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DigestiveHealth Matters

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Living with Bowel Incontinence
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Seeking Support for GI Research
Advocate for Change or Participate in Research

INTERNATIONAL FOUNDATION FOR
FUNCTIONAL GASTROINTESTINAL DISORDERS

Information. Assistance. Support.

DigestiveHealth Matters

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"Strength does not come from physical capacity. It comes from an indomitable will."

– Mahatma Gandhi

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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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Cover Photo by Melanie Pack for i{mpack}t studio 2015

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Tips on Preventive Measures and Management of Gastroparesis

There are lots of things that affect health and illness. Some you cannot control, but some you can.

Beyond making healthy lifestyle choices, having gastroparesis will likely push you to always be looking for what does and does not help, hurt, and work best for you. It's not always easy, but sorting this out can help you improve your health-related quality of life.

Here are some things to keep in mind when dealing with gastroparesis. Taking some preventative steps can help you ease symptoms, lessen the unwanted effects on your daily life, and enhance your well-being.

Be Aware of Causes and Complications

Not only recognizing the symptoms, but also knowing the cause, and complications that can arise from gastroparesis, can help prevent delays in obtaining appropriate treatment.

Although most commonly the cause is unknown (idiopathic), in about one in four people with gastroparesis it occurs as a complication of long-standing diabetes.

Gastroparesis can also arise:

- As a problem after some surgical procedures (particularly esophageal or upper abdominal surgeries)
- After use of certain medications, such as narcotic pain killers, anticholinergic/antispasmodic agents, calcium channel blockers, some antidepressants, and some diabetes medications
- In association with illnesses that affect the whole body, the nervous system, or connective tissue, such as multiple sclerosis, Parkinson's disease, cerebral palsy, systemic lupus, and scleroderma

Gastroparesis can lead to:

- Severe dehydration due to persistent vomiting
- Difficulty managing blood glucose (blood sugar) levels in individuals with gastroparesis associated with diabetes
- The formation of clumps of undigested food (bezoars), which can cause nausea, vomiting, or obstruction
- Malnutrition due to poor absorption of nutrients or a low calorie intake
- Adverse events caused by drug interactions (treatments often may involve taking different classes of drugs to treat several symptoms, such as to reduce nausea, reduce pain, and lower blood glucose levels)

Prevention and Management Tips

- Work with a registered dietician (RD) or nutrition support specialist (nurse or doctor) to design a dietary plan to meet your individual needs; understand how to use and maintain dietary and nutritional therapies.
- Eat frequent, small meals that are low in fat and fiber. Fat, fiber, and large meals can delay stomach emptying and worsen symptoms.
- Keep hydrated and as nutritionally fit as possible.
- If you have diabetes, maintain good glucose control. Irregular stomach emptying can negatively affect blood sugar levels. Keeping your blood sugar under control may help stomach emptying.
- Before having surgery, ask your doctor, surgeon, or healthcare team about risks involved and weigh these against the benefits. Ask about alternatives.
- Let your doctor and pharmacist know about all medications you are taking – prescription and over-the-counter, as well as any supplements.
- Be aware of any drug interactions and discuss alternatives with your doctor.
- Understand the possible side effects of your treatments, and know what to do if side effects occur.
- Avoid or reduce alcohol and smoking tobacco. These can slow gastric emptying.
- Engage in regular physical activity as you are able.

Seek appropriate care and take an active role in your health. Working along with your doctor or healthcare team will help control, reduce, or prevent symptoms and complications. ■

Comments from FDA's Patient Focused Drug Development Initiative

Thank you to everyone who took part in the FDA's Functional Gastrointestinal (GI) Disorders Patient-Focused Drug Development public meeting earlier this year. Some members of the digestive health community traveled to Washington, D.C. to attend the meeting in person, while others took part over the phone or made comments to the public docket.

> Patient-Focused Drug Development is a five-year initiative that calls for the FDA to obtain patient's perspectives on specific disease areas, including thoughts on their conditions and available therapies, as well as the impact the conditions have on their daily lives. These perspectives can play a role in developing new drug therapies and provide key knowledge to the FDA as it reviews applications for new drugs in certain disease areas.
>
> A total of 20 disease areas will be included over the five year period, and several functional gastrointestinal conditions – IBS, gastroparesis, persistent GERD, and chronic idiopathic constipation – were part of the digestive disease area in the program.

IFFGD understands the importance of sharing the patient perspective with regulatory agencies and policy makers. We attended the meeting in Washington to speak on behalf of the patients we hear from each day, and also made comments to the Public Docket, advocating for help to serve the digestive health community.

William Norton, co-founder of IFFGD, presented the following written comments to the Public Docket on behalf of those involved with IFFGD:

> On behalf of the International Foundation for Functional Gastrointestinal Disorders (IFFGD) I appreciate this opportunity to offer additional comments, including the attached reports, regarding the Functional GI Disorders Patient-Focused Drug Development Public Meeting held on May 11, 2015.
>
> IFFGD works on behalf of patients affected by functional GI disorders. We have conducted research to learn about this population, sharing our findings with the public, the healthcare community, and with regulators such as FDA in order to advance understanding of the burden of illness and unmet needs of those affected.

In particular, we wish to share the following research reports with you:

- In 2002 we published findings from our national telephone survey of 350 IBS patients, *IBS in the Real World Survey**, providing insight into the experience of living with IBS including the symptoms, treatments, side effects, and the overall impact of the condition.
- In 2009 we published findings from our online survey, *IBS Patients: Their Illness Experience and Unmet Needs**, in which 1,966 patients provided a vivid profile of their illness experience, how it impacts their lives, and the risks many would accept to find relief from the debilitating effects of IBS. A more detailed report of these findings was published in the peer-reviewed *Journal of Clinical Gastroenterology*.
- In 2015 we conducted an online survey of over 1,000 gastroparesis patients. The preliminary results present a similar picture of chronic, debilitating symptoms, that negatively impact daily living, and for which there are few effective treatments. We look forward to sharing the results of this survey with you when our report on the data is completed.

We believe that patients managing chronic functional GI disorders do best when they work in partnership with their doctors. Accordingly, patients should be allowed to make informed treatment decisions while their doctors exercise clinical judgments based on the unique circumstances of each individual. We ask that the FDA do what it can to help ensure patients have access to as many treatment options as possible, in conjunction with regulatory review that takes into account the tremendous burden which functional GI disorders can place on the individuals affected.

Thank you for your consideration of our comments. ■

How did the FDA decide select the disease areas to be considered as part of Patient-Focused Drug Development?

In addition to public comments, the following criteria were used:

- Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living
- Disease areas for which aspects of the disease are not formally captured in clinical trials; and
- Disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how the patient feels or functions

The FDA asked specific questions in order to obtain a clear picture from patients as to what life is like with these conditions. Here are some examples of the questions asked, as well as public comments made by members of the digestive health community:

How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

"Best days: still have low energy and pain. Worse days: stay in bed and bathroom all day."

"I would say I live with nausea 24/7 so that does impact me in not wanting to really eat, but I still try…Sometimes though I have to use them [Fluids PRN with Dextrose] 24 hours straight on my bad days when I can't even drink water or any other liquid for that matter."

What worries you most about your condition?

"Not being able to care for myself."

"A few years ago I would have told you death. However, my attitude has changed in that death is inescapable and it may not even be these conditions that take me from this earth. So, I will say I am more worried about the quality of life that so many don't have with these illnesses."

*If you are interested in obtaining copies of our published findings, please visit our Library at *www.iffgd.org* or contact IFFGD at 888-964-2001.

IFFGD INDUSTRY COUNCIL

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.

IFFGD INDUSTRY COUNCIL

Valeant Pharmaceuticals International, Inc.

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

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QOL Medical, LLC.

Ironwood Pharmaceuticals, Inc.

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Entera Health, Inc.

Allergan

Linaclotide for Treatment of IBS-C

Linaclotide, a guanylate cyclase type-C (GC-C) agonist, is a prescription drug used to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). It has been shown to be safe and effective in trials. It works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing abdominal pain.

Linaclotide (Linzess) has been available in the U.S. to treat IBS-C and CIC in adults aged 18 and older since 2012. It is currently available in several European countries with the EU brand name Constella.

Linaclotide should *not* be used in patients 17 years of age or younger or in patients with known or suspected mechanical gastrointestinal obstruction. The most common side effect reported during clinical studies was diarrhea.

Linaclotide is being co-produced in the U.S. by Ironwood Pharmaceuticals and Allergan. Ironwood has out-licensed linaclotide to Almirall, S.A. for development in Europe; to Astellas Pharma for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand; and to AstraZeneca in China.

Positive Results Announced for Phase 3 Clinical Trial of Linaclotide in Japan

In July 2015, Ironwood Pharmaceuticals and AstraZeneca Pharmaceuticals announced positive results of a Phase 3 clinical trial of linaclotide in China. Approval of the drug for marketing and distribution in China by the China Food and Drug Administration (CFDA) is pending. Linaclotide has met all primary and secondary endpoints, including multiple abdominal and constipation symptoms in all six of its Phase 3 and Phase 3b trials.

Linaclotide is currently approved in the U.S. for the treatment of adults with IBS-C or CIC and in a number of other countries for adults with IBS-C.

Seeking Participants with Chronic Idiopathic Constipation for Trial of Linaclotide

Purpose of study: This 12-week, Phase 3 study will assess the efficacy and safety of linaclotide in patients with chronic idiopathic constipation (CIC).

Sponsor: Ironwood Pharmaceuticals, Inc.

Collaborator: Forest Laboratories

Participation: Eligible male and female patients demonstrating CIC aged 18 and older

Contacts: Find a recruiting location online at *ClinicalTrials.gov*; Refer to this study by its *ClinicalTrials.gov* identifier: NCT02291679

Study on the Efficacy and Safety of Linaclotide for Opioid-Induced Constipation

Purpose of study: This 8-week, Phase 2, multicenter study will evaluate the safety and efficacy of linaclotide for the treatment of opioid-induced constipation (OIC) in adults receiving opioid treatment for chronic non-cancer pain.

Sponsor: Forest Laboratories

Collaborator: Ironwood Pharmaceuticals, Inc.

Participation: Eligible male and female patients 18 years and older who have presented chronic non-cancer pain for a minimum of 3 months and are receiving a stable dose of opioid treatment for at least 4 days.

Contacts: Kathy Hynek, phone: 866-369-5227, email: *kathy.hynek@frx.com*; Be sure to refer to this study by its *ClinicalTrials.gov* identifier: NCT02270983 (study is active, but no longer recruiting)

Medical Food in the Management of Diarrhea

EnteraGam™ is a prescription *medical food* product to help people manage ongoing problems with chronic loose and frequent stools (diarrhea). Medical foods are required to be used under physician supervision as part of ongoing medical care for a specific condition or disease.

EnteraGam is manufactured and distributed by Entera Health, Inc. It is indicated for the clinical dietary management of intestinal disease (enteropathy) in patients who, because of therapeutic or chronic medical needs, have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients.

The main ingredient in EnteraGam is a specially formulated protein preparation that consists of more than 50 percent of immunoglobulin (molecules involved with immune function). This ingredient, SBI (serum-derived bovine immunoglobulin/protein isolate), is made up of beef serum proteins. The proteins in SBI remain in the intestine and are not absorbed whole. EnteraGam is contraindicated for patients with a hypersensitivity (allergy) to beef, or any components in EnteraGam.

SBI may Improve IBS Symptoms

Researchers in a small study that followed 14 patients with various forms of IBS (2 IBS-C, 7 IBS-D, 2 IBS-Mixed, and 3 IBS-Undefined) concluded that SBI, oral serum-derived bovine immunoglobulin/protein isolate (EnteraGam), as a medical food provides a safe option for patients with IBS-D, but may have application in other forms of IBS. Twelve of the 14 patients indicated some level of overall improvement within 4 weeks after the addition of SBI to their standard therapy. The study results were published in March 2015 in the *World Journal of Gastroenterology*.

Review Looks at Effects of SBI on Managing Conditions like IBS-D

A review, which summarizes accumulated data from prior studies, concluded that specially formulated immunoglobulin sources like SBI have multiple effects which collectively serve to improve and maintain nutrient utilization, including water balance. This aids in the management of intestinal disorders (enteropathy) in patients with chronic loose and frequent stools in conditions like irritable bowel syndrome with diarrhea (IBS-D).

The mode of action appears to be combined effects on inflammation, gut barrier function, and immune balance. The study review, by Petschow et al, was published in August 2014 in the journal, *Digestive Diseases and Sciences*. The authors are employed by Entera Health.

Study Evaluates Impact of SBI in People with IBS-D

Results from a randomized, double-blind, placebo-controlled pilot study suggest that nutritional therapy with SBI, the ingredient found in EnteraGam – used in addition to traditional medical care – can help manage various symptoms associated with irritable bowel syndrome with diarrhea (IBS-D). The study, by Wilson et al., was published in 2013 in the journal, *Clinical Medicine Insights: Gastroenterology*.

A total of 45 persons completed the study per the protocol, with 31 in the SBI group and 14 in a placebo group. The symptom profile of each participant was determined during the first week, followed by a six-week treatment period. The safety profile of SBI in the study was similar to that of placebo.

The study showed that nutritional therapy with either 10 g/day or 5 g/day of SBI in patients was well tolerated and resulted in statistically significant improvements

in days with symptoms and a trend for improvement in symptom severity scores in participants with IBS-D. In particular, the 15 participants who received 10 g/day of SBI showed significant reductions in abdominal pain, loose stools, bloating, flatulence, and urgency.

Participants Sought for Congenital Sucrase-Isomaltase Deficiency (CSID) Genetic Prevalence Study in Children with Chronic Diarrhea or Chronic Abdominal Pain

Congenital sucrase-isomaltase deficiency (CSID) is a rare genetic disorder that affects a person's ability to digest the sugars sucrose and maltose. Sucrose is found in fruits, and is also known as table sugar. Maltose is the sugar found in grains.

In this study, clinicians are looking at using two different tests to rule out CSID, which often causes chronic diarrhea and/or abdominal pain for at least 4 weeks, may qualify to participate in this study.

If your child is eligible, there is the potential for up to three doctor's office visits that could include: having the inside of cheeks swabbed to look for common CSID genetic mutations, taking a breath test, providing a medical history review, and completing a few questionnaires.

Purpose of Study: Determine the prevalence of CSID genetic variants in subjects 18 years of age or younger with a primary symptom of chronic idiopathic diarrhea or chronic abdominal pain without constipation.

Sponsor: QOL Medical, LLC

Collaborators: 19 Medical Centers located throughout the U.S.

Contact: Healther Elser, Ph.D., 919-832-4949, *helser@qolmed.com*. Refer to this study by its *ClinicalTrials.gov* identifier: NCT01914003.

Review Article Concludes that Bile Acid Transport Inhibitor Elobixibat is Effective in Treating Chronic Idiopathic Constipation

Elobixibat is a first-in-class compound under investigation by Ferring Pharmaceuticals for treatment of chronic idiopathic constipation (CIC), and for irritable bowel syndrome with constipation (IBS-C).

An article recently published in the journal *Therapeutic Advances in Gastroenterology* reviewed data that examined the mechanisms by which bile acids can affect symptoms in CIC and the role of the drug elobixibat in managing these symptoms. Bile acids are digestive juices that have a stimulating effect in the colon. Elobixibat reduces bile absorption in the small intestine. This stimulates bowel movements by increasing fluid secretions and motility in the colon.

The authors concluded that published research shows that elobixibat significantly affects the symptoms of CIC, with minimal and tolerable side effects.

FDA Approves Eluxadoline (Viberzi) for Treatment of IBS-D in Men and Women

On May 27, 2015 the U.S. Food and Drug Administration (FDA) approved eluxadoline (Viberzi™), a new drug treatment for irritable bowel syndrome with diarrhea (IBS-D) in adult men and women. Viberzi is taken orally twice daily with food. The drug activates receptors in the nervous system that can lessen bowel contractions.

Viberzi is a novel drug compound to treat diarrhea and abdominal pain associated with IBS-D. The safety and effectiveness of the drug for treatment of IBS-D were established in two double-blind, placebo-controlled clinical trials in which 2,425 patients were randomly assigned to receive the eluxadoline or placebo. Results showed Viberzi was more effective in simultaneously reducing abdominal pain and improving stool consistency than placebo over 26 weeks of treatment.

In clinical trials the drug was generally well tolerated. The most common side effects in patients treated with Viberzi were constipation and nausea.

The most serious known risk associated with Viberzi is the risk of spasm in the sphincter of Oddi, the smooth muscle that surrounds the end portion of the common bile and pancreatic ducts, which can result in pancreatitis. Viberzi should *not* be used in patients with a history of bile duct obstruction, pancreatitis, severe liver impairment, or severe constipation, and in patients who drink more than three alcoholic beverages per day.

Viberzi has mixed opioid receptor activity. It is a mu receptor agonist, a delta receptor antagonist, and a kappa receptor agonist.

The FDA has recommended that Viberzi be classified as a controlled substance. This recommendation has been submitted to the U.S. Drug Enforcement Administration (DEA). Product availability is expected in early 2016.

Teduglutide Granted Orphan Drug Status in Japan

In January 2015 the Japanese Ministry of Health, Labor, and Welfare (MHLW) granted teduglutide (Gattex in the U.S.; Revestive in the E.U.) orphan drug status for the treatment of adult patients with short bowel syndrome (SBS).

Data Supports Long-Term Use of Gattex for Treatment of Short Bowel Syndrome

In June 2014 the U.S. Food and Drug Administration (FDA) approved updated labeling for teduglutide (Gattex) for injection to include long-term data from adult patients with Short Bowel Syndrome (SBS). The revised labeling provides important information for healthcare professionals and patients about long-term use of teduglutide.

The data, published in 2013, demonstrated that there was an increased response to treatment over time in all groups receiving teduglutide. The open-label extension study included 88 adult patients with SBS. Investigators reported that the long-term use of teduglutide in patients with SBS resulted in additional, clinically meaningful reductions in the volume and days per week of parenteral support requirements in this extension study. Thirteen patients in the study achieved complete independence from parenteral support with long-term teduglutide therapy. No new unexpected safety concerns were observed with long-term teduglutide treatment and the product's safety profile remains consistent with the product's label.

The drug 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 parenteral nutrition (PN) and intravenous (IV) fluid volume in adult subjects with SBS.

Teduglutide was approved by the FDA as Gattex in 2012 for treatment of adult patients with SBS who are dependent on parenteral support. To help ensure that the benefits of the drug 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. 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 dosage.

SBS 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.

Patients with SBS Sought for Long-term Study

Purpose of Study: This global clinical study is enrolling patients with short bowel syndrome (SBS) in order to provide additional long-term data on safety of teduglutide and on the natural history of SBS in patients in routine, real world settings. The information gathered is intended to assist health care providers in optimizing their clinical decision making in managing SBS patients.

Enrollment will include SBS patients treated and not treated with teduglutide.

Sponsor: NPS Pharmaceuticals, Inc.

Study Population: Male and female patients of any age with a diagnosis of SBS, including those who have never taken teduglutide, as well those who have or are using teduglutide.

Study Follow-up Duration: 10 years

Contact: NPS Clinical Operations, phone: 908-450-5300, email: *SBSregistry@quintiles.com*; Refer to *ClinicalTrials.gov* identifier: NCT01990040

FDA Approves Rifaximin (Xifaxan) for Treatment of IBS-D in Adults

On May 27, 2015 the U.S. Food and Drug Administration (FDA) approved the antibiotic rifaximin (Xifaxan®) 550 mg for treating irritable bowel syndrome with diarrhea (IBS-D) in adult men and women.

The safety and effectiveness of Xifaxan for treatment of IBS-D were established in three double-blind, placebo-controlled trials. In the first two trials, 1,258 patients were randomly assigned to receive Xifaxan or placebo for 14 days, and then followed for a 10-week treatment-free period. More Xifaxan-treated patients reported improvements in abdominal pain and stool consistency than those on placebo.

A third trial evaluated repeat courses of Xifaxan, because patients with IBS-D can develop recurrent signs and symptoms after a single treatment course of Xifaxan. A total of 636 patients with recurrence were randomized to receive either Xifaxan or placebo for two additional 14-day courses separated by 10 weeks. More patients treated with Xifaxan than placebo were responders in abdominal pain and stool consistency in this phase of the study.

Xifaxan works by reducing or altering bacteria in the gut. It is only slightly absorbed in the gut and is generally tolerated well. The most common side effects in patients treated with Xifaxan for IBS-D include nausea and an increase in alanine aminotransferase (ALT), a liver enzyme measured in blood.

If diarrhea does not improve or worsens after treatment with Xifaxan, then evaluation for development of *C. difficile* enterocolitis should be performed. Caution should be used when using Xifaxan in patients with severe liver impairment or when combined with certain other drugs.

Guidance Issued in U.K. for Amitiza in Treating Chronic Idiopathic Constipation

The National Institute for Health and Care Excellence (NICE) has issued guidance on the use of lubiprostone (Amitiza) for treating chronic idiopathic constipation in the United Kingdom. The guidelines stipulate that the drug should only be considered in adults who have tried at least 2 laxatives at the highest tolerated recommended doses for at least 6 months, but who have not seen an improvement in their symptoms. NICE clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the National Health Service (NHS) in the United Kingdom.

Lubiprostone Study Published Showing Efficacy in Opioid-Induced Constipation

A study published in 2014 in the medical journal *Pain Medicine* examined the efficacy and safety of lubiprostone (Amitiza) for relieving symptoms of opioid-induced constipation (OIC) in chronic non-cancer pain. The study found that patients treated with lubiprostone showed significant overall improvement for abdominal discomfort, straining, constipation severity and stool consistency when compared to placebo. The authors concluded that lubiprostone was effective and well tolerated in OIC patients with chronic non-cancer pain.

Lubiprostone is a prescription drug first FDA approved in 2006 to relieve abdominal pain, bloating, and straining and produce softer and more frequent bowel movements in men and women who have chronic idiopathic constipation (CIC). It is also FDA approved to treat irritable bowel syndrome with constipation (IBS-C) in women who are at least 18 years of age. Lubiprostone works by increasing the amount of fluid that flows into the bowel and allowing the stool to pass more easily.

The drug was FDA approved in 2013 for the treatment of OIC in patients with chronic, non-cancer pain. Opioids (such as morphine and codeine) are narcotics used to treat pain. The effectiveness of lubiprostone has not been established in those taking methadone. A number of gastrointestinal (GI) symptoms are potential side effects of using opioid-based medications. The most common symptom is constipation. Other symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed-GI transit.

Two Studies of Lubiprostone in Pediatric Subjects with Functional Constipation

Purpose of study 1: This is a 12-Week study to evaluate the efficacy, safety, and pharmacokinetics of oral lubiprostone as treatment for pediatric patients with functional constipation.

Collaborators: Sucampo Pharma Americas, LLC and Takeda

Participation: Eligible male and female patients aged 6–17 years

Contacts: Shadreck Mareya, PhD, phone: 301-961-3400, email: *pedgen@sucampo.com*; Refer to *ClinicalTrials.gov* identifier: NCT02042183

Purpose of study 2: This is a 9-Month study to evaluate the long-term safety, efficacy, and pharmacokinetics of oral lubiprostone as treatment for pediatric patients with functional constipation.

Collaborators: Sucampo Pharma Americas, LLC and Takeda

Participation: Eligible male and female patients aged 6–17 years

Contacts: Shadreck Mareya, PhD, phone: 301-961-3400, email: *pedgen@sucampo.com*; Refer to *ClinicalTrials.gov* identifier: NCT02138136

Seeking Participants with Diabetic Gastroparesis

Purpose of Study: To assess the safety of IW-9179 in individuals with diabetic gastroparesis and its effects on the principal symptoms of diabetic gastroparesis.

Sponsor: Ironwood Pharmaceuticals, Inc.

Study Population: Eligible male and female patients over the age of 18 and with a diagnosis of type 1 or type 2 diabetes mellitus and a diagnosis of diabetic gastroparesis.

Contacts: Find a recruiting location online at *ClinicalTrials.gov*; refer to *ClinicalTrials.gov* identifier: NCT02289846 ■

Living with Bowel Incontinence

Continence, our control over when and where we go to the bathroom, is something most of us learn at an early age. We generally take it for granted – until something goes wrong. "Incontinence" is the word used to describe loss of this control.

Bowel incontinence occurs when the loss of control of gas, liquid stool, or solid stool is enough to cause discomfort or distress. Bowel incontinence is a sign that something is wrong – some part of the bowel control system is not working as it should.

Having an episode of bowel incontinence can be very upsetting. People often feel so embarrassed when this happens to them that they do not tell anyone about it, not even their spouse or doctor.

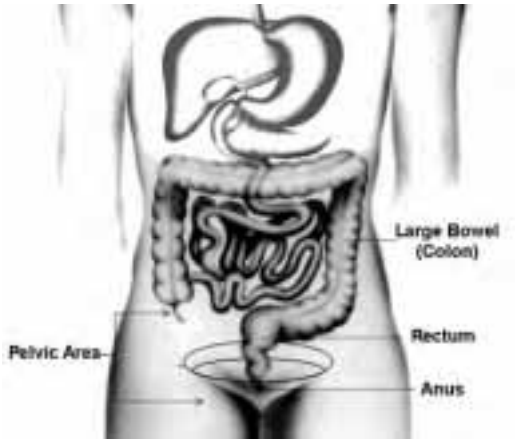
It is common for persons who suffer this to go to lengths to hide the condition. As a result, they may experience a loss of personal freedom. They may feel many parts of their life slipping away – and they may not receive the help they need.

Causes of Incontinence

Incontinence has many causes. It is not a normal part of aging, but as you age, you may be more at risk for the condition.

Injury or illness can cause a loss of normal function and bowel control. Physical limitations or disabilities, and poor general health are key factors that can play a role.

Nerves must function correctly to sense the urge to have a bowel movement or the presence of gas in the rectum. Muscles must function correctly to hold in the rectal contents. Many conditions that affect men and women may result in loss of bowel control.



The Effect of Age on Continence

As you age, many physical changes will occur naturally. These changes have an effect throughout the body including on the organs, nerves, and muscles that control continence. Muscles will lose their strength, some nerves will function less well, and tissue and organs will lose some of their ability to stretch.

The Bowel Control System

Many things must happen in the body so that you know when you need to have a bowel movement (or pass gas) and are able to hold it in until you decide when and where to empty.

If the muscles around the rectum are weak, you may feel a sudden and very strong urge and need to rush to the toilet. Stool may leak before you reach the toilet.

If nerves are damaged, you may not know when stool is present. The urge to have a bowel movement may not be felt and you make leak stool without even feeling it.

Seepage of stool may also occur if the muscles around the rectum do not work right. If the rectum does not stretch, it will not be able to store enough stool and incontinence can result.

What to Do – Talking to your Doctor

If you experience bowel incontinence, the first thing to do is tell your doctor about it. Most people feel uneasy talking about their stool, intestinal gas, or bowel movements. But doctors understand that these are very normal and necessary processes in all of us.

Doctors and other therapists are there to help when bodily processes go wrong. So the first very important step is to talk plainly about the problems you are experiencing.

Begin by describing your troubling symptoms. Be specific so your doctor (or therapist) clearly understands the problem. Here are some examples:

- Diarrhea – Diarrhea is a common factor that can cause incontinence. If you are experiencing loose or runny stool that is leaking, do not simply say to your doctor that you "have diarrhea." That does not tell the doctor that you are losing control of the stool. Be clear. "When I have diarrhea it leaks into my clothing with little or no warning. I can't stop it in time to get to the toilet."

- Constipation – You may be surprised that constipation is another common factor that can lead to incontinence. Hard stool stuck in the rectum can build up to the point where watery stool leaks around it. Be sure to tell your doctor if you are constipated – not simply that you "have leakage of loose stool." Your doctor might naturally think you have diarrhea and prescribe a treatment that makes you even more constipated. Be clear about any changes in your bowel habit, such as ongoing constipation or diarrhea.

- Pain – Continually squeezing together the muscles around your rectum, because of fear that stool may leak, can cause the muscles to cramp and get tired. The result will be pain, which can be severe, and muscle weakness. Both will make your incontinence worse. If this is happening to you, explain it to your doctor.

Next, let your doctor know how this is affecting your daily life. Ask yourself this question, "How have my bowel control problems changed my life?" The answer, such as, "I'm afraid to leave my house" or "I don't socialize anymore" is important information for your doctor.

These kinds of changes may have come on gradually. They are important for you to recognize. This is your own personal test of how serious your disorder is. How often you experience incontinence is not always as important as how the problem has changed your life. A goal of your treatment will be to help you get back, as much as possible, the parts of your life that have been lost because of incontinence.

If you have lost sensation, you may have no feeling of the urge to pass gas or stool. Knowing you may experience incontinence with no warning, at any time, may mean that you are worried about it all the time. This can be a heavy burden that takes a toll on daily life. Be sure to explain this to your doctor as well.

Your doctor will want to know how long you have been experiencing episodes of incontinence and if it has been getting worse or has changed over time. Other things to tell your doctor about include:

- Any other illnesses that may be affecting your health
- A list of all medicines you are taking, including
  - Prescription and over-the-counter
  - Herbal supplements
  - Vitamins or mineral supplements
- How much and how often you take any of these
- Any surgeries you have ever had in the past

If you are a woman who has given birth, even many years ago, let your doctor know. Tell your doctor:

- How many children you had by vaginal delivery
- How many hours you were in labor
- If you had an episiotomy (a cut the doctor sometimes makes in the vaginal area)
- If forceps were used
- If you had any tearing that needed surgical repair

Any of these factors could play a part in damage to nerves and muscles, which then get weaker or less able to do their job with age. The resulting problems affecting continence may take 20 or more years to show up.

Your doctor may want to run tests before coming up with a treatment plan. Various tests can look at how well the organs, muscles, and nerves that affect your continence are working. They can also look for signs of disease or injury. The doctor should explain to you the reason for the test. You should also understand what to expect during and after the test. If you do not understand something, be sure to ask.

If you experience bowel incontinence, here are three important things to know:

1. You are not alone – many people have this condition
2. You do not have to just "live with it"
3. You can find help, and ways to treat and manage the condition

Treating Bowel Incontinence

The goal of treatment is to improve function – both in your body and in your daily life. Ways to eliminate or reduce symptoms may involve changes in what you eat, bowel retraining, therapy to change the way nerves or muscles respond, surgery, or other therapies.

You can learn strategies that help you manage the symptoms that cannot be cured. Your doctor or therapist can be your partner in putting together an effective treatment and management plan.

Treatment for incontinence involves good communication with your doctor and/or your therapist so you both understand:

- How the disorder is affecting your daily life
- What is the underlying cause
- Factors that bring on an episode of incontinence or makes it worse

Constipation and diarrhea are common causes that often can be managed. Your doctor or therapist may ask you to keep a diary for a couple of weeks of what you eat and drink. What you do or do not eat and drink can affect how often your bowels move and how hard or loose your stools are. For example, some foods are normally gas-producing.

It is important to learn what foods or drinks affect your bowels so that you can take in more of those that help, and less of those that cause you problems. Your doctor or a registered dietician can help adjust your diet.

Bowel retraining works by teaching new skills to develop a regular and predictable schedule for evacuation. This helps decrease unpredictable bowel movements. Doctors, nurses, or therapists who are skilled in treating disorders of the colon or rectum can help you with this. The bowel retraining will include methods, and sometimes medicines, to help normalize stool consistency so the stool is formed (neither too hard nor too soft), and to establish and stimulate a regular time for having a bowel movement.

No matter what the cause of incontinence, dietary and bowel retraining measures can often help. Additional treatment may be needed if nerves or muscles in the pelvic floor area are not working properly.

Biofeedback is a painless therapy that uses special sensors and a video screen to help improve the nerve sensation and muscle control that is needed to control bowel movements. Working with a therapist skilled in using biofeedback for disorders of the pelvic floor and rectum can help you improve your ability to sense contents in the rectum and to hold in the contents.

Other newer procedures are being developed to treat incontinence. These range from electrical stimulation to implants to injections. If muscle is damaged but nerves are functioning, surgery is sometimes suggested. Another option some people choose when other treatments fail is to have a colostomy; this involves a surgical procedure to divert stool to a pouch outside the body.

Be sure to talk to your doctor about all options, possible risks, and chances of success. Think about what "success" means to you. Does it mean cure; or does it mean managing symptoms so you can get on with your life? A cure may not be possible. Treatments may have their own set of side effects. It is important that you understand your options and work with your doctor or therapist to set your own treatment goals.

> A goal of your treatment will be to help you get back, as much as possible, the parts of your life that have been lost because of incontinence.

Putting It All Together

Incontinence is a symptom – a sign that something is wrong. Treatment may improve but not always cure the symptom. There are ways to help manage incontinence. The first step is to recognize that something is wrong and seek help.

Doctors do not receive much training about bowel incontinence in medical schools, and no type of doctor specializes in treating bowel incontinence. Start with your primary care physician.

It is important that when you talk to a doctor about your incontinence he or she respond to you with interest and concern. If that does not happen, we suggest you find another doctor. Your doctor may not have all the answers – much remains to be learned about the condition – but he or she should listen to you and work with you to find existing solutions that work best for you. ■

Medical News Update

EndoStim LES Stimulation Therapy Shows Promise for GERD Symptoms

Interim 6-month study results show promise for treatment of gastroesophageal reflux disease (GERD) symptoms using an implanted electrical stimulation device (EndoStim) that targets the lower esophageal sphincter (LES) muscle. The international multicenter trial included 41 patients with GERD symptoms partially responsive to treatment with proton pump inhibitors (PPIs). Long-term, controlled studies are needed to better understand the role of this therapy in treating GERD.

Source: Kappelle WFW, et al. *Aliment Pharmacol Ther*. July 2015.

Cellular Abnormalities Discovered in Individuals with Chronic Unexplained Nausea and Vomiting

A pilot study of 9 individuals with chronic unexplained nausea and vomiting (CUNV) and 9 controls discovered cellular and bioelectrical abnormalities among those with CUNV, including depletion of interstitial cells of Cajal (ICC) – specialized cells found throughout the gastrointestinal (GI) tract required for normal GI motility. These features of CUNV were found to be similar to those of gastroparesis, even though CUNV presents without the abnormal gastric emptying characteristic of gastroparesis.

Identifying the underlying features of CUNV, including overlaps with gastroparesis, could lead to quicker and more confident diagnosis of this condition and the development of better treatments.

Source: Angeli TR, et al. *Gastroenterology*. August 2015.

Anxiety Associated with Risk for Developing Functional Dyspepsia

A population-based 10-year follow-up study in Sweden of 703 individuals discovered a statistically significant association between anxiety and the development of functional dyspepsia, particularly postprandial distress syndrome (PDS) in which meal-related symptoms of early fullness after a meal typically occur.

Identification of the underlying mechanisms linking anxiety and functional dyspepsia may provide insight into new approaches to reduce or eliminate symptoms.

Source: Aro P, et al. *Gastroenterology*. May 2015.

Positive Results Announced for EVK-001 for Women with Diabetic Gastroparesis

Results of a randomized, double-blind Phase 2b clinical trial of investigational drug EVK-001 (Evoke Pharma), a novel nasal metoclopramide spray, in 285 individuals with diabetic gastroparesis demonstrated a statistically significant improvement in symptoms over 4 weeks, including nausea and upper abdominal pain, in women, but not in men, compared to placebo.

The treatment had an acceptable safety profile, with the most common adverse effects being altered taste, headache, and fatigue. The drug is now being studied in a Phase 3 clinical trial.

Source: Parkman HP, et al. *Clin Gastroenterol Hepatol*. 2015 July.

Preliminary Results Announced for CIC Treatment

Positive results were reported from a Phase 3 randomized controlled study of the investigational drug plecanatide in 1,346 adult patients with chronic idiopathic constipation (CIC) over a 12-week treatment period. A second Phase 3 trial of approximately 2,700 patients with CIC is currently underway to confirm these results.

Source: *Business Wire News Release*. July 2015.

Pinaverium Found to Reduce Symptoms of IBS

Results of a randomized, double-blind, controlled clinical trial of the antispasmodic drug pinaverium compared to placebo for the treatment of irritable bowel syndrome (IBS) demonstrated a significant improvement in symptoms, including abdominal pain and discomfort and stool consistency, in 218 individuals with IBS over a period of 4 weeks. The treatment had an acceptable safety profile.

While widely used in many countries around the world, including European countries, Canada, and Mexico, pinaverium is not yet approved for use in the U.S. by the U.S. Food and Drug Administration (FDA).

Source: Zheng L, et al. *Clin Gastroenterol Hepatol*. 2015 July. ■

Help Advance Understanding by Participating in Research

Research studies and clinical trials are important in finding more and better treatments. By taking part in studies or trials, you can help gain more understanding of different functional GI and motility disorders and help advance GI research.

A clinical trial or clinical study (they mean the same thing) is a research study to answer specific questions about new products, therapies, or new ways of using known treatments. Through these research studies, investigators find new and better ways to treat, control, prevent, diagnose, or detect conditions, or to improve the quality of life for those with an illness.

Types of clinical research studies

- Natural history studies provide valuable information about how disease and health progress.
- Prevention studies look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Better approaches may include medicines or lifestyle changes, among other things.
- Screening trials test the best way to detect certain diseases or health conditions.
- Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition.
- Treatment studies test new treatments, new combinations of drugs, or new approaches to therapies.
- Quality of life studies (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness.

Here is a list of several studies that are currently seeking participants. To find additional open studies, please visit the IFFGD website at *www.giresearch.org/site/studies/nih*.

Seeking Children with Irritable Bowel Syndrome with Diarrhea (IBS-D) for Treatment Study

Purpose of study: This study is being conducted to see if serum-derived bovine immunoglobulin/protein isolate (SBI) is safe and well tolerated in pediatric patients with IBS-D.

Sponsor: Connecticut Children's Medical Center, Farmington, Connecticut

Participation: Male and female patients aged 8 to 18 with a diagnosis of IBS-D who meet inclusion criteria

Contacts: Ajay Rana, MD, 860-545-9560, *arana@connecticutchildrens.org*; or Jeffrey Hyams, MD, 860-545-9560, *jhyams@connecticutchildrens.org*. *ClinicalTrials.gov* identifier: NCT02358694

Seeking Individuals with Gastroparesis for Online Questionnaire

Purpose of study: The purpose of this study is to explore how you experience your gastroparesis and how it impacts your life. Questions will explore gastroparesis symptoms, illness perceptions, coping, psychological distress, personality, and quality of life.

Sponsor: Swinburne University of Technology, Royal Melbourne Hospital, and St. Vincent's Hospital

Participation: Eligible male and female individuals aged 18 and older who have been diagnosed with gastroparesis and are not currently experiencing severe mental illness nor are currently seeking support from a mental health expert.

Contacts: Visit *http://opinio.online.swin.edu.au/s?s=17235* for more details and to access the survey.

Participants Sought for Study on Complementary Approaches to the Treatment of IBS

Purpose of study: The purpose of this study is to find a complementary treatment to help Irritable Bowel Syndrome (IBS) patients in need of relief.

About the study: The length of this study will be three weeks long, with a short online intervention everyday to help individuals deal with their body's reactions to their environments. Participants will have additional surveys to assess their overall state at the beginning of the study, at the end of the three week intervention, and again at six weeks for a follow-up.

There will be a $15 Target gift card for first 30 participants upon completion of study.

Participation: Eligible individuals between the ages of 18–65 years of age who are experiencing pain or discomfort associated with their gut. Cannot be smokers or have an inflammatory bowel disease.

To participate: Go to *http://bit.ly/IBS_study* to sign up.

Contact: Jenna N. Ray, Health Psychologist. Phone: 919-257-7291, Email: *jray51@uncc.edu*

Seeking Families with Children with Recurrent Abdominal Pain

Purpose of study: This study will test a non-medicine treatment approach which, if successful, would substantially change the treatment of functional abdominal pain and potentially for a wide range of childhood medical problems where parental responses to symptoms affect child experiences of these events.

Sponsor: University of Washington

Collaborators: University of North Carolina and Mary Bridge Children's Hospital

Participation: Eligible children aged 7 to 12 who have experienced at least 3 episodes of unexplained abdominal pain over a 3 month period.

Locations: Chapel Hill, North Carolina; Seattle, Washington; and Tacoma, Washington

Contact: Melissa DuPen. Phone: 206-616-2358, Email: *mcap@uw.edu*; *ClinicalTrials.gov* identifier: NCT01620606

Two Online Studies on Cyclic Vomiting Syndrome (CVS)

Purpose of study 1: A research study is being conducted in order to learn what the experiences are regarding two nutritional supplements, co-enzyme Q10 (also known as "Co-Q") and L-carnitine (Carnitor), and one medication, amitriptyline (Elavil), for the treatment of CVS.

Sponsor: Eligible individuals of any age previously diagnosed with CVS

Participation: Eligible children aged 7 to 12 who have experienced at least 3 episodes of unexplained abdominal pain over a 3 month period.

How to begin the study: Visit *www.surveymonkey.com/r/?sm=JxdBSx2AtuqxSAey7YJ6Pw%3d%3d* to access the online study.

Purpose of study 2: CVSA is undertaking a formal process of educating Emergency Room physicians and para-professionals about CVS. They are asking for your participation in a brief survey in order to help plan this educational approach.

Sponsor: Cyclic Vomiting Syndrome Association (CVSA) and Children's Hospital of Wisconsin

Participation: Eligible individuals of any age who have ever visited the emergency room for the care of CVS either as a patient or as a caregiver to a patient.

How to Begin the Study: Visit *www.surveymonkey.com/r/?sm=neuXsslN8CzKp%2bGUbC9ZCw%3d%3d* to begin the online survey.

Seeking IBS Patients and Their Partners

Purpose of study: IBS patients know that their intimate relationships can have an effect on how they are feeling. However, it is not known whether agreement or disagreement regarding issues such as cause of IBS, beliefs about illness, harmony in relationship may have an effect on IBS symptoms. This is an important question that may affect the way IBS is treated.

About the study: Our study requires patients to complete 5 brief questionnaires and partners to complete 3 brief questionnaires. Patients and partners will be contacted separately and results will be strictly confidential with no way of identifying subjects.

Contact: Please contact *mindbodydigest@gmail.com*, and links to a secure survey site will be sent individually to both patient and partner, with instructions. From that point on, no identifying information will be stored.

Online Survey on Symptoms in IBS

Purpose of study: One of the most important questions for individual patients with irritable bowel syndrome (IBS) is how long the symptoms will continue. A number of factors are thought to be important in determining recovery from IBS but so far studies have not been big enough to be certain of the results. The aim of this world-wide survey will be to gather together the experience of a large number of patients with irritable bowel syndrome, both those in whom it has begun with an infection and those in whom it has not. By comparing these we will be able to understand more about both conditions.

About the study: This is a web-based survey designed to help learn more about irritable bowel syndrome in order that physicians might better plan treatments and management. Of particular interest is how symptoms develop over time. The study is multilingual and is currently available in nine languages.

Sponsor: European Gastroenterology Federation

To participate: Go to *www.postinfectious-ibs.eu* and click on your language of choice to complete the simple online questionnaire.

Recruiting Individuals with Rare Genetic Disorders

Purpose of study: In an effort to help researchers working to understand gastrointestinal motility diseases like mitochondrial nueorgastrointestinal encephalopathy, blood samples and clinical data from individuals with rare genetic diseases are being collected. The samples are made anonymous and shared with scientists to use in their research for treatments and causes. Families living outside the U.S. are also welcome to donate a sample to the repository.

Sponsors: The National Institute of General Medical Sciences (NIGMS) Human Genetic Cell Repository Program and Coriell Institute for Medical Research

Participation: Eligible individuals with an inherited genetic disease or chromosomal abnormality

Contacts: Families who want to participate in this research effort can contact the NIGMS Human Genetic Cell Repository genetic counselor, Tara Schmidlen, MS, CGC, for postage-paid sample collection kits and the necessary paperwork:
Phone: 856-757-4822, Email:*tschmidl@coriell.org*.

Participants Sought for Genetic Study of Hirschsprung's Disease

Purpose of study: Dr. Aravinda Chakravarti's laboratory at Johns Hopkins University has been investigating the genetics of Hirschsprung's disease for more than twenty years. The purpose of this study is to continue the search for genes involved in Hirschsprung's disease and to further characterize the known genes and the interactions between them. The study will hopefully lead to a better understanding of the genetics of Hirschsprung's disease and improve diagnosis, treatment, and genetic counseling.

About the study: Study volunteers and their parents (as available) are asked to complete a medical/family history questionnaire, provide access to select medical records, and submit to blood or cheek swab/saliva samples. If interested, a kit containing all the materials necessary to participate can be sent at no cost to the volunteer.

Sponsor: Johns Hopkins University

Participation: Eligible individuals with Hirschsprung's disease and their family members.

Contact: Courtney Berrios; Phone: 410-502-7541, Email: *hirschsprung@igm.jhmi.edu*. You can also visit the study website at www.*aravindachakravartilab.org/pro/Hirschsprung_Study.html.*

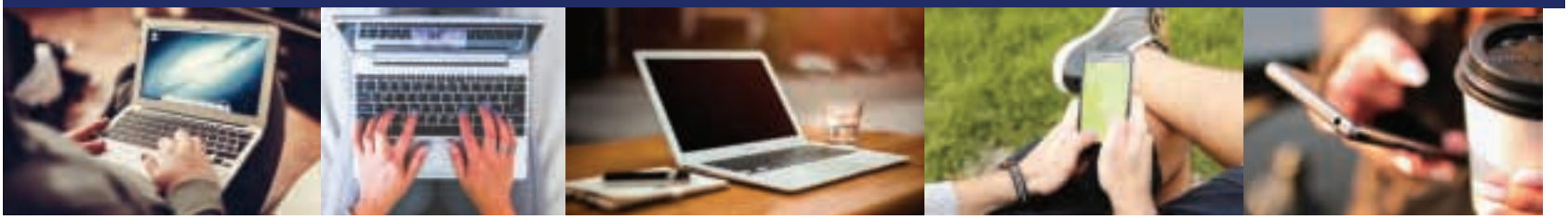
NIH Gastroparesis Clinical Research Consortium (GpCRC) Registry

Purpose of 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. The GpCRC is a network of medical centers, sponsored by the National Institutes of Health (NIH), Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), established to improve our understanding of the cause and natural course of gastroparesis and to advance the diagnosis and treatment of this disorder.

Sponsor: NIDDK

Participation: Eligible male and female individuals aged 18 and older who have been previously diagnosed with gastroparesis and delayed gastric emptying

Contacts & Registration: For more information on locations and contacts, see the listing at h*ttp://clinicaltrials.gov/ct2/show/NCT01696747* ■



Twitter Support for Gastroparesis Awareness

August was Gastroparesis Awareness Month and many people took to social media sites like Twitter to show their dedication to spreading the word about this condition, calling out the need for awareness and increased research for gastroparesis. Check out some of the Twitter activity below.

ADVOCATE FOR CHANGE!

Help Find a Cure for Functional GI & Motility Disorders!

The Functional Gastrointestinal and Motility Disorders Research Enhancement Act (H.R. 2311) seeks to advance the scientific understanding of functional GI and motility disorders, including gastroparesis, IBS, GERD, and improve treatment options for those with these conditions.

Contact your House Representative and ask that he or she cosponsor this critical piece of legislation!

- **Find the contact information for your Representative at *www.house.gov*.**
- **Reach out to your Representative (online form, email, phone, Twitter)**
- **Identify yourself as a constituent.**
- **Ask that your Representative become a cosponsor of H.R. 2311, *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act*.**
- **Provide a short explanation of these kinds of digestive conditions (see Quick Facts on the back).**
- **Briefly share your personal story of how one of these disorders has affected your life, or the life of someone you know.**
- **Explain that H.R. 2311 will significantly improve understanding of these conditions, and improve diagnosis and treatments.**
- **Thank them for their time and attention.**

DIGESTIVE HEALTH ALLIANCE

iffgd

INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

This issue of *Digestive Health Matters* is sponsored, in part, by Allergan, Ironwood Pharmaceuticals, Inc., and donors to IFFGD.

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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Information. Assistance. Support.

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