



Digestive Health Matters

Information. Assistance. Support.

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IFFGD

INTERNATIONAL FOUNDATION FOR
FUNCTIONAL GASTROINTESTINAL DISORDERS

GERD

Awareness Week

November 24-30, 2014

It may be more
than simple
heartburn.



To learn more visit www.aboutGERD.org

Diet Changes for GERD

Proper treatment of gastroesophageal reflux disease (GERD) always begins with a visit to a healthcare professional to obtain an accurate diagnosis. It is important to recognize that chronic reflux does not get better on its own. Over-the-counter remedies may provide short-term symptom relief, but can mask an underlying disease if used long-term.

Treatment for GERD may include medications advised by your doctor and certain diet and lifestyle changes. A combination of approaches, and some trial and error, may be necessary.

Diet and lifestyle changes often begin with what to avoid. These include things that can trigger or worsen symptoms.

Examples of things to reduce or steer clear of in your diet include:

- High fat foods
- Caffeine
- Chocolate
- Onions
- Peppermint
- Carbonated beverages
- Alcohol
- Citrus and tomato products

Coming up with the appropriate diet and lifestyle changes involves discovering what works best for you. Not all triggers and treatments will affect all people in the same way. Bear in mind that *when* you eat may be just as important as *what* you eat. A particular food that causes reflux when eaten 3–4 hours before bedtime may be harmless earlier in the day.

While no proven “GERD diet” exists, the following foods may help you ease or avoid symptoms.

Fruits and Vegetables

Fruits. While most likely avoiding citrus fruits and juices, like oranges and lemons, choose from a variety of non-citrus fruits such as bananas, melons, apples, and pears among others.

Vegetables. Select from the wide variety of vegetables. Avoid or reduce sauces or toppings that are high in fat or other irritants like tomatoes or onions.

Symptoms of GERD

Just about everyone has had heartburn — that uncomfortable burning feeling in the chest after eating a heavy meal — at some point in their life. But, while occasional heartburn is nothing to worry about, heartburn that occurs more than once a week, becomes more severe, or occurs at night and wakes you from sleep may indicate gastroesophageal reflux disease (GERD). And, a visit to the doctor is advised.

GERD is a common disorder that occurs when stomach contents repeatedly flow backward, or reflux, into the esophagus through a barrier called the lower esophageal sphincter (LES). Over time this can cause damage to the lining of the esophagus and, if not treated, can lead to other complications.

Most people with GERD have mild symptoms, with no visible tissue damage and little risk of developing complications. But, tell your doctor if you’ve had heartburn off and on for several years, you have difficulty or pain when swallowing, or you have symptoms that interfere with your daily activities.

While chronic heartburn and acid regurgitation (the reflux of material into the mouth) are the most common symptoms of GERD, numerous less common symptoms may also occur, such as:

- Belching
- Difficulty or pain when swallowing
- Waterbrash (sudden excess saliva)
- Dysphagia (the sensation of food sticking in the esophagus)
- Chronic sore throat
- Laryngitis
- Inflammation of the gums
- Erosion of tooth enamel
- Chronic irritation of the throat
- Morning hoarseness
- A sour taste in the mouth
- Bad breath

Lean Proteins

Eggs. These are high in protein. However, if eggs are a problem for you, stick to the whites and stay clear of the higher fat yolks, which are more likely to cause symptoms.

Lean meat. High fat meals and fried foods tend to decrease LES pressure and delay stomach emptying, increasing the risk of reflux. Choose lean meats that are grilled, poached, broiled, or baked.

Complex Carbohydrates

Oatmeal, whole grain bread, rice, and couscous. All of these are good sources of healthy complex carbs. Whole grains and brown rice add fiber to your diet.

Potatoes and other root vegetables. These are great sources of healthy carbs and digestible fiber, but make sure to avoid adding onion and garlic during preparation, as these are common irritants.

Healthier Fats

Fat is a type of nutrient – high in calories but a necessary part of your diet. Not all fats are created equal. Generally *avoid* or *reduce* saturated fats (usually from meat and dairy) and trans fat (in processed foods, margarines, and shortenings). Try replacing them, in moderation, with unsaturated fats from plants or fish. Here are some examples:

Monounsaturated fats. Examples include oils such as olive, sesame, canola, and sunflower; avocados; peanuts and peanut butter; and many nuts and seeds.

Polyunsaturated fats. Examples include oils such as safflower, soybean, corn, flaxseed, and walnut; soybeans and tofu; and fatty fish such as salmon and trout.

Other Helpful Tips

Chew gum. Chewing gum (*not* spearmint or peppermint, which can relax the LES) increases saliva production and reduces the amount of acid in the esophagus.

“Eating right for GERD does not have to mean cutting out all of your favorite foods. Making just a few, simple modifications to your current diet is often enough...”

Avoid alcohol. Alcohol is a known irritant that can weaken the LES and trigger reflux symptoms. However, while some people may experience a spike in symptoms after just one drink, others can tolerate moderate amounts. Experiment to see what works for you.

Keep good posture during and after a meal. It's a good idea to sit up while eating and avoid lying flat for a minimum of two hours after eating a meal. Standing up and walking around after a meal helps encourage gastric juices to flow in the right direction.

Avoid eating immediately before bed. Digestion increases the amount of gastric acid present in the stomach. When you lay down, the ability of the LES to prevent stomach contents from traveling up the esophagus decreases. Occurring together, lots of stomach acid and a reclined position are a recipe for reflux. Timing can vary from individual to individual, but generally, eating a full meal less than three or four hours before bed is not advisable for GERD sufferers.

Eating right for GERD does not have to mean cutting out all of your favorite foods. Making just a few, simple modifications to your current diet is often enough to help reduce the discomforts of GERD. The goal is to create a diet based on a healthy variety of foods that include fruits and vegetables, lean sources of protein, complex carbohydrates, and healthy fats. ■

7-Day Food and Symptom Diary

If you suspect that foods may trigger or worsen your symptoms of GERD, try keeping a one week daily diary. Share the information with your doctor during your next visit. It may help to gain a better understanding of your symptoms.

For the next 7 days, keep a record of any and all heartburn and other symptoms you may have, and how often they occur. Record each symptom each time it occurs, even if it occurs several times a day. Make sure your diary is accurate and complete.

Throughout each day record the time of day, description (food and amount), activity, and any symptom that follows (including “none”).

Name the symptoms you experience (refer to the list on page 3). Examples include:

- Heartburn (burning discomfort that rises into the chest)
- Sour/acid taste in the mouth
- Difficult or painful swallowing

Sample diary entries. Continue making notes for the rest of the day, for 7 days.

Time	Food/Drink	Amount	Activity	Symptoms that followed
6:00 am	Eggs scrambled	2	At home	None
	Whole wheat toast	1 slice	Sat outside on porch	
	Apple juice	4 oz.		
8:30 am	Coffee w/ half & half	12 oz.	Drive to work	Sour taste
10:30 am	Coffee w/ creamer	8 oz.	Meeting at work	Some burning
11:15 am	banana	1	Reading e-mail	None



Medical News Update

Different Anatomy in Individuals with GERD

A study using magnetic resonance imaging (MRI) of 48 people found that those with mild to moderate gastroesophageal reflux disease (GERD) had several anatomical differences relating to the reflux barrier compared to healthy volunteers.

Primary among them, the angle of the esophagus (food tube) into the stomach was found to be wider in individuals with GERD compared with healthy individuals. This angle is an essential part of the way the body prevents reflux, called the “flap valve” mechanism. Also, the opening from the esophagus to the stomach (the esophagogastric junction), a key defense against the reflux of stomach contents after a large meal, was found to open wider in individuals with GERD. Differences in both of these structures in individuals with GERD are suspected to contribute to reflux.

Source: Curcic J, et al. *Am J Gastroenterol*. May 2014.

Probiotics in Constipation and IBS

A review of existing randomized controlled studies aimed to summarize the usefulness of probiotics in health and disease. The researchers concluded that certain strains or combinations may be of benefit in managing constipation and in improving irritable bowel syndrome (IBS) symptoms, among other things. The summary is intended to provide a guide to healthcare providers working with patients.

Source: Taibi A, Comelli EM. *Appl Physiol Nutr Metab*. May 2014.

Gene Mutation Identified in IBS

A survey of over 500 individuals confirmed a 2.2% prevalence of a mutation in a gene (SCN5A) in individuals with irritable bowel syndrome (IBS), as reported in an earlier pilot study. The SCN5A gene encodes a mechanism (sodium channels) involved in maintaining normal gastrointestinal (GI) motility.

The role of individual genes in symptom generation and expression in IBS remains largely unknown. Identification of these genes and their effects on the structure and function of the GI tract has the potential to reveal the mechanism of IBS in a subset of individuals with the disorder and to shed light on new treatment pathways.

Source: Beyder A, et al. *Gastroenterology*. June 2014.

Authors Call for Standardization of the Decision to Refer for Anti-Reflux Procedures

No current standards exist regarding decisions by medical professionals to refer children with severe gastroesophageal reflux disease (GERD) for anti-reflux procedures, including surgery. Decisions may be greatly influenced by parental and referring physician opinions. Standardization based on data showing the safety and effectiveness of treatments is recommended by the authors.

Source: Papic JC, et al. *Surgery*. May 2014.

6-Year Safety Report of the LINX System for GERD

A safety analysis recently published for the LINX system magnetic sphincter augmentation device (MSAD) for gastroesophageal reflux disease (GERD) reported a low risk profile with no serious events leading to long-term complications associated with the device.

LINX is a surgically implanted device that works by reinforcing the lower esophageal sphincter (LES).

The first 1,000 individuals who underwent the procedure were reevaluated after 6 years. The analysis concluded that the safety profile for the procedure performed by an experienced surgeon establishes it as a viable option for individuals with uncomplicated GERD who are considering antireflux surgery.

Source: Lipham JC, et al. *Dis Esophagus*. June 2014.

Home Parenteral Nutrition for Infants with Ultra-Short Bowel Syndrome

Because of the long-term complications associated with intestinal transplantation, the authors in a new study for the treatment of infants with ultra-short bowel syndrome (U-SBS) recommend a non-transplant home parenteral nutrition approach (in the absence of liver disease). Parenteral nutrition is an intravenous feeding technique that delivers nutrition directly into the blood stream.

Source: Diamanti A, et al. *J Ped Gastroenterol Nutr*. April 2014.

New Serotonin (5-HT) Drugs

Researchers are finding new serotonin drugs that may help treat a variety of functional gastrointestinal (GI) disorders with improved safety.

A new generation of 5-HT₄ receptor agonists is useful in treating symptoms of functional constipation, and has an improved safety profile compared to older drugs in this class.

A relatively new serotonin drug to treat irritable bowel syndrome with diarrhea (IBS-D) is also being developed. The drug, ramosetron (a 5-HT₃ receptor antagonist), has been associated with improved stool consistency in nearly 300 men with IBS-D in Japan. It appears to have an improved safety profile compared to other drugs in this class.

Source: Camilleri M. *Neurogastroenterol Motil*. August 2014.

GERD or Functional Dyspepsia?

In a review of records, researchers at Mayo Clinic found an increase over a 2-decade period in gastroesophageal reflux disease (GERD) diagnosis rates, but no increase in reported GERD symptoms. About 6 out of 10 persons reporting GERD symptoms received a GERD diagnosis while only about 1 out of 10 persons reporting functional dyspepsia (FD) symptoms received an FD diagnosis.

Common symptoms of GERD – heartburn and/or acid regurgitation – are also reported in about one-third of people with FD. However, treatments differ for these 2 conditions and PPIs that treat GERD do not work for FD.

Source: Pleyer C, et al. *Neurogastroenterol Motil*. August 2014.

Microbiota Transplant for Treatment of *C. difficile*

A study involving existing medical information collected from 16 different medical centers on 75 adults and 5 children concluded that fecal microbiota transplant (FMT) appears to be safe and effective for treating *C. difficile* infection in people who have weakened immune systems.

Up to 15–20% of cases of antibiotic-associated recurrent diarrhea and colitis presented in hospitals are attributed to *C. difficile* infection. FMT helps restore the balance of beneficial microorganisms lost to antibiotic use, and is indicated for people who have not been helped by standard therapies for *C. difficile*. However, the use of this treatment among individuals with weakened immune systems has been limited due to concerns about safety.

Source: Kelly CR, et al. *Am J Gastroenterol*. July 2014.

Acid Reflux Therapy

Proton pump inhibitors (PPIs) reduce stomach acid production and are widely used to treat gastroesophageal reflux disease (GERD). However, in about 30% of patients PPIs do not adequately resolve symptoms.

Researchers looking at the occurrence of acid reflux events concluded that strategies which target the pool of acid (called the acid pocket) that floats on the top of ingested food after a meal may be effective for people with GERD who are not helped by PPIs alone.

Altering the size, position, and acidity of the acid pocket while using a PPI may add therapeutic benefit.

Source: Rohof WO, et al. *Clin Gastroenterol Hepatol*. July 2014.

Naloxegol Indicated for Opioid-Induced Constipation

In two large phase 3 studies, the drug naloxegol was assessed for safety and efficacy in the treatment of opioid-induced constipation in individuals taking opioids for non-cancer related pain. At daily doses of both 12.5 mg and 25 mg the drug was associated with a significant reduction in constipation symptoms. Side effects were more frequent at higher doses and most often included gastrointestinal (GI) effects (abdominal pain, diarrhea, nausea, and vomiting).

Naloxegol is a member of an emerging class of drugs (peripherally acting μ -opioid receptor antagonists) that decrease the GI side effects of opioids without reducing their painkilling effects.

Naloxegol is indicated for use by individuals suffering from opioid-induced constipation who have not responded satisfactorily to standard laxative therapy.

Source: Chey WD, et al. *New Engl J Med*. June 2014.

Restrictive Eating and Abnormal Gut Function

Results from a preliminary study of adolescents with irritable bowel syndrome (IBS) suggest that frequent bouts of restrictive eating – such as not eating when hungry or eliminating certain foods – are associated with abnormalities in gastric sensation and gut motility. These gastrointestinal symptoms have been noted in association with other conditions characterized by restrictive eating. Results of this study warrant further investigation.

Source: Van Tilberg MAL, et al. *J Ped Gastroenterol Nutr*. April 2014.

Prevalence of Fructose Malabsorption in IBS

Fructose can trigger or worsen symptoms in irritable bowel syndrome (IBS). A new study investigated the prevalence of symptomatic fructose malabsorption in those with IBS and tested whether any patient characteristics can help to detect fructose malabsorption.

After ingesting 25g of fructose, fructose malabsorption was found in 22% of those studied. Symptoms indicating intolerance to fructose were found in 28% of sampled individuals, not all of whom demonstrated malabsorption. There were no differences in IBS subtype or clinical symptoms between those who did or did not have malabsorption. However, young males had a greater incidence of malabsorption.

The authors recommend further studies to determine whether a low-fructose diet would help IBS patients who are intolerant to fructose, with and without malabsorption.

Source: Melchior C, et al. *United European Gastroenterol J*. April 2014.

New Guidance on Treatments for Sphincter of Oddi Dysfunction

Results of a new study indicate that ERCP and surgery (sphincterotomy) are not reliably effective treatments of pain resulting from sphincter of Oddi dysfunction (SOD). Because these procedures carry substantial risk, the authors do not recommend the continued use of ERCP and sphincterotomy for abdominal pain following cholecystectomy – removal of the gallbladder.

SOD describes a condition in which the sphincter of Oddi does not relax at the appropriate time, most often due to scarring or muscle spasm. The back-up of digestive juices that results can cause episodes of severe abdominal pain.

Source: Cotton PB, et al. *JAMA*. May 2014.

Targeting IBS Treatment

Researchers reviewing existing studies found an imbalance of certain cells (cytokines) involved in regulating inflammation and sensitization in people with irritable bowel syndrome (IBS) compared to people without IBS. Using a cytokine profile may eventually be one way to help individualize treatment for people with IBS.

Source: Bashashati M, et al. *Neurogastroenterol Motil*. May 5, 2014.

Chronic Constipation Associated with Increased Risk for Colorectal Tumors

A retrospective database study of existing records has found that people with diagnoses of severe chronic constipation (CC) have a potentially higher risk of developing colorectal cancer and non-cancerous (benign) colorectal tumors over time, compared to people without CC.

The study, which looked at medical record databases, reviewed data from over 100,000 patients (28,854 patients with CC and 86,562 without) for 2–5 years. In those with CC, 2.7% developed colorectal cancer vs. 1.7% of those without. For non-cancerous colorectal tumors, the proportion was 24.8% for those with CC and 11.9% for those without. The risks increased with the severity of the chronic constipation.

These findings demonstrate an association only – *not a causation* – between CC and the development of colorectal cancer and/or benign tumor. While further studies are needed to determine whether there is an underlying causal link, the authors recommend that doctors be aware of this potential association in order to monitor and treat their patients appropriately.

Source: Guérin A, et al. *Aliment Pharmacol Ther*. July 2014.

Non-Intestinal Symptoms in Childhood Predict IBS in Adulthood

Recent findings suggest that symptoms existing outside the intestinal tract, such as reflux, joint pain, skin abnormalities, and psychological dysfunction, in association with childhood functional abdominal pain are significant predictors of the development of functional gastrointestinal disorders, particularly irritable bowel syndrome (IBS), in adulthood.

Source: Horst S, et al. *Clin Gastroenterol Hepatol*. Apr 13, 2014.

IBS and IBD Similarities

A review of existing studies of inflammatory bowel disease (IBD) and of irritable bowel syndrome (IBS) found a number of shared factors contributing to both disorders. In some instances these shared factors may involve brain-gut dysfunction, genetics, abnormal microbiota, low-grade inflammation in some IBS patients, and IBS symptoms in some patients with IBD in remission.

Source: Barbara G, et al. *Curr Opin Gastroenterol*. May 7, 2014.

Foods that Worsen GI Symptoms

A study of 25 children with functional gastrointestinal (GI) disorders revealed that specific foods are perceived by children to worsen their GI symptoms. These most often included spicy foods, cow's milk, and pizza. Common coping strategies identified were consuming smaller portions, modifying foods, and avoiding problem foods.

Source: Carlson M, et al. *J Acad Nutr Diet*. March, 2014. ■

Strategies for Improving Bowel Habits in Children

Improving bowel habits involves education to help a person with bowel disorders establish or reestablish control. Learning new skills or strategies to develop a routine for evacuation can help treat or prevent constipation and the inability to control bowel movements.

Children most often develop constipation as a result of holding in stool. There may be any one of several reasons for this. For example, they may wait too long after feeling the urge to have a bowel movement because they are playing or feel embarrassed to use a public restroom. Or they may withhold stool because they had a painful bowel movement and now fear it will happen again.

A child who is constipated may soil his or her underpants. This happens when liquid stool from farther up in the bowel seeps past the hard stool in the rectum and leaks out. The child does not do this on purpose and may not know when it happens.

A doctor or other healthcare provider that is familiar with treating bowel disorders can provide guidance. This will include a review of the child's medical history, diet, and daily routine.

Generally, improving bowel habits involves three basic principles:

- 1. Improve consistency of stool** – The optimal goal for stool consistency is a formed, soft stool that is easy to pass.
- 2. Establish a regular time for elimination** – This should be at the same time each day. A good time is after meals, and preferably at a time that is unhurried.
- 3. Stimulate emptying on a routine basis** – Usually a stimulus of some kind may be needed to help have a bowel movement. The stimulus will vary from person to person. Eating a meal is one example. The least stimulus that is effective in promoting a painless bowel movement is recommended.

Once bowel habits have been normalized, you will want to take steps to prevent constipation from recurring. Help make improving bowel habits a positive experience for your child and remember not to punish your child for related soiling episodes. ■

Book of Interest

Title: The Gut Solution: For Parents with Children Who Have Recurrent Abdominal Pain & Irritable Bowel Syndrome

Author: Michael Lawson, M.D. and Jessica Del Pozo, Ph.D.

Publisher: Lemke Health Partners

Pages: 144 (paperback)

Children suffer and parents worry when gastrointestinal problems like tummy pain, diarrhea, constipation, indigestion, and bloating become chronic. Managing these problems can be disruptive to the whole family.

In The Gut Solution, Dr. Lawson and Dr. Del Pozo reveal their approach to treating functional gastrointestinal disorders like irritable bowel syndrome (IBS) and recurrent abdominal pain (RAP). Their program, SEEDS (which stands for Stress Management, Education, Exercise, Diet & Sleep), guides the child patients and their families on how to manage these common and often difficult digestive problems.

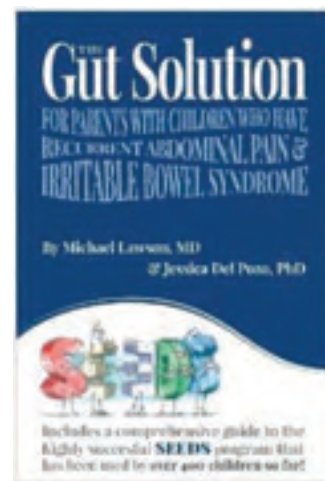
The book explains not only the underlying physiological and biological issues at play, but the neurological,

behavioral, and emotional factors in IBS and abdominal pain and most importantly, what can be done about it.

The case example of a child named Sara is followed through the book to illustrate how the SEEDS program helps her and her parents identify and modify her thoughts, feelings, and behaviors around her symptoms. The child is treated as an active partner in her own health care, and the authors stress the importance of hearing and validating the child's perspective.

The Gut Solution includes an easy-to-follow guide to the SEEDS program, offering family discussion topics as well as specific tips and strategies that both parent and child can practice. The program has been taught to over 400 children since 2006 with sustained and positive results.

Available online at [Amazon.com](https://www.amazon.com).



IFFGD Recognizes August as Gastroparesis Awareness Month by Discussing Need for Increased Understanding

August has widely become known across the country as Gastroparesis Awareness Month. In order to share more much needed messaging about the impact this condition has, on both the digestive health community and society as a whole, IFFGD released a statement on improving care for people affected by gastroparesis.

We were gratified that the press release was picked up on the newswire, as well as in trade publications and industry-related newsletters. Increased awareness about gastroparesis is key to helping those suffering with the symptoms find the proper care.

Lack of Awareness of Gastroparesis May Impact Medical Care

MILWAUKEE, WI (August 26, 2014) – Gastroparesis, also called delayed gastric emptying, is a medical condition where symptoms occur and the stomach cannot empty properly. The impact of the condition is significant.

The number of people with gastroparesis appears to be rising. Yet gastroparesis is poorly understood. More community awareness is needed about the condition.

“Gastroparesis can have a significant impact on a person’s daily life,” said Nancy Norton, president and founder of the International Foundation for Functional Gastrointestinal Disorders (IFFGD). “Symptoms can be disabling and for some people even life-threatening.”

The symptoms usually happen during or after eating a meal. They include:

- Nausea and/or vomiting
- Stomach fullness after a normal sized meal
- Dry heaves
- Early fullness and inability to finish a meal

Bloating, stomach discomfort or pain, weight loss due to decreased appetite, and heartburn are other possible symptoms. Complications from symptoms can include severe dehydration, obstruction, and malnutrition due to poor absorption of nutrients.

“Symptoms of gastroparesis can be similar to those that occur in other conditions,” said Norton. “It’s important to get an accurate diagnosis from a doctor so that effective treatment can begin.”

Gastroparesis can occur in people of all ages. In most people affected the cause is unknown, termed “idiopathic.” It can also occur as a complication of other diseases, surgeries, or medications. The most common known cause of gastroparesis is long-standing diabetes. Most people with diabetes do not develop gastroparesis, but for those who do it can make it hard to manage glucose levels.

Treatments for gastroparesis most often include long-term dietary measures and/or medications. If diet or medications aren’t helpful enough, in more serious cases other therapies may be tried. This could involve tube feeding to maintain nutrition, or a surgical procedure to help reduce severe symptoms.

August is Gastroparesis Awareness Month. The goals of raising awareness of this condition include improved understanding and care for patients and families affected by gastroparesis.

For more information on gastroparesis, visit IFFGD’s website dedicated to information on the condition, www.aboutgastroparesis.org.

Dietary Tips for Gastroparesis

Dietary suggestions for gastroparesis are based largely on clinical experience. More scientific studies are needed to demonstrate what foods are better tolerated than others by individuals with gastroparesis.

It is recommended that anyone with gastroparesis seek dietary counseling with a doctor or Registered Dietician to help individualize nutrition therapy and maximize nutritional benefits.

Dietary recommendations are likely to be of greatest benefit to those with mild to moderate disease. They are also tried in people with more severe gastroparesis to complement other medical treatments.

General dietary recommendations for gastroparesis include:

- Eat smaller, more frequent meals
- Eat less fatty foods
- Avoid fiber
- Avoid foods that cannot be chewed well

Foods that are generally encouraged are:

- Breads, cereals, crackers, ground or pureed meats
- Vegetables – cooked and, if necessary, blenderized/strained
- Fruits – cooked and, if necessary, blenderized/strained
- Juices, beverages, milk products, if tolerated

Small frequent meals

Reducing the meal size reduces the distention of the stomach from the meal. By eating smaller meals, you may not feel as full or bloated and the stomach may empty faster. With the reduction in meal size, increasing the number of meals to 4–6 per day is needed to maintain adequate nutritional intake.

Avoid foods high in fat

Fat can delay emptying of the stomach. Eating less fat-containing food will decrease the amount of time food stays in the stomach. However, fat-containing liquids, such as milkshakes, may be tolerated and provide needed calories.

A diet low in fiber is suggested

Fiber delays gastric emptying. In addition, fiber may bind together and cause a blockage of the stomach, called a bezoar.

Examples of high fiber foods that should be avoided include:

- Fruits – apples, berries, coconuts, figs, oranges, persimmons
- Vegetables – Brussels sprouts, green beans, green peas, lettuce, potato peels, sauerkraut
- Bran/whole grain cereals
- Nuts and seeds
- Legumes/dried beans – baked beans, lentils, soy beans

Fiber supplements for treatment of constipation should also be discontinued if possible.

Avoid foods that may not be easily chewed

Examples of hard to chew foods include:

- Broccoli
- Corn
- Popcorn
- Nuts
- Seeds

Chew food well before swallowing

Solid food in the stomach does not empty well. Dental problems, such as missing or broken teeth, may lead to poorly chewed food. This may add to the problem of inadequate breakdown of food into smaller particles in the stomach for passage into the small intestine for absorption.

Position

Taking fluids throughout the meal and sitting upright or walking for 1–2 hours after meals may help in the emptying of the meal from the stomach.

Vitamins and minerals

A daily multivitamin/mineral supplement can be taken if dietary intake is inadequate.

Liquids

When basic guidelines aren't enough to control your gastroparesis, you may be advised to consume the bulk of your meals as semi-solids or liquids, such as puréed foods or soups. Stomach emptying of liquids is often normal in individuals with gastroparesis. Calorie-containing drinks, such as Hawaiian Punch or Hi-C, provide fluid and calories, hence are better than water alone.

Some options while on a liquid diet include:

- Milk
- Instant breakfast
- Milkshakes
- Yogurt
- Puddings
- Custard
- Cereals (soft/easy to chew)
- Smoothies

Supplements

To meet your nutritional needs, it may be necessary to supplement the diet with a commercially available liquid nutrient preparation that is low in fiber such as Ensure, Boost, or even baby foods.

Blenderized foods may also be used as a liquid nutrient source. Any food can be blenderized. Solid foods will need to be thinned with some type of liquid, such as broth, milk, juice, water. Remember to clean the blender well after each use.

Medications to Avoid

There are quite a few medications that can delay stomach emptying. Tell your doctor about all of the medications you are taking and ask if any could be slowing down your stomach emptying.

Here are some examples that can slow your stomach emptying:

- Aluminum-containing antacids (Amphojel)
- Narcotic pain medication (Percocet, Tylenol #3, Oxycontin, and others)
- Anticholinergic agents (Bentyl, Levsin, Elavil, and others)
- Bulk-forming agents (Metamucil, Perdiem, Fibercon, and others)

Diabetes

If the gastroparesis is due to diabetes, an important goal is to achieve or maintain good glucose control. This is achieved more easily by frequent monitoring of blood sugar levels and adjustment of insulin. Keeping your blood sugar under control may help stomach emptying. Let your doctor know if your blood sugar runs more than 200 on a regular basis. ■

A Sample Diet for Patients with Gastroparesis

With gastroparesis, eating smaller meals may help you feel less full. With smaller meals, you'll need 4–6 meals per day to maintain nutritional intake. Here are sample meal plans for 6 small meals throughout one day. Your doctor and a Registered Dietician can help create meal plans that work best for you.

BREAKFAST

- 1 c. cream of wheat cereal
- ½ c. skim milk
- ½ c. grape juice
- 1 scrambled egg

SNACK

- 10 oz. instant breakfast with skim milk

LUNCH

- ½ c. vegetable soup
- ½ turkey sandwich
- ½ c. applesauce
- ½ c. milk
- 1 T. mayonnaise

SNACK

- 10 oz. banana shake made with 1 plain or vanilla yogurt, milk, and sugar

DINNER

- 2–3 oz, baked chicken or fish
- ½ c. mashed potatoes
- 1 t. margarine
- ½ c. spinach
- ½ c. milk
- ½ c. fruit cocktail

SNACK

- ½ c. pudding, custard, or gelatin

This article was adapted from IFFGD publication #537, *Dietary and Nutritional Recommendations for Patients with Gastroparesis*.





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

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

Salix Pharmaceuticals, Ltd.

NPS Pharmaceuticals, Inc.

Ironwood Pharmaceuticals, Inc.

Ferring International
PharmaScience Center US, Inc.

Entera Health, Inc.

Actavis (formerly Forest Laboratories, Inc.)

Relistor FDA Approved for Expanded Use in Treatment of Opioid-Induced Constipation

In September 2014 the U.S. Food and Drug Administration (FDA) approved an expanded use of the drug, Relistor, for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The European Medicines Agency is also reviewing the drug for this treatment application. The European Union already allows for the use of Relistor in patients with advanced illness.

Linaclotide (Constella) Available in Europe for Treatment of IBS-C

Linaclotide is the first medicine approved by the European Commission for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adult patients. It is currently available in several European countries with the EU brand name Constella.

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 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 visceral pain.

Linaclotide (Linzess) has been available in the U.S. to treat IBS-C and CIC in adults aged 18 and older since 2012. The safety and effectiveness of Linzess for the management of IBS-C were established in two, double-blind studies in which a total of 1,604 patients were randomly assigned to take 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.

Linzess should *not* be used in patients 17 years of age or younger. Linzess should *not* be used 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 Forest Laboratories. 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.

Seeking Participants for Study of Linaclotide for Patients with IBS with Constipation

Purpose of study: This 12-Week, Phase 3, international, multicenter study will evaluate the effectiveness and safety of linaclotide in adult patients with IBS-C.

Sponsor: AstraZeneca

Collaborator: Ironwood Pharmaceuticals, Inc.

Participation: Eligible male and female patients aged 18 and older

Location: China, Australia, and New Zealand

Contacts: Lennie Wu, 86-2038183761; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01880424

Participants Sought for Study of Linaclotide's Effect on Bi-directional Brain & Gut Axis in IBS-C Patients

Purpose of study: This study will assess how Linaclotide affects bowel function and abdominal pain in patients with irritable bowel syndrome with constipation (IBS-C). It will also examine effects of the drug on communication between the brain and the pelvic-floor region.

Sponsor: Georgia Regents University

Collaborator: Forest Laboratories

Participation: Eligible male and female patients aged 18–64 years

Location: Augusta, Georgia

Contacts: Amanda Schmeltz, B.A., 706-721-1968, aschmeltz@gru.edu or Satish Rao, M.D., 706-721-2238; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT02078323

Medical Food in the Management of Diarrhea

EnteraGam™ is a new 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. EnteraGam 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.

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

A research review summarizing accumulated data from prior studies, reported that specially formulated immunoglobulin sources like SBI, the main ingredient in the prescription medical food EnteraGam, have multiple effects which collectively serve to improve and maintain nutrient utilization, including water balance. This review demonstrates that other protein sources, besides immunoglobulins, do not effect 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 binding microbial components, maintaining immune balance, and managing gut barrier function, which has the result of improving nutrient utilization, including water.

The reviewers concluded that, taken together, results from studies with SBI reveal a distinctive nutritional requirement for immunoglobulins for the purpose of restoring functional homeostasis to aid in the management of enteropathy. This meets a critical requirement that the FDA has for medical foods.

The review study, 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 Diarrhea-Predominant IBS

Results from a randomized, double-blind, placebo-controlled pilot study enrolling 66 subjects 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. Of the subjects who did not complete the study, five were lost to follow-up, three did not comply with the study requirements, one discontinued due to lack of efficacy, and two were removed at the Principal Investigator's discretion. The safety profile of SBI in the study was

similar to that of placebo. A total of four people withdrew, from both the placebo and the SBI groups, due to nausea. No serious adverse events were reported. The proportion of subjects who withdrew was not significantly different between treatment groups.

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.

The product has been extremely well tolerated for up to a year in HIV patients and up to eight months in infants. The major side effects in clinical trials (2–5%) included mild nausea, constipation, stomach cramps, headache, and increased urination.

EnteraGam is contraindicated for patients with a hypersensitivity (allergy) to beef, or any components in EnteraGam. Therefore, patients who have an allergy to beef or any component of EnteraGam should not take this product. The effect of EnteraGam on nursing mothers and the infant is unknown. The choice to administer EnteraGam in pregnant or nursing mothers is up to the clinical decision of the physician.

Medical foods like EnteraGam are required by the U.S. Food and Drug Administration (FDA) regulations to be dosed and monitored by physicians as part of ongoing care for patients with chronic conditions or diseases.

Study Underway to Evaluate New Treatment for GERD

A phase 2 study is underway on a new drug to treat gastroesophageal reflux disease (GERD) in patients not adequately helped by proton pump inhibitors (PPIs). The study will assess the effect of the drug (IW-3718) compared to placebo as an added treatment in GERD patients who will continue to also take a once-daily PPI. Ironwood Pharmaceuticals is developing the drug.

Seeking Participants for Phase 2 Study to Evaluate IW-3718 as Part of Treatment for GERD

Purpose of study: This is meant to assess the effect of IW-3718 as an added treatment to ongoing, once-daily PPI treatment for patients who continue to experience symptoms of gastroesophageal reflux disease (GERD).

Sponsor: Ironwood Pharmaceuticals, Inc.

Participation: Eligible male and female patients aged 18–65 years

Locations: various throughout the United States

Contacts: Research Coordinator; Arkansas, 501-945-9300; California, 714-774-7777 ext. 240; Louisiana, 318-807-0819; Michigan, 586-598-3329; North Carolina, 919-781-2514; Ohio, 216-778-5278; Tennessee, 423-698-4584 and 615-322-4643; Utah, 435-213-2400 and 801-409-2040;

Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT02030925

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.

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 Gattex (teduglutide) 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 Gattex.

The data, published in 2013, demonstrated that there was an increased response to treatment over time in all groups receiving Gattex. The open-label extension study

included 88 adult patients with SBS. Investigators reported that the long-term use of Gattex 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 Gattex therapy. No new unexpected safety concerns were observed with long-term Gattex 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.

Gattex was approved by the U.S. Food and Drug Administration (FDA) in 2012 for treatment of adult patients with SBS who are dependent on parenteral support. 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. 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. They cannot absorb enough water, vitamins, and other nutrients from food and may then need to use parenteral nutrition and intravenous fluids.

Study Assesses Teduglutide as Treatment for Pediatric Short Bowel Syndrome

Purpose of study: 12-Week, open label study is evaluating the effectiveness and safety of teduglutide as a treatment for pediatric patients with short bowel syndrome on parenteral support.

The ongoing study is no longer recruiting participants.

Sponsor: NPS Pharmaceuticals, Inc.

Participation: Eligible male and female patients aged 1–17 years

For More Information:

ClinicalTrials.gov identifier: NCT01952080

Patients with Short Bowel Syndrome Sought for Long-term Study

This global clinical study has begun 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.

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

Sponsor: NPS Pharmaceuticals, Inc.

Contact: NPS Clinical Operations: 908-450-5300 Email: SBSregistry@quintiles.com; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01990040

FDA Considers Rifaximin for Treatment of IBS-D

The supplemental new drug application (sNDA) for the antibiotic rifaximin 550 mg has been accepted for review by the U.S. Food & Drug Administration (FDA). A decision regarding the approval status of the drug for the treatment of irritable bowel syndrome with diarrhea (IBS-D) is expected by February 28, 2015.

In July 2014 Salix Pharmaceuticals reported positive results from the TARGET 3 – Phase 3 study to evaluate the efficacy and safety of repeat 14-day treatment with rifaximin for the treatment of IBS-D in people who responded to an initial 14-day treatment course with rifaximin. Compared to placebo, subjects treated with rifaximin showed statistically significant improvement in IBS-related abdominal pain and stool consistency during the 4-week, treatment-free follow-up period in the double blind repeat treatment phase.

Results from the two initial Phase 3 clinical trials had reported adequate relief of multiple symptoms in patients with IBS-D. Rifaximin works by reducing or altering bacteria in the gut. It is only slightly absorbed in the gut and is generally tolerated well.

Solesta Available in the U.S. to Treat Bowel Incontinence

Solesta, a biocompatible tissue bulking agent, is approved by the U.S. Food and Drug Administration (FDA) for the treatment of bowel incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). The drug has been approved to treat bowel incontinence in the U.S. since 2011 and in Europe since 2006. Bowel 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.

Solesta is an injectable gel delivered into the anal canal. The medication is administered by physicians certified in its use in an outpatient procedure taking approximately 10 minutes without the need for surgery or anesthesia. 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 under license from and manufactured by Q-Med AB for Salix Pharmaceuticals.

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 (U.K.). 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 U.K.

Lubiprostone Study Published Showing Efficacy in Opioid-Induced Constipation (OIC)

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.

Amitiza 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. Amitiza 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 Amitiza 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 Seeking Participants

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, Ph.D., 301-961-3400, pedgen@sucampo.com; Be sure to refer to this study by its 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, Ph.D., 301-961-3400, pedgen@sucampo.com; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT02138136 ■

The State of Research at NIH & NIDDK

Stephen P. James, M.D., Director, Division of Digestive Diseases and Nutrition, NIDDK was kind enough to join us several times this year to inform our network of healthcare professionals, members of industry, DHA advocates, and others about the current state of research related to functional GI and motility disorders at NIH and NIDDK. The following is a summary of what Dr. James shared with us.

Funding at NIH has been challenging, having to deal with the long-term effects of reductions in Federal spending. Although there has been a partial restoration of cuts in the NIH budget, the U.S. continues to trail the developed and developing world by reducing investments in biomedical research. Most of the rest of the world, despite economic challenges, continues to expand their investments in biomedical research.

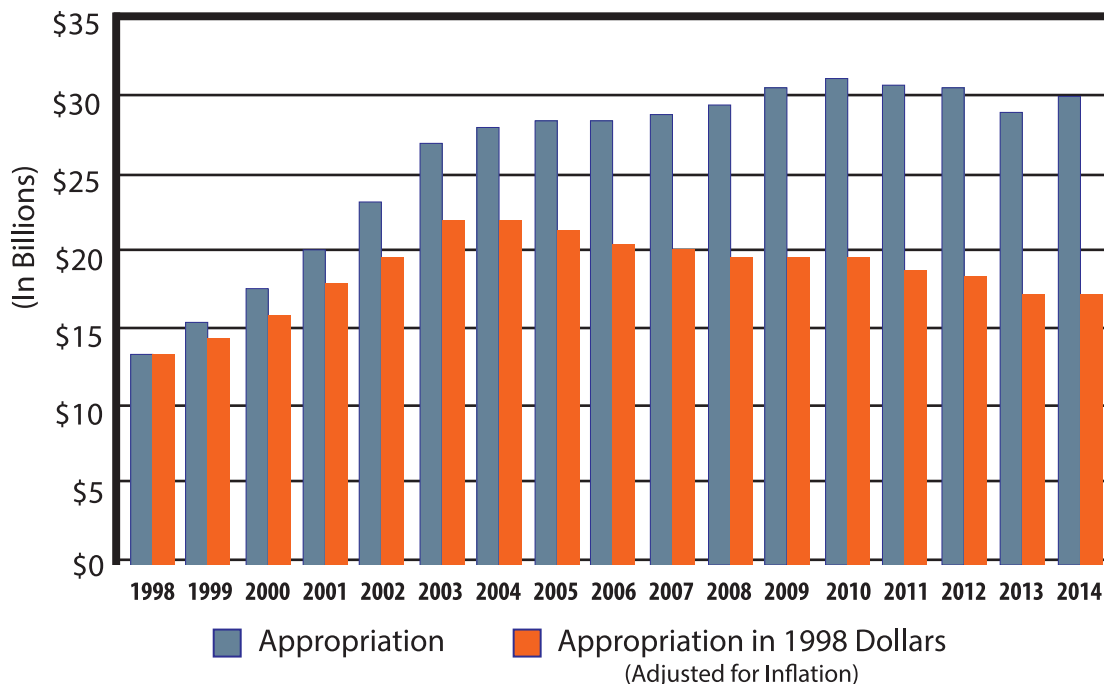
In inflation adjusted dollars, NIH appropriations are approximately at the same level as 15 years ago. The tremendous momentum gained from the NIH doubling from 1998 to 2003 has been eliminated.

NIDDK is the National Institute for Diabetes and Digestive and Kidney Diseases.

One of the 27 NIH Institutes and Centers, the NIDDK conducts and supports basic and applied research and provides leadership for a national program in diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases. Access the NIDDK website at www.niddk.nih.gov.

NIH stands for the National Institutes of Health and is the focal point for biomedical research in the U.S. NIH conducts research in its own laboratories; supports the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helps in the training of research investigators; and fosters communication of medical information. Access the NIH website at www.nih.gov.

NIH Program Level in Nominal Dollars and Constant 1998 Dollars, FY1998 – FY2014



These policy decisions are causing down-sizing or closure of research programs in the U.S., discouraging young people from choosing to enter the long and arduous training pathways that are needed in biomedical research. Reductions in material and human capital investments threatens U.S. pre-eminent leadership in biomedical research.

Ironically, this is happening at a time when rapid advances in medical research and technology offer the promise of improvement in the lives of people suffering from many chronic diseases. Conditions like chronic hepatitis C infection, heart disease, diabetes, and many forms of cancer and AIDS have benefited.

Progress in developing better diagnostic and treatment approaches for functional GI and motility disorders has been slow. However, due in part to the substantial efforts made by IFFGD, there is increased awareness of the needs of affected individuals and the burdens of illness imposed by these conditions.

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NIDDK-funded investigators are making major contributions in the area of basic science discovery helping better understand these conditions. The current NIDDK portfolio spans a broad range of basic and clinical research projects involving tissue and muscle cells, the enteric nervous system (ENS), and mechanistic studies in GERD, dysphagia, and mechanisms of symptom generation, to name a few. The clinical research portfolio includes multi-center studies in gastroparesis, functional dyspepsia, irritable bowel syndrome (IBS), and Sphincter of Oddi dysfunction, among others.

One of the relatively new areas of interest involves understanding the microbiota that we all have in our digestive systems that are believed to play important roles in health and illness. This area is rapidly moving towards therapeutic approaches to improve digestive diseases.

Another exciting area is stem cell research. Tissue models can now easily be made in the laboratory (enteroids) from small endoscopic biopsies of patients to use for study and to lay the foundation for regenerative medicine approaches.

New technologies are opening up ways to better understand how diet is involved in health and illness. NIDDK has contributed to support that focuses on understanding brain gut connections and visceral pain.

NIDDK also recognizes the need to provide specialized infrastructure support for research and supports 16 digestive diseases research core centers and 12 nutrition/obesity research centers around the U.S. In order to help assure a continuing pipeline of new investigators for the future, NIDDK vigorously supports training and career development awards.

Finally, NIDDK devotes substantial effort to educate and inform the public on health issues in digestive diseases and the latest advances that result from NIH research. Extensive online materials for the general public are often developed in partnership with organizations such as IFFGD. The NIDDK continues to support the Bowel Awareness campaign, which was developed with considerable input and assistance from IFFGD, with the aim to provide helpful information to individuals with bowel incontinence.

Dr. James remains optimistic that, despite current economic challenges, NIDDK will continue to bring improvements to people with functional GI and motility disorders due to the dedication of many scientists around the country, continued funding from the NIH, and the important contribution of professional societies, organizations such as IFFGD, and patients who participate in research projects and inspire us all. ■



Stephen P. James, M.D., Director, Division of Digestive Diseases and Nutrition, NIDDK

H.R. 842 Updates

Thanks to the advocacy efforts of many of you involved with DHA, *The Functional GI and Motility Disorders Research Enhancement Act* (H.R. 842) currently has 20 cosponsors in the House of Representatives. The bill was originally introduced and sponsored by Representative Sensenbrenner.

- Peter King – New York, 2nd District
- Carol Shea-Porter – New Hampshire, 1st District
- David Price – North Carolina, 4th District
- Richard Neal – Massachusetts, 1st District
- Mo Brooks – Alabama, 5th District
- Andrè Carson – Indiana, 7th District
- Jim Himes – Connecticut, 4th District
- Ed Perlmutter – Colorado, 7th District
- Bill Posey – Florida, 8th District
- Louise McIntosh Slaughter – New York, 25th District
- Gerald Connolly – Virginia, 11th District
- James McGovern – Massachusetts, 2nd District
- Peter Welch – Vermont
- Susan Davis – California, 53rd District
- Ron Kind – Wisconsin, 3rd District
- Gwen Moore – Wisconsin, 4th District
- Bobby Rush – Illinois, 1st District
- Julia Brownley – California, 26th District
- James Moran – Virginia, 8th District
- F. James Sensenbrenner, Jr. – Wisconsin, 5th District

Ask for Additional Support of H.R. 842!

Here are three easy ways to ask your Congressional Representative to support *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act*.

Phone: Dial the U.S. Capitol Switchboard at 202-225-3121 and ask to be connected to your Representative's office.

Email: Log on to www.iffgd.org/HR842action and send an email directly to your Representative through our system.

Letter: Write to your Representative and send it to us at IFFGD, 700 W. Virginia St. #201, Milwaukee, WI 53204. We will make sure it's hand delivered to your Congressperson's office.

Not sure what to say? Here are a few rules of thumb.

Identify yourself as a constituent and thank the staff member for their time and attention.

Briefly explain what a functional gastrointestinal and motility disorder is.

Share your personal story about how one of these conditions has affected your life, or the life of someone you know.

Explain that H.R. 842 will significantly improve our scientific understanding of functional GI and motility disorders and stimulate breakthroughs in diagnosis and treatment.

Ask that your Representative cosponsor H.R. 842.

Statement from IFFGD to FDA on Applications for New Drugs

In July 2014, IFFGD President and Co-Founder, Nancy J. Norton, submitted the following written statement to the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research in regard to regulatory changes made by FDA for Investigational New Drug Applications (INDs). New guidelines from the FDA, which were published without prior notice or public discussion, require INDs for clinical research studies involving foods. The new guidelines are vague and may also inhibit clinical research in areas that are essential to investigation of functional GI and motility disorders.

On behalf of the International Foundation for Functional Gastrointestinal Disorders (IFFGD), I would like to thank the U.S. Food and Drug Administration (FDA) for its work to evaluate the safety of treatments for conditions that affect the public. IFFGD is a 501(c)(3) nonprofit education and research organization dedicated to improving the understanding of functional gastrointestinal and motility disorders (FGIMDs). Our mission is to inform, assist, and support people affected by these chronic and often debilitating digestive conditions for which too few treatment options exist.

I am writing to you in regard to Docket No. FDA-2010-D-0503, section VI, subsection D (“Foods”) of the FDA’s September 2013 “Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND.” Although the open comment period is closed, we hope you will consider our comments on this Guidance.

We applaud the goals of the Guidance to “address a range of issues that, in FDA’s experience, have been the source of confusion or misperceptions about the application of the IND regulations.” However, we are concerned that the Foods section of the Guidance is vague and unclear, and will inhibit clinical research that can benefit patients.

Food and nutrition related therapies represent a growing area of investigative interest. In addition to use in managing specific dietary needs or distinctive nutritional requirements, they have shown potential to reduce symptoms of FGIMDs. The new guidance has introduced confusion and uncertainty regarding the conditions under which a food is to be considered as a drug requiring an IND for research. We are concerned this places an unnecessary, and possibly unintended, burden on researchers that can inhibit development of new treatments.

We therefore offer the following suggestions regarding the Guidance:

- Postpone the implementation of the Guidance so that concerns and recommendations regarding changes to IND procedure can be voiced through public comment.
- Open a dialogue with interested parties, including patients, investigators, and industry representatives.
- Refine the language of the Guidance to reduce confusion and unnecessary burden about the exact research conditions for which an IND will be required.

Thank you for your consideration of our comments.

Proceeds from one DHA Fundraiser's Online Gastroparesis Awareness Store Benefit DHA from November 1–15

The GP Fight Store, an online store promoting awareness for gastroparesis, is hosting a fundraiser in support of gastroparesis research. The store's creator has designated that 10% of the proceeds from each sale from November 1–15 will be donated to the Digestive Health Alliance!

Use the QR code below to access the store or visit www.dha.org/dw/fundraiser/1049 for additional information.



- **STICKERS, BUMPER STICKERS, AND WINDOW CLINGS**
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- **KEY CHAINS**
- **BRACELETS**
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Think holiday gifts!
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IFFGD

INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

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Occasionally, specific products are cited in articles or acknowledgments. However, no endorsement is intended or implied. Our intention is to focus on overall treatment or management issues or strategies.

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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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.



International Foundation for Functional Gastrointestinal Disorders IFFGD

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