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FALL/WINTER 2014

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The magazine of PREMIER *medical group of the Hudson Valley*

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FALL/WINTER 2014

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A Healthier You

Weight Loss Is a High Priority


Chinyere Ofonagoro, MD

Obesity is a global epidemic. Nearly 35 percent (78.6 million) of American adults now suffer from obesity, according to a 2014 study by the U.S. Centers of Disease Control.

"It is extremely important that we help our patients to address their weight issues successfully," says Dr. Chinyere Ofonagoro of Premier's Internal Medicine Division. "Overweight and obesity are implicated in such a long list of negative medical conditions… some of the leading causes of preventable death." These include heart disease, type-2 diabetes, high blood pressure, high cholesterol, sleep apnea, arthritis, stroke and a number of cancers.

"We make it a priority to help patients understand the impact of obesity on their overall health and the importance of weight loss," Ofonagoro says. "When a patient comes to us for an appointment, has a weight problem and does not raise the issue, we take the opportunity to counsel them on how to manage their problem, set goals and begin their journey to better health, beginning with education."

"We make it a priority to help patients understand the impact of obesity on their overall health and the importance of weight loss."

Obesity can be caused by a constellation of factors, not just overeating and failing to exercise. "Certainly those are pieces of the problem," says Ofonagoro, "but so are genetic predisposition, environmental factors, psychological and situational stressors."

"We explain that weight loss and weight management are comprised of three major areas: diet, exercise and, if required, medication. We explain how weight loss and maintenance will reduce the risk of negative medical complications."

Avoiding obesity-caused complications also avoids high medical bills. "Medical costs associated with obesity are staggering: an estimated $147 billion a year," says Ofonagoro. On a per person basis, obese individuals' medical bills paid for by third parties have been $1,429 higher than those of normal weight individuals since 2008. "That information can be a real eye-opener. For some patients that provides a real incentive to become more fit," Ofonagoro says.

The health care team provides recommendations for exercise and what type of diet might work for the individual. "If the patient asks for a referral to a weight loss program, we provide that."

On subsequent appointments, "we reinforce the individual's achievements and explain the health benefits they have already achieved, such as lowered blood pressure," Ofonagoro says. "This helps to keep them committed to the goals they set."

"But what is key is the constant reinforcement and support from the health care team, incorporating family, friends and significant others," she says. "It goes a very long way toward helping the individual stay the course."

You Are Due for a Flu Shot


Michael Gaesser, MD, FACP

From October to May, it's flu season in the U.S. Every year, millions of Americans come down with the flu, several hundred thousand are hospitalized because of it, and between 30,000 and 42,000 people die from complications of the virus.

"Flu vaccine is the single best protection against this potentially serious disease. We highly recommend that everyone who is eligible for the vaccine gets vaccinated," says Dr. Michael J. Gaesser of Premier's Internal Medicine Division.

The U.S. Center for Disease Control (CDC) recommends a yearly flu vaccination for everyone 6 months of age or older. "Every year, the active strains of influenza change, so vaccine manufacturers must change the formulation," says Gaesser, a member of the Putnam County, NY Board of Health. "The ideal time to get vaccinated is during October, so that you are protected for the six to seven months that flu is most prevalent. However, if you haven't been vaccinated yet, do so now; you will still be protected for the balance of the flu season."

"Flu vaccine is the single best protection against this potentially serious disease. We highly recommend that everyone who is eligible for the vaccine gets vaccinated."

The vast majority of people who get vaccinated will have no adverse reaction to the flu shot, Gaesser says. Typically, the only side effect is mild soreness and perhaps some redness at the injection site. People allergic to eggs or to the preservatives in the vaccine formula, however, should not receive the vaccine. "Among the rest of the population, there are a few who have a bad reaction to the shot. The vaccine is very safe," says Gaesser.

Premier's Internal Medicine Division offers flu vaccine to its patients and it recommends that individuals age 60 or above also have a one-time pneumonia vaccination to avoid infection with streptococcus pneumonia.

In addition to getting a flu shot, "there are other, simple protective measures you can take to avoid the flu," says Gaesser: Stay away from people who are infected; wash your hands frequently to reduce the spread of germs; and, if you have the flu, stay home from work or school so that you don't give it to anyone else.

"But remember," says Gaesser, "getting a flu shot is the best thing you can do to protect yourself, your family and friends; it's the first line defense against outbreaks."

AN ADVANCE IN PROSTATE CANCER TREATMENT:

Chemohormonal Therapy Extends Survival in Late-Stage PC


Naeem Rahman, MD

In early June, 2014, at the annual meeting of the American Society of Clinical Oncology, a researcher from The Dana-Farber Cancer Institute presented findings from their multi-center, phase-III trial investigating the efficacy of chemohormonal therapy vs. androgen deprivation therapy (ADT) in men with metastatic prostate cancer.

ADT has long been the standard of care for patients newly diagnosed with hormone-sensitive PC. The therapy delivers anti-tumor activity, enhanced quality of life and an improved overall survival time. Eventually, however, ADT ceases being effective and the patient is considered to be "hormone-resistant." At this point, chemotherapy with a drug called docetaxel is often prescribed.

The NIH-funded trial tested the hypothesis that immediately barraging the cancer with a combination of docetaxel and androgen deprivation therapy would yield an increased overall survival benefit. Results proved significant: The median overall survival rate for those receiving both docetaxel and ADT was 57.6 months—a survival advantage of 13.6 months over those who received only ADT as initial treatment.

"This is the first major clinical benefit that has been seen in hormone-sensitive prostate cancer in many years," says Dr. Naeem Rahman, MD, a Senior Partner in Premier's Urology Division. "It is the first study to identify a strategy that prolongs survival in newly diagnosed, metastatic prostate cancer. That is an exciting development."

The combined therapy showed the greatest success in patients with "high-volume" prostate cancer, that is, when the cancer had spread to other organs (such as the lung or liver) or when there were multiple bone lesions. In addition to increased survival, men receiving the combination therapy had an average of 32.7 months' delay before their prostate cancer progressed or their symptoms worsened—12.9 months longer than the men treated with ADT alone.

"New protocols and medications for prostate cancer provide more opportunities for patients who are willing to take an aggressive stance much earlier in the effort to extend their life," says Rahman. 'Now that this breakthrough has been made, more positive developments in the treatment of prostate cancer are on the horizon. The next big advance will be sequencing the 'cocktail' of drugs and treatments to deliver the greatest positive outcome for the patient."

Smoking: You Can Quit


Davide Michael DeBellis, MD

Over 16 million Americans suffer from a disease caused by smoking: cancer, heart disease, stroke, lung diseases (such as emphysema, bronchitis, and chronic airway obstruction) and diabetes result in 1,300 deaths every day.

"Most people who smoke know they should stop, but it is very hard to kick the habit," says Dr. Davide Michael DeBellis, of Premier's Internal Medicine Division. "Nicotine is the most addictive drug known to mankind. It is what makes smoking, or any other use of tobacco one of the most difficult, but not impossible, addictions to conquer. Over the 30-plus years that our physicians have been in practice in the Dutchess County area, we have helped thousands of patients quit."

What worked for those patients, DeBellis says, is the individualized approach our IM physicians take. "At its heart is the unique physician-patient relationship, the personal rapport we build with our patients that enables us to give each person specialized counseling."

The privacy of the examination room frequently provides an opening for a dialogue about smoking. "How the physician approaches the topic with a patient is based on the individual's medical records and patient profile." This detailed knowledge of each person's health care record enables the physicians to assess how tobacco use is affecting his or her health.

The physicians can also, with the patient's permission, help create a personal support group comprised of their family members. "It's the most important support group that anyone trying to quit smoking can have," he says. And, when appropriate, the physician may provide prescription medication to help ease an individual's withdrawal from smoking.

"We encourage individuals who want to quit smoking to talk to us about smoking cessation options," says DeBellis. "We'll help you choose the option that's best for you, and we'll be with you every step of the way."

WHAT HAPPENS TO YOUR BODY WHEN YOU QUIT SMOKING:

- In 20 minutes, your blood pressure and heart rate drop to normal.
- In 8 to 12 hours, the carbon monoxide and nicotine levels in your blood reduce by half and your oxygen levels return to normal.
- After 2 days, carbon monoxide is eliminated from your body.
- After 4 days, breathing becomes easier.
- In 2 weeks to 3 months, your heart attack risk begins to drop. Circulation improves and your lungs work better.
- In 1 to 9 months, coughing and shortness of breath decrease.
- In 1 year, your risk of heart disease has dropped to half that of a smoker's.
- In 5 years, your risk of stroke is the same as someone who doesn't smoke.
- In 10 years, your risk of dying from lung cancer is half that of a smoker's. Risk of heart attack falls to the same as someone who has never smoked. Your risks of certain types of bladder and kidney cancer also decrease.

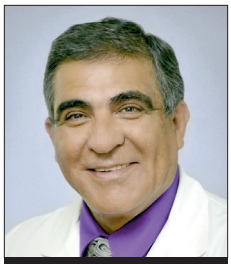
NEW WAYS FOR

Coping With Crohn's Disease

Biologics have been effective for many patients, but not for all. New drugs, with new mechanisms of action, promise more help and hope.

Crohn's disease is an inflammatory bowel disease (IBD) affecting the lining of the digestive tract, often spreading deep into the lining of the affected organ. The cause of the disease remains a subject of investigation. Research has confirmed that the GI-inflammation of Crohn's disease involves several factors: genetics, the patient's immune system and antigens in the gut environment.

Crohn's is considered a chronic disease, without cure. "But we *do* have an increasingly broad array of treatments that can alleviate patients' suffering in the long term, and even push the disease into remission," says Dr. Sunil Khurana, co-CEO of Premier Medical Group and director of the GI Division.



Sunil K. Khurana, MD, FACG

Among the newest medications available are the so-called biologics. Infliximab (Remicade) was the first substance specifically approved (in 1998) for the treatment of Crohn's disease. It, and subsequent drugs, such as Humira and Cimzia, target and suppress tumor necrosis factor (TNF), a protein implicated in creating the inflammation responsible for many of the most debilitating symptoms of Crohn's disease.

These biologics have been shown to be highly effective for many patients, inducing remission and maintaining it for periods of a year or longer. In some of our patients, however, we observed a strong initial response to therapy that diminished over a period of maintenance treatment. Initial research suggested two main potential causes for this phenomenon.

It was possible that non-responding patients were mounting an immunogenic response against the TNF agent, creating antibodies against the antibodies. To combat this, we now prescribe concurrent immunomodular therapy for the majority of patients taking anti-TNF drugs.

It was also possible that some patients were metabolizing the drug in a manner that made them unable to maintain the proper level of the drug in their bloodstreams. "Among the most exciting recent developments in our field is the new ability to measure the level of a drug in a patient's body and determine whether he or she is receiving the right dose for their condition," says Khurana. Before the advent of therapeutic drug monitoring, "Everybody started with the same dosage at a set interval. If the patient did not respond to those drugs, we would arbitrarily change the dosage, hoping that there would be a positive response. Now we can accurately measure the levels in patients and fine-tune dosages to their specific needs." What this also means is that we may find success with these drugs in patients who were originally unresponsive.

The GI-inflammation of Crohn's disease involves several factors: genetics, the patient's immune system and antigens in the gut environment.

There are also significant new developments for Crohn's patients who have previously failed anti-TNF therapy with one or more drugs. In May, 2014, the FDA approved Entyvio (vedolizumab) to treat adults with moderate-to-severe forms of Crohn's disease. This humanized monoclonal antibody has a different mechanism of action than do TNF blockers. It targets proteins called alpha-4-beta-7 integrins, the molecules on inflammatory cells that cause them to adhere to the gastrointestinal tract.

Also promising for TNF-nonresponders, but still undergoing clinical trials, are monoclonal antibodies that target interleukin 12/23, T-cells that mediate the body's inflammatory pathways.

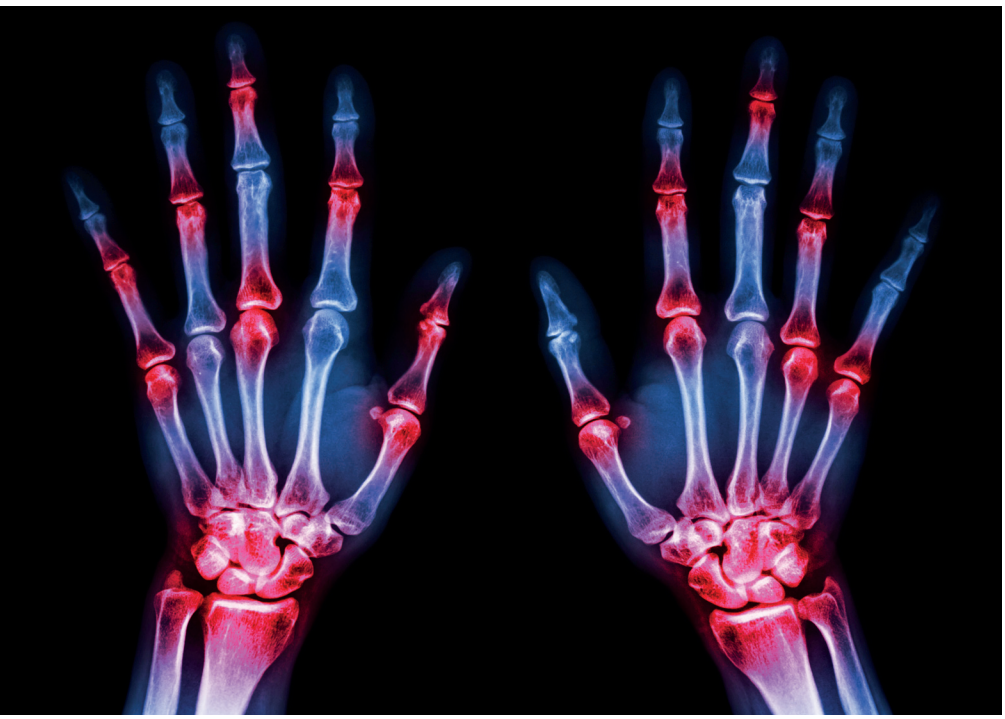
"Premier's Gastroenterology Division is deeply involved in a number of clinical studies designed to test drugs whose mechanism of action is different than recently approved drugs such as Remicade and Humira. We are doing research that will ultimately help our Crohn's disease patients," says Khurana. "Research is important to the development of new, safe medications with better efficacy. Without it, we would not have any medical advances and nothing new to offer the people who turn to us for help, and hope."

Introducing Premier Medical Group's New Rheumatology Division

There are 46 million adults in the U.S. with a rheumatic disease. Rheumatologists are the specialists who can diagnose and help them manage their conditions.

In early August, Premier brought Dr. Farah M. Ashraf aboard to lead its new Rheumatology Division."Dr. Ashraf is a very well established and respected doctor in the community," says Dr. Evan Goldfischer, co-CEO of Premier. "She provides expert, long-term, personal, compassionate care to all of her patients. We're excited that she and her staff have joined our group."

Among the many reasons Ashraf and her practice chose to become part of Premier is its excellent administrative support in dealing with insurance carriers and new government requirements.



Rheumatoid arthritis, affecting approximately 1.3 million people in the U.S., inflames the lining of the body's joints, resulting in pain, stiffness and swelling, most often of the hands and feet.

"It frees us up to focus even more of our attention on our patients than we were able to as a private practice," she says.

"I also am very well acquainted with many of the Premier physicians and staff, whom I have known for a number of years. We share their commitment to provide outstanding patient care and support. In just the few short months since we came under the Premier umbrella, everyone has gone out of their way to extend their welcome and assistance to my staff and to me. We are excited to be here and add a new dimension to Premier as the Rheumatology Division."

What Are Rheumatic Disease and Rheumatology?

An estimated 46 million adults suffer from rheumatic diseases in the United States. These are complex autoimmune and inflammatory diseases that cause the immune system to attack and damage the joints, tendons, ligaments, bones, muscles and sometimes involve damage to internal organs. They cause pain, inflammation, life-changing disability and, in severe cases, can cause or contribute to death. There are more than 100 types of rheumatic disease, each with its own range of symptoms. Rheumatic diseases are responsible for 27 percent of all disability among the U.S. population.

Osteoarthritis is the most prevalent form of arthritis, affecting an estimated 27 million adults. It damages cartilage in joints, causing pain and stiffness and results in disability when it affects the spine, knees or hips. Rheumatoid arthritis, affecting approximately 1.3 million people in the U.S., inflames the lining of the body's joints, resulting in pain, stiffness and swelling, most often of the hands and feet.

Other rheumatic diseases are less well-known by the public, but even more prevalent than some forms of arthritis. One of these is fibromyalgia, estimated to affect 5 million Americans 18 years of age or older. This chronic disorder causes pain throughout the tissues of the muscles that support and move bones and joints. Pain and stiffness occur in the muscles and tendons, especially in the neck, spine, shoulders and hips.

Gout, a type of episodic arthritis caused by needle-like crystals of uric acid deposited in the joints, creates exquisite pain during an attack, which can last for days or weeks. The crystals cause episodic inflammation, swelling, and pain in the affected joint, which is often the big toe. Although not well-known or understood by the public, an estimated 6 million adults age 20 and older have attacks of gout at some point in their lives.

Some individuals are born with a genetic predisposition to get a rheumatic disease, but the disease may not appear until triggered by something else, such as a cold or other virus. An individual's gender

may make them more susceptible to certain rheumatic diseases. For instance, statistically, women are more susceptible than men to lupus, rheumatoid arthritis and other rheumatic conditions, while men are more likely than women to contract gout.

Rheumatologists are the experts in the diagnosis and treatment of all the types of these painful and often damaging rheumatic diseases. Highly-trained internists, rheumatologists are board-certified specialists qualified by additional training and experience to quickly diagnose and treat all types of rheumatic disease soon after the onset of symptoms. Treatment early in the disease can dramatically improve the patient's prognosis and quality of life by preventing joint and organ damage, which in turn improves long-term function and improves the probability of the disease going into remission.

MEET DR. FARAH M. ASHRAF, DO, DIRECTOR OF PREMIER MEDICAL GROUP'S RHEUMATOLOGY DIVISON.

Farah M. Ashraf, DO

What drew Dr. Ashraf to choose rheumatology as her specialty is the multifaceted, systemic nature of rheumatic diseases. "They fascinate me," she says. "No two individuals' bodies react the same way to a particular rheumatic disease. Each person presents with different symptomology. Every day is a challenge."

Although the diseases are incurable, says Ashraf, the good news is that with appropriate treatment, the majority of these diseases go into remission.

Treatment management for rheumatic diseases is life-long. "The specific protocol we devise for each patient is, therefore, long-term care," says Ashraf, who keeps a close watch on the individual and monitors the effects of the regimen on him or her.

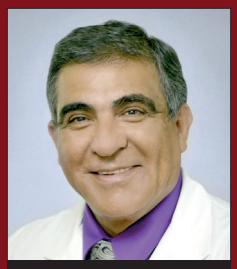
"Most of my patients come to see me for follow-ups every three months. I check to see how they are responding to medication, whether there are any side effects, and look into flare-ups that need to be controlled."

"My commitment is to be there for each of our patients, providing the compassionate, long-term, ongoing care and support that they need. And, if a patient must move out of the Hudson Valley, I will help in finding a new, top-notch rheumatologist in or near their new location."

Dr. Ashraf received her DO from the University of New England, College of Osteopathic Medicine in Biddeford, Maine. She is board certified in Rheumatology and in Internal Medicine, a Diplomate of the American Board of Osteopathic Medical Examiners and is affiliated with the American College of Rheumatology and the American College of Physicians.

Dr. Ashraf's paper on "Gender Specific Differences In the Treatment Outcomes In Polymyalgia Rheumatica," was published in *Arthritis & Rheumatism*, an official monthly journal of the American College of Rheumatology (ACR) in 2000 and the abstract was presented at the ACR later that year.

Teaching Days



Sunil K. Khurana, MD, FACG

"Patients should expect medical practitioners in whom they place their trust to be aware of the latest advances and treatment options in their fields," says Dr. Sunil Khurana, co-CEO of Premier Medical Group. "To ensure that Premier's doctors and clinical staff remain at the leading edge of practice, we hold Teaching Days that deliver information about new developments and how these affect clinical care, diagnosis and treatment."

The annual Teaching Days are open to all area physicians and allied personnel. Organized by Premier Medical Group and Vassar Brothers Medical Center, these advanced professional conferences include presentations by renowned specialists. Course participants receive continuing education credits in their fields.

Urology Teaching Day, May 22, 2014, was held at Villa Borghese in Wappingers Falls. Designed for practitioners in family practice, internal medicine, oncology and urology, the presentations focused on the latest advances in clinical strategies for diagnosis, staging, treatment and follow up of bladder cancer.

This year's conference focused on bladder cancer, with a Bladder Cancer Overview by Dr. Naeem Rahman and presentations by Dr. Michael A. O'Donnell on Superficial Bladder Cancer, BCG Refractory Cancer; and Simon J. Hall on Surgical Approaches to Bladder Cancer. Robert Wild, Esq. presented on The Effect of the Affordable Care Act on Patient Care and Dr. Paul Schellhammer spoke on Treated to Target: A Personal Experience with Prostate Cancer.

Gastroenterology Teaching Day, September 17, 2014, was held at The Grandview in Poughkeepsie. The course was designed for gastroenterologists, hepatologists, family practitioners, surgeons and other health care professionals who care for patients with gastrointestinal and hepatobiliary diseases.

This year's conference presented Dr. Lawrence J. Brandt on C. difficile Infection and Fecal Microbiota Transplantation; Dr. Robert Cowles on Comprehensive Management of Short Bowel Syndrome; Dr. Steven L. Flamm on New Treatments for Hepatitis C; Dr. John E. Pandolfino on High-Resolution Manometry; and Dr. Ellen J. Scherl on IBD: Impact of New Therapies on Old Strategies.

SAVE THE DATE

April 30, 2015

(Patch Adams) Agencia Andes

Patch Adams Comes To Poughkeepsie

"Next year's Urology Teaching Day will not only cover new discoveries and treatment modalities to benefit patients," says Dr. Goldfischer, co-CEO of Premier "it will also focus on doctor-patient relationships. How we relate to the people in our care can be crucial to successful treatment. We are bringing in the leading expert to address this issue: Dr. Patch Adams."

A FRESH APPROACH TO

Peyronie's Disease

Premier Medical Group offers a newly approved, non-surgical treatment for this distressing male urological condition.

In 1743, Francois Gigot de la Peyronie, surgeon to Louis XV of France, described the condition of penile curvature in a medical treatise. Some 270 years later, the condition, Peyronie's Disease (PD), has taken his name but a definitive explanation of its cause has not yet been determined.

At least three percent of adult males, mostly between the ages of 40-60, suffer from Peyronie's Disease. It is far more than a cosmetic problem as severe PD can cause pain upon erection or prohibit intercourse. PD can worsen over time, causing greater and greater degrees of curvature, leading to erectile dysfunction as well as shortening and disfigurement of the penis.

Recent research exploring the causes of PD focus on it being an autoimmune disease or the result of vascular trauma or injury to the penis, through sexual activity, sports or accident. Even minor traumas can result in microscopic damage to vessels and tissues and, over time, result in a hard scar tissue (plaque) build up in the tissue of the tunica albuginea, a thick, elastic membrane in the penis that is involved in maintaining an erection. The plaque deposits decrease the elasticity of the penis and lead to the characteristic curvature of PD.

Until recently, options for correcting moderate to severe PD were limited. "All physicians could offer were off-label use of medications that produced varying degrees of response, or surgery, which was the only way to really fix the problem," says Dr. Evan R. Goldfischer, co-CEO of Premier. "Now, with Xiaflex, there is a new FDA-approved prescription medication that is an exciting, significant development in PD treatment."

Xiaflex—comprised of the enzyme collagenase clostridium histolyticum—serves to weaken and break down the plaque responsible for the penile curvature of PD and has been shown to aid in straightening of the penis for many patients. The medication protocol promises an alternative to major surgery and has the benefit of being performed in the physician's office.

Evan R. Goldfischer, MD, MBA, FACS, CPI, CPE

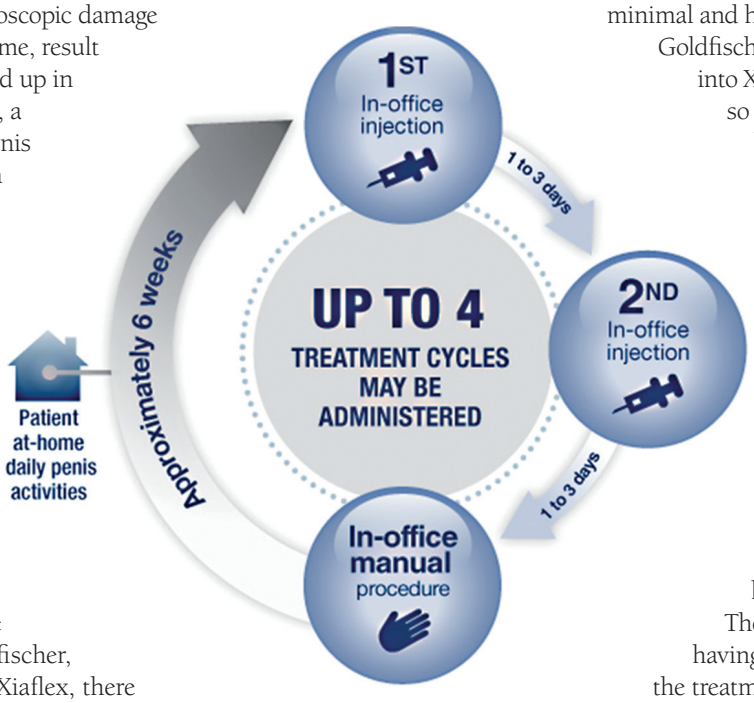
Xiaflex can only be administered by a physician specifically trained in the process. Its use is restricted to adult men with PD who have a plaque that can be felt by palpation and a curve in the penis greater than 30 degrees at the time treatment is initiated.

The protocol consists of direct injections of Xiaflex into the plaque in the penis. The physician helps the process of plaque break down through massage and stretching of the treated area and the patient follows a daily regimen of exercises to aid straightening of the curvature.

"So far, the side effects we've seen have been minimal and have been well tolerated," says Goldfischer. "We are only several cycles into Xiaflex treatment for our patients, so it's too early to say that we've had success. What I can say is that our patients tell us they are very happy."

Xiaflex is expensive. A full course of treatment can require multiple injections and take up to 16 weeks. "Working in concert with our representative in the field, we have been able to arrange third-party reimbursement for every vial our PD Xiaflex patients have needed," says Goldfischer. The medication is still new, having received FDA approval for the treatment of PD in 2013, but it is expected to be covered by most major insurance companies in the near future.

"We hope that this non-surgical treatment, administered in the doctor's office with the very good results we're seeing thus far, will induce other patients with PD to come to us earlier for treatment. To be able to take away their physical pain and the psychological pain of being completely unable to have intercourse makes us happy and we think the patients and their partners will be, too."



(Chart) Courtesy of Xiaflex

A Constellation of Causes

A 53-year-old male presents to the emergency department complaining of severe mid-epigastric (immediately below the ribs) abdominal pain that feels like it is radiating directly through to his back. Patient is vomiting with some regularity, but does not have fever or chills.

Robert S. Dean, MD

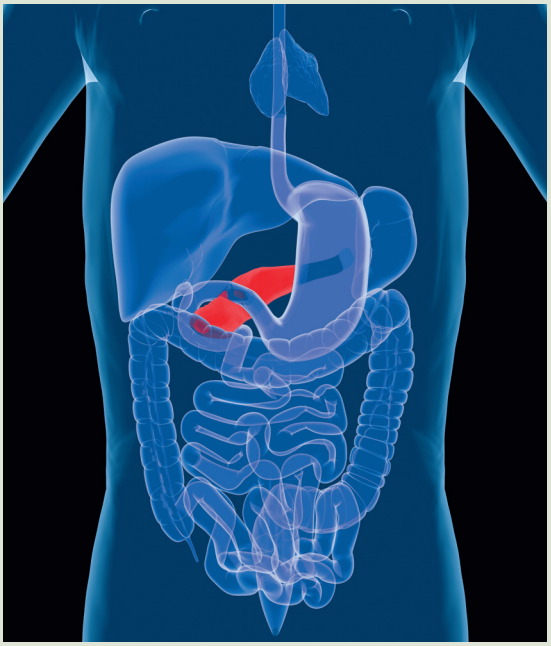
PERTINENT HISTORY

The gentleman has had prior diagnoses of adult onset diabetes, hypertension, hyperlipidemia and asthma that has, on occasion, required steroid therapy. His family history includes diabetes, hypertension, coronary artery disease and gallstones.

Patient says he is a regular alcohol user but that he has never missed work as a result or needed any formal intervention for alcohol use.

DIAGNOSIS

A blood panel provided pertinent readings of white blood cell count, mean corpuscular volume, albumin, lipase, amylase, etc. An abdominal ultrasound revealed the presence of gallstones but a normal common bile duct.



The location and intensity of the pain plus the elevated amylase/lipase readings were classic diagnostic markers.

With the information available through patient's symptoms and test results, one can safely say the patient has acute pancreatitis. The location and intensity of the pain plus the elevated amylase/lipase readings are classic diagnostic markers. Amylase and lipase are pancreatic enzymes involved in digestion. High levels of these are released and detectable in the blood when the pancreas is damaged. The digestive enzymes are usually active only when they reach the small intestines; if they become active inside the pancreas, they start digesting the tissue, causing swelling, bleeding and damage to the organ and its blood vessels.

The patient, in fact, had a constellation of conditions and behaviors that made acute pancreatitis a likely diagnosis. Statistically, the two most common causes of pancreatitis are alcohol abuse, and a migrated gallstone causing obstruction of the pancreatic duct. Abnormal liver tests suggested the patient had more profound alcohol abuse than he described. For patients in whom alcohol consumption is the cause, developing acute pancreatitis typically requires having 5 to 8 drinks per day over the course of five or more years.

Biliary, or "gallstone" pancreatitis was suggested by the results of the ultrasound. Even though the CBD reading was "normal," ultrasound misses stones within the CBD 66 percent of the time. The patient's history of asthma and hypertension were also suggestive because commonly used medications for these conditions, such as thiazide diuretics, or prednisone, may induce acute pancreatitis.

Nevertheless, none of these very valid considerations led to the cause of acute pancreatitis in this patient. The patient's history of diabetes and hyperlipidemia were the key clues. This individual had a fasting serum Triglyceride level of 2782. He developed acute pancreatitis due to hypertriglyceridemia, most likely acquired through genetics. His other medical issues are significant, but did not cause his acute pancreatitis.

TREATMENT

The initial treatment of acute pancreatitis is primarily bowel rest (stopping food by mouth to limit the activity of the pancreas), intravenous fluid replacement and pain control with intravenous analgesics. Of course, identification and treatment of the underlying cause of the acute pancreatitis is a cornerstone of therapy and necessary to avoid recurrence.

The prognosis for this patient, as for most with acute pancreatitis was very good. Eighty percent of patients recover in three to five days and experience no complications. For those twenty percent who have moderate to severe acute pancreatitis, secondary complications may occur with long-term and potentially serious consequences.

Overactive Bladder

Two classic cases of overactive bladder, two different treatments.


Daniel Katz, MD, FPM-RS

A 20-year-old woman came to see me complaining of urinary urgency and frequency. The need to void every 30-60 minutes, day and night, had become debilitating. Exhausted from waking so many times each night, she was unable to finish school or to hold a job.

PATIENT HISTORY & EXAM

Patient reports having experienced urinary urgency and frequency from early adolescence, needing to void hourly. At age 12 she consulted a pediatric urologist for a history of bed wetting. She was prescribed a series of kegel exercises to strengthen her pelvic floor muscles, which help contol urine flow. She reports experiencing no benefit and having given up treatment in frustration.

At her first visit, I took the patient's full medical history and performed a thorough evaluation. Other than chronic constipation, the urinary complaints and occasional migraine headaches, she was healthy.

The results of a full medical workup—including pelvic, rectal and neurological exams—show patient to be normal in all aspects. Her urine is clear, with no evidence of blood or infection and an ultrasound bladder scan after voiding shows no urine retained in her bladder.

THE DIAGNOSIS

With tests revealing the absence of pathological or metabolic conditions that might contribute to the patient's problems, her symptom complex points to a diagnosis of ideopathic Overactive Bladder (OAB). Though frequency, generally described as voiding more than 8 times per day, is common in OAB, the defining characteristic of the condition is urgency, the compelling need to urinate.

TREATMENT

The patient had failed conservative therapy using pelvic floor exercise alone, so we introduced medical therapy and reeducated her in how to perform kegel exercises. Patient was started on classic anticholonergic therapy to block the action of the neurotransmitter that was making her bladder contract so frequently. One month later, patient reported minimal improvement of urinary symptoms and complained of worsening constipation.

Constipation is a relatively common side effect of anticholonergic drugs, so patient was switched to a beta-adrenergic medication. Within weeks, patient reported her urinary symptoms had improved; she was able to go two hours without voiding and woke only once or twice a night. We increased the medication dosage and, one month later, patient reported voiding every three to four hours and only once at night. She was able to return to school and obtained her bachelors degree. She maintains this regimen today, and is satisfied with the results.

SAME PROBLEM, DIFFERENT SOLUTION

A patient in her late 40s presented with similar complaints after some years of experiencing OAB symptoms. Testing showed that she, too, was normal in all aspects. But after several classic therapeutic approaches, the patient's symptoms had still not resolved and she was severely troubled by both frequency and leakage.

A urodynamic test administered to evaluate bladder function showed patient's bladder was contracting against her will whenever even a small volume of urine was present.

We discussed various additional options that were open to her to address this problem, including neurostimulation and botox injection. The patient expressed her desire for the most permanent solution available and so we settled on implantation of a neurosacral modulator—a system that sends electrical pulses to an area near the sacral nerve, regulating neural activity affecting the bladder and lower urinary tract.

TREATMENT

To test the potential efficacy of the treatment for this patient, she was fitted with an external pacemaker and wires temporarily placed near the sacral nerve. Four days later, patient reported a complete cessation of symptoms. She underwent the **permanent Medtronic Interstim Neuromodulator implantation surgery** and her symptoms continue to be abated.

PREMIER OFFERS PTNS TREATMENT FOR OAB

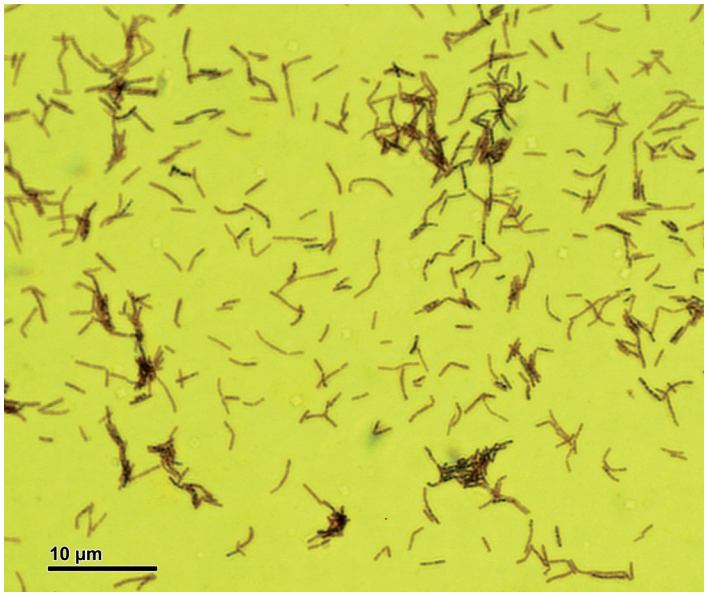
Percutaneous tibial nerve stimulation (PTNS), a non-drug, non-surgical modality may provide positive results in patients with OAB who don't respond to medication. During a series of 30-minute treatments, mild electrical impulses are sent from an electrode placed near the ankle, along the leg and to the nerves in the pelvis that control bladder function. Ask your urologist if PTNS might be helpful for you.

THE PROMISE OF

Probiotics

Farshad Elmi, MD, FACG

Living microorganisms in foods and supplements may provide health benefits. The challenge is in discovering which ones to use.



The gut bacteria Lactobacillus acidophilus viewed through a microscope at 3,000X magnification.

The average person has several trillions of microorganisms which inhabit their body and particularly the gut. Most of these microorganisms are bacteria but they also consist of other organisms, such as yeast. This community of microorganisms is called the "human microbiome." Probiotics are living microorganisms in food and dietary supplements which may promote our well-being.

Research is making it increasingly clear that the microbiome plays a significant role in our health. Studies also indicate that probiotics may provide benefits to the microbiome and, consequently, to an individual's health.

"For instance, they improve the intestinal barrier function to make it resistant to harmful organisms and toxins. They also suppress the growth of other pathogenic bacteria in our gut," says Premier gastroenterologist Dr. Farshad Elmi. "Probiotics also promote the production of cytokines—proteins secreted by immune cells that act on other cells to coordinate appropriate immune responses. There is data that indicates probiotics may modulate pain perception in our guts."

"Although probiotics have been around for years, in the form of active live cultures in yogurt, for example, we have done systematic research on them only over the past two decades," Elmi says. "There is still not enough data for blanket medical approval of their use as a treatment for every illness. In fact, none of the probiotics are considered as a standard care or primary treatment for any gastrointestinal illnesses."

Neverthless, probiotics have become big business. "We are having difficulty keeping pace with the probiotics industry's rate of growth. It is outstripping the speed with which scientific research can verify the probiotic products and their benefits," Elmi says. "Scientists are calling for more studies to help determine which probiotics are beneficial and which might be a waste of money."

Research Leads the Way

There are some good studies showing that certain specific conditions, such as infectious diarrhea, warrant the use of probiotics. "It has also been proven that people on antibiotics who are at increased risk of getting Clostridium difficile (C. diff.)—a bacteria that can overgrow in the gut after using antibiotics, leading to serious infection—benefit from the administration of probiotics, as do children and infants who come down with viral gastroenteritis, or a rotovirus," Elmi says.

Individuals who have had a total colectomy—removal of the entire large intestine—can experience inflammation of a surgically created pouch, which is called "pouchitis." "There is good data that probiotics work well to prevent this inflammatory condition," Elmi says.

It is difficult to ascertain which over-the-counter (OTC) supplements or foods contain the most beneficial type and amount of probiotics for a given condition. "Consumers should be aware that although probiotics are available over-the-counter and considered a safe supplement," Elmi says, "they are not always safe for individuals who have underlying immune deficiencies, as can be the case with the elderly or people who receive chemotherapy."

Probiotics are dietary supplements and are not regulated by the FDA. The cost of these medications is not reimbursed by most medical insurances. Available data in support of probiotic use are mostly based on small studies, many of which have important methodologic limitations. Given these circumstances, Elmi carefully considers a patient's primary disease, available medical treatment options and the patient's comorbidities before deciding to use probiotics. "Our medical knowledge about the benefits of probiotics is evolving and as more research comes out, we'll have more data on the benefit and shortcoming of probiotics to share with our patients," says Elmi. "We have a lot to look forward to from coming scientific studies."

PROBIOTICS HAVE POTENTIAL. THEY MAY:

- Modify the immune system to supress inflammation.
- Prevent growth of harmful bacteria in the gut.
- Strengthen the intestinal barrier function to resist harmful bacteria and toxins.

Some of our 75 dedicated Premier Cares Foundation volunteers take a moment to smile for the camera at the Walk's Registration Table.

5th Annual

Prostate Cancer Walk

The Premier Cares Foundation's signature fundraisers provide the means to help patients in the Hudson Valley get the care they need for their urological and gastroenterological illnesses.

September 27, 2014

It was a glorious fall day for the Fifth Annual Premier Cares Foundation Prostate Cancer Walk. More than 500 adults and children from across the Hudson Valley, as well as the greater New York City area, Albany and Connecticut turned out to stride across the Walkway Over the Hudson in support of the event.

"We all had a magnificent morning filled with sunny skies and a view of the changing leaves, lovely bagpipe music, and that palpable feeling that, together, we were making a difference in the lives of those individuals touched by prostate cancer," says Julie Goldfischer, Executive Director of the Premier Cares Foundation.

The Amerscot Highland Pipe Band, event Grand Marshall Jim Kiseda and keynote speaker Frank Hildenbrand, both from the Men2Men Prostate Cancer Support Group, got the event off to a brisk start, leading the walkers over the bridge. Participants enjoyed breakfast refreshments, the opportunity to interact with 18 different vendors and were invited to to try out the Da Vinci Robot, the latest development in robotic surgery.

The Prostate Walk is the Foundation's biggest fundraiser of the year, taking nearly one year to plan and 75 volunteers—mostly community members and Premier Medical Group volunteers—to bring to fruition. "They are all so dedicated. Some of our volunteers have been involved since the first walk five years ago," says Goldfischer.

"We are deeply grateful to everyone who supported this event – our 96 sponsors and the vendors, fundraising teams, volunteers, the Men2Men Prostate Cancer Support Group and the many families and friends who came out to show their support. Because of their generosity, we raised $100,000."

Funds raised by the Prostate Walk will help support local charities and prostate programs to offer free screenings and supportive services for patients right here in the Hudson Valley.

NY Giants Superbowl Champion, Bart Oates, poses with fans and autographs footballs.

Grand Marshal, Jim Kiseda and Board members of Premier Cares Foundation get ready to start the walk.

SAVE THE DATES

December 6, 2014

4th Annual Premier Cares Foundation Celebrity Chef Fundraising Dinner

For those who reserve a place at the Fourth Annual Celebrity Chef Fundraising Dinner, December 6th will be a night to remember.

Master Pastry Chef Jacques Torres, aka "Mr. Chocolate," will create an unforgettable evening featuring four delectable courses—each infused with his passion for chocolate—paired with the perfect wines. Chef Torres will regale guests with tales of his culinary adventures while they experience his traditional French techniques in the form of luxe, creative and edgy chocolate-tinged creations.

The event will again be held at the Poughkeepsie Tennis Club, beginning with cocktail hour at 6pm, followed by dinner from 7pm to 10pm.

Space is limited and, as with previous years, the dinner is likely to sell out. Reservations are available online at: www.premiercaresfoundation.org.

March 15, 2015

4th Annual "Challenge Your Colon" Chili Festival

A yearly Colon Cancer Awareness Month tradition in the Hudson Valley, the Festival brings together dozens of restaurants and groups from across the region. Each one vies for the Premier Award for Best Chili, chosen by judges from the Culinary Institute of America and the People's Choice Awards, chosen by attendee ballots.

Last year, more than 500 people came to the event, raising over $50,000 to help Hudson Valley residents with gastrointestinal or urologic conditions manage their disease and its treatment.

"We're hoping for an even bigger turnout this March," says Julie Goldfischer, Premier Cares Foundation Executive Director. "We're excited to be holding the event at the beautiful Villa Borghese in Wappingers Falls, and we anticipate more great vendors to join us. Plus, for the first time, we'll be holding a contest for vegetarian chili!"

Last year's winners include:

Arlington Fire Department – *Premier Award for Best Chili*;
The Artist's Palate – 1st Runner-up; Lola's Cafe – 2nd Runner-up.
Cosimo's –*People's Choice Award for Best Chili*;
Arlington Fire Department—Runner-up.
Mill House Brewing Company—*Best Cornbread in 2 categories* (Premier Award and People's Choice).
My Brother Bobby's Salsa—*Table with Best Country Attire.*
Cosimo's—*Table with Best Country Flair.*

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Circumcision: A Parent's Decision

Praneeth Vemulapalli, MD

Parents should weigh the benefits and risks of circumcision in light of their own religious, cultural, and personal preferences, as well as the medical considerations.

"Choosing to circumcise or not to do so is an intensely personal decision," says Dr. Praneeth Vemulapalli, of Premier's Urology Division. "We recommend that it be a fully informed choice that includes discussion of the most recent data and guidance."

Male circumcision, the complete or partial surgical removal of the foreskin of the penis, is one of the oldest known surgical procedures, long performed for religious, cultural and social reasons. Currently, approximately 58 percent of American parents choose to circumcise their male infants.

In the 1960's, circumcision of male infants was performed to a far greater extent than it is now, with over 80 percent of infants undergoing the procedure. In recent decades, however, the practice has become somewhat controversial.

Some opponents of circumcision find it unnecessary or disfiguring and claim that it ultimately interferes with male sexual pleasure. Ethically, they believe circumcision should not be imposed on the infant but be a decision made by the individual himself later in life.

Male circumcision, the complete or partial surgical removal of the foreskin of the penis, is one of the oldest known surgical procedures, long performed for religious, cultural and social reasons. Currently, approximately 58 percent of American parents choose to circumcise their male infants.

The Latest Research

The most recent evaluations of circumcision by research teams for The American Academy of Pediatrics and for the American Urological Society find that neonatal circumcision offers significant potential health benefits while risking generally minor complications.

In May 2014, the *Mayo Clinic Proceedings* published an analysis concluding that, over a man's lifetime, the benefits of circumcision exceed the risks of the procedure by at least 100 to 1.

The study found that circumcision continues to protect a man from numerous conditions throughout his lifetime, ranging from uncomfortable to life threatening, and that "half of uncircumcised males will require treatment for a medical condition associated with retention of the foreskin."

One of the potential protections is against urinary tract infection (UTI). "Uncircumcised infants and children are more likely to develop urinary tract infections, which can affect the penis, urethra, bladder and kidneys," Vemulapalli says. If the UTI progresses into the kidneys, pyelonephritis, a potentially life-threatening type of renal infection may result.

Not only does circumcision protect against a number of foreskin-specific infections and conditions, circumcised men also have fewer instances of penile cancer and sexually-transmitted diseases (STDs), such as syphilis and HIV.

Conversely, an uncircumcised male's female partner is more likely to contract cervical cancer, chlamydia—a common STD that can permanently damage her reproductive system—and herpes simplex virus type two, an incurable, life-long STD.

"Fewer than three percent of men choose to have a circumcision later in life unless they are having penile medical problems," says Vemulapalli.

"We often see these in elderly, uncircumcised men who can no longer properly clean themselves, which can lead to balanitis, swelling of the foreskin and head of the penis. In this case, we surgically create a dorsal slit in the foreskin to allow ease of cleansing."

"We also see diseases in young men," says Vemulapalli. "An uncircumcised patient in his early 20s came in with a foreskin abnormality that turned out to be penile cancer—very rare in the U.S."

"Whether or not you are circumcised," says Vemulapalli, "if you have a problem or feel that something is not right, come in to get evaluated. The earlier you attend to the issue and begin treatment, the better the outcome is likely to be."

State-of-the-Art

A joint venture by Premier and Vassar Brothers Medical Center provides the community a new endoscopy suite that takes patient comfort and security to a new level.

Aesthetically, the lighting is brighter, the colors and furniture are more pleasant and the space is oriented toward the Hudson River, with floor to ceiling windows that provide a gorgeous view of the water and the hills beyond.

Several years ago, Premier Medical Group and Vassar Brothers Medical Center entered into a joint venture to create a new, larger, state-of-the-art endoscopy suite. "This is the first time such a venture has been undertaken between a medical group and a hospital in Dutchess County," says Dr. Sunil K. Khurana, co-CEO of Premier.

"The joint venture between Vassar Brothers and Premier is a new way for both entities to better serve the community," says Ann McMackin, Vice President of Operations, Vassar Brothers Medical Center. "It's a natural fit. Premier and Vassar Brothers have an excellent, longstanding relationship with each other. The new endoscopy suite enables Vassar to have outpatient gastroenterology procedures, which was something we did not have in a big way in the hospital," McMackin says.

"On Premier's side," says Khurana, "we not only will be able to continue providing the safe, state-of-the-art services we always have, but we will be doing so under the auspices of the hospital. Now our patients can feel even more secure, knowing that when you partner with a hospital, as we have chosen to do, your practice is held to the highest standards, from anesthesia to pharmacy policies to every type of protocol. From a safety point of view, in the very unlikely case of an emergency, our patients will be inside the hospital within minutes, receiving all the care they might possibly need."

Patients will also have significantly more privacy. "Privacy is a big issue in medicine today," Khurana says, "and it was one of the major considerations in the design of the new suite." One of the ways the venture has provided more privacy is by making it spacious. The new suite is twice the size of Premier's current facility, with patient rooms, pre-op and recovery areas that are "much

more commodious," Khurana says. An in-suite conference room will enable doctors and staff to talk to patients, their families and caregivers, as well as meet with each other to discuss cases. "Our physicians will be able to talk to patients and their loved ones in complete privacy," he says.

The look and feel of the new suite were also important considerations. "We decided to pay close attention to the non-medical aspects of this suite, as well as the surgical ones," Khurana says. "We created a space in the suite where family can sit and wait in comfort. Aesthetically, the lighting is brighter, the colors and furniture are more pleasant and the space is oriented toward the Hudson River, with floor to ceiling windows that provide a gorgeous view of the water and the hills beyond. We designed it to be more soothing, more inducive to calm."

"I've been over to see the new suite, and it's breathtaking," says Judy Martinez, a Licensed Practical Nurse Associate who has been working with Dr. Khurana for over 30 years. "It's going to be exciting to work in the new space. For me, that's absolutely the best part of the transition."

The suite will be complete when Premier moves the equipment from its current location over to the new ambulatory surgery building on Lincoln Avenue, just next to the hospital. "Patients will really enjoy the convenience of having this so close to the hospital," says McMackin.

What won't be new about the suite are the doctors and staff Premier's gastroenterology patients deal with. "The suite will be managed by our group," Khurana says. "All Premier staff members with whom our patients are used to interacting—to make appointments, schedule procedures and work with when they come to see us will still be there, just in the new location. From the patient's perspective, nothing will change except that."

Dr. Khurana will be the Managing Partner of the facility. There will be an oversight board for the venture, which will include two representatives from Premier Medical Group and two from Vassar Brothers Medical Center's administration, including McMackin. The Board will be responsible for stewardship of finances, and ensure that the management team is functioning at the right level. "We've been meeting monthly for some time and we're confident that the arrangements suit all parties," says Khurana.

"Most large medical groups have their own ambulatory care center," says McMackin. "Here we have the hospital, which is responsive to the community, combined with Premier's topnotch physicians. It's really the best of both worlds, and so exciting to serve the community and work with Premier. It's a great opportunity to do both."

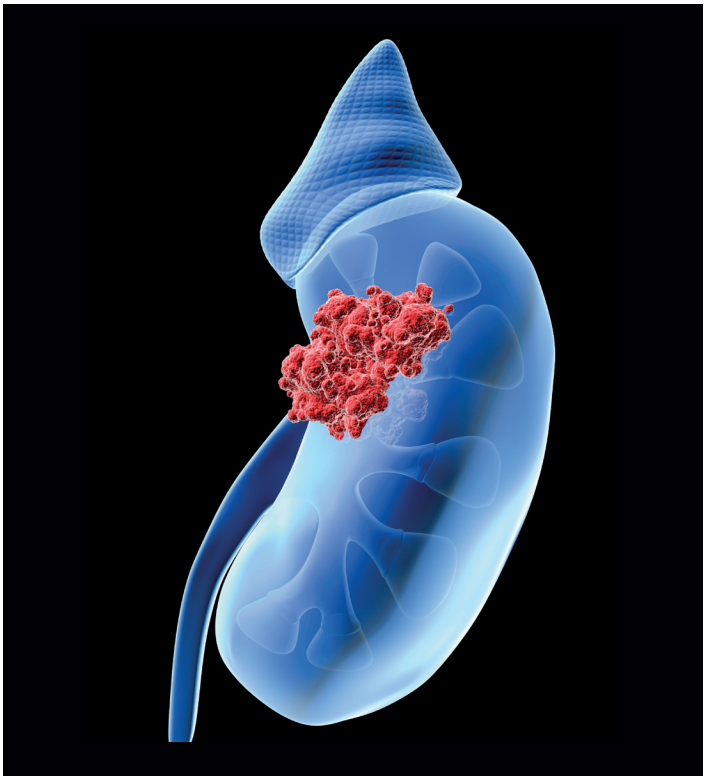
Early in 2015, there will be an open house on the first day the suite is officially in operation. "We will invite our patients to come and take a tour," says Khurana. "We're certain that everyone will be as thrilled as we are with our new space."

BREAKTHROUGHS IN TREATING

Renal Cell Carcinoma

Paul K. Pietrow, MD, FACS

A number of new medications are making our advanced kidney cancer patients more optimistic about their conditions.



When RCC tumors are found in the early stages, the cure rate is excellent, upwards of 90 percent. "We can makes such a difference," says Dr. Pietrow. "Between us, the surgeons of Premier offer a wide range of techniques."

Kidney cancer is one of the 10 most common cancers in the U.S.; according to estimates by the American Cancer Society, approximately 64,000 new cases of the disease will be diagnosed this year and about 14,000 people will die from it. Approximately 90 percent of kidney cancers are categorized as renal cell carcinoma (RCC).

In its early stages, RCC is usually asymptomatic. "The majority of patients have no idea that they have it," says Dr. Paul K. Pietrow, of Premier's Urology Division, a specialist in urologic and kidney cancers. "In fact, most masses in the kidney are picked up incidentally, by other physicians, during scans or procedures for another problem."

When RCC tumors are found in the early stages, the cure rate is excellent, upwards of 90 percent. "We can make such a difference," says Pietrow. "Between us, the surgeons of Premier offer a wide range of techniques. We perform minimally invasive robotic and laparoscopic surgeries, percutaneous cryotherapy (freezing the cancer cells), and thermal ablation (killing the cancer cells with heat without harming healthy cells.)"

Advanced kidney cancer, Stages III and IV, are more difficult to manage. In these stages, a patient is likely to experience symptoms, such as blood in the urine, flank pain, unexplained weight loss, severe fatigue or a long-term fever in the absence of infection. "It is, of course, vital to see your doctor if you have any of these symptoms," says Pietrow.

"Nine years ago there was only one therapy (Interleukin -2) available, which had only a modest benefit compared to newer drugs," says Dr. Naeem Rahman, a Senior Partner in Premier's Urology Division. Now, there are an increasing number of treatment options. "Between 2005 and 2013, two new classes of drugs were approved for treatment of RCC: mammalian target of rapamycin inhibitors (mTORs) and tyrosine kinase inhibitors (TKIs), both designed to target the vascular growth of RCC cells at the molecular level."

Not all patients will respond to a given medication, but with close to a dozen drugs now available in these classes, the likelihood of finding an efficacious medication has increased.

To expand and metastasize, malignant tumors must form new blood vessels through a process called "angiogenesis." TKIs and mTORS both interfere with the action of proteins in the tumor that are crucial to this process. These drugs are administered with the hope of slowing cancer growth and, in some cases, shrinking existing tumors. Results have been promising: Even in patients who have not experienced shrinkage of the tumor, the drugs have provided long periods of stable disease.

Not all patients will respond to a given medication, but with close to a dozen drugs now available in these classes, the likelihood of finding an efficacious medication has increased.

"These drugs are exciting," says Pietrow. "Targeting vessel growth is a very novel line of attack and has led to great strides in the treatment of advanced kidney cancer. There is also another new development showing, in early studies, great promise in combatting advanced RCC." Called "immune checkpoint blockade agents," these antibodies block substances produced by the tumor that serve to hide it from the body's immune system. Without this camouflage, the cancer cells become vulnerable to recognition and attack by the immune system.

Immunotherapy is currently being investigated and used to combat many forms of cancer; there are hundreds of clinical trials underway examining this avenue of treatment.

"Once it is firmly proven that these drugs expose the tumor cells to attack, we will finally have something truly efficacious," Pietrow says. "More breakthrough discoveries will come as a result. Our RCC patients already feel a lot more optimistic about their conditions."

For the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

For men with Peyronie's disease, there's good news: the only FDA-approved treatment option. XIAFLEX

Important Safety Information

WARNING: CORPORAL RUPTURE (PENILE FRACTURE) OR OTHER SERIOUS PENILE INJURY IN THE TREATMENT OF PEYRONIE'S DISEASE

Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX-treated patients in clinical studies. In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX-treated patients.

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention.

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX REMS Program.

- XIAFLEX is contraindicated in the treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure and in patients with a history of severe allergic reaction to XIAFLEX or to collagenase used in any other therapeutic application or application method
- Injection of XIAFLEX into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis
- In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease, a greater proportion of XIAFLEX-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX injection procedures). The incidence of XIAFLEX-associated pruritus was similar after each injection regardless of the number of injections administered
- Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. Although there were no severe allergic reactions observed in the XIAFLEX clinical studies (eg, those associated with respiratory compromise, hypotension, or end-organ dysfunction), an anaphylactic reaction was reported in a post-marketing clinical study in a patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture, demonstrating that severe reactions including anaphylaxis can occur following XIAFLEX injections. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections. The safety of more than one treatment course of XIAFLEX is not known
- In the XIAFLEX controlled trials in Peyronie's disease, 65.5% of XIAFLEX-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis. Patients with abnormal coagulation (except for patients taking low-dose aspirin, eg, up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin, eg, up to 150 mg per day) within 7 days prior to XIAFLEX administration is not known. In addition, it is recommended to avoid use of XIAFLEX in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin)
- In the XIAFLEX clinical trials for Peyronie's disease, the most frequently reported adverse drug reactions (≥25%) and at an incidence greater than placebo included: penile hematoma, penile swelling, and penile pain

Please see Brief Summary of full Prescribing Information, including Boxed Warning, on adjacent pages.

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XIAFLEX® (collagenase clostridium histolyticum) for injection, for intralesional use

Brief Summary of Prescribing Information

For complete information, see the full prescribing information for XIAFLEX.

WARNING: CORPORAL RUPTURE (PENILE FRACTURE) OR OTHER SERIOUS PENILE INJURY IN THE TREATMENT OF PEYRONIE'S DISEASE

Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX-treated patients in clinical studies. In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX-treated patients *[see Warnings and Precautions]*.

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention *[see Warnings and Precautions]*.

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX REMS Program *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

XIAFLEX is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

CONTRAINDICATIONS

XIAFLEX is contraindicated in:

- the treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure.
- patients with a history of severe allergic reaction to XIAFLEX or to collagenase used in any other therapeutic application or application method *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS

Corporal Rupture (Penile Fracture) or Other Serious Injury to the Penis in the Treatment of Peyronie's Disease

Corporal rupture was reported as an adverse reaction after XIAFLEX injections in 5 of 1044 (0.5%) XIAFLEX treated patients in the controlled and uncontrolled clinical trials in Peyronie's disease.

In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture can not be excluded. These patients were managed without surgical intervention, but the long-term consequences are unknown.

Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 patients (3.7%) in the controlled and uncontrolled clinical trials in Peyronie's disease *[see Adverse Reactions]*.

Signs or symptoms that may reflect serious injury to the penis should be promptly evaluated in order to assess for corporal rupture or severe penile hematoma, which may require surgical intervention.

Injection of XIAFLEX into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis.

XIAFLEX REMS Program

Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease, XIAFLEX is available only through the **XIAFLEX REMS Program** *[see Warnings and Precautions]*.

Required components of the **XIAFLEX REMS Program** include the following:

- Prescribers must be certified with the program by enrolling and completing training in the administration of XIAFLEX treatment for Peyronie's disease.
- Healthcare sites must be certified with the program and ensure that XIAFLEX is only dispensed for use by certified prescribers.

Further information is available at www.XIAFLEXREMS.com or 1-877-313-1235.

Allergic Reactions

In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease (Studies 1 and 2), a greater proportion of XIAFLEX-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX injection procedures). The incidence of XIAFLEX-associated pruritus was similar after each injection regardless of the number of injections administered.

Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. Although there were no severe allergic reactions observed in the XIAFLEX clinical studies (e.g., allergic reactions associated with respiratory compromise, hypotension, or end-organ dysfunction), an anaphylactic reaction was reported in a post-marketing clinical study in a patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture, demonstrating that severe reactions including anaphylaxis can occur following XIAFLEX injections. Some patients with Dupuytren's contracture developed IgE-anti-drug antibodies in greater proportions and higher titers with successive XIAFLEX injections. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections. The safety of more than one treatment course of XIAFLEX is not known.

Risk of Bleeding in Patients with Abnormal Coagulation

In the XIAFLEX controlled trials in Peyronie's disease (Studies 1 and 2), 65.5% of XIAFLEX-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis (see Adverse Reactions Table). Patients with abnormal coagulation (except for patients taking low-dose aspirin, e.g., up to 150 mg per day) were excluded from participating in these studies.

Therefore, the efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin, e.g., up to 150 mg per day) within 7 days prior to XIAFLEX administration is not known. In addition, it is recommended to avoid use of XIAFLEX in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin).

ADVERSE REACTIONS

The following serious adverse reactions in patients with Peyronie's disease are discussed in greater detail elsewhere in the labeling:

- Corporal rupture (penile fracture) and severe penile hematoma *[see Warnings and Precautions]*
- In other XIAFLEX-treated patients, a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded *[see Warnings and Precautions]*

Clinical Studies Experience in Patients with Peyronie's Disease

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

In the controlled and uncontrolled clinical studies of XIAFLEX in Peyronie's disease, 1044 patients received a total of 7466 XIAFLEX injections.

Corporal Rupture and Other Serious Penile Injury

- Corporal rupture was reported as an adverse reaction after XIAFLEX injections in 5 of 1044 (0.5%) XIAFLEX treated patients.
- In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. These patients were managed without surgical intervention, but the long-term consequences are unknown.
- Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 patients (3.7%) in the controlled and uncontrolled clinical trials in Peyronie's disease *[see Adverse Reactions]*.

The data described below are based on two identical, pooled, randomized, double-blind, placebo-controlled, multi-center trials through Day 365 in patients with Peyronie's disease (Studies 1 and 2). These trials included 832 patients of whom 551 and 281 received XIAFLEX and placebo, respectively. In these trials, patients were given up to 4 treatment cycles of XIAFLEX or placebo. In each cycle, two injections of XIAFLEX or two injections of placebo were administered 1 to 3 days apart. A penile modeling procedure was performed at the study site on patients 1 to 3 days after the second injection of the cycle. The treatment cycle was repeated at approximately 6-week intervals up to three additional times, for a maximum of 8 total injection procedures and 4 total modeling procedures *[see Clinical Studies in the full Prescribing Information]*.

The majority of Peyronie's patients experienced at least one adverse reaction (92% XIAFLEX-treated patients, 61% placebo-treated). Most adverse reactions were local events of the penis and groin and the majority of these events were of mild or moderate severity, and most (79%) resolved within 14 days of the injection. The adverse reaction profile was similar after each injection, regardless of the number of injections administered.

The most frequently reported adverse drug reactions (≥ 25%) in the XIAFLEX clinical trials in patients with Peyronie's disease were penile hematoma, penile swelling, and penile pain. The Adverse Reactions Table below shows the incidence of adverse reactions that were reported in greater than or equal to 1% of XIAFLEX-treated patients and at a frequency greater than placebo-treated patients after up to 8 injections in the pooled placebo-controlled trials through Day 365.

Adverse Reactions Occurring in ≥ 1% of XIAFLEX-Treated Patients with Peyronie's disease and at a Greater Incidence than Placebo After Up to Four Treatment Cycles in Studies 1 and 2 Combined

Adverse Reaction	XIAFLEX N=551	Placebo N=281
All Adverse Reactions	84.2%	36.3%
Penile hematoma[a]	65.5%	19.2%
Penile swelling[b]	55.0%	3.2%
Penile pain[c]	45.4%	9.3%
Penile ecchymoses[d]	14.5%	6.8%

Adverse Reactions Occurring in ≥ 1% of XIAFLEX-Treated Patients with Peyronie's disease and at a Greater Incidence than Placebo After Up to Four Treatment Cycles in Studies 1 and 2 Combined

Adverse Reaction	XIAFLEX N=551	Placebo N=281
Blood blister	4.5%	0
Penile blister	3.3%	0
Pruritus genital	3.1%	0
Painful erection	2.9%	0
Erectile dysfunction	1.8%	0.4%
Skin discoloration	1.8%	0
Procedural pain	1.6%	0.7%
Injection site vesicles	1.3%	0
Localized edema	1.3%	0
Dyspareunia	1.1%	0
Injection site pruritus	1.1%	0
Nodule	1.1%	0
Suprapubic pain	1.1%	0

[a] Includes: injection site hematoma and penile hematoma were reported with the verbatim term of penile bruising or injection site bruising in 87% of subjects.

[b] Includes: injection site swelling, penile edema, penile swelling, local swelling, scrotal swelling, and injection site edema.

[c] Includes: injection site pain, penile pain, and injection site discomfort.

[d] Includes: contusion, ecchymoses, penile hemorrhage, and injection site hemorrhage.

Severe penile hematoma or severe injection site hematoma were reported in 33/551 (6.0%) of XIAFLEX-treated patients and 0/281 (0%) of placebo-treated patients, in Studies 1 and 2 combined.

Reports of penile "popping" sounds or sensations

A popping noise or popping sensation in the penis, sometimes described as "snapping" or "cracking", and sometimes accompanied by detumescence, hematoma and/or pain, were reported in 73/551 (13.2%) XIAFLEX-treated patients and 1/281 (0.3%) placebo-treated patients.

There were no clinically meaningful differences in the incidence of adverse events following treatment with XIAFLEX based on the severity of baseline erectile dysfunction or concomitant phosphodiesterase type 5 (PDE5) inhibitor use.

XIAFLEX was not associated with shortening of penile length in clinical trials in the treatment of Peyronie's disease.

Immunogenicity

During clinical studies in Dupuytren's contracture and Peyronie's disease, patients were tested at multiple time points for antibodies to the protein components of XIAFLEX (AUX-I and AUX-II).

In the Peyronie's disease clinical studies, at 6 weeks after the first treatment cycle of XIAFLEX 0.58 mg, approximately 75% of patients had antibodies against AUX-I and approximately 55% of patients had antibodies against AUX-II. Six weeks after the eighth injection (fourth treatment cycle) of XIAFLEX, >99% of XIAFLEX-treated patients developed high titers of antibodies to both AUX-I and AUX-II. Neutralizing antibodies were assayed for a subset of 70 samples selected to be representative of high and low titer binding antibody responses at week 12 of treatment. For each subject in whom a Week 12 sample was selected, the corresponding Week 6, 18, 24, and 52 samples were assayed if they were also binding antibody positive. Neutralizing antibodies to AUX-I or AUX-II, were detected in 60% and 51.8%, respectively, of patients tested.

In patients treated for these two indications, there was no apparent correlation of antibody frequency, antibody titers, or neutralizing status to clinical response or adverse reactions.

Since the protein components in XIAFLEX (AUX-I and AUX-II) have some sequence homology with human matrix metalloproteinases (MMPs), anti-product antibodies could theoretically interfere with human MMPs. In vitro studies showed no evidence of cross-reactivity between anti-drug-antibody positive patient sera and a series of relevant MMPs. In addition, no clinical safety concerns related to the inhibition of endogenous MMPs have been observed.

Immunogenicity assay results are highly dependent on the sensitivity and specificity of the assay used in detection and may be influenced by several factors, including sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to collagenase clostridium histolyticum with the incidence of antibodies to other products may be misleading.

DRUG INTERACTIONS

Anticoagulant drugs: XIAFLEX should be used with caution in patients receiving concomitant anticoagulants (except for low-dose aspirin) *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

There are no adequate and well-controlled studies of XIAFLEX in pregnant women. Because animal reproduction studies are not always predictive of human response, XIAFLEX should be used during pregnancy only if clearly needed.

Risk Summary

Based on animal data, XIAFLEX is not predicted to increase the risk for major developmental abnormalities in humans.

Human Data

Human pharmacokinetic studies showed that XIAFLEX levels were not quantifiable in the systemic circulation following injection into a Dupuytren's cord.

Low levels of XIAFLEX were quantifiable in the plasma of evaluable male subjects for up to 30 minutes following administration of XIAFLEX into the penile plaque of subjects with Peyronie's disease *[see Clinical Pharmacology in the full Prescribing Information]*.

Almost all patients develop anti-product antibodies (anti-AUX-I and anti-AUX-II) after treatment with XIAFLEX, and the clinical significance of anti-product antibody formation on a developing fetus is not known *[see Adverse Reactions]*.

Animal Data

Reproduction studies have been performed in rats with intravenous exposures up to approximately 11 times the maximum recommended human dose (MRHD) of XIAFLEX on a mg/m^2 basis, and have revealed no evidence of impaired fertility or harm to the fetus due to collagenase clostridium histolyticum.

Nursing Mothers

It is not known whether collagenase clostridium histolyticum is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when XIAFLEX is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of XIAFLEX in pediatric patients less than 18 years old have not been established.

Geriatric Use

Of the 551 XIAFLEX-treated patients in the double-blind, placebo-controlled, clinical trials in Peyronie's disease (Studies 1 and 2), 100 (18%) were 65 years of age or older and 5 (0.9 %) were 75 years of age or older. No overall differences in safety or effectiveness of XIAFLEX were observed between these patients and younger patients.

OVERDOSAGE

The effects of overdose of XIAFLEX are unknown. It is possible that multiple simultaneous or excessive doses of XIAFLEX may cause more severe local effects than the recommended doses including serious adverse reactions in the injected area (e.g., tendon ruptures or corporal ruptures dependent on the injection site). Supportive care and symptomatic treatment are recommended in these circumstances.

Manufactured and distributed by:

Auxilium Pharmaceuticals, Inc.
Chesterbrook, PA 19087

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Innovations for Life®

XIAFLEX®
collagenase clostridium histolyticum

The Premier Patient Portal

The electronic health record system is streamlining medical care and giving patients access and input to the information that affects their health.

On August 1, 2014, the Premier Medical Group Patient Portal went live. With the Patient Portal, patients no longer have to wait in a phone queue just to request an appointment or get a copy of their medical records. Such requests can now be fulfilled online through Electronic Health Record (EHR) technology.

"Our Portal's technology is designed to improve the quality, safety and efficiency of our services, and empower patients to become more engaged in their health care," says Lorraine O'Donnell, Practice Administrator of the Urology Division. "For example, using the Portal enables a patient to share lab results and immunization records with providers in another practice, so that the individual does not have to undergo the initial tests again, or recite his or her innoculation history. As a result, the patient is more satisfied with their health care experience."

"Our Portal's technology is designed to improve the quality, safety and efficiency of our services, and empower patients to become more engaged in their health care."

"Another benefit of the Patient Portal is that it allows the individual's primary physician to send us a message with a patient's entire history, including radiology and office notes," says Debbie Cantamessa, Practice Administrator for the Gastroenterology and Internal Medicine Divisions. "This speeds up the process of receiving patient information that may affect how a physician treats the patient." The Portal also permits patients to update their own information. "So far, we've seen the majority of our patients using the Portal to update their employer information and other demographics, such as change of address, phone numbers, marital and employment status, and insurance," says Cantamessa.

"Thus far, there have been very few difficulties with the system," says Tony Alexander, Help Desk Analyst and Electronic Medical Record Administrator. "We've had only minor issues, such as resetting people's passwords or fixing prescription refill information. In part, we can attribute the lack of significant problems to the fact that many of our patients have had previous experience with electronic health records, so they already understand the benefits, such as using our secure, private messaging function to send messages to the practice. It's really a very simple system for both patients and medical staff to use. Our patients are happy with it."

"Still, it will take time for everyone to get on board," says Cantamessa. "So far, the patients who have joined the Portal say they love it. It's a great way for them to take ownership of their records."

Sign Me Up!

Signing up couldn't be easier. All you need is a valid email address and an Internet connection. To enroll, stop by the front desk and speak to any of our staff. They will enter your email address into the system and provide you a secure ID along with instructions on how to finish the enrollment process at home.

Manage Your Health Care Online, Anytime.

As a Premier Medical Group patient, you can use your secure password to log in to our online Patient Portal 24 hours a day, 7 days a week to:

- Request or cancel an appointment;
- View past and scheduled appointments;
- Request a prescription refill;
- Download copies of your medication lists or patient medication literature;
- Send a private, secure message to your health team;
- View your personal health information;
- Update your personal information;
- Update your medical and surgical history, allergy and medication information.

Premier Volunteers

Enacting a culture of caring... on and off the job.

Comfort Zone Camp (CZC)

Anne Mulvey, RN—Volunteer Nurse

Anne is one of the RNs of our Urology Division. She has been with the practice since August of 2012 and works in the Newburgh office. Anne also volunteers as camp nurse with a bereavement camp for children called Comfort Zone Camp.

Comfort Zone Camp (CZC) is a nonprofit bereavement camp whose mission is to provide grieving children with a voice, a place and a community in which to heal, grow and lead more fulfilling lives. Free of charge to children ages seven to 17 who have experienced the death of a parent, sibling or primary care giver, CZC, which has camp facilities around the country, holds three-day sessions in a fun environment, offering confidence building programs and age-based support groups that break the emotional isolation grief often brings.

Anne discovered CZC after she lost her youngest son in a tragic accident in April of 2012. That September Anne's son and daughter went to their first camp, and Anne describes the remarkable relief brought by seeing how the camp helped her children to share their burden of loss and aid them in their grief journey. "It is such a powerful thing to see a child who has discovered they are not alone in their struggle," Anne says. "To give a child the tools they need to cope with such devastation in a healthy way—it's invaluable."

Anne began volunteering with CZC this spring. "It's a blessing that I get to be a part of something so precious and needed. I believe that everyone should give back. I am so thankful that Premier, through its core values, supports my volunteer work with CZC so that I can give back."

To learn more about Comfort Zone Camp, become a donor or a volunteer, visit **www.comfortzonecamp.org** or feel free to contact Anne **amulvey@premiermedicalhv.com**

Operation Christmas Child

Judy Martinez, LPN—Volunteer Elf

Every October for the past seven years, as the autumn leaves reach peak color, Judy Martinez, a licensed Practical Nurse Associate in Premier's endoscopy suite, receives two boxes. "They are only the size of shoeboxes," says Judy, "one marked '10 – 14 Girl,' the other, '10 – 14 Boy,' but each one will make a tremendous difference in the life of the child who receives it."

The boxes, and what Judy and her colleagues in the endoscopy suite do with them is part of the world's largest Christmas project, "Operation Christmas Child." Run by Samaritan's Purse, a relief and Christian evangelism organization, the project collects and distributes gift-filled shoeboxes for needy children around the world. During the past 20 years, more than 113 million boxes have been distributed in over 130 countries.

"It's a massive undertaking," says Judy, who first became involved in Operation Christmas Child (OCC) through her local church, "but you don't have to be a church member in order to join OCC," she says. "Anyone can visit the organization's web site and order the shoeboxes," which arrive free of charge. OCC asks for a $7.00 donation per filled box to defray the cost of overseas shipping.

Santa's Helpers: Judy Martinez (front) and (left to right) Tricia Haggerty, Adele Lawler and Joy Jones

"We spend weeks buying and making just the right small gifts to fill each box to overflowing," Judy says. "Joy Jones, the suite's endoscopy technician packs them so everything fits in. We have about a month to get our part all done, and bring them to the Goodwill Church in Montgomery. Then the long journey begins."

"They are carried by camels, elephants and boats into the remotest of places," says Judy. "The level of poverty is astonishing. Most of the children who receive the Christmas boxes have never been given a present in their lives. I look at their faces and see their joy in knowing that someone they have never met cares about them. It's very rewarding."

To learn more about Operation Christmas Child, visit Samaritan's Purse at: **www.samaritanspurse.org/operation-christmas-child/frequently-asked-questions/**

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Faces of Premier

Good healthcare requires teamwork. We're proud of the dedicated staff that makes up the Premier Medical Group team.

Anne Clifford

Office Manager, Internal Medicine Division

"You wouldn't think that my retail management major in college could serve me well in the medical field," says Anne, "yet I've found it extremely beneficial."

Whether it's dealing with the myriad day-to-day matters she handles, such as purchasing new carpeting and appliances, overseeing the painting of a laboratory, dealing with payroll, patient issues or training new providers, "my management training and prior medical practice experience make all the difference."

Before she joined Premier Medical Group in 2010 as a staff supervisor for the practice's Urology Division, Anne spent a dozen years as a staff member in a smaller Internal Medicine group. "I joined Premier because I wanted the challenge of working in a larger practice, and I loved the close rapport among the staff," she says. "Plus, I was able to help build relationships with our patients. That's something that's particularly important to me."

Last January, when the Office Manager position opened up in the Internal Medicine Division, Anne applied for the post. "After so many years running an IM practice before I joined Premier, it felt more like home to me," she says.

Even though her new day-to-day work gives Anne less contact time with patients than before, she says she never forgets that each patient is an individual. "Today, with such large corporate medical practices, it is easy for a patient to come away feeling as though they are a just a number," Anne says. "I feel that here at Premier, we go above and beyond to consistently meet all of the patients' needs. They should always walk away from their visit feeling as though they've been given outstanding service."