapy for functional abdominal discomfort but has not been tested in patients with quiescent IBD.

Specific Aim: To determine the feasibility of audio-recorded guided imagery therapy in pediatric IBD patients in remission experiencing IBS-associated symptoms, specifically abdominal discomfort.

Methods: IBD patients in remission but still experiencing abdominal discomfort were recruited from the UNC Pediatric IBD clinic. Patients received a previously established audio-recorded guided imagery treatment for the treatment of abdominal discomfort, which could be used in the child's home. The patients' primary caregiver completed questionnaires regarding disease - related quality of life, functional disability, and abdominal pain.

Results: 10 patients ages 9-17 (mean: 14.6 ± 2.7 years; 30% male, 70% female), were enrolled. Caregivers reported a mean frequency of abdominal pain in the last two weeks of 3-6 days. The mean frequency of disease related problems effecting quality of life in the past 7 days was "almost never" and mean disease - related functional disability was "little to none". One patient finished the complete treatment and 4 patients completed part of the treatment; in addition, 2 patients discontinued treatment due to IBD exacerbation, and 3 patients were lost to follow-up. Of those enrolled, 2/3 of all patients had a diagnosed psychiatric illness

Conclusion: In this pilot study, home-based guided imagery therapy was not feasible in pediatric IBD patients with quiescent disease who had abdominal discomfort due to IBS. There may be various explanations for this. Treatment material was considered not age appropriate for older adolescents; thus, they may benefit more from adult-based treatments. In addition, functional abdominal pain was high in this patient population, but decreased quality of life and functional disability were almost non-existent. Lack of perceived significant impairment differentiates these patients from pediatric patients with functional abdominal pain and likely reduces willingness to comply with guided imagery exercises daily. Finally, most IBD patients suffered from significant anxiety which is associated with poor treatment outcomes in behavioral trials. Of note, all medical providers reported that they liked guided imagery programs since it decreased parental/patient reluctance to seek psychological treatment for patient anxiety. Further efforts to address the need for treatment of functional gastrointestinal symptoms, with or without associated psychological co-morbidity, may benefit children with IBD. ☺

UPDATE: U.S. CONGRESSMAN FOR FGID RESEARCH

Dane Christiansen
Development Coord., IFFGD



There's an old saying on Capitol Hill, *Congress only works for crisis or Christmas*. This expression refers to the flurry of legislative activity that takes place between Thanksgiving and Christmas-eve as legislators rush to complete important outstanding business and adjourn for the year. However, after an exhausting campaign season that saw Republicans winning control of the House of Representatives, this year neither party seems interested in using this time period to tackle any major legislative issues.

Of the high-profile issues left unfinished, Congress has yet to complete work on their FY 2011 appropriations bills, including the Labor-HHS-Education Appropriations bill, which funds the National Institutes of Health (NIH) and other federal health entities. If legislators opt not to complete the bills this year, they can instead pass a Continuing Resolution (CR). A CR would level-fund all programs at FY 2010 levels and could either be year-long or short-term (giving legislators a few more months to complete work on, and pass, final bills).

Another high-profile issue that legislators are delaying meaningful action on is Medicare Physician Reimbursement. The current short-term patch keeping a 23% cut in Medicare Physician Reimbursement rates from taking effect is set to expire before the end of the year. Congress has opted not to consider more substantial legislation that would avert this cut for 13 months or advance any proposals to permanently address this persistent problem. Instead, legislators will likely pass another short-term patch and resume talks on this issue in the next Congress.

The end of the congressional session also has implications for House Resolution 1309, the

congressional resolution calling for increased study for the Functional GI Disorder (FGID)

Irritable Bowel Syndrome (IBS), which will expire when Congress adjourns. The strategy during the current session of Congress was to take the limited time available to establish a strong core of congressional supporters who could carry this issue forward indefinitely, like Congressman David Price (D-NC). Congressman Price visited the UNC Center to learn about their clinical and research program earlier in 2010. It appears that we have accomplished this goal; of the measure's 11 congressional co-sponsors, only 1 was not re-elected, Congressman Allen Boyd (D-FL). Moving forward, the Resolution will need to be re-introduced into a Republican-lead House of Representatives when the 112th Congress convenes next year. Fortunately, this measure is bipartisan and currently has strong Republican support, including cosponsorship by one of the party's "young guns," Congressman Paul Ryan (R-WI).

Once the Resolution is re-introduced in the next Congress, our sustained grassroots push in support of this measure can begin in earnest. We will have 2 years for advocates to conduct congressional outreach and secure the 218 cosponsors needed for passage through the House of Representatives. As an added bonus, Senator Kay Hagan (D-NC) may introduce the Resolution in the Senate during the next Congress. This means there will be more of an opportunity than ever before to raise awareness of FGIDs on Capitol Hill and call for an increased federal investment in this area. 🌐

THE IBS AND FGID RESEARCH & TREATMENT ACT

The IBS and FGID Research and Treatment Act is a landmark piece of legislation, which would move the science of FGID research forward in an unprecedented way and address many of the persistent issues patients suffer with. Specifically, this bill would:

- Expand the research portfolio for Functional GI Disorders at the National Institute of Diabetes and Digestive and Kidney Diseases, and improve coordination of research activities conducted through the National Institutes of Health.
- Establish the operation and development of academic centers of excellence to conduct research and train healthcare providers.
- Provide support for training new investigators who specialize in FGID.
- Facilitate the creation and implementation of a guidance document by the FDA for industry regarding the development of treatments, and the consequences of adverse events that may occur during post-market surveillance.



Shrikant Bangdiwala, PhD

Dr. Bangdiwala is a professor in the Department of Biostatistics at the University of North Carolina at Chapel Hill. He has extensive experience in the design, conduct and analysis of multi-center studies, having worked on clinical trials in congestive heart

failure, cardiovascular risk factors, functional bowel disease, and cancer prevention. Dr. Bangdiwala also has extensive experience as a member of various data and safety monitoring boards for studies in ophthalmology, HIV/AIDS, and cardiology. He collaborates with investigators at the UNC Center for Functional GI and Motility Disorders on studies functional bowel disease, with investigators in the UNC Injury Prevention Research Center on studies of child abuse and family violence, with investigators in the UNC Center for Health Promotion and Disease Prevention on studies of obesity and lifestyle interventions, and with investigators in the UNC Sheps Center for Health Services Research. Dr. Bangdiwala is currently designated as a 'Fulbright Senior Specialist' in Global Public Health and a member of the Board of Scientific Counselors of the National Center for Injury Prevention and Control at the Centers for Disease Control & Prevention. He holds faculty positions in universities in Chile and has taught extensively overseas. His statistical research interests include nonparametric methods, methodology for clinical trials, reliability and validity of diagnostic tests, and graphical methods for descriptive analyses.

Dr. Leserman also plays a role in mentoring fellows and trainees at the Center.

- **Doug Drossman, MD**, is the chief gastroenterologist who has done epidemiological, psychosocial and clinical research for over 30 years. About 25 years ago he first began consulting with Kant and collaborating with Jane on research studies. The biometry core began with the funding of the abuse and psychosocial outcomes NIH research grant. This was expanded and solidified with

the Center NIH grant and regular meetings with a larger multi-disciplinary group was established.

- **Stephan Weinland, PhD**, is a clinical psychologist who also maintains an interest in academic research. He has contributed research ideas in data collection and analysis that involve real time measurement of psychological and physiological experiences. Stephan works with the team to put together research plans, help develop projects and present study outcomes.
- **Spencer Dorn MD**, is the newest member of our faculty who has brought to the group his developing expertise in health services research.
- We also have trainees, research assistants, visitors from around the world and other guests actively participating.

Working together, everyone in the biometry core brings something to the table to discuss various approaches and methods about how best to answer a research question. At a typical meeting where a new research study is introduced, investigators bring everyone up to speed on the importance of the question and how it differs from what has been done before. The meeting then elicits a discussion of how to address the question in terms of defining the target population, when and how to gather the data, and advice as to what is practical and realistic. We decide what data is necessary to gather and in what form, how to record the information, how to translate the information into an analyzable form, and other logistics large and small relating to how to address the research question. Within this discussion, the actual research question is further defined and is often separated into several distinct sub-questions. Additional questions often emerge. From these questions and the methods designed to answer them, researchers develop testable hypotheses. This forum adds clarity to research by helping to outline and prioritize specific aims, the methods used to address these aims, and aids in preparing a realistic timeline. This multidisciplinary collaboration facilitates the Center's ability to efficiently conduct a research study.

After planning and discussion, the core continues to work behind the scenes, stepping in at various stages in the timeline. JB Hu, our capable data manager, prepares for data collection, depending on the type of information being collected. He then meticulously enters all the paper data and reformats the electronic data into an analyzable form. He anticipates potential confusions and takes every precaution to minimize errors at every step of the way, and stores the data for easy retrieval. Head biostatistician, Kant Bangdiwala,

BIOMETRY *continued from previous*

together with Carolyn Morris, MPH, the hands-on biostatistician, work to address research questions with biostatistical tests that will answer those questions. Given the well-defined research questions, they identify the appropriate tests and analysis techniques to use. Morris performs those tests, and reports the findings, translating the numbers into meaningful conclusions. The biometry core then regroups to review the findings, raise new questions, and clarify any uncertainties. As there are frequently multiple projects going on in various stages, scientific meetings and deadlines, the routine biometry meetings are essential to facilitating the Center's continual prolific research, which can then help secure future funding.

Lastly, the biometry core knows how to have fun. To hone our statistical prediction, each year we have a contest for the person who can guess the most answers to biometry trivia. Such trivia might include: the largest number of tables included in any one paper published that year, the number of trips that Dr. Drossman made overseas that year, or who will win the ACC basketball tournament. To enhance our sensitivities for multicultural behaviors, we test candies from all over the globe, no matter the texture or outer package. Joking aside, this is a hardworking and productive team that can work together to improve the quality of research done in the UNC Center for functional GI and Motility Disorders and the GI division. 🍷

PSYCHOLOGY *continued from page 8*

of Psychiatry. His research and clinical interests are in the prevention and treatment of chronic conditions. Working with the Functional GI clinic he has been getting invaluable experience working with patient suffering from severe, refractory pain and chronic functional GI conditions.

In addition to training for clinical interns, the center offers training opportunities for licensed clinical psychologists who wish to receive additional GI specific training. Dr. Jennifer C. Franklin is a California licensed psychologist who has relocated to North Carolina and is engaging in additional therapy and assessment training with our center.

For practitioners and patients alike, the center offers excellent opportunities to learn about, treat and manage functional GI conditions. The opportunities offered by our center to patients are enhanced by the services our clinical psychology service provides. For more information on how to engage in clinical psychology training with our center please contact Sarah Barrett at slbarret@med.unc.edu. 🍷

UNC-CH GI LATINO CLINIC RECIEVE PRESTIGIOUS HONOR

The UNC Latino Clinic was selected to receive a prestigious Latino Diamante Health & Science Award. This honor is part of a statewide award program created to recognize outstanding achievements and to honor those who are making significant contributions to the Hispanic community of North Carolina. The Award was presented on October 23 at the Marriott Hotel Convention Center in Durham. Douglas Morgan, MD, MPH and Claudia Rojas, Latino Clinic Manager, were present for the award ceremony.



ROME FOUNDATION INTRODUCES CLINIC DIAGNOSTIC TOOL FOR FUNCTIONAL GI

New clinical algorithms will give physicians a practical, efficient and cost-effective aid to diagnose the frequent gastrointestinal symptoms that patients commonly bring to their primary care doctors and gastroenterologists--symptoms of functional GI disorders that are often difficult to diagnose.

Developed by the Rome Foundation and published in the April issue of The American Journal of Gastroenterology, the new tool, Diagnostic Algorithms for Common Gastrointestinal Symptoms, provides an evidence-based approach to the diagnosis of functional gastrointestinal disorders, including irritable bowel syndrome (IBS) and functional dyspepsia, by providing diagnostic pathways for common symptoms such as abdominal pain, nausea and vomiting, diarrhea and constipation.

To read the full story, please visit www.med.unc.edu/ibs.

<http://www.med.unc.edu/ibs>





CHILDREN CAN GREATLY REDUCE ABDOMINAL PAIN BY USING THEIR IMAGINATION

Miranda van Tilburg, PhD
Associate Professor of Medicine

This study was mentioned in the New York Times on November 22, 2010. The article is available at: http://www.nytimes.com/2010/11/23/health/23klass.html?_r=2&ref=health

Children with functional abdominal pain who used audio recordings of guided imagery at home in addition to standard medical treatment were almost three times as likely to improve their pain problem, compared to children who received standard treatment alone.

And those benefits were maintained six months after treatment ended, a study found lead by Miranda van Tilburg, Ph.D a member of the UNC Center for Functional GI & Motility Disorders.

"What is especially exciting about our study is that children can clearly reduce their abdominal pain a lot on their own with guidance from audio recordings, and they get much better results that way than from medical care alone," said van Tilburg. "Such self-administered treatment is, of course, very inexpensive and can be used in addition to other treatments, which potentially opens the door for easily enhancing treatment outcomes for a lot of children suffering from frequent stomach aches."

The study focused on functional abdominal pain, defined as persistent pain with no identifiable underlying disease that interferes with activities. It is very common, affecting up to 20 percent of children. Prior studies have found that behavioral therapy and guided imagery (a treatment method similar to self-hypnosis) are effective, when combined with regular medical care, to reduce pain and improve quality of life. But for many children behavioral therapy is not available because it is costly, takes a lot of time and requires a highly trained therapist.

For this study, 34 children ages 6 to 15 years old who had been diagnosed with functional abdominal pain by a physician were recruited to participate by pediatric gastroenterologists at UNC Hospitals and Duke University Medical Center. All received standard medical care and 19 were randomized to receive eight weeks of guided imagery treatment. A total of 29 children finished the study; 15 in the guided imagery plus medical treatment group and 14 in the medical treatment alone group.

The guided imagery sessions, developed jointly by van Tilburg, co-investigator Olafur Palsson, Psy.D. and Marsha Turner, the study coordinator,


were recorded on CDs and given to children in the study to use at home.

The treatment consisted of a series of four biweekly, 20-minute sessions and shorter 10-minute daily sessions. In session one, for example, the CD directs children to imagine floating on a cloud and relaxing progressively. The session then gives them therapeutic suggestions and imagery for reducing discomfort, such as letting a special shiny object melt into their hand and then placing their hand on their belly, spreading warmth and light from the hand inside the tummy to make a protective barrier inside that prevents anything from irritating the belly.

In the group that used guided imagery, the children reported that the CDs were easy and enjoyable to use. In that group, 73.3 percent reported that their abdominal pain was reduced by half or more by the end of the treatment course. Only 26.7 percent in the standard medical care only group achieved the same level of improvement. This increased to 58.3 percent when guided imagery treatment was offered later to the standard medical care only group. In both groups combined, these benefits persisted for six months in 62.5 percent of the children.

The study concluded that guided imagery treatment plus medical care was superior to standard medical care alone for the treatment of functional abdominal pain, and that treatment effects were sustained over a long period.

The study has been received with much enthusiasm of the medical community, parents and the press. Among many others, the BBC news hour, WebMD, Parents magazine and the NY times have featured the findings. The authors are currently adapting the treatment for other types of pain such as pediatric migraines, and are also working hard on making the treatment available to the public. People interested in the program can find more information on www.childpainsolutions.com

UNC co-authors of the study included Denesh K. Chitkara, M.D., adjunct research professor; William E. Whitehead, Ph.D., professor and co-director of the UNC Center for Functional GI & Motility Disorders, and Nanette Blois-Martin, pediatric nurse-practitioner. Martin Ulshen, M.D., division chief of pediatric gastroenterology, hepatology and nutrition at Duke University Medical Center, is also a co-author. 



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Contributions from individual donors and grants from foundations and corporations are essential to enhancing and expanding the Center's comprehensive and multi-disciplinary approach to clinical care, research, training and education in functional GI and motility disorders.

Memorial Research Fund

The Alan Wayne Ducoff Memorial Fund provides an opportunity for families and friends to remember and honor their loved ones by making a designated contribution to the Center's research program. To make a donation to the Alan Wayne Ducoff Memorial Fund, please check off the appropriate box on the donation form.

For more information about supporting the Center, please contact Sarah Barrett at sbarret@med.unc.edu.



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UPCOMING CHAT SCHEDULE

Our popular **An Evening with the Experts** chat series kicks off the new year with Christine Dalton, PA-C, discussing, "How Well Do You Know IBS?" All chats are scheduled the first Tuesday of every month, from 8-10 pm EST. Please access the chat by logging onto our website at www.med.unc.edu/ibs, and access the chat portal found on our homepage.

January 4, 2011	<i>How Well Do You Know IBS?</i>	Christine Dalton, PA-C
February 1, 2011	<i>Pelvic Pain</i>	Denniz Zolnoun, MD
March 1, 2011	<i>Chest Pain and Swallowing Difficulties</i>	Ryan Madanick, MD
April 5, 2011	<i>Nausea, Vomiting and Functional Dyspepsia</i>	Spencer Dorn, MD, MPH

CENTER'S WEBSITE GETS A FACELIFT

The Center has updated its previous Web 1.0 online presence to a fresher and cleaner navigation. Utilizing the Content Management System (CMS) approved by the UNC-CH School of Medicine Office of Information Systems, the Center has switched its look to be consistent amongst other websites within the departments in the UNC-CH School of Medicine. The Center's Media Coordinator initiated the change August 2009, with full migration in place, January 2011.



You will most certainly agree that the new navigation is much easier to find all of your favorite educational materials, news and goings-on of the Center. Feel free to browse throughout the new and improved site, and drop a line of comment or suggestion to the site's manager, Nicolette DeGroot at ndegroot@med.unc.edu.
Happy browsing!

WWW.MED.UNC.EDU/IBS