



International Foundation for
Functional Gastrointestinal Disorders

IFFGD

Information. Assistance. Support.

DigestiveHealth Matters

Participate in your own health care | Vol. 21, No. 4, © 2013 IFFGD

- 2** Highlights in this issue
- 4** IBS Awareness Month
- 5** What are Functional GI and Motility Disorders
- 6** An 8-step Approach to Chronic Pain Management
- 8** Sphincter of Oddi Dysfunction
- 10** Short Bowel Syndrome
- 11** Selecting a CAM Practitioner
- 12** Treatment News
- 16** Community News

Highlights in this issue

April is IBS Awareness Month

Feature Articles

What are Functional GI and Motility Disorders

If you have chronic pain it is important to develop a pain management plan that works for you.

Sphincter of Oddi dysfunction (SOD) results in episodes of severe abdominal pain.

Normal Movements of the Digestive Tract

Short bowel syndrome (SBS), or simply short gut, is a rare condition that can occur in a person of any age.

Selecting a complementary and alternative medicine health care practitioner is an important decision and can be essential to ensuring that you are receiving the best possible care.

Research and Treatment News

FDA approved linaclotide (Linzess) to treat IBS-C and chronic constipation (CC) in adults.

EC granted marketing approval for linaclotide (Constella) to treat moderate to severe IBS-C in adults.

Solesta for the treatment of bowel incontinence is now available in the U.S.

Patient enrollment continues for clinical trials looking at retreatment with rifaximin, an antibiotic under investigation to treat non-constipation IBS.

A study showed lubiprostone (Amitiza) to be safe and well tolerated over 9–13 months to treat IBS-C.

Lubiprostone (Amitiza) is approved in the U.K. to treat chronic idiopathic constipation.

FDA gives priority review to lubiprostone for the treatment of opioid-induced constipation.

FDA approves teduglutide (Gattex) for adults with short bowel syndrome (SBS).

Patient enrollment has begun for Phase 3 clinical trials looking at a drug under investigation to treat IBS with diarrhea, MuDelta (JNJ-27018966).

Studies are underway for elobixibat, a new drug treatment under development for chronic idiopathic constipation and for IBS-C.

Community News

Courageous story shared about gastroesophageal reflux disease (GERD).

Looking ahead to the new 113th Congress in the U.S.

The Functional GI and Motility Disorders Research Enhancement Act has been reintroduced in the U.S. House of Representatives

IFFGD has launched a new website, www.aboutGastroparesis.org.

IFFGD Research Grants and Awards.

The Cheryl Aaron Memorial Fund created in memory of a courageous woman offers hope to others.



Does IBS take a Toll on your Life?



**...it doesn't have to.
Seek help today.**

Request a free IBS packet from IFFGD
and start on the road of understanding.



**April is IBS
Awareness month**

www.aboutIBS.org

Abdominal pain and/or discomfort associated with a change in bowel habit, diarrhea and/or constipation, are the key symptoms of irritable bowel syndrome (IBS). Other symptoms may also occur. Talk to your doctor if you experience symptoms. The first step to treatment is a confident diagnosis.

April is IBS Awareness month

Get the Facts about IBS

A short bout of abdominal pain and diarrhea or constipation now and then is not unusual. But long-term or recurring symptoms are not normal. They may signal irritable bowel syndrome (IBS) – and are generally treatable.

See your Doctor for an Accurate Diagnosis

There are no tests that identify IBS (like standard blood tests, x-rays, scopes, or scans). Instead, IBS is diagnosed based on defined patterns of signs and symptoms. Your doctor will start by asking about symptoms and health history, and then do a physical exam and limited tests, which help confirm the IBS diagnosis. More extensive testing is reserved for specific situations.

Starting Treatment for IBS

IBS treatment starts with getting your facts straight. Learn all you can about IBS. Here are some things you need to know.

What it's not: IBS . . .

- Is not caused by your diet
- Is not caused by stress
- Is not a risk for cancer
- Is not a risk for colitis
- Does not cause malnutrition
- Does not get worse with age, and
- Does not shorten life span

What it is: IBS . . .

- Is a long-term condition
- Symptoms tend to come and go over time
- Symptoms often change over time
- Symptoms can usually be managed so that you feel better

Investigate

Are there certain things that seem to worsen your IBS? If so, sorting these out can be helpful. This is not always clear-cut. Using a diary (www.aboutibs.org/diary) for 2–3 weeks can help identify factors that seem to worsen or trigger symptoms. Discuss your findings with your doctor.

Other Symptoms May Accompany IBS

Many persons treated for IBS also report one or more other symptoms, such as:

- Heartburn
- Nausea
- Abdominal fullness
- Bloating
- Feelings of urgency (the need to find a restroom fast)
- Feeling of “incomplete” bowel emptying
- Fatigue
- Muscle pain
- Sexual dysfunction
- Headache

Learn more about IBS in this e-book published by IFFGD (2011)

Some Take Things to Heart, Others to Their Belly – Irritable Bowel Syndrome: What is it and how is it treated? By: Ami D. Sperber, M.D. Available online (Kindle Edition) from Amazon or spiral bound from IFFGD.

Here's what readers are saying online about the book:

“This book will prepare parents with children who are suffering from undiagnosed and unexplained pain in the belly as well as any adult who is either newly diagnosed or simply searching for an explanation.”

“It is about time that there is a book that explains this problem in simple easy-to-understand language. Thank you Dr. Sperber!”

“As a practicing gastroenterologist with many IBS patients, I have heard great things from my patients who read this book. Ami Sperber is much more than a fine scientist specializing in IBS; his gentle humane approach makes this book a must-read for people who want to regain control of their lives and their health.”

“(This) book provides a most comprehensive explanation of IBS. It also brings home the human suffering and social cost of IBS and provides a wide range of management strategies.”

“Dr. Sperber writes about a complex issue in a simple way that is easy to understand and helped me to further understand the crazy things my body does. I didn't think I could possibly learn anything new... but I learned a few new tricks! Thank you!”

“I would recommend this book to anyone that is tired of hearing the same old facts about IBS and wants to learn more detailed information. It's great if you have IBS, but I think that it works very well for family members or friends of someone with IBS.”



What are Functional GI and Motility Disorders?

Functional gastrointestinal (GI) and motility disorders refer to conditions where normal function and movement of the digestive tract, sensitivity of the nerves of the digestive tract, or the way in which the brain controls some of these functions is impaired.

The conditions can affect any area of the digestive tract, from the esophagus (swallowing tube) to the stomach to the small and large intestines. They are characterized by:

- long-term courses,
- unpredictable symptom episodes, and
- disruptive or disabling effects.

Some of the conditions are life-threatening.

No structural abnormalities are seen on routine diagnostic tests such as x-rays or blood tests; results appear normal. Diagnosis is based on characteristic symptoms that meet defined criteria, and specialized tests as necessary. Tests of GI motility measure patterns and movements.

Few effective therapies exist and these do not always work for all persons. Treatment focuses on management over a long term.

There are over 2 dozen functional GI and motility disorders.

Examples include:

Gastroesophageal reflux disease (GERD) – repeated or prolonged exposure of the lining of the esophagus to contents from the stomach

Functional chest pain – chest pain of esophageal origin

Gastroparesis (delayed gastric emptying) – symptoms range from uncomfortable to debilitating

Dysphagia – difficulty swallowing

Functional dyspepsia – symptoms including pain or discomfort located in the upper abdomen

Sphincter of Oddi dysfunction – results in episodes of severe abdominal pain

Cyclic vomiting syndrome – recurrent episodes of intense nausea and vomiting lasting hours to days

Irritable bowel syndrome (IBS) – abdominal pain/discomfort associated with a change in bowel habit

Bowel incontinence – the involuntary loss or leakage of solid or liquid stool

Functional abdominal pain – continuous or frequently recurrent abdominal pain

Short bowel syndrome – functional or anatomical loss of a significant length of the small intestine

Chronic intestinal pseudo-obstruction – altered or inefficient contractions (peristalsis) in the intestinal tract

Hirschsprung's disease (HD) – nerve cells are missing within the wall of the colon or rectum



Affecting the Lives of Children

Functional GI and motility disorders occur in children as well as adults. Some disorders are congenital, or present at birth, while others develop in childhood. The disorders can be painful, disabling, hard to manage, and in some children can be life-threatening. Most of these conditions progress into adulthood.

But research studies tend to be in adults, and understanding the disorders in children has lagged behind. That is why, with your support, IFFGD/DHA is taking action. The DHA Children's GI Research Network was created with the purpose to improve the quality of life of children living with functional GI and motility disorders. The Network currently consists of 6 foremost pediatric researchers from institutions across the United States. By pooling data and sharing resources they can more effectively advance the science and understanding of these conditions in children.

You can learn more about the DHA Children's GI Research Network by visiting our web page at www.dha.org/content/kids-gi.

An 8-step Approach to Chronic Pain Management

Source: Adapted from IFFGD Publication No. 140, *Understanding and Managing Chronic Pain*, by Bruce D. Naliboff, Ph.D., Clinical Professor, Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, UCLA; Co-Director, UCLA Center for Neurovisceral Sciences & Women's Health (CNS), UCLA Division of Digestive Diseases, Los Angeles, CA. The complete article is available online at: www.iffgd.org/library/download/140 or by contacting IFFGD.

For those with a functional gastrointestinal/motility disorder, pain is often one of several overlapping unpleasant symptoms. One difficulty in assessing pain in these conditions is that pain in the internal (visceral) organs is often less clear-cut in its location and quality compared with joint or muscle pain.

What causes the pain? There is no conclusive answer to this question. Gut specific causes are currently being investigated, as well as changes in the nervous system that regulates pain transmission or modulation.

**If you have chronic pain
it is important to develop
a pain management plan
that works for you.**

Pain Transmission and Modulation

Although much remains to be known, research over the past three decades has revealed key information about pain and our bodies' response, and this has led to improved treatment in many areas. Although the pain transmission system was once thought to operate like an old-time telegraph (messages input at one end and arrive at the other), we now know that the system is much more like a powerful computer. In order to enable our body to have the best information when it is needed, signals coming in are highly *modulated*. This means pain signals from specific areas can be amplified, suppressed, or altered in quality in the spinal cord or brain.

The description of our own built-in pain modulation system (called the gate control theory) by Drs. Melzack and Wall in 1965 and the subsequent discovery of internal opiate-type chemicals (such as the endorphins) were major first steps in a fuller understanding of pain control within the body. More recently, many more parts of this complex system have been uncovered, as well as new chemical transmitters and interactions between pain modulation and other parts of our sensory and emotional brain systems.

Pain and Threat

We have known for a long time that pain is not a simple sensation and that it is intimately linked with our inborn emotional systems for detecting and responding to threat. In this way it is closely tied to the same fear or "fight or flight" system that responds to external threats. But pain

is unique in that it always has a negative emotional quality (unpleasantness) and is closely associated with emotions of fear and anxiety.

Some of the brain circuits underlying this pain-fear cycle have recently been made clear using functional brain imaging. Connections between the emotional and pain systems may also account for the often successful use of anti-anxiety and anti-depression medications to treat chronic pain.

Chronic Pain Management

In chronic pain we have strong evidence that our pain modulation system is not working well. Instead of suppression, the system may be over-sensitized so that even normal sensations trigger pain transmission and suffering. As a result of their pain, people may also have increased levels of anxiety and depression, decreased quality of life, fear of further pain and disability, sleep loss, and withdrawal from social and pleasurable activities. Both ancient and modern medicine has evolved a variety of ways to help cope with chronic pain and maybe even return the system to more normal functioning.

Putting Together a Pain Management Program

If you have chronic pain it is important to develop a pain management plan that works for you. Some recommended elements include:

1. Understand your pain problem. Try to separate hurt from harm. The pain you experience is real, but the cause may be a heightened sensitivity of the nervous system and not increasing damage to some part of your body (even though it feels that way).
2. Maintain a cooperative but not dependent relationship with your doctors. Doctors have a difficult time treating chronic pain and may feel frustrated as well. Be honest and assertive with your doctors, but also let them know you understand they cannot perform miracles and that chronic pain management is a team effort.



3. Use medications wisely, as directed by your physician.
4. Don't be afraid to acknowledge your emotional response to pain, be it fear, anger, or depression. Seek out psychological help if needed. Remember that the best chronic pain treatment should include both mental and physical elements.
5. Use active and positive coping strategies as much as possible (such as exercising, seeking out information, trying to improve sleep, and planning ahead for possible exacerbations). Passive strategies (such as inactivity, hoping the pain will go away, or waiting for a doctor to find an answer) lead to increasing helplessness and dependence, and are typically associated with poorer outcomes and increased suffering.
6. Seek support when needed but stay in control. Family, friends, and health care professionals are all important resources for you, but often they are not sure how best to help. Let all the important people in your life know that you appreciate their support and that you will ask them directly when you need their help or just someone to talk to.
7. Remember that new knowledge and treatments are coming so stay in touch. Pain is a rapidly expanding area of research. New technologies in functional brain imaging and molecular biology are generating, for the first time, detailed portraits of our brains in action and the biochemistry of pain transmission. There is no doubt that improved pain treatments will not be far behind.
8. If your pain problem continues to be unmanageable, you can contact a pain specialty clinic. Be aware that many practitioners (medical and chiropractic) may call their own practice a "pain clinic." However, a true pain management clinic provides comprehensive care by including multiple medical specialties such as anesthesiology, neurology, psychology and rehabilitation. Many of the best pain programs are located in university medical centers. Your primary care doctor should be able to refer you to a good one.



Understand Risk as well as Benefit

Risk-benefit is a concept that is unfamiliar to many people. Advertising emphasize benefits; and we go to doctors seeking benefits. But medical treatment benefits don't usually mean cure, and many drugs are modestly beneficial, helping to feel better but not always well. At the same time, an understanding of risk, not just benefit, will help to achieve the best possible outcomes.

The FDA Safe Use Initiative encourages public and private collaborations intended to reduce medication risks. They point out, "All medications have inherent risks and when a person decides to use medication, he or she is agreeing to take certain risks. Some of the risks are unavoidable, while others can be avoided and managed."

Here are some general things to consider before starting a medication or other treatment.

- Be educated to understand your disorder, including its natural progression, and your treatment options
- Ask questions and actively seek to have reasonable expectations about the nature of your illness, the level of benefit your treatment may achieve, the risk associated with the treatment, and what alternatives you have
- Understand the risk tied to benefit and the factors that affect both – like prior history, multiple medications, or lifestyle choices
- Know the risks including what they are and how to reduce them, how to recognize adverse events, and what to do when they occur

Sphincter of Oddi Dysfunction

By: Peter B. Cotton, M.D., Professor of Medicine, Digestive Disease Center, Medical University of South Carolina, Charleston, SC

The sphincter of Oddi is a muscular valve that controls the flow of digestive juices (bile and pancreatic juice) through ducts from the liver and pancreas into the first part of the small intestine (duodenum). Sphincter of Oddi dysfunction (SOD) describes the situation when the sphincter does not relax at the appropriate time (due to scarring or spasm). The back-up of juices causes episodes of severe abdominal pain.

Doctors often consider SOD in patients who experience recurrent attacks of pain after surgical removal of the gallbladder (cholecystectomy). More than half a million of these surgeries are performed annually in the United States, and 10–20% of these patients present afterwards with continuing or recurrent pains. SOD is also considered in some patients who suffer from recurrent attacks of unexplained inflammation of the pancreas (pancreatitis).

About half of these patients will have findings on laboratory studies or imaging (blood test, ultrasound, CT scan, or MRCP) to suggest a definite abnormality, such as a stone in the bile duct. MRCP (magnetic resonance cholangiopancreatography) is nowadays a good non-invasive test for checking on the biliary and pancreatic drainage systems.

Based on patients' histories, physical examinations, and other clinical data, doctors can categorize these patients as having SOD Types I and II. The categories help guide treatment of the disease. They are based on a system called the Milwaukee criteria.

When symptoms are severe, standard treatment is to perform an endoscopic procedure called ERCP (endoscopic retrograde cholangiopancreatography). ERCP is a procedure for the examination or treatment of the bile duct and pancreatic duct. The procedure carries a risk of serious complications and is done under sedation by experts trained in the technique. It combines the use of x-rays and an endoscope that is passed down to the duodenum, where the bile duct and pancreatic ducts drain, and a dye that is injected into the ducts. Treatment depends on what is found. It may often involve cutting the muscular sphincter (sphincterotomy) to remove any stones or to relieve any scarring or spasm of the sphincter.

As noted above, a very important problem in this context is that these ERCP procedures carry a significant risk of complications. In particular, ERCP (with or without another test, sphincter of Oddi manometry) can cause an attack of pancreatitis in 5–10% of cases. While most of these result in a few days in the hospital, about 1% of patients suffer a major attack, with weeks or months in the hospital. Sphincterotomy also carries a small risk of other severe complications such

as bleeding and perforation, and the possibility of delayed narrowing of a duct (stenosis) due to scarring.

Functional SOD

Patients with a similar pain problem, but who have little or no abnormalities on blood tests and standard scans (including MRCP), are categorized as having SOD Type III. The episodes of pain are assumed due to intermittent spasm of the sphincter. It is very difficult to effectively evaluate and manage patients with Type III SOD. Some physicians are skeptical of its existence, or assume that it is a part of a broader problem of a functional digestive disturbance, such as irritable bowel syndrome.

Because of the risks of ERCP, patients with suspected SOD III are usually advised to try medical treatments first. Some respond to the use of antispasmodic drugs and/or antidepressants that may help decrease pain. There have been studies of other medical therapies, such as calcium channel blocking drugs. Despite a few encouraging reports, these methods have not proven to be effective generally, and are not widely used.

Patients who fail these approaches (at least those with severe symptoms) are usually advised to see specialists at referral centers. Further evaluation may involve additional or more specialized tests to help guide treatment options.

Clinical Research Study

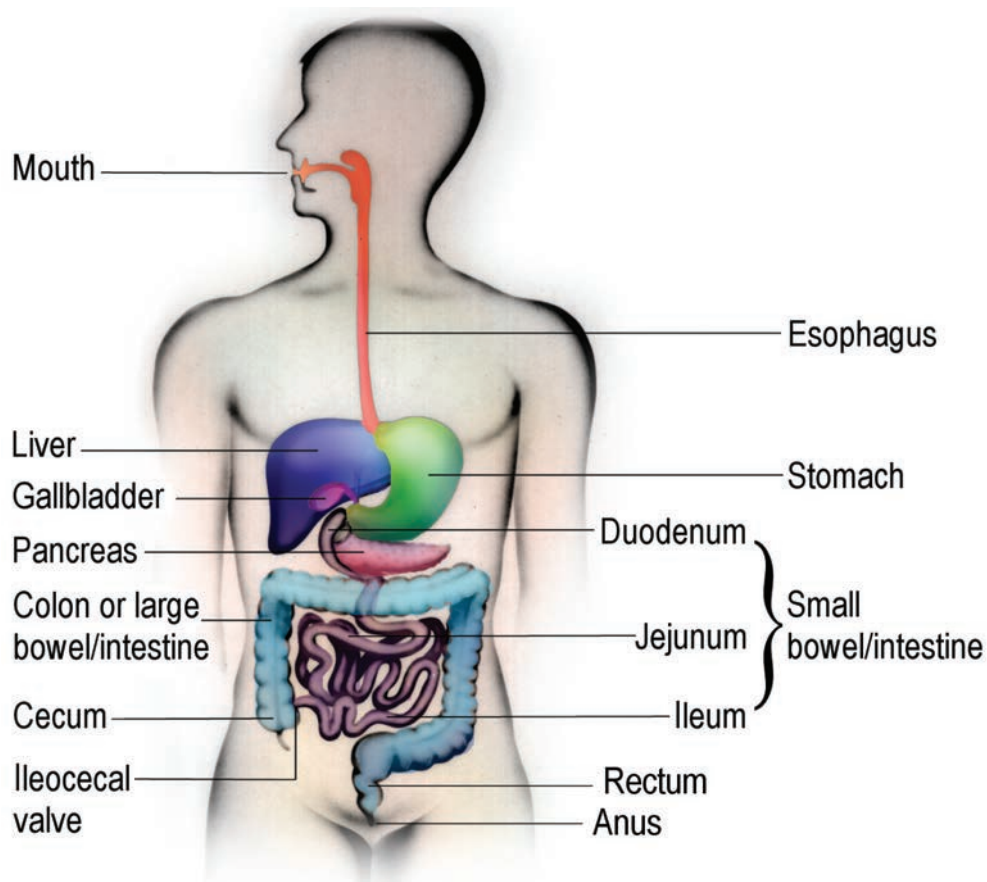
These uncertainties in how best to diagnose and to treat “suspected” sphincter of Oddi dysfunction (and the risks involved) mandate further scientific investigation. The National Institutes of Health has recently funded an important study called “EPISOD” in 6 major Gastroenterology centers in USA. The studies are being conducted at centers located in:

- Johns Hopkins Hospital, Baltimore, MD
- University of Alabama at Birmingham, Birmingham, AL
- Medical University of South Carolina Digestive Disease Center, Charleston, SC
- Indiana University, Indianapolis, IN
- Hennepin County Medical Center, Minneapolis, MN
- Virginia Mason Medical Center, Seattle, WA

Additional details are available at the NIH website at www.clintrials.gov by searching: sphincter of Oddi dysfunction III.



Normal Movements of the Digestive Tract



The digestive tract begins at the mouth and ends at the anus. The esophagus, stomach, small intestine, and large intestine are the main regions of the gastrointestinal (GI) tract. They are separated from each other by special muscles, called sphincters, which regulate the movement of ingested material from one part to another. Each part of the GI tract has a unique function to perform in digestion, and each has a distinct type of motility and sensation.

Gut motility is the term given to the stretching and contractions of the muscles in the GI tract. The synchronized contraction of these muscles is called peristalsis. These movements enable food to progress along the digestive tract while, at the same time, ensuring the absorption of the important nutrients.

Digestion begins in the mouth where food is chewed, mixed with saliva, and swallowed. The esophagus propels food from the mouth to the stomach. In the stomach solid food is broken down by powerful muscle contractions. Different types of food empty from the stomach at different rates. Small food particles then enter the small bowel/intestine, where processes of nutrient absorption begin.

Nutrient absorption primarily occurs in the small bowel. Here secretions from the liver and pancreas aid digestion.

Contents move out of the small bowel passing through the ileocecal valve into the colon or large bowel/intestine. This one way valve helps control the passage of contents into the colon, and minimizes the movement of bacteria from the large bowel up into the small bowel.

The primary function of the colon is to absorb fluids and electrolytes, particularly sodium and potassium, and to convert remaining contents into more solid stool.

Stretching of the rectum by stool produces relaxation of the muscles of the anus and surrounding structures. The rectal contents can then be discharged voluntarily.

Learn more about the digestive tract on our webpage at www.aboutgimotility.org/site/about-gi-motility/digestive-tract.

Short Bowel Syndrome

Source: This article is adapted from the new publication from IFFGD about Short Bowel Syndrome (SBS). Written by Evelin Eichler, M.S., R.D., Richard McCallum, M.D., Susan S. Schneck, M.S., and William F. Norton, IFFGD, the publication aims to help people with short bowel syndrome and their family members understand why symptoms occur and provide an overview of how SBS can be managed. Contact IFFGD to order the pamphlet No. 258 in print, access it in our online library at www.iffgd.org/library, or visit our webpage at www.aboutgimotility.org/sbs

Short bowel syndrome (SBS), or simply short gut, is a rare condition that can occur in a person of any age. It is broadly described as a condition in which needed nutrients are not absorbed because a large part of the small bowel is missing or not functioning properly. Typically a loss of half or more of the small bowel will result in SBS.

Most often it is due to defects existing at birth (congenital), or surgical removal of part of the small bowel. SBS also can be caused by loss of function due to injury or disease in a normal length small intestine. Other explanations include emergency situations related to injury or trauma, perforated bowel, or blocked or restricted blood flow to the bowel.

Short bowel syndrome is a complex, challenging condition for patients, caregivers, doctors, and other health specialists. In addition to dealing with multiple symptoms, special steps must be taken to be sure that fluid and nutrient requirements are met.

Treatments for short bowel syndrome are aimed at controlling symptoms and maintaining nutritional status. This involves special dietary measures and often use of medications. In some situations surgery is required. Many people with SBS are unable to take in adequate fluids and nutrients by oral diet alone and must depend on parenteral nutrition (through a vein) or enteral nutrition (through a feeding tube).

The aims of treatment for short bowel syndrome are to promote adaptation (the ability of the small bowel to compensate on its own for loss of absorptive surface area) and get the best use out of the existing bowel, maintain adequate nutritional status, and manage symptoms and complications. Complications can arise not only as a result of the underlying condition, but also in connection with treatments.

Ultimately, the goal is for the patient to resume daily life as well as possible. In situations where all other treatment approaches have failed, intestinal transplant is considered. The course of treatment will depend on how well the bowel is able to support individual fluid and nutrient needs.

Working with Your Healthcare Team

Treatment of the condition involves life-long therapies and approaches that need to be closely monitored. Successful management of SBS depends most strongly on an informed patient and caregivers working closely with a supportive team of healthcare providers. Members of the healthcare team may

include primary care physicians (for example, family doctor, pediatrician, or gastroenterologist), surgeons, nutritional specialists, nursing specialists, and pharmacists.

The primary care physician will take the lead in managing and coordinating the patient's care. If intestinal transplant becomes necessary, other specialists may be brought in including social workers, psychologists, and financial counselors to help deal with the complexities of organ transplants.

The most important member of the healthcare team is the person with short bowel syndrome. Family members or parents of children with SBS play essential roles as caregivers.

Patients and caregivers need to have a thorough understanding of the condition and how it may best be managed in light of individual needs. This will include recurring contact with healthcare providers, and most likely use of outside resources, all aimed at helping navigate the complexities of managing SBS long term.

SBS Resources

IFFGD, the International Foundation for Functional Gastrointestinal Disorders, is a place you can go to find help and support. Here is a list of several other outside resources that provide information and support for people with short bowel syndrome:

A Patient's Guide to Managing a Short Bowel, by Carol Rees Parrish, M.S., R.D. An easy to read and comprehensive book aimed at patients and family members that helps understand the workings of the GI tract and how patients can get the most from their own short gut. Includes dietary guidelines, sample meal plans, as well as descriptions of treatments and management issues. Available online free of charge in the U.S. and Canada at: www.shortbowelsupport.com.

The Short Bowel Syndrome Foundation, www.shortbowelfoundation.org. A nonprofit organization whose mission is to educate, support, and empower patients who live with the condition and the healthcare providers who help patients to manage short bowel syndrome.

The Oley Foundation, www.oley.org. A nonprofit organization whose mission is to enrich the lives of patients dependent on home intravenous (parenteral) and tube feeding (enteral) through education, outreach, and networking.

Transplant Living, www.transplantliving.org. A project of the nonprofit United Network for Organ Sharing (UNOS), Transplant Living provides resources to help people before and after organ transplantation.

Complementary and Alternative Medicine: Selecting a Practitioner

Source: Adapted from the National Center for Complementary and Alternative Medicine (NCCAM); Pub No. D346. This article is not copyrighted

Many people use complementary and alternative medicine (CAM) in pursuit of health and well-being. Selecting a health care practitioner is an important decision and can be essential to ensuring that you are receiving the best possible care. This article provides information on selecting a practitioner whose services are part of complementary and alternative medicine (CAM), such as acupuncture, chiropractic, and naturopathy.

What is CAM

CAM is a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine. Conventional medicine is medicine as practiced by holders of M.D. (medical doctor) or D.O. (doctor of osteopathic medicine) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses.

Complementary medicine is used together with conventional medicine, and alternative medicine is used in place of conventional medicine. Integrative medicine combines conventional and CAM treatments for which there is evidence of safety and effectiveness.

It is always a good idea to discuss any health options you are considering, including CAM options, with your trusted health professionals. Before selecting a CAM therapy or practitioner, talk with all your health care providers. Tell them about the therapy you are considering and ask any questions you may have. They may know about the therapy and be able to advise you on its safety, use, and effectiveness, or possible interactions with medications.

Finding CAM Practitioners

Several resources are available to help you find CAM practitioners:

- Your doctor or other health care provider may be able to give a referral.
- A nearby hospital or a medical school may have a list of local CAM practitioners or may be able to make a specific recommendation. Some regional medical centers may have CAM centers or CAM practitioners on staff.
- Professional organizations for CAM therapists often provide referrals to practitioners as well as information on therapies, standards of practice and training, and state licensing requirements. These organizations can be located by searching the Internet or directories in libraries (ask the librarian). One source is the National Library of Medicine's Directory of Health Organizations Online (dirline.nlm.nih.gov). Some professions may be represented by more than one organization.
- State regulatory agencies or licensing boards for health care professionals may provide information regarding practitioners in your area. Your state, county, or city health department may also refer you to such agencies or boards.

Even if a friend recommends a CAM practitioner, or if you have found a practitioner through your local Yellow Pages, looking into

the resources suggested above can give you confidence that you have considered all the best possibilities.

Choosing a Practitioner

As when choosing any health care provider, contact the practitioners you are considering to gather some basic information. Although you can do this over the phone, consider asking for a brief, in-person consultation (which may or may not involve a charge). Practitioners may also have a Web site or brochure. Before you make your contacts, think about what is important to you – what you need to know to make your decision. You might ask about:

- Education, training, licenses, and certifications. If you have information from a professional organization, compare the practitioner's qualifications with the training and licensing standards for that profession.
- Areas of specialization, experience treating patients with problems similar to your own, and his or her philosophy of care.
- Any scientific research studies that support the treatment's use for your condition.
- The number of patients the practitioner sees in a typical day and average time spent with each patient.
- Treatment costs, including charges per session, charges for cancelled appointments, payment options, and participation in your insurance plan.
- Office hours, how far in advance you need to schedule an appointment, and typical waiting time in the office.
- Office locations, for example, accessibility to public transportation, parking, and elevators.
- What to expect during the first visit or assessment.

After making your contacts, think about how comfortable you felt during your initial conversations with the practitioners and their staff, and review the information they provided. How do they measure up in terms of what is most important to you? Now, you are ready to decide which practitioner will most likely meet your needs.

Insurance Coverage

If you have health insurance, it may not cover your CAM therapy. Even if it covers the therapy, you may have to pay for part of the cost. Before agreeing to any CAM treatment, ask your insurer what percentage of the cost, if any, will be covered. Also find out whether the practitioner participates in your insurance plan.

For More Information

The NCCAM Clearinghouse provides information on NCCAM and complementary health approaches, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners. Web site: nccam.nih.gov.



When IFFGD began, in 1991, there was little communication between patients living with functional GI and motility disorders and the companies with the means to develop treatment products and services. Subsequently, IFFGD has worked hard to make the needs of our members known – not only to the clinicians who see patients, but also to the researchers and providers of diagnostic and treatment methods and tools.

In an effort to strengthen our voice, in 1998 we formed the IFFGD Industry Council. The Council provides a forum to help ensure that the voice of our membership is heard.

We invite participation from companies with a demonstrated interest in these disorders. While we are grateful to our Industry Council members for their support, we do not endorse any specific product or company. IFFGD retains unrestricted control over the planning, content, objectives, methods, and execution of all initiatives and projects.

We are pleased to welcome Ferring International Pharmascience Center US, Inc. as the newest member of our Industry Council.

IFFGD INDUSTRY COUNCIL

Sucampo Pharmaceuticals, Inc.
and Takeda Pharmaceuticals USA, Inc.

Salix Pharmaceuticals, Ltd.

The Procter & Gamble Company

NPS Pharmaceuticals, Inc.

Medtronic Gastroenterology

Ironwood Pharmaceuticals, Inc.

Furiex Pharmaceuticals, Inc.

Forest Laboratories, Inc.

Ferring International Pharmascience
Center US, Inc.

Treatment News

The U.S. FDA has Approved the Drug Linaclotide (Linzess) for the Treatment of Irritable Bowel Syndrome with Constipation and Chronic Constipation

On August 30, 2012, Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. announced that the U.S. Food and Drug Administration approved the New Drug Application (NDA) for linaclotide (Linzess®), a guanylate cyclase type-C (GC-C) agonist, to treat irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC) in adults aged 17 and older. Linaclotide is a drug used to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have IBS-C or CC. It has been shown to be safe and effective in trials. Linaclotide works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

The safety and effectiveness of Linzess for the management of IBS-C were established in two, double-blind studies. A total of 1,604 patients were randomly assigned to take 290 micrograms of Linzess or a placebo for at least 12 weeks. Results showed Linzess was more effective in reducing the amount of abdominal pain and increasing the number of complete spontaneous bowel movements compared with placebo.

The safety and effectiveness of Linzess for the management of chronic idiopathic constipation also were established in two, double-blind studies. A total of 1,272 patients were randomly assigned to take Linzess at doses of 145 mcg or 290 mcg or a placebo for 12 weeks. Results from these studies showed patients taking Linzess experienced more complete spontaneous bowel movements than those taking the placebo. The 290 mcg dose is not approved for chronic constipation because studies indicated it was no more effective than the 145 mcg dose.

Linzess is approved with a Boxed Warning to alert patients and health care professionals that the drug should not be used in patients 16 years of age and younger. Linzess should not be used in patients with known or suspected mechanical gastrointestinal obstruction. The most common side effect reported in during the clinical studies was diarrhea.

Ironwood and Forest are co-producing linaclotide in the United States. Ironwood has out-licensed linaclotide to Almirall, S.A. for development in Europe; and to Astellas Pharma, Inc. for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

European CHMP Recommends Approval for Linaclotide to Treat IBS-C

On November 28, 2012, the European Commission granted marketing authorization for linaclotide (marketed under the brand name Constella) in Europe to treat IBS with constipation in adults. Constella is expected to be available in Europe in the first half of 2013.

Solesta is now Available in the U.S. to Treat Fecal Incontinence

In May 2011 the Food and Drug Administration (FDA) approved Solesta, a biocompatible tissue bulking agent, for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). Solesta is an injectable gel delivered into the anal canal in an outpatient procedure taking approximately 10 minutes without the need for surgery or anesthesia.

Fecal incontinence is the involuntary loss of bowel control. While the exact mechanism of action has not been identified, it is thought that the Solesta injections may narrow the anal canal and allow for better control of those muscles.

The FDA based its approval on results from a clinical study of 206 patients. In the primary study, most patients received two treatments, consisting of four injections each, for a total of eight injections. After six months, more than half of the patients injected with Solesta experienced a 50 percent reduction in the number of fecal incontinence episodes. One-third of patients who received no Solesta in the study also experienced a similar reduction. Overall, a greater proportion of patients treated with Solesta experienced improvements, indicating the gel provides benefit.

Solesta is approved for use in patients ages 18 and up. It should not be used in patients who have active inflammatory bowel disease, immunodeficiency disorders, previous radiation treatment to the pelvic area, significant rectal prolapse, active infections, bleeding, tumors or malformations in the anorectal area, rectal distended veins, an existing implant in the anorectal region, or allergy to hyaluronic acid based products.

The most common side effects associated with Solesta include injection area pain and bleeding. Infection and inflammation of anal tissue are more serious risks, but are less common.

Solesta is a registered trademark of Q-Med AB of Uppsala, Sweden; Oceana Therapeutics acquired exclusive worldwide sales and distribution rights to Solesta in June 2009. On December 20, 2011 Salix Pharmaceuticals, Ltd. acquired all of the outstanding stock of Oceana Therapeutics, Inc.

Rifaximin Shows Promise for Treatment on Non-Constipated IBS

Rifaximin is an antibiotic currently under investigation for the treatment of non-constipation irritable bowel syndrome (Non-C IBS) and IBS-related bloating. Rifaximin works by reducing or altering bacteria in the gut. In studies it has been found to improve IBS symptoms of bloating, belly pain, and diarrhea (watery or loose stools) after a 10–14 day course of treatment. It is only slightly absorbed in the gut and is generally tolerated well. Rifaximin is not yet approved by the FDA for the treatment of IBS.

FDA Approves new Clinical Trial Looking at Repeat Treatment with Rifaximin

On November 16, 2011 Salix Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) Gastrointestinal Drugs Advisory Committee supported the Salix/FDA developed proposed design of a clinical trial to evaluate the safety, efficacy and durability of response with repeat treatment cycles of Xifaxan (rifaximin) for irritable bowel syndrome with diarrhea (IBS). A multi-center, randomized, double-blind, placebo-controlled trial with IBS patients will look at the efficacy and safety of rifaximin on repeat treatment.

Patient enrollment is planned during the first quarter of 2012. About 24 months could be required for the company to complete the trial and secure an FDA decision regarding approval.

Results from two Phase 3 clinical trials involving 1,260 non-constipated male and female patients with irritable bowel syndrome were reported in the January 6, 2011 issue of the *New England Journal of Medicine* (NEJM) showing adequate relief of IBS symptoms, bloating, abdominal pain, and loose or watery stools.

Results from the multiple center studies indicated that 550mg rifaximin, taken orally 3 times a day for 14 days, achieved adequate relief of global IBS symptoms (primary endpoint) and adequate relief of IBS-related bloating (key secondary endpoint) in a significantly greater proportion of patients, compared with placebo, during the primary evaluation period (first 4 weeks following treatment) as well as during the entire study period (10 weeks following treatment). The statistically significant weekly findings in the primary endpoint and key secondary endpoint noted above were supported by daily findings in the secondary endpoints of global IBS symptoms, bloating, stool consistency and abdominal pain and discomfort. Additionally, the NEJM publication includes results of an analysis of a composite endpoint of abdominal pain or discomfort and loose or watery stools as outlined in the March 2010 draft FDA Guidance for Industry relating to the clinical evaluation of products for treatment of IBS.

The safety profile of rifaximin was similar to that of placebo.

Rifaximin is a gut-selective antibiotic with negligible systemic absorption and broad-spectrum activity in vitro against both gram-positive and gram-negative pathogens. It is currently approved by the FDA for treatment of travelers' diarrhea (under the trade name of Xifaxan®), but at lower doses and shorter duration of therapy than being studied in IBS. It is not yet approved by the FDA for the treatment of IBS.





Amitiza Study Looks at Long-Term Safety

Amitiza (lubiprostone) is a prescription drug used to relieve stomach pain, bloating, and straining and produce softer and more frequent bowel movements in men and women who have chronic idiopathic (functional) constipation, and to treat irritable bowel syndrome with constipation (IBS-C) in women who are at least 18 years of age. Amitiza works by increasing the amount of fluid that flows into the bowel and allowing the stool to pass more easily.

A study of Amitiza published in the March 2012 issue of the journal *Alimentary Pharmacology & Therapeutics* looked at the long-term safety, tolerability, and patient outcomes in people with irritable bowel syndrome with constipation (IBS-C). The researchers concluded that in patients with IBS-C, lubiprostone 8 mcg twice daily was found to be safe and well tolerated over 9–13 months of treatment. The study provides preliminary evidence for the safety of lubiprostone in the long-term treatment of IBS-C.

The study was funded in part by Sucampo Pharma Americas, Inc., Bethesda, MD and in part by Takeda Pharmaceuticals USA, Deerfield, IL.

Amitiza Approved in U.K to treat Chronic Constipation

The U.K. Medicines and Healthcare Products Regulatory Agency has approved lubiprostone (Amitiza) for the treatment of chronic idiopathic constipation (CIC) and associated symptoms in adults, when response to diet and other non-pharmacological measures are inappropriate.

Lubiprostone Results Positive in Treating Opioid-Induced Bowel Dysfunction

The U.S. Food and Drug Administration (FDA) has given priority review to an additional indication for lubiprostone for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain. FDA's decision is expected by late January 2013.

Lubiprostone met the primary endpoint in a phase 3 clinical trial for the treatment of opioid-induced bowel dysfunction in patients with chronic, non-cancer pain, excluding those taking methadone.

Opioids are narcotics, such as morphine and codeine, used to treat pain. A number of gastrointestinal (GI) symptoms are potential side effects of using opioid-based medications. The most common symptom is constipation. Others symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed GI transit.

The phase 3, randomized, placebo-controlled, double-blinded trial looked at the efficacy and safety of lubiprostone in patients with opioid-induced bowel dysfunction. The primary endpoint was the overall spontaneous bowel movement response rate. Over a 12 week period, the response rate for 219 lubiprostone-treated patients was 26.9% versus 18.6% for 220 placebo-treated patients.

The trial included patients in the U.S. and Europe who continued opioid therapy throughout the study.

No drug-related serious adverse events were reported for patients taking lubiprostone. The most common treatment-related adverse events (experienced by 5–10% of patients) were diarrhea, nausea, and abdominal pain.

Lubiprostone currently is available under the name Amitiza to treat chronic idiopathic (functional) constipation and irritable bowel syndrome with constipation.

FDA Approves Gattex to Treat Short Bowel Syndrome

On December 21, 2012 the U.S. Food and Drug Administration (FDA) approved teduglutide (Gattex) for the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support. Gattex will be available in the first quarter of 2013. To help ensure that the benefits of Gattex outweigh the risks for causing other serious conditions, the drug is approved with a Risk Evaluation and Mitigation Strategy, which patients need to discuss with their doctors.

Short bowel syndrome is a rare condition related to poor absorption of nutrients. It typically occurs in people who have a significant portion of their small intestine removed due to disease or injury, and cannot absorb enough water, vitamins, and other nutrients from food. They may then need to use parenteral nutrition (PN) and intravenous (IV) fluids, the slow infusion of a solution of nutrients and fluids into a vein.

Gattex works by regeneration of cells in the intestinal lining, slowing down transit through the gut and increasing blood flow, allowing for increased nutrient absorption. In studies, the drug was associated with achieving and maintaining clinically meaningful reductions in PN and IV fluid volume in adult subjects with short bowel syndrome.

Gattex is a novel peptide involved in gastrointestinal regeneration and repair (recombinant analog of human glucagon-like peptide 2). NPS Pharmaceuticals is a specialty pharmaceutical company developing orphan therapeutics for rare gastrointestinal and endocrine disorders.

The company's SBS clinical development program represents the largest and most comprehensive to date. The information in the New Drug Application (NDA) submitted to the FDA was derived from fourteen completed and one ongoing clinical study. Of the 566 subjects treated with teduglutide, 299 subjects were treated in the clinical pharmacology studies, 94 subjects in Crohn's Disease studies, and 173 subjects in the SBS efficacy and safety studies. Of the 566 Gattex-treated subjects, 97 SBS subjects had at least 12 months of exposure to Gattex. Across the company's Phase 3 studies, a total of 15 patients were able to achieve independence from PH/IV. Side effects include abdominal pain, upper respiratory tract infections, nausea, injection site reactions, headaches, gastrointestinal stoma complications, and abdominal distension.

Study Reports Safety and Efficacy of Teduglutide over 52 Week Treatment Period

January 24, 2013 – An international multi-center study involving 52 patients looked at the safety, tolerability, and efficacy of teduglutide (Gattex) taken once per day over 52 weeks for the treatment of people with short bowel syndrome receiving parenteral nutrition (PN). The study concluded that for patients with short bowel syndrome and intestinal failure, the efficacy of teduglutide was maintained over 52 weeks and the safety profile was sufficient for it to be considered for long-term use.

A reduction of more than 20%, equivalent to 1 day per week, of parenteral nutrition dependency was achieved in a significant number of participants receiving the drug. Four (4) patients were able to discontinue PN fluids completely over the 52 weeks.

The most common adverse events reported included headache, nausea, and abdominal pain. Of 7 patients who withdrew because of adverse events, 4 were considered treatment related. While the researchers found the safety profile to be acceptable, they advise that physicians closely monitor patients beginning the drug for side effects and possible need to adjust dose.

Patients taking part in clinical trials are closely monitored. Continued clinical practice studies are needed to understand real world implications for improving quality of life and reducing potential long-term PN complications for people with short bowel syndrome.

The study titled, “Safety and efficacy of teduglutide after 52 weeks of treatment in patients with short bowel syndrome intestinal failure,” was reported in the journal, *Clinical Gastroenterology and Hepatology*, Jan 17, 2013.

Phase 3 Clinical Trials Begin for new Treatment of Diarrhea-Predominant Irritable Bowel Syndrome

MuDelta (JNJ-27018966) is a novel drug under development for the treatment of irritable bowel syndrome with diarrhea as the predominant bowel symptom (IBS-D). The drug was designed with the purpose of treating both the diarrheal and pain symptoms of IBS-D.

Phase 3 Clinical Trial

Recruitment of male and female adult patients has started for the Phase 3 clinical study of this drug. The purpose of Phase 3 studies is to look at effectiveness, monitor side effects, and collect information that will allow the drug or treatment to be used safely.

Take Part in a Treatment Study

Purpose of the study: To evaluate the efficacy, safety, and tolerability of JNJ-27018966 compared with placebo in the treatment of patients with irritable bowel syndrome (IBS) with the subtype of diarrhea.

Participation: Eligible male and female patients aged 18 to 80 years with a diagnosis of irritable bowel syndrome (IBS) with a subtype of diarrhea.

Sponsored by: Furiex Pharmaceuticals

For information call:

(USA)1-877-345-2145 (UK): 0800-977-8391

A completed Phase 2 proof-of-concept clinical trial evaluated the safety and efficacy of MuDelta (JNJ-27018966). In the study, MuDelta was well-tolerated and had a favorable safety profile.

The drug met its primary objectives of establishing tolerability, safety, and efficacy in a 12-week randomized, double-blind, placebo-controlled study. The study achieved statistically and clinically significant results for its primary as well as a number of key secondary endpoints. MuDelta also demonstrated durable efficacy through the 12-week treatment period.

A total of 807 patients with IBS-D were enrolled in the phase 2 trial. The primary endpoint was a composite analysis of stool consistency and abdominal pain at week four compared with baseline symptoms. The study demonstrated that treatment with MuDelta was statistically superior to placebo for this primary endpoint.

The compound now has an agreed-upon, clear regulatory path forward with the U.S. Food and Drug Administration (FDA). The drug has been granted fast-track status by the FDA in acknowledgement of the potential to address a significant unmet

medical need for patients with IBS-D.

Phase 3 trials will accumulate data that further evaluates the drug's safety and effectiveness. Furiex Pharmaceuticals, Inc. is developing the drug under a November 2009 development and license agreement with Janssen Pharmaceutica N.V.

Elobixibat is a New Drug Treatment Under Development for Chronic Idiopathic Constipation and for IBS-C

Elobixibat is a first-in-class compound under investigation for treatment of chronic idiopathic constipation (CIC), and for irritable bowel syndrome with constipation (IBS-C). It works by reducing bile acid absorption in the small intestine. This stimulates bowel movements by increasing fluid secretions and motility in the colon.

In Phase 2b clinical trials, elobixibat (formerly A3309) has been evaluated in patients in the U.S. and Europe for the treatment of CIC. The studies demonstrated clinically meaningful, statistically significant, and dose-dependent improvements. These included increased stool frequency and improved constipation-related symptoms such as straining, stool consistency, and bloating maintained over 8 weeks of treatment.

Elobixibat is due to enter Phase 3 trials for the CIC indication and Phase 2b trials for the IBS-C indication shortly.

What are Phases? Treatment trials or studies are in phases:

- **Phase 1** tests a new drug or treatment in a small group to evaluate its safety, determine a safe dosage range, and identify side effects;
- **Phase 2** expands the study to a larger group of people to see if it is effective and to further evaluate its safety;
- **Phase 3** expands the study to an even larger group of people to confirm its effectiveness, monitor side effects, and collect information that will allow the drug or treatment to be used safely.



IFFGD will host the 10th International Symposium on Functional Gastrointestinal Disorders on April 12–14, 2013 at the Pfister Hotel, Milwaukee, WI. This CME accredited 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).

- 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.

For further information, contact:

Or go to the IFFGD web page at
www.iffgd.org/symposium.

Notes:

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Special Events & Meetings

Upcoming events of interest to the digestive health community.

10th International Symposium on Functional Gastrointestinal Disorders

When: April 12–14, 2013

Location: Milwaukee, WI

Organizer: University of Wisconsin School of Medicine and Public Health, Office of Continuing Professional Development and the International Foundation for Functional Gastrointestinal Disorders (IFFGD)

Email: symposium@iffgd.org

Website: <http://www.iffgd.org/symposium>

ASCRS Annual Scientific Meeting

When: April 27 to May 1, 2013

Location: Phoenix, AZ

Organizer: American Society of Colon & Rectal Surgeons

Email: meetings@fascrs.org

Website: www.fascrs.org

Digestive Disease Week (DDW) 2013

When: May 18–21, 2013

Location: Orlando, Florida, USA

Organizers: American Association for the Study of Liver Diseases (AASLD), American Gastroenterology Association (AGA), American Society for Gastrointestinal Endoscopy (ASGE), and The Society for Surgery of the Alimentary Tract (SSAT)

Email: ddwadmin@gastro.org

Website: www.ddw.org

AANP 28th National Conference

When: June 19–23, 2013

Location: Las Vegas, NV

Organizer: American Association of Nurse Practitioners

Email: conference@aanp.org

Website: www.aanp.org/conferences/national-conference

ANMS Annual Meeting 2013

17th Neurogastroenterology & Motility Scientific Meeting, 8th Postgraduate Course on Gastrointestinal Motility and Neurogastroenterology in Clinical Practice and a Young Investigator Forum

When: September 20–22, 2013

Location: Huntington Beach, California

Organizer: The American Neurogastroenterology and Motility Society (ANMS)

Abstract Deadline: March 29, 2013

Email: admin@motilitysociety.org

Website: www.motilitysociety.org

World Congress of Gastroenterology (Gastro 2013)

When: September 21–24, 2013

Location: Shanghai, China

Organizer: Asian Pacific Digestive Week Federation (APDWF), Chinese Societies of Digestive Diseases (CSDD), World Endoscopy Organization (WEO) and the World Gastroenterology Organisation (WGO)

Email: congress@gastro2013.org

Website: www.gastro2013.org

NASPGHAN 2013 Annual Meeting & Postgraduate Course

When: October 10–12, 2013

Location: Chicago, IL

Organizer: North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

Email: naspghan@naspghan.org

Website: www.naspghan.org

ACG Annual Scientific Meeting and Postgraduate Course

When: October 11–16, 2013

Location: San Diego, CA

Organizer: American College of Gastroenterology (ACG)

Email: info@acg.gi.org

Website: www.gi.org

United European Gastroenterology Week (UEGW)

When: October 12–16, 2013

Location: Berlin, Germany

Organizer: United European Gastroenterology (UEG)

Email: office@ueg.eu

Website: www.ueg.eu/week/



Community News

DIGESTIVE HEALTH ALLIANCE

The Digestive Health Alliance (DHA) is the grassroots arm of IFFGD

The DHA is a community of individuals affected by functional GI and motility disorders including people who are burdened with symptoms, as well as their friends and families. We work together to increase awareness, raise funds for research, and advocate for scientific advancement and improved patient care for those suffering from these digestive disorders. Join the DHA and our efforts to make a difference at DHA.org

Many lives have been impacted by digestive disease. Visit our webpage at www.dha.org/courageous_stories to view stories from people who are going through some of the same struggles as you or a loved may be experiencing. We invite you to share your own story of living with a digestive disorder – it can be therapeutic for you and inspiring to others who are suffering. Here's a recent story.

I grew up with two parents who had constant heartburn. Dad always had antacids in his pocket and mom kept them on her nightstand. I just thought it was a thing that all adults suffered from. So when I started to suffer from heartburn in college, I didn't think of it as something I should seek treatment for. I just started buying big bottles of antacids and sleeping on a pile of pillows to elevate my head. I put on too much weight during grad school, and between eating a student's poor diet, the excess weight, and the stress, heartburn became just a way of life.

When I was about 30 I got a job at a hospital. One of the doctors saw me popping antacids after lunch and asked if I had ever talked to my doctor about my heartburn. He was shocked that I had never even mentioned it! I consider myself an educated person but that was the first time I heard that long term heartburn can be a sign of GERD, and that going too long untreated, GERD can lead to esophageal cancer.

I found a doctor in the hospital who was doing a clinical trial on people with untreated GERD. I got a free endoscopy as part of the trial, and I was lucky to find that I didn't have any damage to my esophagus despite years without treatment. I was told to follow-up with my primary care doctor and get treatment. She put me on a proton pump inhibitor and I can't tell you how amazing it was – I took the first pill, and that night for the first time in years I didn't have heartburn! She told me I'd probably need to be on PPIs the rest of my life if I didn't want the heartburn to come back.

I started trying to make other changes – eating smaller dinners and not eating right before bedtime – and within a few months I was able to cut back to one pill every other day. But boy if I forgot which day I was on and missed a pill, the GERD came back with a vengeance. It took another five years for me to find the willpower to start making serious changes to improve my health. I started bicycling in 2008, and started losing a lot of weight. Part of my diet plan was to stop eating at all after about 3pm.

Now I no longer need the PPIs. However, this doesn't mean I'm “cured” of my GERD. I still have to use antacids on the rare occasions that I eat too close to bedtime or have too large of a meal. It's still there, waiting for me to slip back into bad habits, and it always will be. It's just like any other chronic disease. I just wish I had learned earlier that heartburn is not something you have to live with; that treatments and lifestyle changes exist that can help. Good luck to all of you who are still struggling.

– *Gastroesophageal Reflux Disease (GERD)*

Community News

Looking Ahead to the 113th Congress

The 112th Congress officially ended on January 3, 2013, when members of the 113th Congress were sworn into office. The 112th Congress was a monumental session for functional gastrointestinal and motility disorders. It saw the first fiscal year in which funds were dedicated specifically for Gulf War Illness research, which includes functional gastrointestinal disorders, through the Department of Defense, as well as the introduction in the House of Representatives of *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act*, the first ever federal research bill focused on functional GI and motility disorders (FGIMDs).

She emailed her Representative,
“Your voice will make a difference in
Washington on my behalf.”

Some people attended DHA Advocacy Days in Washington DC and shared their own stories with Congress of life with a functional GI or motility disorder. Brian travelled from Wisconsin to advocate on behalf veterans. He shared his experience of returning from service in Iraq with cyclic vomiting syndrome (CVS), highlighting the lack of awareness and need for education about FGIDs in the community, both among

people afflicted and health care providers. Hollie made the trip from Ohio to help Congress understand the day-to-day impact of gastroparesis, and Reneé travelled from Florida to describe the challenges of living with IBS and GERD.

Other digestive health advocates, like Pamela, were unable to travel, but did not let that stop them from speaking out. Pamela was too weak to attend DHA Advocacy Day in June 2012. She emailed her Representative, “Your voice will make a difference in Washington on my behalf.”

Whether recently diagnosed, like Bret who developed gastrointestinal symptoms after his deployment to the Gulf War region, or someone who has dealt with their condition for many years, like Lisbeth, a “mother of 3 kids” who has “had Achalasia for over ten years,” each personal story shared is a heartfelt plea for Congress to take action.

Other advocates were inspired to speak by someone close to them affected by a FGIMD. At 18 months old, young Sophia suffers pseudo-obstruction. Hundreds of her friends and family wrote postcards imploring Congress to “please help us get the answers she deserves.”

The Digestive Health Alliance is made up of all kinds of people with a common interest in functional GI and motility disorders. In the new 113th Congress, DHA advocates will seek re-introduction of *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act*. In addition, we will continue to seek Congressional funding for research at the National Institutes of Health, and for the Gulf War Illness Research Program.

Your continued support is critical to success of these efforts. To learn how you can take action, visit our website at www.DHA.org.



News Update

The Functional Gastrointestinal and Motility Disorders Research Enhancement Act has been reintroduced in the House of Representatives by Representative F. James Sensenbrenner (R-WI) with bill number H.R. 842. Representative James Moran (D-VA) has become the original cosponsor in a show of bipartisan support for this revenue-neutral bill.

This bill was previously introduced in the last Congress as H.R. 2239, but with the start of a new Congress, the legislative process must begin again. The Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011 resulted in over 1,000 advocates contacting their Representative, leading to 17 cosponsors. We are hopeful for even greater support in this Congress.

In addition to raising critical awareness of functional GI and motility disorders and the needs of patients, passage of H.R. 842 will:

- Grant the National Institutes of Health (NIH) new authority to initiate innovative research projects
- Establish a Centers of Excellence Program in this area
- Coordinate research activities with the Department of Defense and the Veterans Administration when appropriate
- Call on the Food and Drug Administration (FDA) to improve review, approval, and oversight of treatments for FGIMDs

In order for this bill to pass, Members of Congress need to hear from you. Your Representative will only become a cosponsor if YOU – their constituent – ask them. Share your story and ask them to support the patients and families affected by functional GI and motility disorders by becoming a cosponsor of this important legislation.

It just takes a minute to email your Representative today by visiting www.iffgd.org/HR842action.

Community News



About Gastroparesis

Gastroparesis Help

Welcome to aboutGastroparesis.org. On this site you will find help and information you can use about understanding, treating, and managing gastroparesis.

Gastroparesis can occur in children and adults. It is characterized by symptoms where the stomach does not empty properly. No obstruction or blockage is evident. It is a poorly understood condition, even by many physicians.

aboutGastroparesis.org

Your Action is Needed

It only takes a minute to support the Functional GI & Motility Disorders Research Enhancement Act. Urge your member of congress to cosponsor the bill (H.R. 842) Take Action Now! [Go »](#)

Courageous Stories

Share your experiences [Go »](#)

Join the Conversation

Connect through Facebook [Go »](#)

Follow us on Twitter [Go »](#)

New Website from IFFGD

In December 2012 IFFGD launched a new website at www.aboutGastroparesis.org. The site features information about understanding, treating, and managing gastroparesis.

Gastroparesis is characterized by the presence of certain long-term symptoms together with delayed stomach emptying in the absence of any observable obstruction or blockage. The delayed stomach emptying is confirmed by a test.

There are a number of things that may contribute to or cause gastroparesis. In most people with gastroparesis, the cause is unknown and is termed “idiopathic.” Some people with idiopathic gastroparesis report symptoms following a virus infection (post-infectious or post-viral gastroparesis). Other possible causes include diabetes, some surgeries, certain medications, and other illnesses.

Treatments are aimed at managing symptoms over a long-term. Treatment approaches may involve one or a combination of dietary and lifestyle measures, medications, nutritional support, and/or procedures that may include surgery.

The incidence and severity of gastroparesis seems to be on the rise. More research is needed to advance understanding of the condition that will lead to preventing, better treating, and one day curing gastroparesis.

You can Help Advance Understanding of Gastroparesis

The NIH, through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), has established the *Gastroparesis Clinical Research Consortium* (GpCRC), a network of 9 medical centers in the U.S. The aim is to improve understanding of the cause and natural course of gastroparesis and to advance the diagnosis and treatment of this disorder.

You can help by taking part in a clinical trial/study. The GpCRC is recruiting patients for their gastroparesis registry. Individuals with gastroparesis who sign up for the registry may be contacted about participating in trials or surveys about gastroparesis.

Learn more on our webpage at: www.aboutgastroparesis.org/gpcrc



IFFGD Research Grants and Awards

Call for Grant Applications Supporting Innovative Research Related to Idiopathic Gastroparesis

The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is seeking applications for research grants.

Description

Grant awards of \$40,000 (pre-tax USD) each in direct costs are available to three (3) investigators for innovative research related to idiopathic gastroparesis.

Basis

We are seeking proposals for research in humans that will ultimately lead to improvements in the understanding of idiopathic gastroparesis, its pathophysiology, and the care of patients.

The mission of IFFGD is patient-oriented. Our goal is to fund high-quality research. A preference will be given to clinical research, as well as basic research that is translational in nature.

Review Process

In evaluating the merits of an application, the Selection Committee will consider its scientific merit, its significance to the field, and its feasibility.

Application Process

Applicants must have completed an M.D., Ph.D., or equivalent degree. The deadline for submitting applications is midnight, Monday August 6, 2013. Grant details and application forms are available online at www.iffgd.org/gp-grants.



IFFGD to Present Research Awards

On April 12, 2013 we will present IFFGD Research Awards to 8 investigators whose work is advancing understanding of functional GI and motility disorders in adults and children. The contributions of these men and women cover a wide range of accumulated knowledge relative to the conditions such as:

- how systems work and interact,
- factors that lead to illness and disease,
- potential targets for effective treatments, and
- how to improve care for patients.

The award winners were chosen from among dozens of highly qualified nominees. They will be recognized at a ceremony scheduled to take place during the 10th International Symposium on Functional GI Disorders in Milwaukee, WI in April. We will post more information about the winners and their work online and in future issues.

Community News

Working for Change – A Story of Courage, Strength, and Inspiration



Every member of the Digestive Health Alliance (DHA) is united in the desire to advance science, improve patient care, and end the suffering caused by functional gastrointestinal and motility disorders. Like the individuals that make up the alliance, each of their stories is unique. Here is Lonnie and Cheryl's story.

In 2009, Cheryl began to experience digestive problems. Though she seemed to be okay with very small meals, she was having trouble keeping larger ones down. What Cheryl thought was just a “bug” did not go away, rather her symptoms got worse. She was vomiting more often and noticed other problems developing: nausea throughout the day, a constant pain between her abdomen and ribcage, and problems with acid reflux.

At one point, the pain became so unbearable that she was taken to the emergency room where doctors could not find anything wrong and suggested that she have her heart fully evaluated. All the tests came back negative; Cheryl did not have any issues with her heart. While Cheryl continued without a diagnosis, new symptoms started: bouts of dizziness throughout the day and Cheryl noticed that her weight was decreasing.

The next year Cheryl was finally diagnosed with severe gastroparesis. Also called delayed gastric emptying, gastroparesis is a motility disorder in which the muscle contractions that move food along the digestive tract do not work properly and the stomach empties too slowly. Like many others with idiopathic gastroparesis, it is uncertain what caused Cheryl's gastroparesis. There is also no known cure.

Cheryl was unable to eat any solid food or anything having a heavy consistency for three years. For three years she could not eat grilled chicken salad, her favorite food, or anything else without getting nauseous and immediately running to the bathroom to vomit.

During this difficult time Cheryl lost 40 pounds. She also endured several surgeries and procedures, numerous tests, and tried many different prescriptions. Nothing seemed to help her and Cheryl passed away in March 2012.

Lonnie worked with family and friends to create The Cheryl Aaron Memorial Fund in his wife's memory. Their goal is to help others with gastroparesis and ultimately put an end to this potentially deadly, but relatively unknown, disease. They hope that after hearing Cheryl's story you will want to help as well!

Cheryl's family and friends will be hosting a variety of fundraising events in 2013 including a golf tournament on June 1. Any assistance you can provide to make these events successful is much appreciated. Their first event held in January raised \$4,000 and their goal is to raise \$20,000 in 2013. The funds raised will go towards gastroparesis research through IFFGD and the Digestive Health Alliance.

You can lend your support and learn more about Lonnie and Cheryl at: www.dha.org/cheryls-fund.



Trust Your Gut Feeling!

...and learn more about the Digestive Health Alliance!

ABOUT DHA

The Digestive Health Alliance (DHA) is a nonprofit organization working tirelessly to help find treatments and cures for chronic digestive disorders. Through coordinated fundraising, advocacy, and awareness efforts, we lead the push for research breakthroughs that will improve the quality of life for people affected by functional GI and motility disorders. These are long-term conditions that affect children and adults in your community.

WE NEED YOU!

We invite you to join us! The DHA community consists of patients, families, friends, supporters, and healthcare providers. There is strength in numbers, and it is for this reason that we stand up together and speak out with one voice to advance science, improve patient care, and end the suffering caused by chronic digestive conditions.



YOU CAN...

- Fundraise for Research
- Spread Awareness & Education
- Read & Share Courageous Stories
- Find People Like You
- Reach out to Lawmakers
- TAKE ACTION!

Please visit

WWW.DHA.ORG

to learn more and join
our team!

Digestive Health Alliance



The Digestive Health Alliance (DHA) is the grassroots arm of the International Foundation for Functional Gastrointestinal Disorders (IFFGD), a nonprofit 501(c)(3) organization.

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The articles in *Digestive Health Matters* are in no way intended to replace the knowledge or diagnosis of your doctor. We advise seeing a physician whenever a health problem arises requiring an expert's care.

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This issue of *Digestive Health Matters* is sponsored, in part, by Forest Laboratories, Inc., Ironwood Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc., and the members of IFFGD. We are grateful for their continued support of IFFGD.

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Our Unique Mission: The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is a nonprofit education and research organization dedicated to informing, assisting, and supporting people affected by gastrointestinal disorders. IFFGD has been working since 1991 with patients, families, physicians, practitioners, investigators, employers, regulators, and others to broaden understanding about gastrointestinal disorders and support research.



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