



PANCREATITIS EXTERNALLY-LED  
 PATIENT-FOCUSED DRUG DEVELOPMENT MEETING

# NATIONAL PANCREAS FOUNDATION VOICE OF THE PATIENT REPORT

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## **Introduction**

The U.S. Food and Drug Administration (FDA) established the Patient-Focused Drug Development (PFDD) program to hear directly from patients and their caregivers. Patients and caregivers are the experts on their disease, and their insights can inform the design of clinical trials, including selection and development of measures of benefit, as well as the benefit/risk analysis that FDA review staff conduct when reviewing and considering the approval of a new drug. PFDD meetings focus on the patients' symptoms, the effects of the disease on daily life, and patients' experiences with available treatments. The National Pancreas Foundation (NPF), with support from partners Mission: Cure and Rebecca's Wish and the Familial Chylomicronemia Syndrome (FCS) Foundation, hosted an externally-led PFDD (EL-PFDD) meeting highlighting people living with pancreatitis as well as their caregivers. The meeting took place in Silver Spring, Maryland, on March 3, 2020, at the Silver Spring Civic Building. The information gathered at the meeting is presented in this Voice of the Patient report and may inform and impact decisions regarding FDA drug development and review and, ultimately, improve the overall quality of life for patients living with pancreatitis.

## **Overview of Pancreatitis**

Pancreatitis is an inflammatory condition of the pancreas which can be acute or chronic. It is a complex disease, with significant variability in cause and presentation, and affects both children and adults. If the disease progresses from acute to chronic, the inflammation of the pancreas does not heal or improve and, instead, worsens over time and inevitably leads to permanent damage. The natural progression of pancreatitis is that most patients first have an episode of acute pancreatitis. About 20% will continue to have attacks of acute pancreatitis, known as "recurrent acute pancreatitis." At least 40% of recurrent acute pancreatitis patients will progress to chronic pancreatitis. Some people, however, present with chronic pancreatitis without having had an identifiable acute pancreatitis episode. Advanced disease is characterized by loss of exocrine (digestive enzyme) function, significant progressive pancreatic fibrosis, recurrent or chronic pain syndromes, diabetes mellitus, an increased risk of pancreatic cancer, and premature death.

Loss of exocrine function can lead to malnutrition, which often leads to dangerous weight loss. Oily, fatty, clay-colored, or pale stools can indicate this secretion deficiency, which is often underdiagnosed. The majority of individuals with pancreatitis present with intense upper abdominal pain; this severe pain often spreads to the patient's back. The pain can be exacerbated by eating or drinking; thus, food and liquid avoidance can lead to weight loss and dehydration. Dehydration in some patients may be both the cause of an attack as well as a symptom. Other common symptoms include severe nausea, vomiting, fatigue, diarrhea, and constipation. People with chronic and recurrent acute pancreatitis have very high hospital utilization rates. Acute pancreatitis is the most frequently documented discharge diagnosis (> 270,000 per year) for hospitalizations caused by gastrointestinal diseases. Pancreatitis is diagnosed based on a detailed medical history, physical examination, and blood tests to identify elevated amylase and lipase (enzyme) levels. However, amylase and lipase

levels do not become significantly elevated after pancreatitis becomes chronic, leading to misdiagnosis, delays, or refusal to treat. Chronic pancreatitis patients usually present in the emergency room with severe pain. Abdominal imaging is often utilized for diagnosis, including but not limited to transabdominal ultrasound, endoscopic ultrasound (EUS), computerized tomography (CT) scan, and magnetic resonance imaging (MRI), including magnetic resonance cholangiopancreatography (MRCP). However, there is often not an accurate correlation between imaging results and the severity of a patient's symptoms, especially pain.

There are several causes of pancreatitis, including stones in the gallbladder, blockages in the pancreatic duct, certain medications, high triglyceride or calcium levels in the blood, and certain autoimmune conditions. Additionally, it is now known that there are numerous genetically-driven causes of pancreatitis, including the CFTR gene (commonly associated with cystic fibrosis), PRSS1 and SPINK genes (familial/hereditary pancreatitis), and several other genetic variants as well as environmental factors such as tobacco or long-term alcohol abuse cause or contribute to the severity or progression of the disease. Unfortunately, for a large number of patients, the causative factor is never identified, and these patients are referred to as having "idiopathic" pancreatitis.

Historically, chronic pancreatitis disease mechanisms were not well understood, and chronic pancreatitis was mistakenly attributed solely to alcohol abuse. More than 60% of adult cases of chronic pancreatitis and more than 98% of pediatric and adolescent cases of chronic pancreatitis are not associated with alcohol abuse, and these percentages continue to increase, especially as we learn more about underlying genetic causes. However, this misunderstanding persists among many physicians. For men, drinking five or more drinks per day for an extended period of time is a risk factor, but fewer than 15% of alcohol abusers will develop pancreatitis. The risk of alcohol-induced disease is less clear for women. The recently published International Consensus Guidelines for Risk Factors in Chronic Pancreatitis acknowledged this research and revealed that smoking confers a greater risk of pancreatitis than alcohol consumption.

Starting in 1996 and accelerating in the last decade with advances in gene sequencing, researchers have identified the genetic drivers of hereditary and spontaneous forms of chronic pancreatitis. The PRSS1 gene was discovered by Dr. David Whitcomb, Professor of Medicine, Cell Biology, and Physiology at the University of Pittsburgh Medical Center. It encodes for the production of cationic trypsinogen, which is normally converted in the intestine to the proteolytic enzyme trypsin. A gain-of-function mutation in PRSS1, where trypsinogen is converted to trypsin within the pancreas, causes a highly aggressive form of the disease that begins in childhood, runs in families, and is highly associated with pancreatic cancer. More recently, variants in the cystic fibrosis transmembrane receptor (CFTR) gene have been found to contribute to chronic pancreatitis in a significant subset of cases. Several other genetic variants, such as the SPINK1 gene, which regulates the prevention of trypsinogen being converted into active trypsin within the pancreas, are also linked to chronic pancreatitis. A mutation in the claudin 1 (CLDN) gene appears to increase the risk of alcohol-induced

pancreatitis, particularly in males.

Currently, there are no FDA-approved drug treatments for pancreatitis. Treating symptoms such as severe pain or nausea and preventing recurrence are presently the primary goals of treatment, with efforts focused on identifying the underlying cause and triggers to avoid future episodes. Dietary changes such as avoiding high-fat foods may help some patients with symptom management, and pancreatic enzyme replacement therapy (PERT) is prescribed to alleviate the effects of pancreatic exocrine insufficiency.

International consensus treatment guidelines for chronic pancreatitis pain prescribe a stepwise approach. If non-opioid analgesics do not relieve pain, opioids are typically prescribed. If there is a narrowing or blockage of the pancreatic duct by scar or stone formation, endoscopic stent placement or lithotripsy can be employed. When the previous therapy fails, and chronic pain persists, surgical treatment may be an option for qualifying candidates. Drainage procedures such as the Puestow procedure, or hybrid drainage-and-resectional procedures such as the Frey and Beger operations sometimes result in pain relief. The Whipple procedure is considered if there is suspicion of underlying pancreatic cancer. Total pancreatic resection (alone) is usually avoided except in advanced, severe disease, because of the obligatory development of severe diabetes that follows the complete removal of the pancreas.

In 1977, surgeons at the University of Minnesota developed a method to extract the hormone producing islets from the resected pancreas, and the islets are then auto-transplanted into the liver of patients undergoing a total pancreatectomy. The total pancreatectomy with islet auto transplantation (TPIAT) procedure is now offered in at least fifteen centers in the U.S. It has been found to offer pain relief and modest protection against post-resectional diabetes in both adults and children.

Many pancreatitis patients suffer from prolonged periods of inflammation or pain with little relief, and some succumb to the complications of treatment due to being exposed to repeated or progressively aggressive treatment approaches. The lack of effective drug treatments for this progressive disease contributes significantly to the disability and symptomatology of pancreatitis patients.

### **Meeting Overview**

The NPF, the only foundation dedicated to patients suffering from all forms of pancreas disease, held the first EL-PFDD meeting on pancreatitis, with the support from partners; Mission: Cure, Rebecca's Wish, and the Familial Chylomicronemia Syndrome (FCS) Foundation. The meeting was dedicated to the entire pancreatitis community. The EL-PFDD meeting served to advance the NPF's mission of providing hope for those suffering from pancreatitis and pancreatic cancer through funding cutting edge research, advocating for new and better therapies, and providing support and education for patients, caregivers, and health care professionals.

The EI-PFDD meeting drew more than 286 individual registrants, including virtual participants, with close to 60 participants present in the room. Staff from the FDA attended the meeting to listen to patients, caretakers, and other patient representatives discuss patients' experiences with pancreatitis, the disease burden on daily life, available management approaches, and hopes for future treatments.

The meeting included presentations from experts in the field to offer a broader context and high level description of the disease to provide foundational information to meeting attendees. The half-day event was comprised of two patient and caregiver panels; the first panel included adults living with acute and chronic pancreatitis, and the second panel included pediatric pancreatitis patients and caregivers. The moderator, James Valentine, introduced the meeting to the audience, established meeting ground rules, and posed a series of polling questions throughout the meeting. Participants responded to the polling questions by using an electronic application on their cell phones and tablets. The initial polling questions collected demographic information about the participants both in the room as well as those attending virtually. A total of 144 patients and caregivers participated in the polling and responded. The full results from the polling questions are located in Appendix 3.

It is difficult to encompass the many nuances of this disease; however, the meeting participants provided a broad range of information. Patients and caregivers shared a range of disease symptoms and life impacts, and the accounts shared touched on virtually all the treatment options available.

This report captures some of the key highlights of the meeting. It is hoped that the information and input gathered at this meeting will inform and shape the FDA and stakeholders' decisions regarding drug development and their review of future marketing applications for new treatments for pancreatitis.

Full meeting recording: <https://www.youtube.com/watch?v=BoUH6aliNWs>

### **Report Overview and Key Themes**

The key themes that emerged were:

- Patients commented on how relentless pain, nausea, fatigue, and many other mental and physical symptoms affect everyday life.
- Patients reported the impact that pancreatitis has on their social lives, relationships, careers, schooling, families, and mental health.
- More broadly, participants stressed the need for greater awareness of the insidiousness of pancreatitis, the hopelessness of living with an irreversible, debilitating disease, and the problems of interacting with providers who reflect the stigma of assuming that the disease is self-induced or that chronic pain symptoms are an excuse for drug-seeking behavior.

- Participants offered insights on how treatments, such as the TPIAT, have helped to alleviate symptoms, and how the lack of any available drug treatment, especially to alleviate severe pain, has hindered their lives.
- Since chronic pancreatitis is a debilitating and degenerative disease, patients stressed the urgency of new and better treatments and FDA-approved medication for pancreatitis. Treatment goals include preventing inflammation and damage to the pancreas, alternatives to major surgery such as the TPIAT, and better alternatives to opioid pain medications.

This report summarizes the input generously provided by patients and caregivers during the meeting, both in-person and remotely via webcast. It also contains a summary of the answers given during the real-time polling questions (Appendix 3) and the comments submitted to the post-meeting survey (Appendix 4). In addition, in 2018, the nonprofit organization Mission: Cure, which is focused on developing effective therapies for pancreatitis to improve patient outcomes, conducted an online chronic pancreatitis patient survey. Designed as a precursor to this PFDD meeting with guidance from FDA's Patient-Focused Drug Development staff, this survey asked patients what they would want the FDA to know about pancreatitis. The results are reported in Appendix 5. Dr. Dana Andersen, Scientific Program Manager in the Division of Digestive Diseases and Nutrition at the NIDDK and adjunct Professor of Surgery at Oregon Health and Science University in Portland, provided opening remarks and a disease overview. Dr. Erica Lyons from the FDA's Division of Gastroenterology and Inborn Errors Products provided insights from the FDA's perspective.

### **Topic 1: Acute and Chronic Pancreatitis – Adult Patient Perspectives on the Burdens of the Disease and Current and Future Approaches to Treatments**

The NPF chose to divide the focus of the meeting into panels of adult patients and pediatric or adolescent patients who had been diagnosed with chronic pancreatitis. The first panel was for adults. A pancreatitis expert, Dr. Wahid Wassef, Professor of Medicine (Gastroenterology) and Director of the Pancreatitis Clinic at the University of Massachusetts Medical School, spoke briefly before the panelists. Dr. Wassef developed and validated a survey tool called the Pancreatic Quality of Life Instrument (Appendix 6) that has been used internationally to assess and quantify the effects of pancreatitis on patients' lives.

Dr. Wassef gave an overview of the epidemiology of chronic pancreatitis. He stated that chronic pancreatitis is a significant worldwide health problem. He described the various causes of pancreatitis, the difficulties in diagnosing early chronic pancreatitis, and the challenges of selecting the best treatment for patients suffering from the disease. A study published in 2015 (Sam Han. *Global Journal of Medical Research* Volume XV (2), 2015) provides a graph showing how pancreatitis has a significant impact on quality of life as compared to a healthy control group (Appendix 6)



Four adult panelists provided comments to start the dialogue. They included:

- A female patient, from Boston, age 67, with idiopathic pancreatitis who has dealt with the disease for most of her adult life. "My journey began in early January 1988. Over the last 32 years, I've done everything I can to try to fix this disease or at least find out more about it."
- A 43-year-old female from Indianapolis, Indiana, highlighted how her extended struggle with pancreatitis interrupted her career and relationship. She discussed how, while she is a "success" story, she still lives with a long list of medications, including enzymes, insulin, and various drugs for nausea. "I underwent 17 procedures to stop the pain, calm the nausea, provide organ rest, and to help diagnose why my pancreas had decided to flare up on a regular basis. I was diagnosed with chronic pancreatitis and pancreas divisum."
- A 51-year-old male, living in California stated, "I was diagnosed with chronic pancreatitis in 2012 after becoming gravely ill, essentially becoming bedridden for long stretches and after being misdiagnosed with diverticulitis for almost five years." He emphasized the alternative ways he manages the impact of the disease while stressing the detriment of pancreas inflammation and deterioration, and the need for better treatments.
- A 54-year-old female and Los Angeles native stated, "I was diagnosed with pancreatic cancer in February of 2002 at the age of 36. I had a Whipple procedure ten days after diagnosis. Over the last 16 years, I've had eight surgeries related to my pancreas. No one had told me [pancreatitis] was a potential side effect of pancreatic cancer." She highlighted her painful journey with pancreas disease, how it has affected her other organs, and her quest to find peace and a personal regimen to combat pancreatitis.

The panelists' opening comments provided a range of perspectives on the daily impact of symptoms, including the physical, social, and psychological implications of pancreatitis from the onset through the present.

Generally, the term "flare-up" describes the experience of an intense bout of acute inflammation and pain in the setting of chronic pancreatitis. In a patient's words, "The flare-ups are the worst parts. At those points, I am not at 50%; I'm at 5%, much worse than say having the flu. I'm drained of all energy, nauseous, weak, bedridden, barely able to function, in horrible pain, and unable to eat any solid food for up to five days at a time. The things that can cause a flare-up include a single inadvertent high fat meal, intense exercise, stress, working too hard, travel, or sometimes there is no discernible cause. If you do not constantly practice very good self-care, you can be very sick much of the time, and even with constant vigilance, you suffer almost daily."

### ***Disease Symptoms***

Patients described a spectrum of disease symptoms. Per the polling results, over half the participants have been hospitalized over ten times, and the top three symptoms were pain, nausea/lack of appetite, and fatigue (Appendix 3). This finding was also consistent in the post meeting survey (Appendix 4).

- **Pain**

All of the panelists said they experience intense, almost indescribable pain. Each panelist described their pain a little differently, yet in all accounts, it is clear that the pain is excruciating and debilitating.

- "I woke up in the middle of the night in excruciating pain, it felt as though my insides were exploding."
- "I doubled over into the worst pain of my life."
- "I thought I was having a heart attack."
- "I'm in pain virtually every day. At its worst, which is several times a week, it is simply the most intense pain you have ever experienced. The best analogy is feeling as if acid has been poured into your intestines, or you've been stabbed by a flaming hot knife."

Pain also causes additional symptoms, including lack of sleep. One panelist stated, "You cannot fall asleep in that much pain, and getting to sleep often takes hours and a combination of pain medication and sleep aids." Since pain is frequently exacerbated by eating and drinking, pain can be the catalyst for dehydration and consequential weight loss as one panelist stated, "I was down to 86 pounds."

- **GI Symptoms**

Nausea was another common symptom and can be equally as disruptive as the pain. As a panelist explained, "My major symptoms were pain and nausea." Another speaker verbalized, "I was still getting flares with debilitating pain, awful nausea, and vomiting." Nausea and vomiting can be so frequent that a feeding tube or an extensive combination of medications is required. A panelist detailed, "I take (an anti-emetic) three times a day, and then I take a nausea medication that's for cancer patients. It's designed to be taken twice a month. I take it every day, so 30 times a month. So, they don't really know the long-term effects of that, without those medications, I would be back on a feeding tube." Other symptoms patients experienced were diarrhea and constipation. A panelist revealed, "We have the one extreme to the other with bowel movements."

- **Fatigue**

Another common symptom experienced is fatigue. Fatigue is not merely the occurrence of feeling tired. It is the feeling of being utterly drained, exhausted, or worn-out. A panelist explained, "Fatigue affects me nearly every day. For months at a time, I feel I'm at maybe 50% or less of my old energy level, affecting nearly all aspects of my daily life." He went on to say, "I can fight through pain, but you can't fight through having zero energy."

- **Temperature Fluctuations**

Other patients experience temperature fluctuations, as one panelist mentioned, "I travel with my heating pad. I mean, it is my lifeblood because otherwise, I'm just too cold to function."

### ***Burden on Daily Life***

The physical manifestations of the disease create a ripple effect in a patient's entire world as everyday obligations become increasingly challenging to accomplish. Furthermore, "It interrupts and changes day to day life. It sets parameters on your life and affects those around you", said one participant. The disease affects every aspect of life, including career, finances, family, social, and mental health.

- **Stigma**

The vast majority of patients, including pediatric patients, experience stigma since many clinicians assume inaccurately that pancreatitis is a consequence of alcohol abuse or an excuse to seek pain medication. Some patients are dismissed or mistreated due to this assumption. A panelist articulated, "Quality of life is the most important thing to me. Knowing I must accommodate to so many things others don't have to think about is challenging enough. Dealing with the pain of acute pancreatitis should be the most difficult part, not negotiating with doctors and medical professionals to help me and not dismiss me." A panelist declared, "I never smoked. I was not a heavy drinker. And I've had basically zero alcohol since my diagnosis. But I encounter people all the time, including physicians, who assume that people with this disease must be alcoholics." This shameful and exhausting experience often stops patients from seeking the care they need. An audience member revealed, "Oh, I've been to the hospital over 20 times, but I've had more flares than that. But knowing what it is and then going to the hospital, it's kind of like, you've got to be so bad off to go to the hospital and try to explain yourself. I'm not an alcoholic. I'm not a drug seeker."

- **Impact on Work and Careers**

Many patients with pancreatitis struggle to maintain employment due to the constant pain and interruptions of extended hospital stays. Without work, there may be no health insurance, which makes it difficult to receive adequate care, and many pancreatitis patients find it exceedingly difficult to qualify or receive disability compensation. One patient mentioned, "I spent a total of six months in the hospital, lost my new job, my new home, and my livelihood." Another disclosed that it hindered her from the career she always desired, she stated, "I always wanted to be in public safety. Actually, I wanted to go into the armed forces and follow my family's' footsteps. Couldn't even do that, couldn't do public safety."

- **Impact on Relationships**

The burden of this disease stretches much further than just the patient experiencing it. People reported that relationships and friendships become lost in the shadow pancreatitis casts. As a parent or spouse, the ability to be fully present both physically and mentally proves problematic. A panelist emphasized, "Having relationships, having a partner and having them see you in constant pain, there's a debilitating psychological aspect of that for them. It's exhausting for the people around you to watch you go through it. And I think sometimes even harder for those people because they love you and they feel so helpless, constantly being told there's nothing else that can be done. I'm starting to see my kids who are in their early twenties going into therapy after all those years of being a kid and watching me go through what I went through and all of the baggage that they now carry because of that." The "what if" of the future can be terrifying. Another panelist expressed, "My now fiancé's father passed away unexpectedly. Halfway through the funeral, I had to find a quiet corner. A severe attack came on, and I was... doubled over with pain on the floor. I thought, why now? Why, when he needs me most, is my body failing me?"

Frequently the disease leaves a patient depleted. A panelist stated, "Many days I fight to make it to the end of the workday. When I get home, I am done, in bed, and not able to be the parent or husband I would like to be." Due to extremes with bowel movements, diet restrictions, pain, preplanning, and modifications, it makes it difficult to maneuver in social situations. A patient described the fear over simply going hiking with friends, "So it was the fear of, and then what would happen if." One panelist mentioned, "I've lost many of my friends."

- **Mental Health and Future Fears**

The ongoing pain and lack of successful treatment plans for pancreatitis can create depression and despair. A patient communicated, "Hopelessness is one of my biggest symptoms." Another went on to say, "When you feel this way for a long time, it is difficult not to experience at least some hopelessness and depression." The not knowing when a flare-up will occur or if a patient will be around for the future induces significant anxiety. A pregnant mother of three expressed her fears, "Do my kids have this gene? Am I going to be around for their birthday parties? Am I going to miss out on life? That's so scary to me. Quality of life. I want to be there for my kids. That's my number one goal." The physician's inability to diagnose begins to chip away at a patient emotionally. A speaker expressed his experience with physicians, "We're going to send you to a mental health professional because we can't find anything wrong physically. I think that the effect that those kinds of comments have can be pretty tough on somebody." However, notwithstanding an accurate diagnosis, this too can be equally as disheartening, a woman expressed how the diagnosis felt like a "death sentence" because nobody knew what to do. They said, 'we can't help you.' And I was devastated. I mean, what do I do with that information?"

## ***Adult Perspectives on Current Treatments***

Patients are often undiagnosed or incorrectly diagnosed for years. A panelist articulated, "Our story really starts with a diagnosis. The beginning is more of a journey." The journey is a drudging process, with countless procedures and treatments of trial and error. There are no FDA approved medications for pancreatitis, although there are treatments and drugs to help treat and alleviate symptoms.

Per the polling results, the top three treatments used by adult patients were non-opioid pain medicines, endoscopic procedures, and digestive enzymes. Nonetheless, the following polling question showed only about a quarter of people reported that the treatments available helped significantly. Two-thirds said that existing treatments only helped somewhat, and 7% reported no benefit at all (Appendix 3).

**Opioids.** Opioids are prescribed by doctors to treat moderate to severe pain. Unfortunately, they can have risks and side effects. The opioid epidemic has caused a massive barrier in patients getting the necessary pain medications to treat the extreme pain they endure. In some cases, even with pain medication, pain is still challenging to manage. A panelist shared, "For years I was on daily oxycodone. While I constantly tried to manage my dose, it increased over time just to have the same effectiveness. The medication I've been given as a substitute, including Gabapentin and Clonidine rarely comes close to stopping the pain. Because of this, opioids remain an essential daily need for many patients."

Opioids are very often necessary yet are merely treating a symptom, not the underlying issue. Moreover, they often come with their own set of problems. One patient disclosed, "Opioids caused me to have pancreatitis. A lot of the medications they give me in the hospital have the warning sign, it's in the directions can cause pancreatitis, yet they give it to you. And so that's scary."

**Enzymes.** Pancreatic Enzyme Replacement Therapy (PERT) can help patients absorb nutrients and digest food normally. However, it is not always effective. One participant shared, "I've had chronic pancreatitis for at least five years with acute flare-ups. My doctors have put me on amitriptyline, pantoprazole, hyoscyamine, and those sorts of things. So, they put me on digestive enzymes as well. None of those have been effective for me. So, when I have an acute bout [I am] on the floor [and I] can't get up.". While PERT can assist with malnutrition, a panelist commented, "I have not seen any discernible effect on the level of pain." Enzymes can be beneficial for a pancreatitis patient, yet they are often unattainable or financially prohibitive. Enzymes can cost upwards of thousands of dollars a month. A panelist affirmed, "I have learned how to live on digestive enzymes that can cost a small fortune."

### *Endoscopy Options*

- **ERCs**

Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure where a flexible endoscope is passed through the stomach to the level of the pancreas, and images of the bile duct or pancreatic ducts can be obtained to diagnose and treat pancreatic diseases. While it is suggested that ERCPs have a limited role, a panelist explained, "I had 62 ERCPs, which I have since found out was a horrible thing to do. You shouldn't have more than two or three." Another went on to describe, "I'd had 16 ERCPs, which many CP patients have one or two, and my pancreatic specialist said that I was no longer a viable candidate for additional endoscopic procedures." It should be noted that ERCP's themselves can cause pancreatitis.

### *Surgical Options*

- **Gallbladder Removal**

Gallbladder removal is frequently the first procedure suggested or performed. Gallstones are often assumed to be the source of the pain or the cause of pancreatitis. One panelist declared, "They initially thought it was my gallbladder, so that was removed. They were wrong. It was an acute pancreatitis attack." Another panelist emphasizes, "My gallbladder was removed. Many of us had had our gallbladder removed, and the pain returns. I went back to the surgeon two weeks later, still in pain."

- **TPIAT**

Total pancreatectomy with islet auto transplantation can be an effective treatment as the last option. It is an extreme procedure involving the removal of the pancreas, duodenum, reconstruction of the intestine, and customarily the removal of the spleen. Islets, which produce insulin and other hormones, are harvested from the pancreas and infused into the liver. The engrafted islets produce enough insulin to prevent diabetes in more than one-third of patients and allow for very small doses of insulin to be needed by others. Typically, severe diabetes would result from just the removal of the entire pancreas, and the islet auto-transplant mitigates this risk. One of the long-term complications of chronic pancreatitis is diabetes, so TPIAT candidates have to be non-diabetic to be considered for the procedure. Not every individual with pancreatitis is a TPIAT candidate, and other less radical operations are sometimes recommended instead.

- "I am 72 years old. From the age of zero to 22, I was told I had the flu. I was nervous, I was put on Valium in college, I had an ulcer. But at 22, I was diagnosed in Boston as having pancreatitis. From 1996 to 2008, I was in the hospital 250 times. I was in the hospital the average of about eight months out of 12 months a year for 13 years. I was ready to kill myself. I was on Dilaudid, Fentanyl, Ketamine. They told me I couldn't have any more ERCPs, and there was no more pain medicine. I went to every major medical center in this country, heard about the one place in the country that did do this TPIAT. In 2008 I had it, and it was my only choice. I am here now 12 years later."
- A mother speaking on behalf of her adult daughter detailed, "It's been a complete life changer. She is finally pain-free and can eat normally without nausea. However, there are some lingering complications. She is fully diabetic. She takes pancreatic enzymes

with every morsel of food. She does get more fatigue, and there is the, who knows if it'll ever go away PTSD aspect and the mental aspects and the challenges of completely changing your life from a mental, emotional perspective, but she's getting on with her life.

- "I had my surgery in 2013 and did well, for a period of time afterwards, but then I started to get some gastroparesis type symptoms [delayed gastric emptying]. I was getting constant nausea and vomiting, lots of pain again. They found that I had issues with adhesions and scar tissue and issues with the anastomosis sites for when they put my intestines back together. I had another revision surgery. I'm still on my enteral feeds, but everything's looking a lot better than it was beforehand. So, there is a lot of adhesion type issues that do come up, and I agree completely that there's not a whole lot of what do we do afterwards. "

Although the TPIAT procedure has been shown to be effective for the relief of pain due to chronic pancreatitis, it is the most radical of all the surgical options for the disease and, as mentioned earlier, is only available at few institutions around the country. Fewer than 1,000 TPIAT procedures have been performed over the past 30 years. However, the U.S. prevalence of patients with chronic pancreatitis is estimated to be over 200,000. It is estimated that only 5% of patients with chronic pancreatitis are potential candidates for this procedure. The panelists at the EL-PFDD, therefore, represented an atypical cross-section of chronic pancreatitis patients. Two other invited panelists who had not undergone TPIAT were forced to withdraw from participation due to acute symptoms.

- **Other Surgical Procedures**

Procedures such as the Puestow Procedure, the Frey Procedure, the Beger Procedure, distal pancreatectomy, and the Whipple Procedure have been used in the treatment of chronic pain. One panelist explained her experience with the Whipple Procedure, "I was told I had to have the Whipple Procedure, or I would die. I went into surgery for nine hours. They removed half my pancreas, just over half my stomach, most of my small intestine, and my bile duct. It took me 12 months to recover from the Whipple. In those 12 months, I was on over 20 medications daily and back on a feeding tube. I had care for 24/7 for four months, as I couldn't bathe, dress, or feed myself, and I was wheelchair-bound. It was painful, humiliating, and disabling, and for some reason, the Whipple wasn't taking."

#### *Non-Medical Options*

- **Cannabis**

Many participants spoke about the relief that cannabis gives, not in relieving pain but in the symptom management. One panelist expressed, "Cannabis for me does not reduce the pain, but makes it much easier to bear. I would urge anybody to take cannabis very seriously as a treatment for conditions like this and to give very serious consideration to newer treatments." Another expressed how her options are limited, "Just because of my liver now I can't take any

pain medicine nor can I take Advil or any of that. So, for me, I started using cannabis last year, and that has helped as well."

Dr. Dana Andersen, pointed out, "A lot of folks with pancreatic disease and chronic pancreatitis, in particular, are wondering whether and how and when to use cannabis as a therapeutic aid or to add to the treatment that they're receiving. But the use of cannabis is legal in some states and not legal in other states. And that has complicated the scientists' ability to gather data about the use of cannabis and the effectiveness of cannabis. As a result, we don't know what to recommend to patients because we don't have good evidence. So, patients are left to experiment on their own."

Some patients find varying relief with diet changes, a combination of medications, heating pad applications, stenting, and other procedures. While some rely merely upon extended hospital stays with fasting and heavy pain medications until the pancreas calms. Others notice practices like yoga, journaling, and meditation help manage symptoms and stress. However, there continues to be a large unmet medical need, and many only find temporary relief or none at all.

## **Topic 2: Pediatric Pancreatitis – Patient (and Caregiver) Perspectives on the Burdens of the Disease and Current and Future Approaches to Treatments**

Pediatric pancreatitis accounts for about 10% of all patients with chronic pancreatitis and is less well understood by many providers.

The panelists ranged from 7-years-old to 17-years-old. Every panelist suffers from chronic pancreatitis, and due to severity, two of the patients have undergone the TPIAT surgery, while the other two have been evaluated for the TPIAT. The majority of the panelists also had genetic mutations associated with their pancreatitis. Dr. Melena Bellin, Director of Research for Islet Autotransplantation at the University of Minnesota and Associate Professor of Pediatric Endocrinology and Diabetes, spoke briefly about pediatric pancreatitis prior to the panelist presentations and referenced a study on pediatric pancreatitis which found that 50% to 70% of pediatric patients studied have hereditary pancreatitis. Polling question number four asked: "At what age did you have your first pancreatitis attack?" The majority of respondents answered during their adult years, while 40% of patients had their first attack from less than 1-year old to 18-years-old.

The four panelists shared their pancreatitis journey to start the second session. The panelists included:

- A 17-year-old female from Texas who suffers from chronic pancreatitis caused by an unknown immunologic disorder and has undergone the TPIAT. Her TPIAT surgery has created life-altering complications and has necessitated numerous other surgeries to try and remedy the problems that it created. "I have since spent over 1,300 nights in a



hospital bed, have had over 85 anesthetic procedures, 22 of which were ERCPs. My search for a cure led me to eight of the major hospitals across the United States, none of which provided an answer.”

- A 7-year-old male from New Jersey. His story was shared through his mother. At the age of four, he had surgery to remove a choledochal cyst, had pancreatitis attacks, and was diagnosed with hereditary pancreatitis. His mother highlights the difficulty of navigating a disease when medical professionals are not certain on how to treat pancreatitis.
- Two sisters from Oklahoma who are 16 and 17-years-old and suffer from hereditary pancreatitis. They highlight the differences in the disease as the younger sister had symptoms at 4-years-old while the older sibling’s symptoms manifested on her 16<sup>th</sup> birthday. They shared their different treatment options and how pancreatitis touches every aspect of their life.

### ***Describing the Pain***

Each of the panelists described their symptoms as a stabbing pain (“a punch to the pancreas”), coupled with nausea, and fatigue. The duration of the pain is extended, and patients do not know when it will end. A panelist and audience member both mentioned that they knew the difference between pancreas pain and other forms of stomach pain, and could distinguish when their pancreas was “working.” “Stomach pain is uncomfortable and eases within minutes, pancreas pain is like a knife stabbing in my chest, and I can't breathe with the sharpness of it.” Other additional comments about pain are as follows:

- “The symptoms increase in severity and frequency. We will have to leave activities abruptly. We have carried my son off the soccer field, and after a morning of activity, he has to rest and recover.”
- “It makes it hard to ask for help when it is so severe. I've even spent time in the school office crying, seeking a quiet place, so my peers didn't see me in pain.”
- “Each attack brought with it nausea, excruciating pain, dehydration, and sometimes a hospital visit. I would lay on the floor and move all around trying to get the pain to ease.”

Participants were asked about triggers that came with pancreatitis attacks on their worst days. Patients mentioned diet (fat), stress (from school, social, health), and dehydration. Some found their attacks and symptoms are worse in the summer. Two participants noticed that their attacks come on or around their menstrual cycles and the complications with that, “The main downside of this treatment is more frequent and heavier periods, and I feel more emotional, discouraged, and mad when experiencing pain.”

### ***Overall Impacts on Daily Life***

Pediatric pancreatitis patients discussed not only having to deal with their pancreatitis pain and treatments, but also the social (eventually leading to non-social) aspects of the disease. All of the patients spoke about how pancreatitis affected their relationships, schooling, and friendship circles due to not understanding the disease and its limiting effect on activities. The

founder of Rebecca's Wish (a partner with the NPF) and parent mentioned that many pediatric pancreatitis patients have to be homeschooled because they cannot keep up with the regular education schedules. In turn, the school may not understand why the patient is missing multiple days and weeks of school, as pancreatitis is not widely known. As a possible solution, a parent advised other parents to educate their children's teachers as much as they can on pancreatitis. Participants echoed that with pancreatitis attacks, there was a balance of not only having to manage the attacks and triggers but also "trying to maintain this balance to be seen as normal by everybody else when clearly everything is wrong."

- **Impact on School**

All patients and caregivers shared that due to numerous missed days, it made attending school and managing the pain while in school very challenging. One panelist mentioned, "The school won't allow me to attend when [a] certain number of students are absent due to sickness and which means more missed school on my behalf." Another participant said, "The pain requires me to leave school or work in order to take medications that allow it to subside. I try not to let the disease stop me from doing the things I enjoy, but sometimes it is inevitable." One panelist shared that, "It's very difficult to be separated by that barrier from everybody else while you're attending school to only be able to go certain times when you're feeling well or to have to leave school so often from pain and to have people think you're just seeking attention. So, you try to hide it all so that other people don't see that."

- **Impact on Activities**

Navigating through pain and still trying to be active was also an issue for pediatric patients and their families. One patient shared the fear that comes along with GI issues, "I always wanted to be active, but then there's a lot of GI issues, and I did not have a diagnosis with it. I was just sick all the time. I didn't get to do anything enjoyable, didn't go to summer camps, couldn't go [to] anything like that." Another parent made it a priority for her child to still participate in activities that she enjoyed, "We tried to not pull my daughter from as many things as possible. We tried to keep her active in dance because that was what she loved, and that was what kept her going. There were times that she would go from the hospital to the stage or from the stage to the hospital, one way or the other."

- **Impact on Family and Friends**

Pancreatitis also affects your loved ones. A patient shared the steps that her friends and family had to take when being around her, "Because I do not have a spleen, extra precautions need to be taken - family and friends get vaccinated early, and I avoid being around anyone that is sick." Another parent shared, "We are constantly shuffling in our brains how to manage an inpatient stay when a flare of symptoms begins. He has a younger brother, now four, who senses the preparation and needs consistent reassurance that he will not be left at school. Never have we done this, but this is the fear created in him."

## ***Emotional and Mental Effects***

Participants discussed the emotional toll and pain that is coupled with having a chronic illness that all agreed is not widely talked about, understood, or discussed with physicians. The emotional pain of being socially isolated, depressed, and anxious were all shared. Several participants mentioned “phantom pain,” pain that radiates from a body part (the pancreas) that is no longer there (after surgical removal).

- “To have pain so bad that five years later the phantom pain impacts you should not be allowed and needs to be fixed. It's difficult to deal with both PTSD and medical depression as a high schooler because as of yet, the emotional aspect of pancreatitis is not fully comprehended.”
- “The trauma to my body or the drugs were causing violent nightmares, which lasted about six months after the surgery and still happen sometimes.”
- “We (Rebecca's Wish) have children, many that have attempted suicide, some that have committed suicide, and a lot of that is actually based upon the pain factor.”

Participants all mentioned the emotional and mental pain that comes from living with a rare disease when doctors are not well-informed, coupled with government drug restrictions on opioids (many patients were accused of being drug-seekers), and the psychological consequences that come with it. A caregiver stated, “The psychological ramifications with a developing child's mind to not be able to understand that this doctor's telling them something that's wrong, we are seeing it magnified to the point where these children not only don't get a proper childhood but they don't understand the emotional and mental and cognitive ramifications of what they're going through, and we don't address that at all.” Other patients below echoed similar experiences with their diagnosis and the medical community.

- “We (Rebecca's Wish) had a patient of ours that went to the ER, had already been diagnosed with pancreatitis, went to a major hospital in Dallas, Texas, and the ER doctor looked at her and said, that's impossible, that was a fluke on the test, pulled the child's feeding tube out and told her it was all in her head.”
- “I mentioned earlier, my first round was at seven years old. We had no idea what it was. I had no idea. I was just told it was in my head.”
- “The doctor pulled me outside the room and said, your child is just drug-seeking. My child had not had a drug in her system in nine months, and yet she was a 10-year-old that's drug-seeking?”
- “Occasionally, ER doctors have made me feel stupid, telling me that I couldn't have pancreatitis because that's an alcoholic's disease, though I've never had a sip of alcohol or any other substance.”

## ***Perspectives on Current Treatments***

Participants were then asked what treatments are currently being used and have been used in the past. The online poll asked, “In general, how much have the medications and treatments improved your quality of life?” The poll showed that 66% said that they “somewhat helped” with no one responding that there was a significant benefit. Aside from enzyme pills for treatment of pancreatitis (which does not stop an attack), pain medication was the most popular form of treatment for patients. This led to discussions of the downsides of repeated narcotic usage and the inability to receive needed pain medications due to the opioid crisis in the United States. A caregiver from Rebecca’s Wish elaborated with this statement, “The doctors were fearful of giving the opioids because of the opioid crisis. We are from Texas, there is no cannabis or any of those options, so the child is not getting pain medicine to manage the pain, they have no other alternatives, and they do want to die.” Two of the most popular forms of treatment mentioned in this panel were pain medication and the TPIAT surgery. The downsides and side-effects are discussed below.

### **Opioids and Non-medicinal Pain Management Methods**

- “Narcotic usage, which in turn leads to the slowing down of the intestines, which leads to an endless cycle of stop and go with the GI system. But the narcotics are the only option to alleviate even a fraction of the pain. And so, they have to be used, and the cycle continues.”
- “I was given Phenergan pills and gels. The gels didn't do much, and the pills put me straight to sleep, but I would wake up just as sick. On top of that was the pain. I would first feel like I had pressure on my chest.”
- “The hydrocodone first made me feel groggy and absent. If I began throwing up, we would go to the hospital for IV fluids and morphine to offset the dehydration and try to get control of the pain. Over time, the symptoms became worse, and the treatment became less effective. I built up a tolerance to hydrocodone and oxycodone, and the morphine would give me awful headaches. My liver began shutting down due to pancreatic stones and blockages in the duct.”
- “My son's first three attacks were time regulated for some reason, every hundred days give or take. Our physician suggested the combination of Centrum silver and methionine. I have absolutely no doubt that (initially) it expanded the time between attacks as well as the duration of (relief), (but) as it started to wear down, we figured out that because he was a growing boy, we needed to increase the dosage. I still believe this drug combination contributes to some factor to those well periods, although they are a little bit shorter in between now.”
- “My kindergarten teacher sewed a bag filled with dried corn or rice for me that could be placed in the microwave and heated. The heat and pressure of these bags was a comfort for me throughout the years of my illness.”

## **Impacts of TPIAT as a Treatment**

Like adults, children who received the TPIAT had varying results. One panelist stated: “The transplant was necessary. It is not a cure. Instead, it is an exchange of one set of problems for the next.” The moderator asked participants to share their experiences with the TPIAT and, while there are success stories, how the surgery is not a fix-all. Many complications often accompany the procedure. These two experiences below are examples of post-TPIAT surgery.

- “I would definitely say I feel very lucky that I can say I'm one of the success stories, but the lack of pancreatitis I would say is worth it even though there are other things you're facing. For me, some of the things that have been more impactful are mainly the uncontrollable bowel movements. Right after the surgery, I was getting tired so easily, and I lost so much weight. As a kid, I don't want to slow down.”
- “My daughter has not been the most great, wonderful story, but she's alive, so we're thankful. A lot of patients go into TPIAT thinking this is going to be an end-all, be-all, fix it. And so, when their mindset is set on that, and it's not, they become even more depressed and more upset afterward because they feel like they've gone through this huge, enormous surgery. One of the negative sides of surgery is the scar tissues and other things that are happening on growing children's bodies. And again, that's something that seems to be a little more unique with children than it is in the adult population that we've found, because the growing children's bodies with 40-some odd staples in their body, as it's growing. It's ripping and tearing, and we're having lots of repercussions and lots of children hospitalized afterward for that. For my daughter's situation, there's no surgeon in Texas as of right now that will take her to clean up the scar tissue. So, she just lives in this constant state of pain.”

## ***Defining Improvement of Pancreatitis***

The moderator asked participants, “Short of a cure, what specifically would you look for from that next future treatment?” All participants who spoke agreed that aside from pain management, quality of life was of the utmost importance to them. They would like to be able to socialize, engage in activities, and go to work. All patients were realistic that a cure or end-all treatment would not be coming soon. One patient commented, “I think if we can find anything that will affect our quality of life and make our quality of life better, it would be a huge thing for us. I mean, I don't think any of us think we're going to get a cure. We just want a better quality of life.” An adult panelist mentioned that as a parent, it was vital for her to have a treatment where “you were still you.” “My kids hated seeing me on pain medicine because I wasn't me. So, I would like to have the ability to still be me and still manage to do what I needed to do while not being knocked out on pain medication.” Another patient mentioned the importance of having a plan with the diagnosis to help patients prepare, “Just to have a roadmap so that folks know that this is a degenerative disease, that's eventually going to get worse until you have to go maybe through radical surgery, but there is a plan, to me is in some ways the most critical part.” Another said that with the government focusing on the opioid crisis, it was

essential to find other alternatives for treatment, and make sure that pancreatitis patients were included in this process.

### ***Meeting Closing***

After Panel 2 was completed, a summary of some of the key findings from the meeting was provided by Larry Bauer, Sr. Regulatory Drug Expert from Hyman, Phelps, & McNamara. After closing remarks, the meeting was adjourned.

## **Summary of Post-Meeting Survey Results**

After the meeting, the NPF wanted to capture the voices of patients who could not attend the meeting and share their comments on their symptoms and treatments. Approximately 120 patients chose to answer the six question post-meeting survey. Overall, the survey response echoed what was mentioned in the meeting.

### **Submitted Comments on the Overall Impact of Pancreatitis on Daily Life**

Over 55% of survey respondents suffer from chronic pancreatitis. (Appendix 4) When asked about the top three symptoms of their pancreatitis, almost everyone reported pain and the consequences of the pain. The other top symptoms reported were fatigue and nausea.

They mentioned that the pain prevents them from doing hobbies they enjoy, spending time with their friends/family, and being able to plan events. Not knowing when the pain will come also creates anxiety, and the psychological and emotional cycle from pancreatitis continues.

### **Impact on Daily Activities**

Patients shared the same experiences with pain as those in the live meeting but described further examples of how the pain prevented them from doing daily activities. One wrote, “Too much physical activity causes pain, eating anything triggers pain, and nausea and sitting too long in a car causes pain and nausea.” Even the act of drinking water causes pain for one patient, “Right now I cannot drink water without hurting, cannot do anything much because of being in bed all day. Hurting my nerves. It makes me feel like I'm losing [my] grip on life when the pain is intolerable, which is daily.” Another patient also said, “I experienced debilitating pain for several months, causing me to be unable to do my normal daily tasks such as care for my daughter. Lack of appetite caused me to lose over 50 pounds and increased my fatigue. With fatigue, there were times when I could barely walk to the bathroom, I was so tired.” Not being able to work due to pain was echoed as well, “I can't work because the pain is constant. I stay in my house because I don't want to explain my illness. Panic attacks are a way of life. I couldn't even graduate high school because of this.” While another patient had to give up his

career, “I had to give up my job as an English university instructor because often I don’t have the energy to go to school, which makes me an unreliable employee.”

### **Impact on Relationships and Planning**

Many shared that with pain, they were hesitant to plan ahead due to the unpredictability of the pain and how it has a negative impact on their relationships. For those who do plan ahead, their plans revolve around the what-ifs of pancreatitis. “There is an inability to make plans ahead of time because of bouts of pain, the necessity of always being relatively close to a hospital, when I worked my vacation time was always used for sick time.” Another expressed, “Pain and nausea, it makes it impossible to make plans because I never know when I’ll get too sick and have to go home.”

### **Submitted Comments on Current Treatments for Pancreatitis**

Patients had the opportunity to share the treatments they have used for their pancreatitis. They mentioned various pain medications they have taken (not all have been effective), cannabis, enzyme pills, nerve blocks, stent placements, feeding tubes, TPIAT surgery along with other surgical procedures (Whipple, Frey, ERCPs) and heat. Other treatments mentioned were a liquid diet for 17 months, celiac plexus blocks, meditation, and acupuncture. A theme in the comments was that the pain medications were a temporary fix for pain, which came with side effects. “I loved how effectively the massive oral and topical narcotics worked to control the pain - but not the side effects of making me a zombie. I now have a pain pump, which works well without the side effects, but I hate having that foreign object in my stomach, and every time I bump my stomach it hurts.” Only one person mentioned a diet that seemed to help them, “gluten-free, keto, and intermittent fasting, and it seems to have cured me.” This voice is not the norm. As mentioned previously, with pancreatitis, finding the balance of managing pain in life is a new normal.

#### *Most important in treatment*

Echoing similar comments from the meeting, patients said it was most important to find a treatment for the pain and nausea and improving their quality of life. Educating medical professionals (and the public) about pancreatitis was very important, for doctors to know that not everyone is an alcoholic and not to label pancreatitis patients as drug seekers. “Every trip to the pain doctor results in a prejudgment by staff of drug seeking and addiction, massive stress, and exacerbated pain and other symptoms.” A few people expressed wanting to have a “normal life.” One compared their current life to Russian Roulette, as they didn’t know when the next attack would be, and “not knowing if the next episode is the next that takes me to my grave.”

Finding a way for medication to be less expensive was also important to some patients and mentioned in their comments. “The only thing I can think of is that whatever successful future treatments are developed that they are accessible, available, and affordable to everyone. For

those dealing with hereditary or genetic pancreatitis, the benefit would be immeasurable if it meant their children and grandchildren wouldn't have to suffer.”

## **Incorporating Patient Input into a Benefit-Risk Assessment Framework for Pancreatitis**

The Benefit-Risk Assessment includes identifying four vital decision factors: Analysis of Condition, Current Treatment Options, Benefit, Risk, and Risk Management. The chart serves as the proposed introductory framework for Analysis of Condition and Current Treatment Option rows which could be included in the FDA’s Benefit-Risk Assessment for new pancreatitis treatments. The information, particularly the Analysis of Condition and Current Treatment Options rows speak to the details and severity of pancreatitis and the currently limited treatment options available.

The below information draws from the data discussed at the EL-PFDD meeting held on March 3, 2020, polls taken during the meeting, and the post-meeting survey.

	<b>EVIDENCE AND UNCERTAINTIES</b>	<b>CONCLUSIONS AND REASONS</b>
<b>Analysis of Condition</b>	<p>Pancreatitis is an inflammatory condition of the pancreas which can be acute or chronic. Pancreatitis is a complex disease, with significant variability in cause and presentation. It presents with various symptoms that affect some or all patients as the disease advances. It affects both children and adults. If the disease progresses from acute to chronic, the inflammation of the pancreas does not heal or improve and, instead, worsens over time and inevitably leads to permanent damage.</p> <ul style="list-style-type: none"> <li>• There are several causes of pancreatitis, including stones in the gallbladder, blockages in the pancreatic duct, certain medications, high triglyceride or calcium levels in the blood, and certain autoimmune conditions. Additionally, it is now known that there are numerous genetically-driven causes of pancreatitis, including the CFTR gene (commonly associated with cystic fibrosis), PRSS1 and SPINK genes (familial/hereditary pancreatitis), and several other genetic variants. Environmental factors such as tobacco or long-term alcohol abuse may cause or contribute to the severity or progression of the disease. Unfortunately, for a large number of patients, the causative factor is never identified, and these patients are referred to as having “idiopathic” pancreatitis.</li> </ul>	<p><b>Pancreatitis can cause permanent damage to the pancreas and can ultimately result in death.</b></p> <p><b>A large number of pancreatitis cases are considered “idiopathic.” There is still much to be learned about the disease.</b></p> <p><b>Individuals with pancreatitis have complex treatment needs that address both the cause of the disorder and the consequence of multiple disease complications on the body.</b></p>



	<ul style="list-style-type: none"> <li>• Advanced disease is characterized by loss of exocrine (digestive enzyme) function, significant progressive pancreatic fibrosis, recurrent or chronic pain syndromes, diabetes mellitus, an increased risk of pancreatic cancer, and premature death.</li> <li>• Patients with pancreatitis endure continuous debilitating pain which prevents them from participating in school or work; as well as daily tasks such as being able to drive, eat, ability to exercise, have a social life, attend events/functions, and all plans revolve around in-case of pancreatitis attacks. Opioid pain medications provide the only relief for many patients, but they come with side effects: nausea, vomiting, constipation, and diarrhea to name a few. Along with the pain, the relief provided by opiates can also prevent patients from participating in normal life, causing feelings of isolation and depression and hopelessness.</li> <li>• People with chronic and recurrent acute pancreatitis have very high hospital utilization rates. Acute pancreatitis is the most frequently documented discharge diagnosis (&gt; 270,000 per year) for hospitalizations caused by gastrointestinal diseases</li> <li>• Most patients present with intense upper abdominal pain that often spreads to the back. Other common symptoms include severe nausea, vomiting, fatigue, diarrhea, constipation, and weight loss.</li> </ul> <p>Symptoms vary from individual to individual—however, relentless pain, nausea, fatigue, and many other mental and physical symptoms affect everyday life, including relationships, careers, schooling, families, and mental health.</p>	<p><b>Pancreatitis symptoms can profoundly impair a patient’s ability to lead a “normal” life and can result in a low quality of life.</b></p> <p><b>Patients have high hospitalization rates for chronic pancreatitis. Acute pancreatitis is the most frequently documented discharge diagnosis caused by gastrointestinal diseases.</b></p>
<p><b>Current Treatment Options</b></p>	<p>Treating symptoms such as severe pain and nausea and preventing a recurrence are the primary goals of treatment, with efforts focused on identifying the underlying cause and triggers to avoid future episodes. The treatment journey is challenging, with countless procedures and treatments of trial and error, often with minimal improvement in symptoms. There currently are no FDA approved medications for pancreatitis, although there are treatments and drugs to help treat and alleviate symptoms; nevertheless, many patients experience only modest to no relief.</p>	<p><b>Chronic pancreatitis is currently only treated symptomatically which provides patients with little to no significant relief and does not stop, slow or reverse the disease. There is an urgent need for FDA-approved medications for pancreatitis.</b></p>

<p>Treatments may include:</p> <ul style="list-style-type: none"> <li>• Pancreatic enzyme replacement therapy (PERT) is prescribed to alleviate the effects of pancreatic exocrine insufficiency and generally does not relieve pain.</li> <li>• If non-opioid analgesics do not relieve pain, opioids are typically prescribed.</li> <li>• If there is a narrowing or blockage of the pancreatic duct by scar or stone formation, endoscopic stent placement or lithotripsy can be employed.</li> <li>• If chronic pain persists, surgical treatment may be an option for qualified candidates.</li> <li>• Drainage procedures such as the Puestow procedure, or hybrid drainage-and-resectional procedures such as the Frey and Beger operations may sometimes result in pain relief.</li> <li>• The Whipple procedure is considered when there is suspicion of underlying pancreatic cancer.</li> <li>• The total pancreatectomy with islet auto transplantation (TPIAT) is an effective treatment in some patients. It is an extreme procedure involving the removal of the pancreas, duodenum, reconstruction of the intestine, and customarily the removal of the spleen. Islets, which produce insulin and other hormones, are harvested from the pancreas and infused into the liver. This procedure is performed on both adults and pediatric patients. Not every individual with pancreatitis is a candidate for the surgery. Other factors to consider regarding TPIAT are: (A) the operation is irreversible; (B) there is a risk of serious and life-threatening complications; (C) pain relief is not always experienced; (D) protection from diabetes is often incomplete and of variable durability; (E) all patients will require life-long, full-dose pancreatic digestive enzyme replacement therapy; (F) significant post-surgical gastrointestinal motility dysfunction may occur, and (G) none of these patients could benefit from any future medial approaches for controlling pancreatic pain, cancer risk, or other complications. (<a href="#">Pancreatology</a>, Volume 14, Issue 1, January–February 2014)</li> </ul> <p>Pancreatitis is stigmatized, and both pediatric and adult patients can be labeled as “alcoholic” or “drug seeking”, affecting the level and quality of treatment a patient receives. Studies show heavy drinking is not the most common cause of pancreatitis.</p>	<p><b>Treatment goals include; preventing inflammation and damage to the pancreas, reducing the need for major surgery such as the TPIAT, and finding more effective alternatives to opioid pain medications.</b></p> <p><b>The opioid epidemic has caused a massive barrier in patients getting the necessary pain medications to treat the extreme pain they endure.</b></p> <p><b>Although the TPIAT procedure can be effective for the relief of pain, it is the most radical of all the surgical options for the disease. Generally, it will cause the patient to develop diabetes and often has other serious complications.</b></p> <p><b>Many of the long-term effects of the TPIAT on a still-growing body are unknown. Caregivers of pediatric pancreatitis patients are therefore faced with choosing between a relentless debilitating illness and a radical operation with unknown long-term effects.</b></p>
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<i>See the Voice of the Patient report for a more detailed narrative.</i>	
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## **Conclusion and Next steps**

The voices heard throughout the meeting and also in the survey shared a commonality – they all expressed a need for future pancreatitis treatments other than enzyme replacement therapy or a major surgery that requires removal of the pancreas and multiple organs, and does not guarantee a life free of pain or other surgical complications. Pancreatitis affects almost every aspect of patients' lives. Children with pancreatitis lose out on their childhood, miss school, and miss time spent with friends. Their childhood is replaced with days and weeks in the hospital or isolation in their room, having to manage mental and emotional trauma in their young lives. Often adult patients need to change the trajectory of their lives (change in career, early retirement) due to living with intense pain and needing to manage the mental health issues that come with having a chronic, invisible illness.

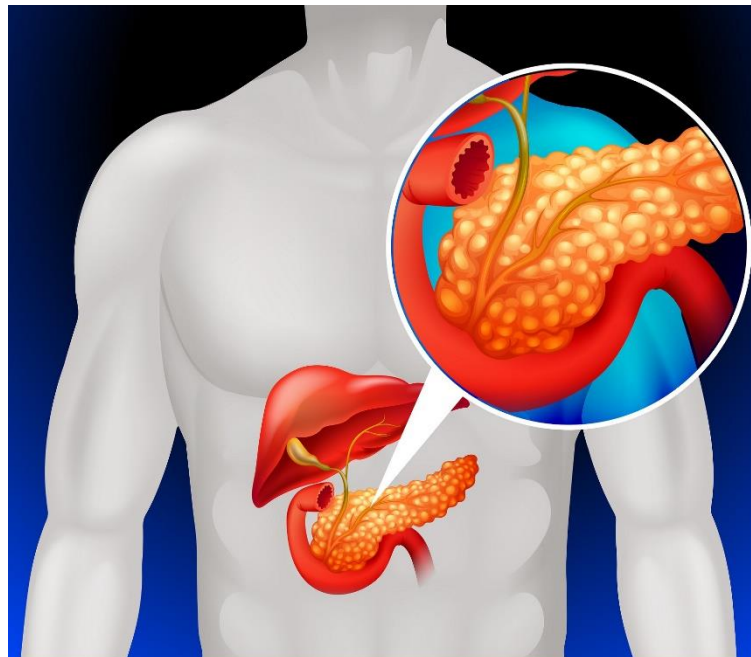
All participants (as well as the NPF and partners) agree that further education about pancreatitis is needed in the community and for medical professionals. We hope that all patients will be treated with care and not stigmatized and labeled “alcoholic” or “drug seeking” and are not going years misdiagnosed with this degenerative disease. The NPF is grateful for this opportunity to share the voices of this community through this report and, in turn, teach shareholders and decision-makers about this disease to work on finding better treatment options for pancreatitis and improving the quality of life for the patient.



The  
**National Pancreas**  
Foundation

# **Externally-Led Patient-Focused Drug Development Meeting on Pancreatitis**

*March 3, 2020 | Silver Spring, MD*



## **WELCOME LETTER**

### **Dear Members of the Pancreatitis Community,**

On behalf of the National Pancreas Foundation, I want to welcome you to the Externally-Led Patient Focused Drug Development Meeting for Pancreatitis. We are so pleased that you are taking part in this event either in person or by webcast. We and our partners, Mission: Cure, Rebecca's Wish and the FCS Foundation, are eager to put a spotlight on the stories of patients and their caregivers who have been affected by acute and chronic pancreatitis.

We know that it will be impossible to hear the experiences of the hundreds of thousands of patients, including children, adolescents and adults, who have been the victims of these diseases each year in the United States. But representatives of the U.S. Food and Drug Administration are here today to hear a sample of the experiences that describe the burdens of these diseases, the problems in finding treatment, and the lasting effects of these conditions.

People affected by acute and chronic pancreatitis suffer from long-term complications of these diseases and are especially aware that there are no approved drug treatments to shorten the course or prevent ongoing problems due to these conditions. They are eager for cures or for treatments which will make real improvements in the outcomes of pancreatitis.

By being here today, you are providing valued input to the processes which can guide the clinical trials of new drugs and treatments for pancreatitis. Your testimony is invaluable to illuminate the full spectrum of the effects of these diseases. Thank you so much for helping to make a difference and for helping us to understand the real impact of pancreatitis.

Sincerely,

A handwritten signature in cursive script that reads "Dana K. Andersen" followed by a horizontal line.

Dana K. Andersen, MD  
Chair, Board of Directors, National Pancreas Foundation



## Externally-Led Patient-Focused Drug Development Meeting on Pancreatitis

### Silver Spring Civic Building

1 Veterans Pl, Silver Spring, MD 20910

8:30 AM – 12:30 PM | March 3, 2020

<b>8:00 – 8:30 AM Registration and Continental Breakfast</b>	
<b>Opening Remarks and Morning Overview</b>	
8:30 – 8:45 AM	<b>Welcome and Opening Remarks</b> <i>Dana K. Andersen, MD</i> <i>Chair, Board of Directors, National Pancreas Foundation</i>
8:35 – 8:45 AM	<b>Erica Lyons, MD – Overview of PFDD</b> <i>Medical Officer Team Leader</i> <i>Division of Gastroenterology and Inborn Errors Products</i> <i>Center for Drug Evaluation and Research</i> <i>U.S. Food and Drug Administration</i>
8:45 – 8:55 AM	<b>Overview of Pancreatitis</b> <i>Wahid Y. Wassef, MD</i> <i>Chief of Endoscopy</i> <i>Director, Pancreas Clinic, UMASS Memorial Health Care</i> <i>Professor, University of Massachusetts Medical School</i>
8:55 – 9:05 AM	<b>Introduction, Overview of Meeting, and Demographic Polling</b> <i>James Valentine, JD, MHS</i> <i>Meeting Moderator</i>
<b>Panel 1: Acute and Chronic Pancreatitis - Patient Perspective on the Burdens of the Disease and Current and Future Approaches to Treatments</b>	
9:05 – 10:25 AM	<b>Symptoms and Daily Impact   Current and Future Approaches to Treatments</b> <ul style="list-style-type: none"> <li>• Presentations by 4 Affected Individuals and Caregivers (20 minutes)</li> <li>• Moderated Audience Discussion Panel #1 (60 minutes)</li> </ul>
<b>10:25-10:40 AM Break</b>	
<b>Panel 2: Pediatric Pancreatitis - Patient Perspective on the Burdens of the Disease and Current and Future Approaches to Treatments</b>	
10:40 -10:50 AM	<b>Pediatric Pancreatitis – Patient Challenges and Obstacles to Care</b> <i>Melena D. Bellin, MD</i> <i>University of Minnesota Medical Center</i> <i>Schulze Diabetes Institute</i> <i>Associate Professor Pediatric Endocrinology</i> <i>Director of Research, Islet Autotransplant Program</i>
10:50 AM -12:10 PM	<b>Symptoms and Daily Impact   Current and Future Approaches to Treatments</b> <ul style="list-style-type: none"> <li>• Presentations by 4 Affected Individuals and Caregivers (20 minutes)</li> <li>• Moderated Audience Discussion Panel #2 (60 minutes)</li> </ul>
12:10 - 12:20 PM	<b>Summary Remarks</b> <i>Larry Bauer</i> <i>Sr. Regulatory Drug Expert, Hyman, Phelps, &amp; McNamara, P.C.</i>
12:20 PM –12:30 PM	<b>Next Steps, Summary, and Closing Remarks</b> <i>Jane M. Holt</i> <i>Co-Founder, National Pancreas Foundation</i>

## **ABOUT THE NATIONAL PANCREAS FOUNDATION**

[www.pancreasfoundation.org](http://www.pancreasfoundation.org)

### **Our Mission**

The National Pancreas Foundation (NPF) provides hope for those suffering from pancreatitis and pancreatic cancer through funding cutting edge research, advocating for new and better therapies, and providing support and education for patients, caregivers, and health care professionals.

### **Our History & Research Impact**

To fulfill its mission, the NPF raises and manages a charitable foundation from which grants are made directly to researchers seeking to resolve the challenging medical problems of pancreatic diseases. The NPF is the only foundation dedicated to patients who are suffering from all forms of pancreas disease – pediatric pancreatitis, acute pancreatitis, chronic pancreatitis and pancreatic cancer. A National Patient Registry is being developed for individuals suffering the isolating and debilitating conditions associated with pancreatic disease.

The NPF and its founding members and volunteers are committed to maximum efficiency. The Foundation's goal is to direct as much of our revenue to programs. To achieve this we rely heavily on the invaluable donations of time, energy and financial support of the many friends and interested parties who have been touched by the suffering of so many people. Research grant proposals from a wide variety of researchers are solicited. With the help of the Foundation's Grant Review Council, the NPF makes grants to those whose proposals appear most likely to lead to scientific advancements in the field of pancreatic disease. Founded in 1997, the NPF has given over \$4 million to fund 121 groundbreaking research projects. The Foundation advocacy efforts have also been very effective, actively participating on the advisory council for National Institute of Diabetes and Digestive and Kidney Diseases, the National Cancer Institute Gastrointestinal Steering Committee, and as Department of Defense Consumer Reviewers. Furthermore, the NPF has supported initiatives that have led to millions of dollars of additional research funding by the National Institutes of Health, the Department of Defense, and other institutions.

## OUR PARTNERS



The Familial Chylomicronemia Syndrome (FCS) Foundation was established by Lindsey Sutton and Melissa Goetz, two disease advocates directly impacted by FCS. In addition, The FCS Foundation board of directors includes additional leaders from the FCS patient community.

FCS is a genetic condition that causes a buildup of fats in the blood that can increase the risk of severe abdominal pain and potentially fatal attacks of pancreatitis. It is also sometimes known as lipoprotein lipase deficiency (LPLD), Fredrickson Type 1 hyperlipoproteinemia and familial hypertriglyceridemia. There are currently no FDA approved therapies for the treatment of FCS. This disease frequently leads to symptoms such as pancreatitis and fatty deposits in the skin. Most patients take steps to reduce their risk of pancreatitis through lifestyle modifications including strictly limiting fat intake. FCS occurs in about 1 in 1 million people and the genetic disorder causes the body to not be able to break down certain fats correctly. The mission of The FCS Foundation is to make sure that all people have access to the information and support they need to get a proper diagnosis and manage FCS more effectively.

**Mission: Cure** Mission: Cure is a nonprofit organization founded and led by Chronic Pancreatitis patients and their families with a single mission- to find effective treatments and ultimately cures that will improve the lives of children and adults affected by chronic and recurrent acute pancreatitis. To achieve this urgent goal, Mission: Cure applies an innovative funding approach that leverages the best aspects of venture philanthropy, angel investing and monetary incentives to fund promising research and development aimed at delivering effective treatments to patients as quickly and efficiently as possible. Mission: Cure brings together patients and their families, researchers and industry leaders from a range of disciplines to align priorities and advance multiple areas of research in parallel, driving progress toward our goal to measurably improve patients' lives. This PFDD meeting is an important part of that effort. We have already made significant progress and leading scientists say chronic and recurrent acute pancreatitis treatments are within reach. With the support of the pancreatitis community and collaboration with all stakeholders, we are optimistic that we will achieve our goal to find a cure and put an end to pancreatitis pain and suffering!



### **Rebecca's Wish**

Rebecca's Wish is a nonprofit organization started by a 17- year old high school junior from San Antonio, Rebecca Taylor. Rebecca founded this 501(c)3 in 2018 as a result of her ten-year struggle with chronic pancreatitis and post TPAIT complications. Rebecca's Wish came to life after Rebecca was referred to Make-A-Wish and asked to



share her one, true wish. She replied that she wanted to meet with a medical philanthropist to help start a nonprofit that helps children just like her. Among our many accomplishments, Rebecca's Wish spearheaded an unprecedented agreement with local hospitals to help train the world's first pediatric-trained pancreatic endoscopists. We have funded the placement of two of these highly-specialized physicians in hospitals (Los Angeles and New Orleans). We are currently training a third pediatric-trained pancreatic specialist and intend to train one new physician every year. The mission of Rebecca's Wish is to promote the prevention and treatment of pancreatic diseases through education, partnership, and research while supporting the children and their families affected by these ailments.

## **SPEAKERS**



### **Dana K. Andersen, MD, FACS**

Dr. Andersen received his undergraduate and medical school training at Duke University, where he was a member of Alpha Omega Alpha, the medical honorary society. He initially planned to become a Gastroenterologist, but a 6-month elective as a General Surgery resident convinced him that abdominal surgery was more interesting and more fun. He became Board Certified in both Internal Medicine and Surgery, and rose through the ranks of academic surgery to become Chief of General Surgery at Yale, Chair of Surgery at UMass, and Chief of Surgery and

Vice Chair of Surgery at Johns Hopkins Bayview Medical Center. In 2012 he joined the Digestive Disease Division at NIDDK.

In 2015, Jane Holt (co-founder) asked him to join the Registry Steering Committee, and in 2017 he joined the NPF Board of Directors. Dr. Andersen's research and clinical interests include both chronic pancreatitis and pancreatic cancer, and the mission of the NPF fits squarely with those interests. Before joining the NIH as a program officer in NIDDK, he cared for many patients with both forms of pancreatic disease and knows fully the challenges facing both patients and physicians. His transparent agenda at NIDDK is to increase funding programs related to pancreatic disease. The success of other disease-oriented foundations in driving awareness and research funding convinces him that the NPF has an important role in improving the care of patients with both benign and malignant pancreatic disease through its educational, support, and advocacy programs and is happy to contribute in any way to advance that mission.

Dr. Andersen currently serves as the Chair of the NPF Board of Directors and is an adjunct Professor of Surgery at Oregon Health and Science University in Portland, where he lives.



**Larry J. Bauer**

Larry provides counsel to drug manufacturers on a wide range of regulatory topics including Rare Pediatric Disease Designation requests, Orphan Drug Designation requests, Fast Track and Breakthrough Therapy Designation requests, drug development regulatory strategy, preparing regulatory submissions, and drafting regulatory policies and procedures. Mr. Bauer has extensive experience in patient advocacy and has expertise in the planning and execution of Patient Focused Drug Development meetings.



**Melena D. Bellin, MD**

Dr. Bellin is an Associate Professor of Pediatric Endocrinology and Diabetes and the Director of Research for Islet Autotransplantation at the University of Minnesota. She completed her medical school, pediatric residency, and endocrinology fellowship at the University of Minnesota, where she currently works in the Division of Endocrinology, Departments of Pediatrics with a joint appointment in the Department of Surgery (Schulze Diabetes Institute). Her research focuses include clinical islet transplantation for type 1 diabetes, chronic pancreatitis related diabetes mellitus, and total pancreatectomy and islet autotransplantation (TPIAT) for patients with severe chronic pancreatitis. In 2019 she received

a Presidential Early Career Award for Scientists and Engineers (PECASE) for her research on the treatment of chronic pancreatitis with TPIAT.



**Jane Holt**

Jane has spent the last 25 years committed to volunteer work in the Boston area. As a young mother, she became very involved in educational activities for her children. Having spent a decade surviving chronic pancreatitis, Mrs. Holt saw an acute need for greater awareness and education around diseases of the pancreas. And so, in 1997, she founded the National Pancreas Foundation with Co-Founder, Patter Birsic. She has been very involved in getting pancreatitis listed as one of the research topics for the Department of Defense Peer Review Medical Research Program and has served as a consumer reviewer for these programs. She also served as a member

of the Advisory Council of the National Institute of Diabetes and Digestive and Kidney Diseases. Ms. Holt is a graduate from Skidmore College with a B.A. in Biochemistry, and lives in the Back Bay of Boston.



**Erica Lyons, MD**

Dr. Lyons is a clinical team leader for the Gastroenterology team in the Division of Gastroenterology and Inborn Errors Products (DGIEP). Dr. Lyons was educated in Biology as an undergraduate and received her medical degree at the University of Louisville, where she subsequently completed a pediatric residency prior to joining the university faculty. During her time in Louisville, she served as the Medical Director for a pediatric practice focused on special needs populations and acted as the site's research coordinator, investigator, and PI for several clinical studies. She joined the Center for Drug

Evaluation and Research as a Medical Officer in DGIEP in January of 2017, where she evaluates numerous drug development programs for gastrointestinal indications. Her medical interests include pediatric rare diseases, eosinophilic gastrointestinal disorders, antiemetic therapies, and pancreatitis.



**James Valentine, JD, MHS**

James assists medical product industry and patient advocacy organization clients in a wide range of new drug and biologic development and approval matters. Mr. Valentine has been central to the transition of the FDA Patient-Focused Drug Development (PFDD) program to externally-led meetings, having helped plan and moderated two-thirds of those. Before joining his current firm in 2014, he worked at the FDA as a patient liaison where he facilitated patient input in benefit-risk decision-making and regulatory policy issues. There, Mr. Valentine

administered the FDA Patient Representative Program, helped launch the PFDD program, and developed the FDA Patient Network. He holds a law degree from University of Maryland and a masters from Johns Hopkins School of Public Health.



**Wahid Y. Wassef, MD, MPH, FACP**

Dr. Wassef is the Associate Chief Quality Officer Department of Medicine, Director of Advanced Endoscopy and Pancreatic Disease Clinic, and, Medical Director of Advanced Fellowship Program at the University of Massachusetts School of Medicine. His awards have included: Medical College of Virginia award for excellence in teaching, Governor's Award for excellence in clinical research by the American College of Gastroenterology for development of the PANQOLI (Pancreatitis Quality of Life Instrument) and Nobility in Science Award by the National Pancreas Foundation. His publications have included 65 original manuscripts in peer reviewed journals, multiple abstracts and chapters. Focus of research has been that of pancreatic disease.

The most significant study has been the development of the first quality of life instrument for the evaluation of patients with chronic pancreatitis: Pancreatitis Quality of Life Instrument (PANQOLI). This instrument was supported by

grants from the National Pancreas Foundation as well as the American College of Gastroenterology. It is currently available for use in the NPF website and since its publication in 2016 has been used in 6 original manuscripts, 4 ongoing clinical trials for the evaluation of various treatments in chronic pancreatitis patients, and 2 international studies in China and Denmark.

## **PANELISTS**

### **ADULT PANCREATITIS (PANEL 1)**



#### **Adriana Llamas Cowdin**

Adriana was first diagnosed with acute pancreatitis in 2015, with her first hospitalization lasting for 10 days. Between 2015 and 2016 she has undergone 17 procedures for her pancreatitis and was then diagnosed with chronic pancreatitis and pancreatic divisum and was living on and off feeding tubes. In November 2019, she had the TPIAT surgery and has regained parts of her life back.

In her personal time, Mrs. Cowdin is an avid reader, writer and published author who resides in Indianapolis, Indiana with her husband and fur baby, Henry Winston. She also enjoys traveling to IndyCar races where you can find her in the pits with an insider view as her husband is a Technical Director and Race Engineer in the IndyCar series.



#### **Eric Golden**

Eric is an investment banker, executive and attorney living in Santa Monica, California with his wife Rebecca and three children, Jonathan, Emma and Jackson. Mr. Golden was diagnosed with chronic pancreatitis in 2012 after years of worsening digestive issues. In an effort to learn as much as possible about the disease and help those suffering from it, he joined the board of the NPF and the Collaborative Alliance for Pancreatic Education and Research (CAPER) and co-founded Mission: Cure, a non-profit aimed at finding effective treatments for the disease within 10 years.

Professionally, Mr. Golden is the founder and Managing Director of Fluential Partners, an advisory firm focused on mergers and acquisitions, financing and other strategic transactions. He received a JD from Harvard Law School and an AB from Brown University.

**Jane Holt (please see bio above)**



### **Hillary Mendelsohn**

At the age of 36, Hillary was diagnosed with pancreatic cancer. Because of her dietary restrictions due to her streamlined digestive system, if she ate something that didn't work, acute pancreatitis would ensue. Over the last 16 years, she has had have had eight surgeries related to the pancreas. She is a pancreatic cancer survivor and pancreatitis patient that lives with the motto: Whatever it takes.

Professionally, Mrs. Mendelsohn's life is very busy as the Executive Vice President of The Carlyle Group, Ltd., a real estate company, that specializes in the manufactured housing industry. The company founded 40 years ago, owns and operates one of the largest privately held portfolios in the United States with properties in 10 states. In 1999, she created an internet company and is Founder and CEO of thepurplebook: The Definitive Guide to Exceptional Online Shopping, producing and publishing nine resource guides for online shopping in book form and launching the online version ([www.thepurplebook.com](http://www.thepurplebook.com)), in addition to consulting in the field of e-commerce and go-to media expert on online shopping trends.

Ms. Mendelsohn is the proud mother of Max (23) and Gabriella (21), and has expanded her family to include her new husband Mike and his children, Jonathan (21) and Brooke (20). They live in Los Angeles.

### **PEDIATRIC PANCREATITIS (PANEL 2)**



### **Logan Williams** *(As told my his Mother, Erica Williams)*

Logan is an amazing 7-year old boy on an epic journey with his pancreas. He is in the second grade, playing soccer and soon to start baseball. He is caring, insightful, feels emotions to the fullest, and has a great sense of humor. Mr. Williams was first diagnosed with pancreatitis at the age of four. It was not until he was five that his parents learned it was caused by a genetic mutation. As his journey continues, Mr. Williams continues to leave his family in awe of his resiliency. Hereditary pancreatitis is progressive and in this last year they are beginning to see it express itself more on a daily basis. Mr. Williams has been approved for the TPIAT – his family is grateful to have it as an option, knowing it is a huge

leap, and they are very hopeful to help carve out steps in between.



### **Attie Jamison**

Diagnosed with pancreatitis at the age of 4, Attie spent time in the hospital each year as she was growing up. Eventually, the diseased pancreas began to affect her health in ways that caused her quality of life to suffer. As a dancer, she was extremely active and disciplined, but her body was beginning to let her down. After missing auditions and dress rehearsals, the frustration and pain were becoming more than she could handle. In December of 2018, Ms. Jamison underwent surgery at Cincinnati Children's Medical Center to remove her pancreas. Recovering from a TPIAT and adapting to a new normal has been challenging and rewarding. Ms. Jamison is a freshman at Muskogee High School in Muskogee, Oklahoma. She is a member of the Varsity Dance Team and participates in many AP classes. She is also an active leader in her youth group at Timothy Baptist Church. She enjoys teaching children's church and excels at organizing and interacting with small children. She loves to dance ballet, tap, jazz and hip hop, and she is a master "TikTok" performer.



### **Gracie Jamison**

On Gracie's 16th birthday, she sat shocked in the emergency room as she realized she was facing the same pancreatic disease she helped nurture her younger sister through for years. Fearful, she faced a journey of medical inquiries, blood work, and recording attacks and pain values ("on a scale of one to ten"). Ms. Jamison is a leader in her youth group at Timothy Baptist Church, where she also teaches children's church and is adored by the young children she works with. She is a member of the Muskogee High Video Productions Crew where she assists in photographing, filming, and live streaming sporting events each week. After three summers of mowing yards to purchase her first car, Ms. Jamison now enjoys working in the gifts section and customer service at a local pharmacy after school.



### **Rebecca Taylor**

Rebecca is 17 years old and lives in San Antonio, Texas. Her first attack of pancreatitis occurred at the age of 7. After years of hospitalizations and further pancreatitis attacks, Ms. Taylor underwent a TPAIT at the age of 12. Rebecca still suffers complications from her transplant that continues to require long-term hospitalizations. She is a constant advocate for better pediatric pancreas care and founded a nation-wide charity named Rebecca's Wish that has raised over a million dollars to help research, patient care and charitable services for children in need.



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## Appendix 2: Meeting Panelists

The PFDD meeting on pancreatitis was a half-day event comprised two patient and caregiver panels; the first panel included adults living with acute and chronic pancreatitis, and the second panel included pediatric pancreatitis patients and caregivers. All the panelists have chronic pancreatitis as the disease can start out as acute and progressively worsen to chronic.

### ADULT PANCREATITIS (PANEL 1)

**Adriana Llamas Cowdin, 43, Indianapolis, Indiana:** Patient was first diagnosed with acute pancreatitis in 2015. Between 2015 and 2016 she has undergone 17 procedures for her pancreatitis and was then diagnosed with chronic pancreatitis and pancreatic divisum. She had the TPIAT surgery in 2019.

**Eric Golden, 51, Los Angeles, CA:** Patient was diagnosed with chronic pancreatitis in 2012 after years of worsening digestive issues.

**Jane Holt, 67, Boston, MA:** Patient with idiopathic pancreatitis who has dealt with the disease for most of her adult life. She was diagnosed with pancreatitis in early January 1988.

**Hillary Mendelsohn, 54, Los Angeles, CA:** Patient was diagnosed with pancreatic cancer in February of 2002 at the age of 36. She had a Whipple procedure ten days after diagnosis. Over the last 16 years, she has had eight surgeries related to her pancreas. She is a pancreatic cancer survivor and pancreatitis patient.

### PEDIATRIC PANCREATITIS (PANEL 2)

**Logan Williams, 7, Mullica Hill, NJ:** The patients' story was shared through his mother, Erica Williams. At the age of four, the patient had surgery to remove a choledochal cyst, had pancreatitis attacks, and was diagnosed with hereditary pancreatitis. He has been approved to have the TPIAT surgery.

**Attie Jamison, 15, Muskogee, OK:** Patient was diagnosed with pancreatitis at the age of 4 with hereditary pancreatitis. In 2018, the patient underwent surgery for the TPIAT.

**Gracie Jamison, 17, Muskogee, OK:** Patient had her first pancreatitis attack on 16<sup>th</sup> birthday and has hereditary pancreatitis. She had the TPIAT surgery in October 2020.

**Rebecca Taylor, 17, San Antonio, TX:** Patient suffers from chronic pancreatitis caused by an unknown immunologic disorder and has undergone the TPIAT at age 12. Patients' first attack of pancreatitis occurred at the age of 7. She still suffers complications from her transplant that continues to require long-term hospitalizations.

14

Polls

81

Participants

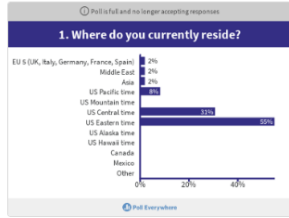
132

Average responses



Average engagement

# 1. Where do you currently reside?



Response options	Count	Percentage
EU 5 (UK, Italy, Germany, France, Spain)	1	2%
Middle East	1	2%
Asia	1	2%
US Pacific time	4	8%
US Mountain time	0	0%
US Central time	15	31%
<b>US Eastern time</b>	<b>27</b>	<b>55%</b>
US Alaska time	0	0%
US Hawaii time	0	0%
Canada	0	0%
Mexico	0	0%
Other	0	0%

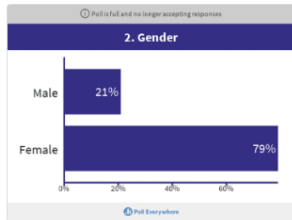


Engagement

49

Responses

# 2. Gender



Response options	Count	Percentage
Male	9	21%
<b>Female</b>	<b>34</b>	<b>79%</b>

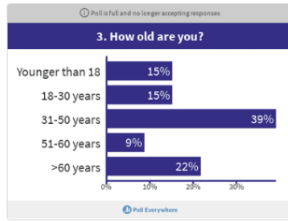


Engagement

43

Responses

### 3. How old are you?

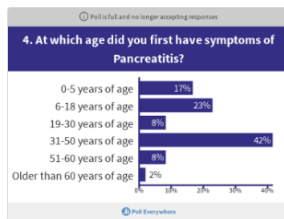


Response options	Count	Percentage
Younger than 18	7	15%
18-30 years	7	15%
<b>31-50 years</b>	<b>18</b>	<b>39%</b>
51-60 years	4	9%
>60 years	10	22%

57%  
Engagement

46  
Responses

### 4. At which age did you first have symptoms of Pancreatitis?

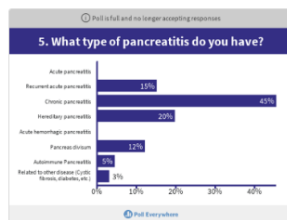


Response options	Count	Percentage
0-5 years of age	8	17%
6-18 years of age	11	23%
19-30 years of age	4	8%
<b>31-50 years of age</b>	<b>20</b>	<b>42%</b>
51-60 years of age	4	8%
Older than 60 years of age	1	2%

59%  
Engagement

48  
Responses

### 5. What type of pancreatitis do you have?

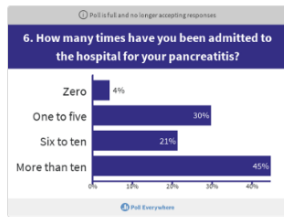


Response options	Count	Percentage
Acute pancreatitis	0	0%
Recurrent acute pancreatitis	10	15%
<b>Chronic pancreatitis</b>	<b>30</b>	<b>45%</b>
Hereditary pancreatitis	13	20%
Acute hemorrhagic pancreatitis	0	0%
Pancreas divisum	8	12%
Autoimmune Pancreatitis	3	5%
Related to other disease (Cystic fibrosis, diabetes, etc.)	2	3%

59%  
Engagement

66  
Responses

## 6. How many times have you been admitted to the hospital for your pancreatitis?

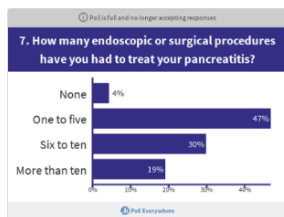


Response options	Count	Percentage
Zero	2	4%
One to five	14	30%
Six to ten	10	21%
<b>More than ten</b>	<b>21</b>	<b>45%</b>

58% Engagement

47 Responses

## 7. How many endoscopic or surgical procedures have you had to treat your pancreatitis?

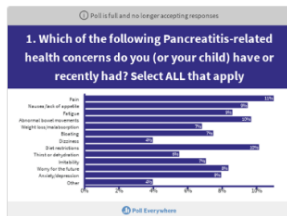


Response options	Count	Percentage
None	2	4%
<b>One to five</b>	<b>22</b>	<b>47%</b>
Six to ten	14	30%
More than ten	9	19%

58% Engagement

47 Responses

## 1. Which of the following Pancreatitis-related health concerns do you (or your child) have or recently had? Select ALL that apply

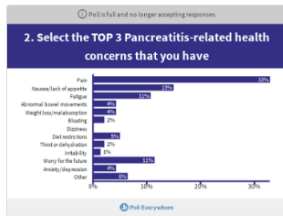


Response options	Count	Percentage
<b>Pain</b>	<b>50</b>	<b>11%</b>
Nausea/lack of appetite	43	9%
Fatigue	39	9%
Abnormal bowel movements	44	10%
Weight loss/malabsorption	31	7%
Bloating	34	7%
Dizziness	18	4%
Diet restrictions	46	10%
Thirst or dehydration	25	6%
Irritability	32	7%
Worry for the future	38	8%
Anxiety/depression	36	8%
Other	18	4%

58% Engagement

454 Responses

## 2. Select the TOP 3 Pancreatitis-related health concerns that you have

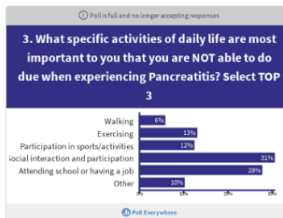


Response options	Count	Percentage
<b>Pain</b>	<b>46</b>	<b>33%</b>
Nausea/lack of appetite	21	15%
Fatigue	15	11%
Abnormal bowel movements	6	4%
Weight loss/malabsorption	6	4%
Bloating	3	2%
Dizziness	0	0%
Diet restrictions	7	5%
Thirst or dehydration	3	2%
Irritability	2	1%
Worry for the future	16	11%
Anxiety/depression	6	4%
Other	9	6%

58%  
Engagement

140  
Responses

## 3. What specific activities of daily life are most important to you that you are NOT able to do due when experiencing Pancreatitis? Select TOP 3

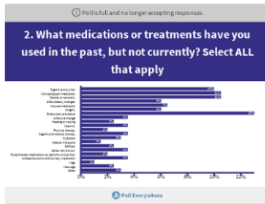


Response options	Count	Percentage
Walking	8	6%
Exercising	18	13%
Participation in sports/activities	17	12%
<b>Social interaction and participation</b>	<b>42</b>	<b>31%</b>
Attending school or having a job	38	28%
Other	14	10%

59%  
Engagement

137  
Responses

## 2. What medications or treatments have you used in the past, but not currently? Select ALL that apply

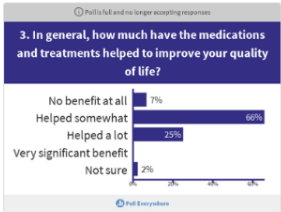


Response options	Count	Percentage
Digestive enzymes	20	10%
Non-opioid pain medication	21	11%
Opioids or narcotics	21	11%
Diets/dietary changes	12	6%
Nausea medication	13	7%
Surgery	12	6%
<b>Endoscopic procedure</b>	<b>26</b>	<b>13%</b>
Lifestyle change	7	4%
Heating or cooling	5	3%
Vitamins	7	4%
Physical therapy	4	2%
Cognitive/emotional therapy	7	4%
Hydration	6	3%
Medical marijuana	3	2%
Spiritual	5	3%
Celiac nerve block	7	4%
Experimental medications as part of a clinical trial	4	2%
Antidepressant or anti-anxiety medication	7	4%
Yoga	2	1%
Massage	5	3%
Other	6	3%

56%  
Engagement

200  
Responses

### 3. In general, how much have the medications and treatments helped to improve your quality of life?

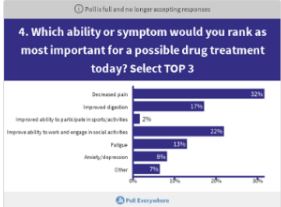


Response options	Count	Percentage
No benefit at all	3	7%
<b>Helped somewhat</b>	<b>29</b>	<b>66%</b>
Helped a lot	11	25%
Very significant benefit	0	0%
Not sure	1	2%

54% Engagement

44 Responses

### 4. Which ability or symptom would you rank as most important for a possible drug treatment today? Select TOP 3



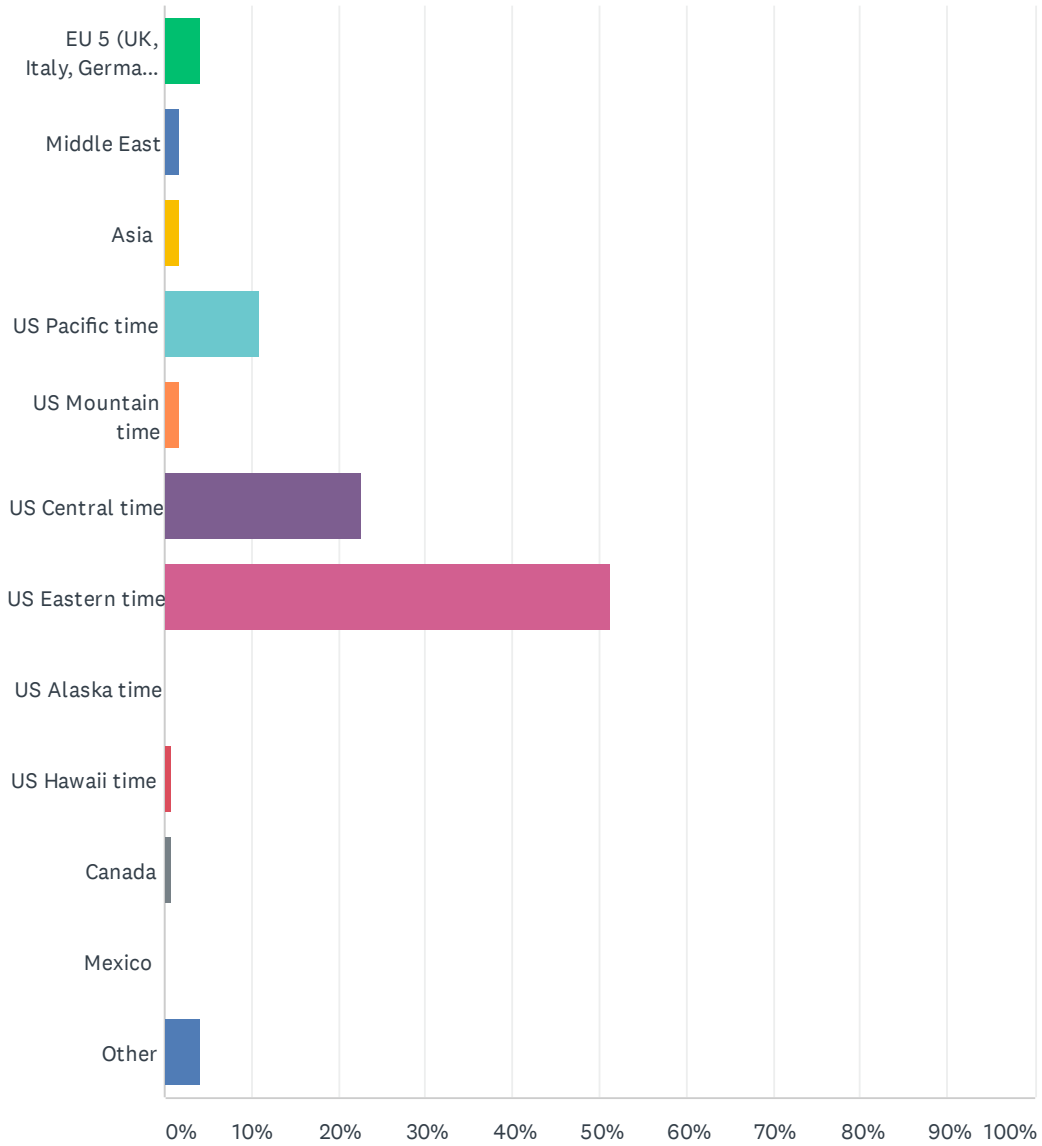
Response options	Count	Percentage
<b>Decreased pain</b>	<b>39</b>	<b>32%</b>
Improved digestion	21	17%
Improved ability to participate in sports/activities	2	2%
Improve ability to work and engage in social activities	27	22%
Fatigue	16	13%
Anxiety/depression	10	8%
Other	8	7%

52% Engagement

123 Responses

# Q1 Where do you currently reside?

Answered: 119 Skipped: 0

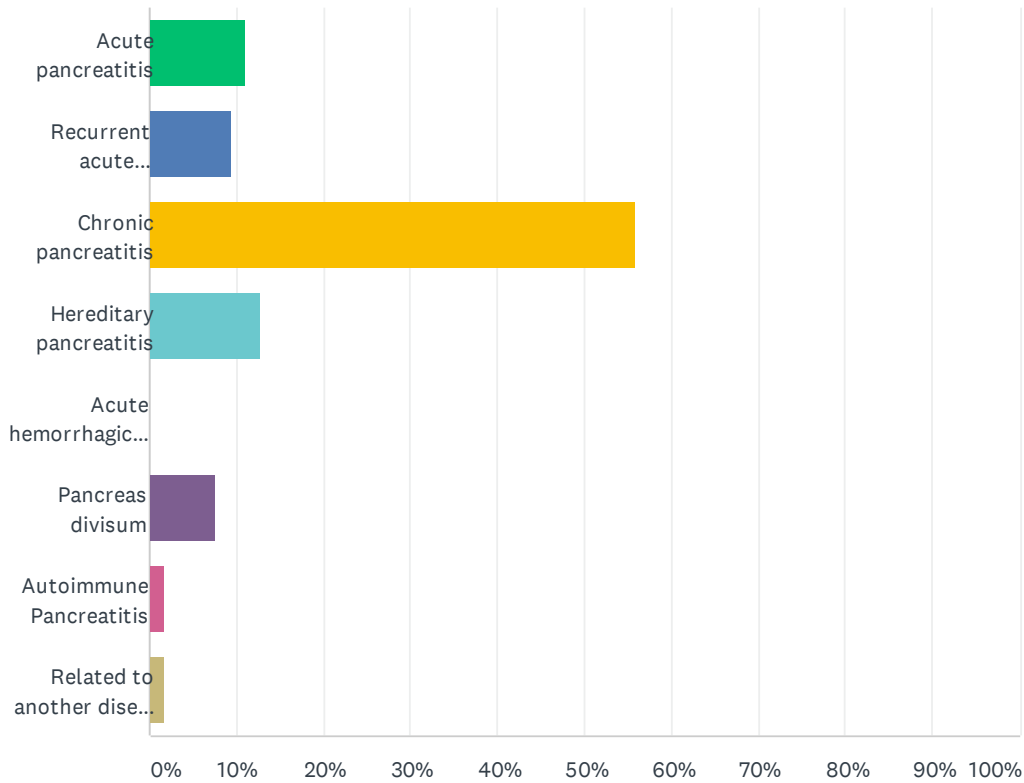




ANSWER CHOICES	RESPONSES	
EU 5 (UK, Italy, Germany, France, Spain)	4.20%	5
Middle East	1.68%	2
Asia	1.68%	2
US Pacific time	10.92%	13
US Mountain time	1.68%	2
US Central time	22.69%	27
US Eastern time	51.26%	61
US Alaska time	0.00%	0
US Hawaii time	0.84%	1
Canada	0.84%	1
Mexico	0.00%	0
Other	4.20%	5
<b>TOTAL</b>		<b>119</b>

## Q2 What type of pancreatitis do you have?

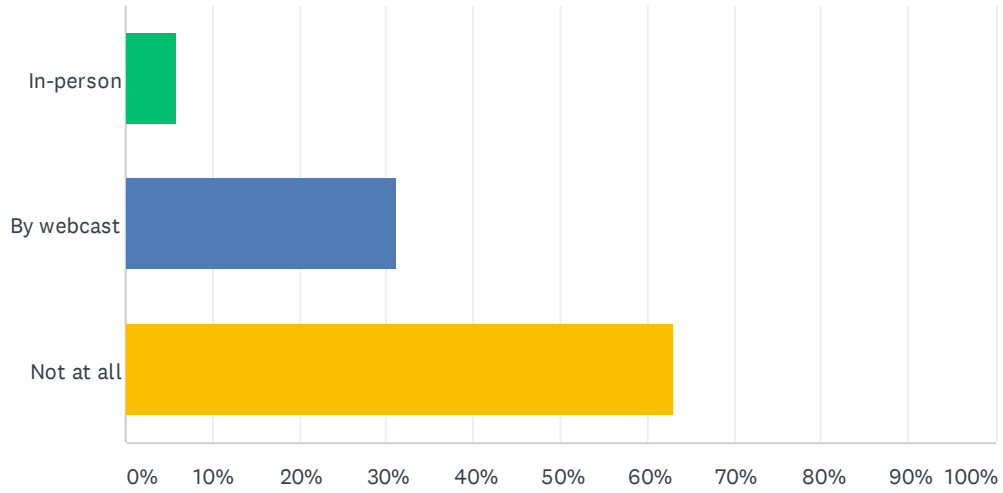
Answered: 118 Skipped: 1



ANSWER CHOICES	RESPONSES	
Acute pancreatitis	11.02%	13
Recurrent acute pancreatitis	9.32%	11
Chronic pancreatitis	55.93%	66
Hereditary pancreatitis	12.71%	15
Acute hemorrhagic pancreatitis	0.00%	0
Pancreas divisum	7.63%	9
Autoimmune Pancreatitis	1.69%	2
Related to another disease (Cystic fibrosis, diabetes, etc.)	1.69%	2
<b>TOTAL</b>		<b>118</b>

### Q3 On March 3rd, were you able to attend the PFDD meeting:

Answered: 119 Skipped: 0



ANSWER CHOICES	RESPONSES
In-person	5.88% 7
By webcast	31.09% 37
Not at all	63.03% 75
TOTAL	119

Q4 What are the top 1-3 symptoms or health effects related to your pancreatitis that are the most burdensome, and why? For example, what activities are you unable to do as much or fully because of the symptoms and health effects of your pancreatitis?

Answered: 118 Skipped: 1

#	RESPONSES	DATE
1	PAIN, Nausea, Feeding tube hell	6/10/2020 8:47 AM
2	Pain, nausea and vomiting/diarrhea. When you have one or all 3 it's very hard to function in life; i.e. children miss out on time with you, unable to attend your child's events, work suffers (especially if you cannot find one that is accommodating). I have also been diagnosed with PTSD, depression, anxiety and panic disorder.	6/10/2020 3:58 AM
3	Constant discomfort, Fatigue, never seem to feel on top of anything. If I go out for a few hours I'm exhausted the next day or days. Weight loss.	6/8/2020 6:06 PM
4	1) eating was always hard because I never knew if it would trigger an episode or not. It has created a very unhealthy and unstable relationship for me with food. 2) mental health. I struggle a lot with control now because you have no control over when an attack will come this causing me to feel the need to heavily control a lot of other aspects of my life. I also had never felt like I could truly trust myself going to hang out with friends since it could end up with me needing to be in the ER. 3) social impact. I always held myself back from trying new things and being a more adventurous person. I always wanted to go try something cool and new but felt held back by pancreatitis. I also never knew if the people I considered friends were actually going to maintain the friendship once they found out I had this major illness in my life.	6/7/2020 9:59 PM
5	1) I get abdominal pain/diarrhea after eating. It is such a hassle to ALWAYS have pills with me (Creon,) that can't get too hot. It would be GREAT to have a long acting Creon, that I take once or twice a day, rather than EVERY time I eat. 2) I have abdominal pain everyday. Usually 3-4 out of 10. Randomly it increases to 8 out of 10. It would be great to have a once a day, long acting pain pill that would take the pain away so I can focus on schoolwork, rather than being distracted by pain.	6/6/2020 6:42 PM
6	Family, work, exercise	6/5/2020 10:20 PM
7	Excruciating pain/ vomiting/diarrhea difficult to do ADLS	6/5/2020 3:45 PM
8	1.Pain 2.Malnutrition 3.Feeling weak always. Some times we feel so much of weakness that we are unable to do any normal activities.	6/5/2020 2:35 PM
9	Chronic pain, extreme food restrictions, damaged duct recovery	6/4/2020 10:13 PM
10	constant nausea, pain, diarrhea	6/4/2020 8:28 PM
11	Pain, diaherria, vomiting, which affects ability to perform everyday routine activities, eating, and frequent dehydration leading to tachycardia & frequent e/r visits resulting in inability to care for family or pets!	6/4/2020 5:10 PM
12	Pain,Nausea, Fatigue	6/4/2020 2:38 PM
13	To much physical activity causes pain, eating anything triggers pain, and nausea and sitting to long in a car causes pain and nausea	6/4/2020 12:54 PM
14	Dehydration, pain	6/4/2020 10:33 AM
15	Constant throbbing pain, Nausea, Unable to enjoy family gatherings due to pain	6/3/2020 11:16 PM
16	Not able to eat, due to nausea, vomiting and pain. not able to walk or stand for long periods due to pain. Not able to sleep due to pain.	6/3/2020 10:41 PM
17	I was unable to go to family functions. I was also unable to work longer than a 3 to 4 hour shift. I was also unable to play sports competitively.	6/3/2020 9:21 PM
18	I am unabke to jog regularly, as I experience great tension in my lower abdomen, like a tearing apart if ny organs, as well, Im unable to fully enjoy a night out with my family and friends because of the extreme restrictions tomy dietary needs, which also involve stabity of my sugar level. Ive recebtly been diagnosed with diabetes 1 and am currently on insulin.	6/3/2020 8:30 PM
19	EPI- maldigestion takes a real toll on daily quality of life, there is a lot of anxiety when leaving the house and worrying about staying close to a bathroom, getting to work on time can sometimes be a challenge because of the symptoms of EPI	6/3/2020 7:28 PM
20	Pain- I experienced debilitating pain for several months causing me to be unable to do my normal daily tasks such as care for my daughter. Lack of appetite; this one took me the longest	6/3/2020 6:54 PM

	to get past, caused me to lose over 50lbs and increased my fatigue. Fatigue would be my third most burdensome— there were times when I could barely walk to the bathroom I was so tired	
21	Diet, and pain management	5/30/2020 1:14 PM
22	Not able to work due to continuous, intense pain and fatigue.	5/18/2020 3:54 PM
23	Pain, inability to digest food, Nausea	5/18/2020 11:33 AM
24	Nausea - Pain - unable to be as active as I used to be... pain on the left side stays consistent and gets wherecno position is comfortable	5/12/2020 9:28 AM
25	Back pain levels hinder most activities. But I'm 83 and aging issues also contribute.	5/9/2020 9:34 AM
26	Back pain and fatigue and nausea	5/8/2020 10:04 PM
27	Pain. Have to leave class. Have to leave work	5/8/2020 9:26 PM
28	Pain in back, sometimes unable to work.	5/8/2020 8:50 PM
29	pain limits any activites that I can do and impedes my desire to eat and drink	5/8/2020 8:34 PM
30	Work	5/8/2020 6:10 PM
31	Pain (cannot work, exercise even slightly or do chores), Shakiness/weakness from the EPI (also life limiting in terms of leaving the house), nausea (gets very severe on a constant basis)	5/8/2020 5:39 PM
32	Constant pain and inflammation	5/8/2020 4:55 PM
33	Inability to make plans ahead of time because of bouts of pain, the necessity of always being relatively close to a hospital, when I worked my vacation time was always used for sick time	5/8/2020 3:39 PM
34	Digest things properly, tiredness, anxiety	5/8/2020 3:12 PM
35	The pain is the hardest for me to deal with. Some days any activities are hard for me to do but still try to do it	5/8/2020 2:14 PM
36	I have to modify my diet, a lot. The pain makes it unbearable to do simple household chores and I can't travel to far from a hospital.	5/8/2020 2:10 PM
37	Pain, nausea, quality of life	5/8/2020 2:00 PM
38	Cant sleep. Not hungry.	5/8/2020 1:56 PM
39	Nausea,Pain,Fatigue	5/8/2020 1:52 PM
40	Pain, nausea, Diabetes , cannot work due to uncertainty	5/8/2020 1:31 PM
41	Pain in my back and at just under my sternum prevent me from most things	4/29/2020 10:40 PM
42	Pain, malabsorption, and nausea	4/29/2020 12:47 AM
43	Abdominal pain and back pain. I need to watch my diet so that the symptoms don't get worse. I manage to do all of my usual activities but on a limited basis	4/28/2020 9:04 AM
44	a circular pain in the top of the stomach, feeling tired	4/28/2020 4:01 AM
45	Pain because its debilitating and stops me from being a normal mom, wife, and employee. Nausea and vomitting i feel so sick that i feel like i should bring a pillow and blanket into the bathroom, sadness so many dont understand and it hurts	4/27/2020 9:12 PM
46	Pain. Diabetes from the pancreatitis.nausea	4/27/2020 8:58 PM
47	Hospital when flares up	4/27/2020 7:33 PM
48	Pain that is constant on right side, occasional nasuea and fatigue. I'm 50 years old and feel like 70 when this hits me	4/27/2020 4:53 PM
49	Pain, depression and other digestive issues	4/27/2020 2:54 PM
50	Activities ,pain	4/27/2020 11:29 AM
51	Doctors don't believe me about my pancreatic pain, and misdiagnosed me with pleurisy; Digestive issues/chronic diarrhea; I can't get medical help in the Biloxi, MS area	4/26/2020 11:31 PM

52	Unable to work full time anymore. Deal with chronic pain and nausea and vomiting.	4/26/2020 10:05 PM
53	Pain	4/26/2020 4:54 PM
54	I am always tired,low energy,and always in the bathroom. I have some pain it not as bad as it used to be.	4/26/2020 1:12 PM
55	Exertion causes acute pain, I can't exercise or clean house. I never know if something is safe to eat.	4/26/2020 1:08 PM
56	Unrelenting pain that is only minimally relieved for a few hours at a time. Inability to eat without increasing pain which is not controlled well, malnutrition from not eating,	4/26/2020 11:42 AM
57	Pain,pain,pain	4/26/2020 2:22 AM
58	Chronic pain and discomfort is mentally and physically exhausting. I cannot return to my prevuous profession in correctuons and law enforcement for fear of getting hit in the abdomen. And my bowel issues have become a real problem when I'm out and about.	4/25/2020 10:54 AM
59	Pain in my back,feels like you can't breathe, nausea,which puts me off eating,time if the month more painful, avoiding all fatty foods, spices etc	4/25/2020 4:56 AM
60	Driving to work, flying (I'm an amateur pilot), and of course running, which I love to do	4/24/2020 8:44 PM
61	Pain, nausea, vomiting bile	4/24/2020 6:31 PM
62	Eat whatever I want. I have to watch out that I don't get too fatigued. Traveling can be difficult.	4/24/2020 4:26 PM
63	(Providing pre-TPIAT info)- 1. No predictability- severe pancreatitis episodes would come on suddenly and result in 3 weeks of being completely incapacitated and hospitalized, severe malnutrition that caused hair loss, excruciating pain in the stomach and upper back	4/24/2020 1:24 PM
64	Eating & feeling bloated or sick. Pain & cramping	4/24/2020 1:09 PM
65	Stomach pain, lack of energy, loss of doing things with friends, eating out , going on day trips	4/24/2020 1:04 PM
66	Eat whatever she wants, has to limit fatty foods. Miss school due to hospitalization.	4/24/2020 1:00 PM
67	Daily throbbing pain	4/24/2020 10:41 AM
68	Get out of bed, eat, enjoy day to day activities.	4/24/2020 10:33 AM
69	Pain, vomiting	4/22/2020 1:49 PM
70	I have developed PTSD, panic disorder and agoraphobia due to this disease. I am unable to do almost anything now days without the fear of nausea, vomiting, diarrhea and pain.	4/21/2020 9:51 PM
71	Weight loss, dietary needs and restrictions, fatigue, periodic pain.	4/21/2020 6:32 PM
72	Plan a vacation. Drive for more than few mins in case i get the severe pain. Work at a job	4/19/2020 7:32 AM
73	Fatigue , nausea, loss of appetite	4/17/2020 6:33 PM
74	Exercise walking too far eating	4/17/2020 6:05 PM
75	Can't eat a lot of foods that I like because they cause pain and nausea	4/17/2020 5:51 PM
76	Intermittent pain and nausea makes it impossible for me to get through a meal without excusing myself to go lie down. It also makes it impossible to make plans because I never know when I'll get too sick and have to go home.	4/17/2020 2:11 PM
77	My daughter does not have symptoms unless she is having an episode or flare up. She lives a normal life. She isn't in pain unless she has an episode. She misses being able to eat a fatty meal at times.	4/17/2020 12:29 AM
78	1. I am unable to make "plans" because I never know when or how long of a flare up I will have. 2. The pain is so severe at times that I am unable to do anything other than roll around, kneel in front of my recliner and lean over it in order to out pressure on my sternum area. 3. More often than not, I sleep in my recliner rather than in bed with my husband because I am either awake all night dealing with pain, the pain will wake me up numerous times a night or I am fighting blood sugar levels off and on due to malnutrition because of my pancreatitis.	4/17/2020 12:23 AM
79	Ride my horse, have energy to go and do fun things	4/16/2020 10:06 PM

80	Hospitalization usually required. Minimum of 3 days causing missed work. The pain is excruciating which can mean days in bed with no or very little liquids by mouth. Takes away your independence.	4/16/2020 8:36 PM
81	Severe pain that burns through me.	4/16/2020 5:12 PM
82	The vomiting daily, I am on TPN for nutrition, and not being able to eat	4/16/2020 4:40 PM
83	Pain, could not eat, could not do ADLs. Obviously, that sucks.	4/16/2020 4:29 PM
84	Pain. Sickness and constipation	4/16/2020 2:16 PM
85	Pain, hydration, nourishment/difficulty eating	4/16/2020 1:37 PM
86	Taekwondo (sports)	4/16/2020 1:29 PM
87	Physical stuff like mow the lawn	4/16/2020 11:56 AM
88	Extreme pain, vomiting. Fearful of attack occurring away from home. Unable to work any job due to completely debilitating when occurs. All self/life/home care is ended until pain has passed.	4/16/2020 11:39 AM
89	Pain, nausea and vomiting, difficulty eating	4/16/2020 11:04 AM
90	I have been living with CP for 24years now so I managed to become pain free. I have never stopped myself on doing anything or live in a different country because of my disease. Sometimes I have pain and that can ruin my day but I always try to refocus and forget it.	4/16/2020 11:03 AM
91	Sports, go to school, and trips with family	4/16/2020 10:36 AM
92	Pain, diarrhea, nausea	4/16/2020 3:24 AM
93	Gave up alcoholic, have to watch what I eat, get ulcers in my mouth and outside . You never know VB when an attack comes on. The medical bills just keep adding up. I have discomfort off and on.	4/15/2020 10:20 PM
94	Pain. Malabsorption. Gas. Steatorrea. Diarrhea.	4/15/2020 5:26 PM
95	Pain, nausea, vomiting	4/15/2020 4:27 PM
96	Not being able to eat, weight loss, constipation, diarrhoea	4/15/2020 2:45 PM
97	Can't eat, sleep and my quality of life is not 100%	4/15/2020 2:17 PM
98	Pain, nausea,. I had to quit my job doing home care for seniors, constantly cancelling plans,no stamina.	3/22/2020 4:09 AM
99	Right now I can not drink water without hurting, can not do anything much because of being in bed all day hurting my nerves make me feel like I'm losing grip on life when the pain is intolerable which is daily anymore,whish something could be done to give all of us that suffer fromthis disease away to live life a bit.,Thanks	3/17/2020 11:19 PM
100	Pain, pancreatic atrophy, loss of pancreatic function	3/17/2020 10:17 PM
101	Fatigue	3/17/2020 9:32 PM
102	Pain, fatigue and mood swings	3/17/2020 5:55 PM
103	Pain, nausea, fatigue	3/17/2020 4:02 PM
104	Gastric n pain in back side	3/17/2020 2:59 PM
105	Nausea, pain, headaches	3/17/2020 2:05 PM
106	Chronic pain, intestinal distress, inability to deal with stressful conditions. Unable to work or enjoy recreational activities such as scuba diving, bike riding, fishing, and golf	3/15/2020 12:02 AM
107	Work, Exercise,	3/14/2020 4:34 PM
108	1. I can't make definite plans to go out or take trips. I've had to cancel flights more than four times. 2. Creon makes me constipated. I've been so constipated at times, I become impacted. The laxative my GI prescribed give me painful cramps and explosive diarrhea. I stopped taking	3/14/2020 11:45 AM



	creon. 3. I had to give up my job as a university English instructor because often I don't have the energy to go to school, which makes me an unreliable employee.	
109	Pain, disruption of life,	3/14/2020 8:48 AM
110	Dealing with severe pain, dehydration, and vomiting cause me great difficulty.	3/14/2020 8:21 AM
111	1. The uncertainty and unpredictability of when and how an attack (mine is idiopathic CP) can occur and the associated pain is the most troubling factor. My longest stretch of continuous pain was for about 11 months. This limits my ability to function in every way including and especially my ability to breathe peacefully. Having a career or being financially independent is a huge challenge because of this. Expenses of life-saving drugs only adds to this burden. 2. Insulin-dependent diabetes and associated complications including frequent fungal infections (no oral drug options have shown compatibility), skin eruptions/acne and compromised immunity (had contracted colitis due to hospitalisation and herpes near my eye). This makes it feel like my health is an uphill battle on most days.	3/13/2020 11:46 PM
112	Pain and dehydration	3/13/2020 8:33 PM
113	I can't work because the pain is constant. I stay in my house because I don't want to explain my illness. Panic attacks are a way of life. I couldn't even graduate high school because of this.	3/13/2020 6:38 PM
114	I can not longer work. Pain control. Limited socializing. And I hate being judged as 'alchol' related, I was born with this.	3/13/2020 6:35 PM
115	Pain, EPI-weight loss, fatigue	3/13/2020 6:15 PM
116	The pain causes me to do very little physically. The pain also keeps me from sleep. I only sleep in small increments, so I am tired all the time. Lack of proper nutrition doesn't help that either. The unknown times my bowels will just release without any warning is very stressful.	3/13/2020 6:04 PM
117	Diet restrictions, less social interactions to limit stress	3/13/2020 5:38 PM
118	I'm pretty lucky. Since my second piestow procedure in 1996. I've been pretty healthy.	3/13/2020 5:00 PM

**Q5 What treatments have you used or undergone recently, and how well do they treat the symptoms and health effects of your pancreatitis? What are the downsides of these treatments (e.g., duration of treatment, side effects)?**

Answered: 115 Skipped: 4

#	RESPONSES	DATE
1	Nothing (and I tried it all) worked until my TPIAT	6/10/2020 8:47 AM
2	I have had oral pain medication, a celiac block and I currently have a pain pump implant that I received a year and a half ago. I also have to take nausea meds daily to help with being so nauseous.	6/10/2020 3:58 AM
3	None they told me after ercp attempt that failed that I would just need to keep taking meds and watch my diet.	6/8/2020 6:06 PM
4	I underwent the TPIAT surgery in February of 2020 and I could not express to anyone how much that surgery did for me. I have had no pancreatitis obviously and while I am diabetic the hope is that I can continue to need less insulin and in the near future be totally insulin independent this not diabetic and no longer have pancreatitis episodes. This was my only option for treatment left as I tried having a stent placed and having pancreatic stones removed and went through several rounds of lithotripsy all for it to not work. I have several genetic mutations and having had this horrible illness my whole life this surgery was my last resort. Though I am still recovering and don't have a pancreas and several other organs and have gone through a lot of pain from the surgery, I'm doing incredible and diabetes is much more manageable than pancreatitis.	6/7/2020 9:59 PM
5	Creon helps prevent abdominal pain and diarrhea, but it only lasts for a short period of time. Tylenol and Advil work but it takes 30-45 minutes for them to kick in.	6/6/2020 6:42 PM
6	Stent: it helps but 8 months after stent I had another attack. Side effects: pancreatitis after surgery. No downsides.	6/5/2020 10:20 PM
7	The process mri, ct scan	6/5/2020 3:45 PM
8	Treatments :- Enzymes with every meal and off course they too have side effects. Duration: Lifetime may be . Downside of treatments : Side effects of drugs	6/5/2020 2:35 PM
9	Liquid/modified diet and observation x17 months	6/4/2020 10:13 PM
10	medical cannabis manages the nausea/pain. Stent in common bile duct removed all symptoms but was removed after 8 weeks - all symptoms returned in 2 hours. Tried again but with 3 stents which was too painful. They were removed in 3 days and never tried again. Docs are no longer with the medical systems either	6/4/2020 8:28 PM
11	Currently taking pantoprazole, zofran, tramadol, & 4-24,000 unit capsules, 4 times a day, of Creon. Due to EPI from chronic pancreatitis, it is a constant struggle to stay hydrated or properly nourished. EVERYTHING becomes affected from inability to maintain a "normal" weight & nutritional levels including my hair, nails, strength, skin, muscles, cognitive, employment, & driving abilities.	6/4/2020 5:10 PM
12	Pain&nausea meds	6/4/2020 2:38 PM
13	i have went to infusion for lv fluids and nausea meds but it does nothing for the pain. I am prescribed Fentanyl patches that don't help the pain. I take hydro morphine for pain and it works the best	6/4/2020 12:54 PM
14	Creon, it helps, but I must take it every time I eat	6/4/2020 10:33 AM
15	Stents placed in pancreatic duct. Did help for a short time but returned when stones got in the way. Sphincter of Oddi cut. Feeding tube placed to give pancreas rest.	6/3/2020 11:16 PM
16	My pancreas specialist said stent therapy and surgery will not work for me due to the complexity of my pancreas divisum. The only thing we can do is control the pain and nausea/symptoms until it gets worse. Pancreas removal recommended for future. I have used nerve blocks - until the side affects got severe. I have had feeding tubes but had severe complications and infections. Currently I use pain medication and nausea meds with enzymes.	6/3/2020 10:41 PM
17	One say phone a gastro That understood the pancreas at the University of Minnesota I did the 1st of 4 stent treatments to try to open up my ducts That was a process over approximately 3 years at the end of the for 3rd year we chose to do the total pancreaticectomy with islet auto transplant In which they remove 5 organs if you have not already had your gallbladder removed then it's only 4 the organs removed are your Pancreas, spleen, radium, gallbladder and appendix	6/3/2020 9:21 PM

18	Currently the only treatment I'm receiving by way of digestive system is taking Creon 3 capdules / every mealtime, and 1 Creon every snack time. I see a GI every 6 months to a year depending on my flare ups.	6/3/2020 8:30 PM
19	I have had endoscopic therapy, pancreajejunostomy surgery and more recently a TPAIT. A total pancreatectomy is an irreversible treatment that comes with heavy sacrifices. The result, diabetes type 3c is very difficult to control. Being %100 reliant on enzymes for every bit of food takes a toll. Because there is no real protocol for the ratio of enzymes to macro we run the risk every day of underdosing or overdosing which leads to very uncomfortable side effects	6/3/2020 7:28 PM
20	I received several stents in pseudo cysts through EUS as well as many pancreatic stents placed by ERCP: the procedures we're uncomplicated for me but the over all treatment from when I got sick to completion was close to 4 months. I also received a feeding tube which helped with my nutrition and weight loss but was very restrictive as far as me being able to go places. I received narcotics to treat pain which worked to some extent but I always was in fear of dependence.	6/3/2020 6:54 PM
21	Stents, doesn't seem to make a difference.	5/30/2020 1:14 PM
22	I had a Puestow procedure done in Birmingham, AL in October. Now able to eat, and pain is much more managed. Still get fatigued very easily.	5/18/2020 3:54 PM
23	Medication only. Helps sometimes. Not very effective	5/18/2020 11:33 AM
24	Creon keeps greasy stool away - low fat diet helps also ... ibuprofen currently helps keep pain at bay unless I have a flare up	5/12/2020 9:28 AM
25	Chronic pancreatitis/EPI with malabsorption. The cost of meds is a big problem. Dietary problems continuous/ pain levels make resting necessary/constant planning, esp during the COVID to be sure Creon is available. And fear of steatorrhea. But I consider myself so fortunate not to have the terrible problems I see on the chat line.	5/9/2020 9:34 AM
26	Enzymes and tramadol	5/8/2020 10:04 PM
27	Started birth control to control pain during menstrual cycle. This seems to be helping the pancreas pain during her cycle. ERCP. Seemed to help temporarily. Pain meds. She gets a headache and doesn't like how it knocks her out.	5/8/2020 9:26 PM
28	Going in for ct scan next week and egd in June since extreme bile has possibly damaged esophagus	5/8/2020 8:50 PM
29	I had a whipple in 1997 and have undergone every available treatment, procedure, etc., that has been available. Nothing new has been available, so I haven't had anything recently	5/8/2020 8:34 PM
30	None	5/8/2020 6:10 PM
31	I was told there is nothing they can do. I was already on medical cannabis but it causes worsened gastroparesis and doesn't help with the pain. I was given morphine and zofran in the hospital in IV and it was a miracle and I felt normal again but that was only for an hour and never had it since.	5/8/2020 5:39 PM
32	Distal, oxycodone, aspirin; surgery and aspirin work, oxycodone does not and ruined my bowel motility	5/8/2020 4:55 PM
33	In 2017 I had a TPIAT which is a huge operation and commitment of time and money but I no longer have pain episodes and I am no longer on insulin.	5/8/2020 3:39 PM
34	Gallbladder removal	5/8/2020 3:12 PM
35	Nerve block thru EUS in January lasted 2 days having another 1 next week	5/8/2020 2:14 PM
36	I have had two bouts of pancreatitis and both times I was treated with it's and pain killers.	5/8/2020 2:10 PM
37	ERCP and Stent placements., TPAIT evaluation	5/8/2020 2:00 PM
38	Oxycodone pain pill. Drowsy...addictive.	5/8/2020 1:56 PM
39	Nerve blocks have been no help, I have become type 3c diabetic	5/8/2020 1:52 PM
40	ERCP, stents, nerve blocks, feeding tube. All work but only for a few months at a time	5/8/2020 1:31 PM
41	I'm doing more holistic treatment these days because pain meds aren't given and mine doesn't	4/29/2020 10:40 PM

	have a treatment	
42	Fentanyl patch, helps pain somewhat...Creon, helps with malabsorption and chronic diarrhea	4/29/2020 12:47 AM
43	EUS surgery every year, and oxycodone which helps a lot. Not a fan of taking this medication, but it helps, so I really have no choice	4/28/2020 9:04 AM
44	I was taking only pancrelipasis but anyway I had another acute pancreatitis	4/28/2020 4:01 AM
45	Eus, various medication, my docotr just recently recommended tp/iat which feels radical	4/27/2020 9:12 PM
46	Took out part of my pancreas that helped some pain	4/27/2020 8:58 PM
47	Changed diet to gluten free, keto and intermittent fasting and it seems to have cured me	4/27/2020 7:33 PM
48	Nothing as of yet as I'm still working things through with my Dr. I can handle all other symptoms on my own except for the pain. There has to be a better way than opiod pills to help with this	4/27/2020 4:53 PM
49	Plexus block, only worked one day, so not worth it. Oxycotin, helps tremendously, but jumping through hoops once a month can get expensive when you have a 40 copay for pain clinic, then having to go to crowed labs, across town for urine test. Ive also had ercp , w stent placement, eus. Mrcp	4/27/2020 2:54 PM
50	I can't get help in my area	4/26/2020 11:31 PM
51	Pain meds, port a cath for hydration infusions, will be having a gj tube placed	4/26/2020 10:05 PM
52	ercp, putting stents in	4/26/2020 4:54 PM
53	I was on strong pain medication for a very long time. I had the pain block done a few years ago.Now I try not to take any pain medication. I don't like the side effects.	4/26/2020 1:12 PM
54	ERCP w/biliary sphincterotomy, enzyme replacement therapy, neither of which has stopped multiples subsequent acute flares.	4/26/2020 1:08 PM
55	Multiple ERCP's and blocks ERCP's make it worse with stunting and blocks are undependable and don't always work or last.	4/26/2020 11:42 AM
56	I had the TP/AIT 8 yrs ago	4/26/2020 2:22 AM
57	I had first onset of symptoms and diagnosis about 18 months ago and I am not currently receiving any treatment or pain control. We have just been "monitoring" with an annual CT. I do however have an EUS happening soon because of concerns on the last CT.	4/25/2020 10:54 AM
58	Gallbladder removed,Frey procedure,MRI,EU's	4/25/2020 4:56 AM
59	Only palliative: oxycodone for pain and hospital care when it's too much	4/24/2020 8:44 PM
60	Celiac plexus block helps with the pain but not a flare	4/24/2020 6:31 PM
61	I usually take over the counter anti-inflammatory pain meds when I have mild flare-ups. If it's a major one I go to emergency and usually have a hospital stay. I am given pain meds, nausea meds, and IV fluids. I am usually in for at least two days. I am at the beginning stages of the disease.	4/24/2020 4:26 PM
62	TPIAT- side effects include increased fatigue, complete pancreatic enzyme insufficiency, type 3c diabetes, 3 months of intense recovery, 6 months of moderate recovery, went septic in ICU, required 18 pills a day to function and digest food	4/24/2020 1:24 PM
63	I take Creon, nortriptyline which help with digestion and spasms. Doesn't really stop the pain though	4/24/2020 1:04 PM
64	Very early in our journey, mostly treat episodes with a very very low fat diet.	4/24/2020 1:00 PM
65	stents placed in pancreatic duct. helped for a while.	4/24/2020 10:41 AM
66	Everything, for me, is about pain management. I take 4mg dilauded every 4 hours. I tried a pain pump and my body rejected it, thereby ending any hope of a pain managed life	4/24/2020 10:33 AM
67	After 5 feeding tubes placed in my nose in the last 2 years I had one permanently placed in my stomach. I've had several complications unfortunately	4/22/2020 1:49 PM
68	I have had a whipple, EUS, EGD, numerous scans. I recently received my pin pump implant	4/21/2020 9:51 PM

that causes a lot of swelling, but it does help with the pain. I wish it would help with the other side effects but I am satisfied with nearly next to nothing pain.

69	Whipple procedure laparoscopy several months ago . Am 3 months into recovery.. I believe I am doing quite well. Though am still fatigued, having trouble gaining weight, periodic pain with bowel movements. Am taking pancreatic enzymes.	4/21/2020 6:32 PM
70	Have been on every opiate available. 14 yrs.work for about 50% of the pain. Pain feels like someone stabbing pancreas with a knife. Can't breathe When it happens	4/19/2020 7:32 AM
71	Taking Zophran for nausea. - have had to go to increased dose ; ERCP - usually help with nausea. ; eating clear liquids only- get very tired of jello. Get weak from not enough nourishment	4/17/2020 6:33 PM
72	Antibiotics had CTscans and mri scans hospitalised 2 weeks	4/17/2020 6:05 PM
73	2 surgeries	4/17/2020 5:51 PM
74	Celiac block - Effect was minimal and didn't last and was extremely painful! Acupuncture - I can't believe I even thought it would help! Distal pancreatectomy, splenectomy, appendectomy, 1999 (too sick and had to trust the doctor and was not told about the TP-AIT) - did not help at all, now they say my 'neurogenic pathways are fried' and removing the shriveled mass of pancreas left would not do anything. Creon - can't live without it, but still get sick when I eat, just not near as badly. Prilosec - I can tell within an hour if I forget to take it. I loved how effectively the massive oral and topical narcotics worked to control the pain - but not the side effects of making me a zombie. I now have a pain pump, which works well without the side effects, but I hate having that foreign object in my stomach and every time I bump my stomach it hurts. I have an insulin pump to manage my pancreatectomy induced diabetes, but it's been too difficult to manage. My warranty period is finally up and I'll be transitioning to the Tandem pump with the integrated CGM 4-22-20. If I don't have to constantly deal with highs and lows maybe I can get a grip on the pancreatitis. (Sorry if I got off topic)	4/17/2020 2:11 PM
75	My daughter is on Creon and a low fat diet. The Creon before meals and snacks along with a low fat diet manage the illness. She does not have any side effects from the Creon. My daughter has had her gallbladder out also.	4/17/2020 12:29 AM
76	I recently had a Celiac Plexus Block back on March 11th in hopes of getting pain relief but the procedure was unsuccessful. I am scheduled to have another one on April 24th. I have also recently started taking Creon to help with food digestion.	4/17/2020 12:23 AM
77	Medication- tiredness and brain fog & meds wears off	4/16/2020 10:06 PM
78	Pain meds to get thru the flare. ERCP stent placement. Results in pretty sore throat for a couple days. Most recent ERCP was Dec 2018. Haven't had a flare since.	4/16/2020 8:36 PM
79	ERCP and pancreatic enzymes	4/16/2020 5:12 PM
80	I had the Frey procedure done in Jan. I am still getting flares. I am on pain meds daily to still deal with the pain	4/16/2020 4:40 PM
81	I was only monitored with blood tests and took tylenol	4/16/2020 4:29 PM
82	Cyst drained. Grow back	4/16/2020 2:16 PM
83	ERCP (multiple), Removal of gallbladder, sewing open of major & minor sphincter of oddi, pain management, feeding tube placement	4/16/2020 1:37 PM
84	Opioids in hospital setting and for a couple days following release (week total)	4/16/2020 1:29 PM
85	Stints, biliary drains	4/16/2020 11:56 AM
86	Downside - doctors and ER don't recognize the condition and waste time spinning wheels and leave you suffering	4/16/2020 11:39 AM
87	I do not take treatment as even if I have severe ÉPI i si not want to worsen my diabetes (diabetes I I believe harder to manage)	4/16/2020 11:03 AM
88	MRCs, ERCPs, and stint in pancreas. My son Had TPIAT in February 2020 and doing great!	4/16/2020 10:36 AM
89	Pain medicine, eus, ercp the eus/ERCP was so painful they had to cut my pancreas and bladder because I had a stone and afterwards I couldn't even talk to my mom I just put my	4/16/2020 3:24 AM

	heating pad on and bared through it even with the pain meds they gave me through injection didn't work at all	
90	I have pancreas divisum. They tried to put a stent in or cut it but couldn't. Had a mri done also	4/15/2020 10:20 PM
91	Enzyme replacement pills	4/15/2020 5:26 PM
92	EUS with Celiac Plexus Block using alcohol	4/15/2020 4:27 PM
93	Told nothing can be done	4/15/2020 2:45 PM
94	Diloted, morphine, fast	4/15/2020 2:17 PM
95	I usually get celiac plexus blocks every two to three months, which control the daily pain very well. My husband has to tKe a day off work and drive me three hours to have these done. I am usually in pain or exhausted for a week after.	3/22/2020 4:09 AM
96	I have not had anything done in very long time since 2007 all they say is take meds an keep stress levels low,downsidess to that treatment was when they did feeding tube an messed up shoulder I was weighing only 86 pounds..finally getting to see a GI Dr again hoping for more help with this disease	3/17/2020 11:19 PM
97	ERCP placed Stents, caused additional pain, had to have them removed in a week, medications tha include amtryptaline, zofran, promethazine. Side effects of drowsiness, weight gain and not particularly effective	3/17/2020 10:17 PM
98	Lack of knowledge within the medical community about AIP	3/17/2020 9:32 PM
99	Being hospitalized and getting feeding tube put in with tube feed helped heal. Duration of treatment is terrible because it lasts a long time	3/17/2020 5:55 PM
100	Enzymes. Don't help with any of the above symptoms, zofran for nausea helps a lot but have to take at least two doses before it begins to help	3/17/2020 4:02 PM
101	4 year treatment in metro hospital faridabad India . Allopathy treatment	3/17/2020 2:59 PM
102	I've fluids, we only tried twice and it did help the pancreas to recover some but I would usually be in the hospital, TPIAT the only downside is the recovery process.	3/17/2020 2:05 PM
103	2 ERCP with sphincterotomy, balloon-sweep of tail which resulted in severe acute attack and life-damaging effects, celiac plexus blocks (5) absolutely worthless last one increased pain, spinal cord stimulator also worthless, gabapentin- worthless, opioids are only treatment that has any effect and that is minimal	3/15/2020 12:02 AM
104	TPIAT, Nausea, Pain	3/14/2020 4:34 PM
105	Recently I've had no treatment because we moved to Atlanta from Orlando. I had good, solid care with my GI and Dr. Hawes at Florida Hospital. I was admitted for flares where they followed standard protocol..npo, iv fluids, and pain management. When I have flares now and go to the ER, several times I've been treated like a drug seeker. I am given a bolus of fluids. The drip is set at full speed. The last time I was there, I asked the nurse to turn down the drip. She said it was their protocol in the ER so they could get me out of there(her words). I haven't had a MRCP since 2017.	3/14/2020 11:45 AM
106	I am first generation of 3. Had 1/3 of pancreas removed in the 80's. No longer suffer from pancreatitis.	3/14/2020 8:48 AM
107	ER visits help with hydration and pain relief. MRCP and CT scans keep me apprised of tissue atrophy and potential blockages. ER treatments, while extremely helpful, are temporary fixes. I worry about losing weight and strength over time as my condition persists.	3/14/2020 8:21 AM
108	I take insulin and digestive enzymes on a daily basis i.e. with every food/drink intake. I've undergone celiac plexus block for the pain- it did not give me sustained relief beyond the initial 3-4 days. Right now I'm asymptomatic wrt pain but experience bloating, mild discomfort in abdominal region, lack of energy on and off.	3/13/2020 11:46 PM
109	Creon helps me eat without pain but it's a hassle to always have the pills with me for every time I eat out	3/13/2020 8:33 PM
110	Four ERCPs, gastric emptying test. I'm hospitalized each time due to pancreatitis. Nothing helps.	3/13/2020 6:38 PM

111	I am in palliative care now. Past treatment included EUS, ERCP, MRCP, stenting, pain blocks, enzymes, hospital stays for NPO. I also was treated prior to correct diagnosis for ulcers, appendicitis, gallstones, and the usual gastroenteritis.	3/13/2020 6:35 PM
112	Regular stent placement results in acute attacks that require hospitalizations. There is a 1-2 week recovery period that often causes missed work. Typically weight loss is 5-10 pound from the acute attack and recovery. There is a prolonged period of fatigue due to my bodies reaction to the surgery itself I.e, anesthesia, disturbance of my pancreas, etc. Creon has been a double edged sword. It is helpful for digesting and absorbing food but the constipation has been a struggle to control. Both the stents and Creon have been deemed by me to be a greater help than hinderance at this time.	3/13/2020 6:15 PM
113	I have undergone all known treatments at this time. A few of them more than once. There are currently no other treatments avail at this time, so now I have to rely on narcotics. That comes with many downsides. Not only am I now dependent on them, access to them is becoming increasingly hard and the worry of my personal safety is even an issue. I even wrestled with sharing that info online in this meeting because of safety concerns.	3/13/2020 6:04 PM
114	No real treatment bescides enzyme pills and plenty of water	3/13/2020 5:38 PM
115	No eating. Pain meds. When I was younger I basically learned to survive on no food and pain meds	3/13/2020 5:00 PM



Q6 Short of a cure for your pancreatitis, what benefit would be of greatest importance to you in a future treatment? Please explain how this benefit would be meaningful to you.

Answered: 117 Skipped: 2

#	RESPONSES	DATE
1	TPIAT works great, but life is still permanently affected by chronic illness for more than 12 years	6/10/2020 8:47 AM
2	Advocating for disability, for those of us who do suffer everyday.	6/10/2020 3:58 AM
3	More honest empathy and attention how difficult is to live with this disease from the medical profession	6/8/2020 6:06 PM
4	I believe that in the community of those with pancreatitis there needs to be an increase in support of meditation. I used meditation rather than narcotics several times throughout having attacks and I was able to get into such a relaxed headspace that I could no longer feel the pain. This is crazy to me as some narcotics wouldn't even take the pain away. I believe that in our community so many are dependent on pain killers which also adds more negativity and side effects into life whereas something such as meditation is good to help with pain but also to help keep negative thoughts regarding why such an awful and painful illness must be put on harmless and good people.	6/7/2020 9:59 PM
5	Finding something so I can eat normally. It is burdensome to always have a purse, or pocket, to carry pills in. If I am spontaneous, and get a coffee drink, I will have pain if I am carefree and don't take pills. I would love to just be able to eat, without having to worry about getting pain or diarrhea afterwards. I would LOVE to not have to take 15-18 pills a day so I can digest food. One to two pills a day would be heavenly!	6/6/2020 6:42 PM
6	Being able to anticipate or be warned of the attack. This would allow me to travel for work or pleasure more, prep my work team, reduce anxiety about the food so eat and what would trigger an attack.	6/5/2020 10:20 PM
7	Debilitating pain so I can manage my life.	6/5/2020 3:45 PM
8	.	6/5/2020 2:35 PM
9	Pancreatic enzymes, different pain control	6/4/2020 10:13 PM
10	Something affordable that removes the nausea completely, not just managing it; that is not illegal and doesn't cause nasty side effects. The pain is manageable if the nausea would us go away	6/4/2020 8:28 PM
11	Public Awareness & Education: Not all pancreatitis is related to alcohol abuse or use!	6/4/2020 5:10 PM
12	Helping with pain control	6/4/2020 2:38 PM
13	when in a bad flare up I would like to be able to be given Iv meds to calm my pancreas down or be admitted until it settles without be treated like a drug seeker and just overall being judged by a disease that doesn't always show them results from tests they perform. I also would like dr's and nurses to be better educated on my disease	6/4/2020 12:54 PM
14	Something to target the pain when my pancreas flares up, but without bad side effects	6/4/2020 10:33 AM
15	It would be wonderful to not have to take so many medications and for the pain to be kept under control. I could deal better if I had minimal pain rather than what I deal with daily.	6/3/2020 11:16 PM
16	Better hospital care. Better pain control.	6/3/2020 10:41 PM
17	Better understanding by the emergency room doctors that once your Pancreas is damaged enough your enzyme levels do not raise anymore yes we are still in pain not all of us or even most of us are not alcoholics nor are we drug seekers we need relief not judgement	6/3/2020 9:21 PM
18	The fact that I constantly have to keep an eagle eye out for any food items that have fats and or oils, not to mention the fact that Im even unable to cook with oil, is a frustrating task in itself. More importantly, Ive become so restrictive in my socialization with peers and friends simply because if the temptations of social drinking with something like wine coolers is too much of a burden. I would love to have a "normal life, nit having to worry or fear another life threatening episodes. I inwardly feel like my life is a russian roulette, not knowing if the next episode is the one that takes me to my grave.	6/3/2020 8:30 PM
19	The synthetic production of islets that can be transplanted into the liver would make a major difference for those who have had failed islet transplants post tpiat. We need a deeper understanding of the role the pancreas plays that goes far beyond the exocrine and endocrine function. The pancreas produces more hormones and chemicals then enzymes and insulin,	6/3/2020 7:28 PM

post tpait we need a more clearer understanding of what patients like me are missing and then we can figure out how to compensate. We need a better understanding of the ratio of lipase and protease to fat and protien. How much lipase does a healthy pancreas produce when a person eats 5g of fat? If we would have a better understanding of the timing, the amount then we will have better management and not feel like we are playing Russian roulette every day

20	A better treatment for pain— If my pain had been controlled I think I could have returned to normal activity and life sooner than I was able to due to lingering pain	6/3/2020 6:54 PM
21	Quality of life to improve. so I wish it was better managed.	5/30/2020 1:14 PM
22	Understanding from physicians for the need of pain medications. Most doctors don't understand this condition well enough. I have been treated like an addict seeking narcotics more times than I care to think about.	5/18/2020 3:54 PM
23	Pain Management. My entire life now revolves around fear of pain and what it will do to my belly	5/18/2020 11:33 AM
24	To not fear a flare up due to another infection like s UTI or flu —	5/12/2020 9:28 AM
25	Less Med cost. I have no idea how anyone qualifies for creon's 5.00 refills unless they are homeless. My charge for 90 days with Medicare and. An expensive drug plan for 2 different doses was 854.00. I am also on another expensive drug. I have expended over 125,000 in the last 5 years. So far as treatment. My meds are adequate plus probiotics and Prilosec and phazyme. I don't think there's much more treatment for me unless this turns to the big C or deteriorates into another problem.	5/9/2020 9:34 AM
26	Let me make this clear. The webcast was important to me b/c I have only in the last 10 years become aware of pancreatitis, that is why I watch the webcast. I am so onboard for treatment for children ,for a cure. I personally don't have pancreatitis. However, Rebecca Taylor is known for her Perseverance in Seeking treatment and cure. I wanted to hear what each panelist voiced. Hope I'm not skewing you're Survey.	5/9/2020 2:16 AM
27	Less expensive drugs and further genetic research	5/8/2020 10:04 PM
28	Need a plan... less pain..something for bile/reflux -be able to eat easier	5/8/2020 8:50 PM
29	A medicine that relieves the pain that is not addictive or that I have to be dependent on	5/8/2020 8:34 PM
30	Having doctors that actually listen and are prepared to give you meds to help have quality of life. Not just say there's nothing they can do or that yes, u feel like this bc of cp then leave u to walk out of appointments with no meds or refuse to give you ones that have helped like Diaz and pain meds	5/8/2020 6:10 PM
31	If there could be a drug that stops and/or reverses the damage being and acute attacks	5/8/2020 5:39 PM
32	Better anti-inflammatory control; prevention of pseudocysts	5/8/2020 4:55 PM
33	TPIAT has been a solution for me after 17 years of pancreatic pain ,surgeries and procedures	5/8/2020 3:39 PM
34	Increased awareness and understanding	5/8/2020 3:12 PM
35	Not being a diabetic if I was to have pancreas taken out	5/8/2020 2:14 PM
36	Pain management	5/8/2020 2:10 PM
37	Medical professionals understanding the disease.	5/8/2020 2:00 PM
38	Improve quality of life	5/8/2020 1:56 PM
39	A drug that could treat pain or nausea better	5/8/2020 1:52 PM
40	Gee.. stop the ongoing destruction of my pancreas before it leads to more side effects like gastroparesis, kidney issues, blood sugar issues	5/8/2020 1:31 PM
41	Assistance with diet, and cheaper mrcp and MRIs	4/29/2020 10:40 PM
42	If my pain and nausea was gone I could live a normal life. Every day I have pain and nausea	4/29/2020 12:47 AM
43	Family education. They don't really understand what pancreatitis is, or how dangerous it can be. Also, how stress can contribute to symptoms. If they could better understand, it would really help .	4/28/2020 9:04 AM

44	Non having recurrent pancreatitis. But for me the best could be understand the causes	4/28/2020 4:01 AM
45	Educated healthcare staff. You are never treated the same by any 2 doctors and so many think youre lying. Another would be better pain control and better nausea control	4/27/2020 9:12 PM
46	Being believed when I'm in pain and need pain control	4/27/2020 8:58 PM
47	Wish my dr knew my diet was causing it. And that it was related to eating to many carbs and. Not fat	4/27/2020 7:33 PM
48	Looking at Pain Management Technology like Pain Pumps or Spinal Stimulators. Something has to be able to reduce the pain felt	4/27/2020 4:53 PM
49	No pain. The ability to get our " controled " medications wo having to report to pain clinics, where they dont treat you w dignity, and you rarely even see a DR.	4/27/2020 2:54 PM
50	I need a pancreatic center in my area, and patients need to be diagnosed quickly. I keep being told there is no treatment and nothing can be seen on tests.	4/26/2020 11:31 PM
51	to be able to have less pain and be able to eat whatever I want	4/26/2020 10:05 PM
52	i only have 30% of my pancreas left, a cure would prevent me from having to take insulin in the future	4/26/2020 4:54 PM
53	I am not sure.	4/26/2020 1:12 PM
54	Pain relief. I can take 12 pills a day, I can handle not having energy, but all that and still being in excruciating pain is abhorrent	4/26/2020 1:08 PM
55	Pancreatectomy with islet cell transplantation. Allow people to have a life, society uses food with all celebrations birthdays have cake, Christmas has dinner as well as Thanksgiving. I have shopped and cooked to set table and walk away because I tube fed.	4/26/2020 11:42 AM
56	Take the pain away	4/26/2020 2:22 AM
57	Understanding that CP is incredibly uncomfortable and painful and giving us what we need to be as painfree and comfortable as possible, without judgement.	4/25/2020 10:54 AM
58	More understanding doctors, I've found myself begging for pain relief, but made to feel like a drug seeker .	4/25/2020 4:56 AM
59	Not having pain. I could give up almost any food. But if I have no pain and I can carry on with my normal life, that would be awesome	4/24/2020 8:44 PM
60	My is hereditary but I was misdiagnosed/mistreated even now still. I was only diagnosed 10 years ago at age 54. I have kids and grandkids that are kind of blown off because doctors don't know much about hereditary pancreatitis. I would like to see better treatment or cure for them.	4/24/2020 6:31 PM
61	Knowing what causes my flare-ups because it's not just food related.	4/24/2020 4:26 PM
62	PAIN MANAGEMENT! Including proper physician education around the use of opiates to treat people with pancreatitis. I have noticed a massive pain management barrier for legitimate patients in the wake of opioid crisis policy changes.	4/24/2020 1:24 PM
63	Greater awareness in others	4/24/2020 1:09 PM
64	No pain or indigestion. Being able to eat like a normal person. Llive a normal life	4/24/2020 1:04 PM
65	Treatment of pancreatitis would be a huge relief. Since we are early in our disease process, the future is very scary. The need for future hospitalizations, surgeries, missed school and other social activities, and the ever looming threat of pancreatic cancer are terrifying. More reliable and quicker treatment options that would decrease the damage on the pancreas would provide some comfort and peace of mind. Being able to treat or even prevent flare ups would be wonderful in not missing school, vacations, activities etc.	4/24/2020 1:00 PM
66	puesuit of alternative treatments for symptoms	4/24/2020 10:41 AM
67	If I had easy access to my meds without all of the hoops it would greatly reduce the monthly stress of maybe not having access.	4/24/2020 10:33 AM
68	Pain control. My quality of life is horrible due to constant pain	4/22/2020 1:49 PM

69	A bionic pancreas...? Affordable medicine (I take enzymes, and phenergan). I am a single mother afraid to apply for disability because I hear all of the horror stories. I would love to have it recognized as a disability and affordable healthcare.	4/21/2020 9:51 PM
70	Stopping the progression of the pancreatitis...Getting my strength back.	4/21/2020 6:32 PM
71	No more pain	4/19/2020 7:32 AM
72	Preventing nausea and fatigue. Could eat more normal and more normal activities	4/17/2020 6:33 PM
73	Operate then I could walk up right better than stopping as pain across my stomach and back	4/17/2020 6:05 PM
74	A way to replace the pancreas	4/17/2020 5:51 PM
75	Sometimes when you are in the thick of suffering it's hard to find vision for your hopes and dreams. The only thing I can think of is that whatever successful future treatments are developed that they be accessible, available, and affordable to everyone. For those dealing with hereditary or genetic pancreatitis the benefit would be immeasurable if it meant their children and grandchildren wouldn't have to suffer. Mine is called idiopathic, but also came after gallbladder surgery. (although, I wonder which came first?)	4/17/2020 2:11 PM
76	If there was a medication to allow my daughter to be able to have a fatty meal occasionally and not end up in the hospital.	4/17/2020 12:29 AM
77	I believe it is EXTREMELY important for Emergency Room physicians to become more educated on pancreatitis. I have struggled with this disease for 12 years now, seen numerous specialist searching for a diagnosis and been to the ER so many times that I couldn't begin to even come up with an actual number. Those ER visits are very stressful because in my case, my lipase and amylase levels have never been elevated and any scans that are done don't show inflammation. This is when the physician comes back and basically looks at you like you just want drugs. I have had physicians tell me the pain was all in my head, that my pain (located at my sternum and radiating into the back) was caused by cyst on my ovaries. I have been asked point blank what pain medicine I wanted..... The list goes on. This is not how patients that are struggling with chronic daily pain, that isn't something that any of us have asked for, should be treated. I understand that they have to be mindful because there are those select few people that are addicted to these types of medicines but, when you go through what we do on a daily basis, have had all of these procedures, seen all of these specialist and all you are asking for is some form of relief in order to have a better quality of life, the LAST thing that CP patients need is to feel like they have nowhere to turn to get any help out of fear of being misjudged or stereotyped because their disease isn't black and white or considered "textbook". For me, a benefit of the greatest importance would be EDUCATION! EDUCATION! EDUCATION!	4/17/2020 12:23 AM
78	Something to ease my pain and not give me such brain fog. It would help give me back my life	4/16/2020 10:06 PM
79	I don't know.	4/16/2020 8:36 PM
80	Somehow manage pain without opioids or nerve blocks	4/16/2020 5:12 PM
81	That someone can help with the pain. The pain is unbearable at times and I just want to be able to enjoy my grandkids	4/16/2020 4:40 PM
82	I'd like ot understand how to manage it, how to keep stones from forming in bile ducts	4/16/2020 4:29 PM
83	Doctors who understand your illness and how it effects your everyday life	4/16/2020 2:16 PM
84	Hydration	4/16/2020 1:37 PM
85	Nurses not asking if I'd like some Tylenol when is significant pain the first day of hospital admittance.	4/16/2020 1:29 PM
86	To gain weight and control bowel movements	4/16/2020 11:56 AM
87	literate ER staff and end the "alcoholic" cause myth, you are mistreating the patient. Legitimate legal access for pain and nausea treatment with THC.	4/16/2020 11:39 AM
88	New medications to better relieve pain	4/16/2020 11:04 AM
89	For me I would like research to focus on developing pancreas substitution or genetic treatment for my future kid to be able to live normally .	4/16/2020 11:03 AM
90	Pain management	4/16/2020 10:36 AM

91	Stop the pain and the attacks of chronic pancreatitis it is so painful	4/16/2020 3:24 AM
92	Being able to control pain and not have to go to hospital. Really wish they could find out what triggers it. I only have had this issue for last few years.	4/15/2020 10:20 PM
93	Enzyme therapy that works.	4/15/2020 5:26 PM
94	Long lasting pain control and reduction. This would improve my life in that I would feel better to the point that I would be less exhausted and irritable feeling.	4/15/2020 4:27 PM
95	A cure or there is no future	4/15/2020 2:45 PM
96	A treatment that would not lower my immune system would be great	4/15/2020 2:17 PM
97	Nausea bothers me more than pain. I can handle a lot of pain, but find nausea intolerable. And more disabling.	3/22/2020 4:09 AM
98	If I could get some control on the severe pain I'm dealing with right now, so I could try and live somewhat of a life that I have left here on earth	3/17/2020 11:19 PM
99	In absence of a cure, finding a non invasive way to slow pancreatic atrophy, reduce calcifications and address pain in a non narcotic way.	3/17/2020 10:17 PM
100	The absolute best current treatment is Rituximab infusions. Making them actually affordable, and more widely available to anyone with AIP.	3/17/2020 9:32 PM
101	Give me my preferred pain meds	3/17/2020 5:55 PM
102	Pain. This restricts my work the most	3/17/2020 4:02 PM
103	Gastric problem	3/17/2020 2:59 PM
104	A treatment to ease the inflammation of pancreatitis.	3/17/2020 2:05 PM
105	Compassionate treatment of pain, five different pain clinics and even more doctors over eleven years most of which are adversarial and punitive in their approach due to opioid crisis and a general lack of compassion and/or clear understanding of proper treatment. Every trip to the pain doctor results in a prejudgment by staff of drug seeking and addiction, massive stress, and exacerbated pain and other symptoms. Every person with chronic pain is treated as if they are a drug addict and repeated violations and denial of basic human rights. A change in the medical community's attitude towards pancreatitis could mean a possibility of a longer life as seeking care for pain causes a stronger longing for death.	3/15/2020 12:02 AM
106	Treatment other than opioids for pain. Strong nausea meds.	3/14/2020 4:34 PM
107	Being taken seriously by medical personnel would be best along with kindness and compassion.	3/14/2020 11:45 AM
108	Understanding and treatment for grand children and future generations	3/14/2020 8:48 AM
109	Additional research that could possibly identify other causes for these attacks would be very beneficial.	3/14/2020 8:21 AM
110	1. I would like the doctors to be able to diagnose and pin point which pain medication would work best for each patient. Since many experience pain and respond differently to different pain medications, there needs to be a system to identify which pain medication/combination would work best. For e.g. I respond well to Diclofenac more than Tramadol but I'm also aware that I can't use them long term without risking kidney damage. This is especially relevant since I'm already a diabetic. Pain management therapy to be patient centric and to evolve to eliminate the side effects associated with long term use of such medications. 2. A drug to stop fibrosis of the pancreas. The body and tail of my pancreas is not even visible anymore. The head region is covered in calcifications and cysts. There needs to be a drug that halts the degeneration of the organ so we can at least manage the disease in the best way possible without continually risking more damage no matter how well we are able to tend to our health.	3/13/2020 11:46 PM
111	something for pain and hydration that I wouldn't need to go to the hospital for	3/13/2020 8:33 PM
112	I want to live. I'm 23 and have no friends because they didn't understand. I just want to do what other 23 year olds can do.	3/13/2020 6:38 PM
113	My organ has far too much damage to do much medically. My hope is for those whom might	3/13/2020 6:35 PM

still get early treatment. Better ways to deal with brittle diabetes would help all of us misdiagnosed. Managing pain/nausea is my primary daily goals now.

114	Pain control! It is impossible to convey the extreme pain of this disease. I am NEVER pain free. I simple have a range of pain that determines what activities I can be involved in at any given time. I've come to accept I will always have some level of pain. It would be a great relief to not worry about my doctor's choice of pain control being deemed unnecessary by federal regulations and insurance companies.	3/13/2020 6:15 PM
115	The ability to rid the pain would mean more to me than words can describe. The possibility of becoming active again and even maybe working are just a start to a long, long list of things that would be meaningful. Thank you so much	3/13/2020 6:04 PM
116	A way of understing when my acute pancreatitis is going to flare up as this is severly painful, scary and weakens my pancreas.	3/13/2020 5:38 PM
117	Doctor education and information. Having kids now with pancreatitis. You basically have to self diagnose.	3/13/2020 5:00 PM



# Listening to the Voices that Matter: *Chronic and Recurrent Acute Pancreatitis Patient Perspectives*



A Survey of Patient  
Experiences to Inform Future Decisions

Presented by:

**Mission: Cure**

*Demonstrating a new model for curing disease*

July 2018 • Z. Zhu, C. Kabelac, and G. Gil • ©Mission: Cure

Updated October 2019





**A note from Mission: Cure:**

*Chronic pancreatitis is a painful, complex disease that impacts over 150,000 children and adults in the United States alone. Recurrent acute pancreatitis is a related diagnosis that impacts many more. There is a tremendous need to accelerate research to discover an effective treatment for this disabling disease. Mission: Cure was founded to do just that, and patient involvement is crucial to achieving this goal.*

*Mission: Cure is a growing nonprofit dedicated to measurably improving outcomes for chronic and recurrent acute pancreatitis patients. We believe that patients' voices need to be heard and should be placed at the center of directing drug development and evaluation. We want and need patient input to inform our conversations with the FDA, researchers, and drug developers. After all, only patients understand the facets of a complex disease that have the greatest impact on their quality of life.*

*However, for a community of patients who suffer from a disease that can be isolating and difficult to manage, getting their voices heard is challenging at best. Here, the patients suffering from chronic and recurrent acute pancreatitis get the chance to share their stories, and it is our job to pay attention.*

*By listening to their stories, Mission: Cure will be better equipped to prioritize the outcomes that matter most to patients themselves. The patients' impassioned answers will impact the direction of Mission: Cure's work and will drive us to find a cure.*

**Linda Martin & Megan Golden**  
**Co-Directors**  
**Mission: Cure**

# Chronic and Recurrent Acute Pancreatitis Patient Perspectives

*A Survey of Patient Experience to Inform Future Decisions*

## **Introduction**

In drug development, the ultimate goal is to treat the many conditions patients experience and to improve the way patients feel, function, and survive. Therefore, patients who live with a disease should be placed at the center of the drug development process. However, the medical community has recognized that patient perspectives might differ significantly from what is expected by researchers, drug developers, FDA staff, and providers, and what patients care most about may not always be factored into clinical trials or approved labeling. This phenomenon is especially the case for rare and sometimes stigmatized diseases, like chronic and recurrent acute pancreatitis. Thus, under the direction provided by the FDA Patient-Focused Drug Development (PFDD) Initiative, we at **Mission: Cure** have begun an effort to understand patient experiences, needs, and priorities, starting from this patient survey launched in summer 2018. This report serves to update the preliminary findings released in July 2018 with the complete responses received up to December 2018.

This survey is an open-ended form that allows patients and caregivers to share insights into their experiences living with chronic and recurrent acute pancreatitis. It is intended to better inform **Mission: Cure**'s approach to curing pancreatitis by giving us a sense of the challenges faced by the patient population and laying the groundwork for further patient engagement and other PFDD efforts. With the findings of this report, **Mission: Cure** will be better equipped to make the critical decisions necessary to achieve our goals of patient advocacy and bringing better, more effective treatments to patients as quickly as possible.

## **Objectives and Methods**

Throughout this survey, our primary objective is to better understand the perspectives of the pancreatitis patient community by collecting their stories and priorities.

Using an online, open-ended survey, we asked patients a series of eight questions (see Appendix 1). The first seven of these questions involved the collection of demographic information that will better equip us to advocate for patients and plan patient engagement strategies. The last question is of primary importance to this report, asking "If you had a chance to talk to the FDA, what would you want them to know about your experience with chronic or recurrent acute pancreatitis?" The responses have no structured requirements. Additionally, none of the questions were required for the completion of the survey, giving respondents the opportunity to report only the information they felt comfortable sharing.

We analyzed the results of the demographic questions, producing associated graphs in the process. For the last question regarding their personal experiences, we developed a codebook of recurring themes and coded each story individually using the software NVivo. The codebook and the consecutive coding was developed with collaboration by multiple individuals to minimize individual biases involved in understanding qualitative data. The same codebook was utilized in the data analysis of this report. The open-ended nature of this last question allowed respondents to spontaneously respond and did not direct their response. For this reason, the concordance of themes between narrative was important to examine. We identified major themes from the available set and chose quotations that best represented the overarching topics.

## Results

A total of 261 responses were collected through the survey. The first 145 of these made up the findings reported in the preliminary findings, while the last 116 responses have been incorporated into the findings reported hereafter. The people who participated were in some way involved in the patient community, either as patients themselves or as caregivers of patients. In the case of the latter, we requested that they respond to the survey from the perspective of the patient they care for.

### Respondent Characteristics

#### Age

Reported by 229 respondents.

The mean age of survey participants was 41.5 years. The standard deviation of age distribution was 15.6. The age of patients ranged from 4 years old (where the caregiver responded to the survey) to 74 years old.

#### Gender

Reported by 259 respondents.

194 identified as female (74.9%), and 65 identified as male (25.1%).

#### Diagnoses

Reported by 257 respondents.

213 have been diagnosed with chronic pancreatitis (82.9%), 108 with recurrent acute pancreatitis (42.0%), and 52 with hereditary pancreatitis (20.2%).

Notably, most respondents report being diagnosed with more than one of the aforementioned conditions, leading to a greater number of diagnoses than respondents. Patients also had the option to self-report related diagnoses like diabetes or pancreatic divisum under the “Other” category on the question (see Figure 1).

#### Predominant Symptoms

Reported by 134 respondents.

*In the first long-form question, survey respondents were asked to list three symptoms that have the most significant impact on their day-to-day life.*

Pain is the most frequently mentioned as one of the three symptoms that has the greatest impact on their day-to-day life. It appears in the response of 92.5% of total respondents. Nausea and lack of appetite (62.8%) and fatigue (33.1%) were the second and third most prevalent symptoms reported.

Other symptoms mentioned by patients include abnormal bowel movements, depression or anxiety, and weight loss (see Figure 2).

#### Treatments

Reported by 246 respondents.

*In the second long-form question, survey respondents were asked to describe their current treatment regimen, including medications, non-pharmacological therapies, or anything else that they may deem relevant.*

The most common treatment approaches patients described were digestive enzymes (61.4%), diet modifications (37.0%) and unspecified pain medications (37.0%). If specific pain management techniques (celiac nerve blocks, cannabis, and opioids) are combined with the reports of unspecified pain management, then 61.8% of survey participants reported some form of chemical-based pain management, including 44 respondents who reported using opioids for this purpose. Other frequently cited treatments included unspecified medications (26.8%), nausea medications (14.6%), and surgical options (13.0%) (see Figure 3).

#### What do you want the FDA to know?

*In the final question, survey participants were given an open-ended, narrative prompt that asked “If you had a chance to talk to the FDA, what would you want them to know about your experience with pancreatitis?”*

The themes extracted from the responses to this question are on following pages. To note: Respondents that did not answer this open-ended question or provided invalid/irrelevant answers are excluded from data analysis (e.g. answered “Yes”, “N/A”). Because of this, 42 survey participants were not included, and we have 218 total valid answers for this question.

The percentage/number of respondents provided in this report correspond to participants that spontaneously mentioned the themes. These numbers may not be reflect the total percentage/number of participants that share these experiences.

Because of the open-ended nature of this question, the concordance between answers is particularly important to note. Similar themes were found both in the preliminary findings and those updated in this report, with slight differences in the prevalence of the sub-themes identified. The concordance of responses indicates that the major themes are shared across patient experiences and suggest trends across pancreatitis patients that merit further research.



Figure 1. Diagnoses Reported by Survey Respondents

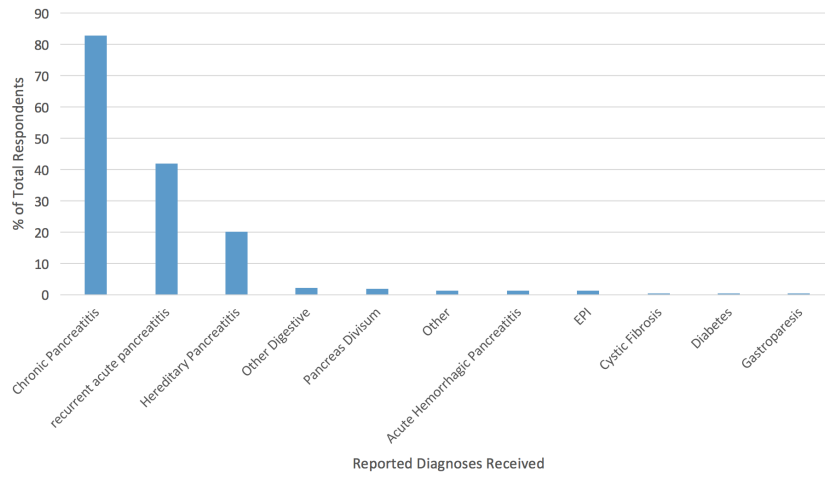


Figure 2. The Most Significant Symptoms as Reported by Survey Respondents

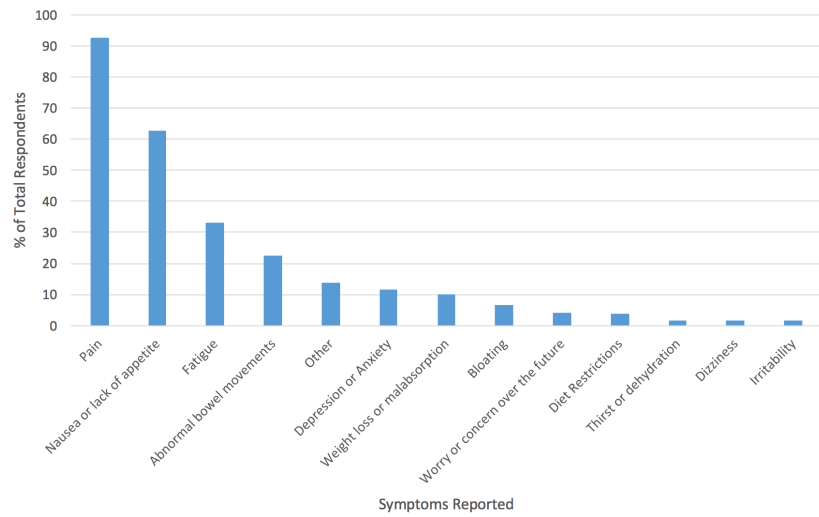
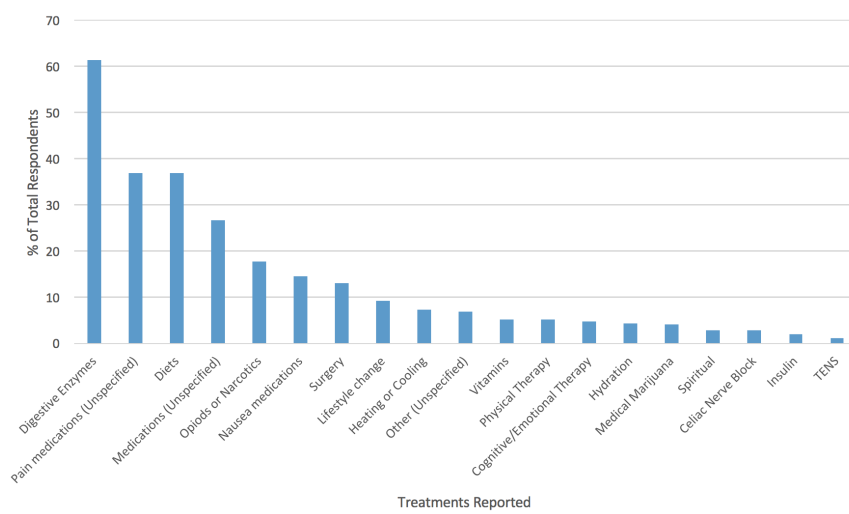


Figure 3. Treatment Regimes as Reported by Survey Respondents



## Major Themes

### 1 Lack of Treatments

Reported by >70% of respondents

More than half of all respondents mentioned the lack of available treatments. Among those, patients overwhelmingly emphasized the limitations around pain medication and management (34.9%), especially under the current opioid restrictions, far surpassing mentions of other treatment inavailability.

Many respondents speak to the limitation of current treatment and the unmet medical needs, including misdiagnosis and late diagnosis, having to go the ER repeatedly when pain is unbearable, ineffective medications, affordability and insurance issues, particularly for experimental options and surgery, and the need to travel far for receiving treatments. 10.6% of respondents mentioned surgical treatment options. Of these, a few reported the positive impact of TP/IAT surgery on their disease condition and quality of life, but the difficulties of getting the surgery, including insurance coverage, were also highlighted, both by those seeking to get surgery in the future and those who had already undergone it. Furthermore, those in the former group generally spoke about the surgery fearfully and as a last resort measure in the absence of other options.

Some survey participants explicitly called for future action. Beyond improved pain management, some of the measures they ask for included:

- The development of more and new treatment options for pancreatitis specifically  
Called for by 20 respondents
- Alternatives to frequent and expensive ER visits due to extreme pain and ineffective pain management  
Highlighted by 20 respondents
- The development of new diagnostic tools that will prevent misdiagnosis or misattribution of the symptoms  
Stressed by 16 respondents

#### Patient Statement

“This disease is horrible, I am in constant pain. I was referred to get the tp/ait surgery but because Medicare won’t cover the ait part I haven’t been able to. It is hard to get pain meds for this even with confirmed damage to the pancreas because of the opioid crack down.”

### 2 Burden of Symptoms and Impact on Life

Reported by >55% of respondents

95 respondents (43.6%) described their symptoms in their answers, including pain, nausea, fatigue, dehydration, and stomach/bowel symptoms. Pain dominates – out of these 95 respondents, 78 of them directly mentioned the debilitating pain.

121 respondents (55.5%) mentioned the impact of chronic pancreatitis on their life. 23 of these respondents highlighted a general decrease in their quality of life following the onset of their symptoms. In more specific terms, patients reported several other major ways chronic and recurrent acute pancreatitis have impacted their lives, including:

- Constraints on food and diet  
Mentioned by 25 respondents
- Impact on life-changing decisions, such as quitting jobs because of chronic pancreatitis  
Mentioned by 14 respondents
- Causing other health problems, such as malnutrition, diabetes, etc.  
Mentioned by 12 respondents
- Influence on mental health, including suicidal ideation  
Mentioned by 23 respondents
- Lack of predictability of symptoms, and thus, the possibility of planning things ahead  
Mentioned by 10 respondents
- Impact on social life and relationships/friendships  
Mentioned by 7 respondents

#### Patient Statements

“I would let them know how this truly affects one’s life. It isn’t a disease that you get over in a few days. It rearranges your whole lifestyle and plans. There are foods that can no longer be eaten, there is pain that doesn’t decline, and you can never make plans because you never know when this disease is going to rear its ugly head. I’ve been battling this for 15 years and it hasn’t gotten any easier.”

“This is a horrible disease. It takes over your life. Pain and nausea that comes on without warning. Effects sleep and everyday life and job. Not wanting to take a narcotic for fear of addiction. The cost of enzyme treatment is horrendous yet you need it. The up and down of not knowing how you will feel for the day affects your outlook on things which leads to being down.”

### 3 A Huge Lack of Understanding from Medical Professionals

Reported by >67% of respondents

Patients frequently feel a lack of understanding from medical professionals (especially ER doctors and general practitioners) who are poorly-informed of the various causes and painful symptoms of chronic pancreatitis. This can lead to dismissal, mistreatment, improper pain management, or lack of diagnosis.

Among the respondents that specifically mentioned their experience with improper treatment, common experiences included:

- Pain being dismissed or labeled as “faking it”; being labeled as “drug seeker,” especially at the ER and by medical professionals  
Reported by 43 respondents
- Being made to feel that their condition was self-inflicted through alcohol use, particularly with non-alcohol etiologies  
Reported by 21 respondents
- Struggling to afford or have their insurance cover the care they needed  
Reported by 27 respondents

#### Patient Statement

“I am always in pain. Even on the morphine and hydrocodone. My amylase and lipase levels don’t raise anymore because my pancreas is so damaged, so I get blown off by doctors. The ones who take the time to scan my stomach see how swollen the pancreas is and know there’s a problem. My doctors where I live are uneducated about pancreas issues so I frequently get sent out of state. The doctors frequently dismiss me even when I have symptoms. I, as well as many others that I know with the disease often get dismissed and called drug seekers even though we really don’t want to be on the meds but we have to be to function.”

### 4 Information and Research Needed

Reported by 14% of respondents

Patients called for more research on the causes and treatments of chronic pancreatitis. Respondents reported feeling “alone” and “scared” in treating the disease because of the huge lack of available information, with multiple patients saying that the “patient usually knows more than the doctors.” Pediatric conditions, as mentioned by some patients and caregivers, is an area that specifically requires research.

#### Patient Statements

“This disease needs much research and doctors need to be up to date on all advancements. I feel like everything I’ve learned has been from support groups, not doctors!”

“Doctors all seem to be giving very different treatment advice. Some will tell you to eat whatever you want, while others tell you to eat a very specific diet, and this kind of mixed information can be very confusing and disheartening to a young patient.”



## Appendix 1:

### Survey Instrument

Dear Pancreatitis Patient or Caregiver,

You probably know that chronic pancreatitis is a painful, complex disease that impacts over 150,000 children and adults in the United States alone, and there are also people who have had multiple acute episodes. There is a tremendous need to accelerate research to discover an effective treatment for this disabling disease. Mission: Cure was founded to do just that, and today you can help us achieve this goal.

Mission: Cure is a growing nonprofit dedicated to measurably improving outcomes for chronic/recurrent acute pancreatitis patients. We believe that patients' voices need to be heard and should be placed at the center of directing drug development and evaluation. We want and need your input to inform our conversations with the FDA, researchers, and drug developers. Please take a few moments to complete this short survey in regards to your patient perspective—your input is extremely important and will truly make a difference.

Thank you for your time and contribution!

Sincerely,

Linda Martin and Megan Golden  
Co-directors, Mission: Cure



### Demographics

*Note: If you are a caregiver, please answer the following questions from the perspective of the pancreatitis patient you care for.*

Age:

Gender:

Where are you from?



### Please share your experience

Have you been diagnosed with the following condition(s)? Please select all that apply.

- Chronic Pancreatitis
- Recurrent Acute Pancreatitis
- Hereditary Pancreatitis
- Other \_\_\_\_\_

Please list three symptoms that have the most significant impact on your day-to-day life.

What is your current treatment regimen? You can include medications, non-pharmacological therapies, or anything you think could be relevant.

If you had a chance to talk to the FDA, what would you want them to know about your experience with pancreatitis?

**Future Information**

*If you would like to further contribute to our relentless mission to cure chronic pancreatitis by providing your patient perspective, or to receive news and information from Mission: Cure, please leave your contact information below. If you have any questions or comments, please email [info@mission-cure.org](mailto:info@mission-cure.org)*

Email:

Cell Phone:

How did you find out about this survey?

- Patient Facebook groups
- Mission: Cure’s website
- Mission: Cure’s social media
- My medical professional
- Other people
- INSPIRE
- Other \_\_\_\_\_





**About Mission: Cure:**

We are a coalition of doctors, researchers, patients, and entrepreneurs pioneering a new approach to curing disease, especially pancreatitis, through innovative outcome-based financing.

We aim to demonstrate that innovative financing can be harnessed in the field of medical research and development for diseases. Our first target is chronic pancreatitis, and our approach involves Pay-for-Success financing. This model brings together payers, patients, researchers, and impact investors to streamline the process of getting treatments into the hands of the people that need them the most. **Mission: Cure** serves as an intermediary for a model that benefits everyone. If a set of measurable, pre-determined outcomes are reached, impact investors get positive financial returns, traditional payers, benefit from lowered long-term healthcare costs, and patients' health outcomes improve.

*To find out more about our organization or how to get involved, visit <https://mission-cure.org>. If you have any further questions regarding this project,*

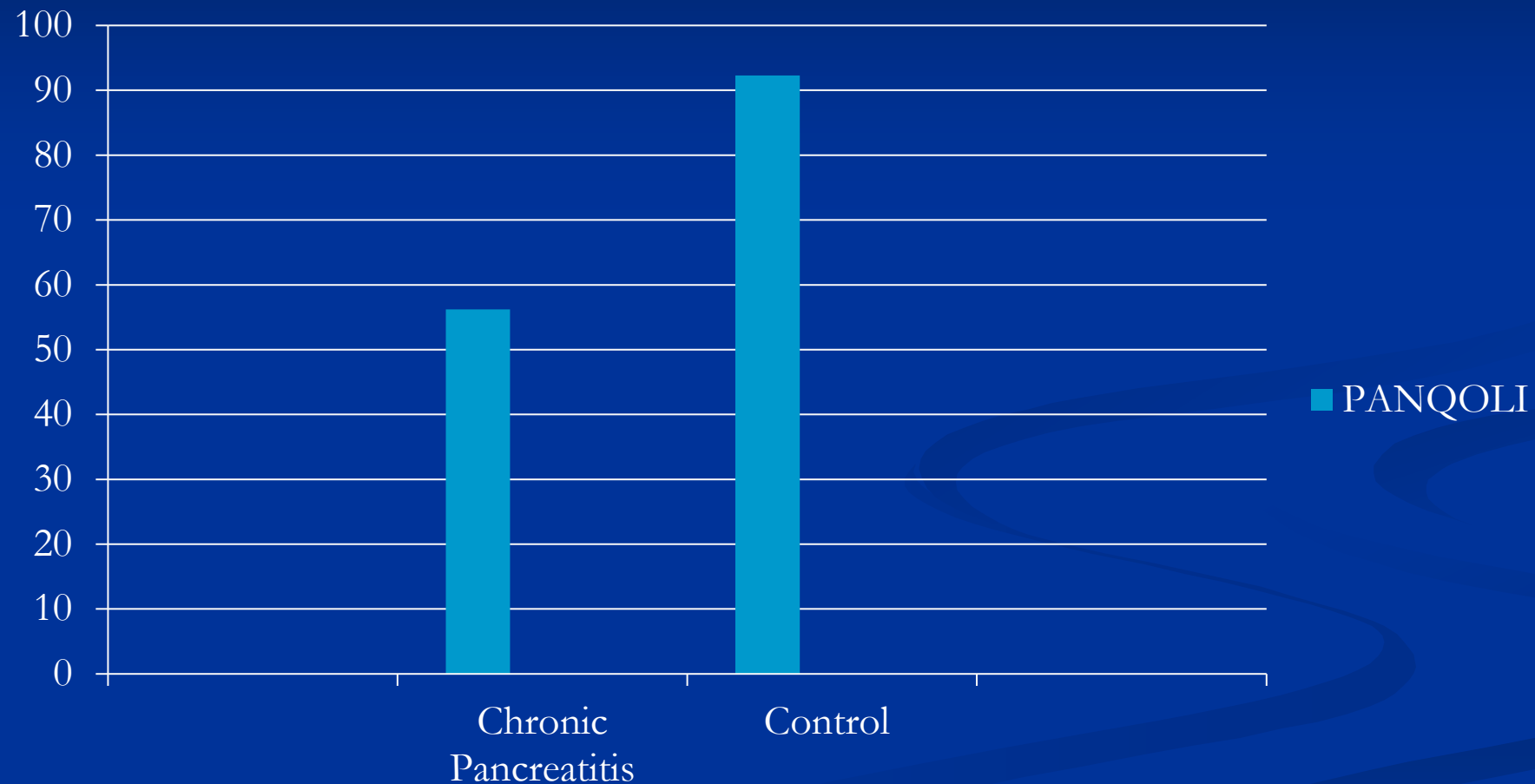
**Presented by:**

**Mission: Cure**

*Demonstrating a new model for curing disease*

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# Quality of Life Comparison in chronic pancreatitis patients: a case-control study



# Quality of Life Comparison in chronic pancreatitis patients: a case-control study

