

Dana K. Andersen, MD ([00:00:04](#)):

[music 00:00:04] Good morning. My name is Dana Andersen and it is my pleasure on behalf of the National Pancreas Foundation and our CEO, David Begelman, to welcome you to this patient focused drug development meeting on pancreatitis. We're grateful for the help of the Food and Drug Administration in the preparation for this meeting and we're very happy to provide this forum for patients and their caregivers to provide direct testimony to the FDA about their experiences with acute and chronic pancreatitis in their own words.

Dana K. Andersen, MD ([00:16:09](#)):

This meeting had its origin in 2018 in a workshop that was sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases that was entitled, Accelerating the Drug Delivery Pipeline for Acute and Chronic Pancreatitis. That workshop was organized precisely because there are no approved drugs to treat these diseases and with the help of the FDA officials who participated in the workshop, we learned that the next necessary step was to provide direct patient testimony to inform the guidelines that the FDA would use to guide all future clinical trials to treat these diseases. The NPF immediately announced that it would take on the job of organizing such a meeting and they have been working for the last year to do exactly that. I particularly like to thank the staff of the NPF including Ms. Brooke Campbell and Mr. Patrick Salami, but in particular the program manager, Ms. Sokphal Tun, who has been working tirelessly to put this meeting together. Sokphal, thank you so much for all the work that you've done. I also want to acknowledge our partners in this effort, Mission Cure, Rebecca's Wish and the Familial Chylomicromenia Syndrome Foundation for helping to organize this meeting and to recruit not only the panelists and the attendees that are here today, but the hundreds of folks who are joining us by webinar. We also thank the Health and Medicine Council of Washington, an advocacy group that has worked on many of these meetings and whose advice was invaluable. And I particularly want to thank our corporate sponsors for this meeting including Abbvie, Incorporated, Sagent Pharmaceuticals, Digestive Care, Incorporated and ChiRhoClin. Their support is critical to helping us to address the needs of the hundreds of thousands of patients who suffer from pancreatitis in this country and we are especially grateful to them for their support of this meeting.

Dana K. Andersen, MD ([00:18:34](#)):

Finally, it's my pleasure to introduce Dr. Erica Lyons, of the Division of Gastroenterology and Inborn Errors Products in the Office of New Drugs in the Center for Drug Evaluation and Research of the FDA.

Dana K. Andersen, MD ([00:18:50](#)):

Dr. Lyons.

Dana K. Andersen, MD ([00:18:50](#)):

Good morning.

Erica Lyons, MD ([00:18:56](#)):

Good morning.

Dana K. Andersen, MD ([00:18:58](#)):

Thank you.

Erica Lyons, MD ([00:18:58](#)):

Thank you so much. Good morning, as you said, my name is Dr. Erica Lyons and I am one of the clinical team leaders within the Division of Gastroenterology and Inborn Errors Products at the FDA. This morning I have the privilege of giving a brief overview of patient focused drug development, but before we begin I would like to express my appreciation for the patients, the caregivers, and the advocates in the audience and on the web today. On behalf of my colleagues at the FDA, I would like to thank you for being part of this meeting and sharing your experiences with us. I would also like to thank the National Pancreas Foundation and all of the staff that was involved in planning this meeting.

Erica Lyons, MD ([00:19:42](#)):

I know we have representation from industry, academia and other medical product development stakeholders in the room and on the web as well. While FDA plays a critical role in medical product development, we are just one part of the process and I am glad to see a high level of interest from those of you who also play very important roles. FDA shares the patient community's commitment to facilitate the development of safe and effective medical products for the treatment of pancreatitis. Now, when I say medical product development, I mean it in the broadest sense of identifying, developing, and evaluating potential therapies that can help patients manage their conditions. FDA protects and promotes public health by evaluating the safety, effectiveness, and quality of new medical products, but we do not develop new medical products or conduct clinical trials. It is, however, our responsibility to ensure that the benefits of a product outweigh its potential risks.

Erica Lyons, MD ([00:20:44](#)):

Therefore, having this kind of dialogue is extremely valuable for us because hearing what patients care about can help us lead the way in figuring out how to best facilitate medical product development for the treatment of pancreatitis and understand how patients view the benefits and the risks of therapies and devices for pancreatitis. We look forward to incorporating what we learned today into the agency's thinking and understanding of how patients view the benefits and risks of therapies and devices for pancreatitis. Once again, we are all here today to hear the voice of the patient, so thank you for your participation. We are grateful to each of you for being here and sharing your personal stories, experiences, and perspectives.

Erica Lyons, MD ([00:21:40](#)):

So let's begin by defining patient focused drug development. Patient focused drug development is a systematic approach to help ensure that patients experiences perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation. We believe that incorporating the voice of the patient into all stages of drug development not only enriches a clinical development program, but as essential to inform our assessment of the overall benefits and risks of our proposed therapy.

Erica Lyons, MD ([00:22:13](#)):

Here's an overview of some of the areas of opportunity to integrate patient input into drug development. As you can see, this begins in the translational phase by identifying and measuring outcomes and symptoms that are meaningful to patients so that they can be carried forward through as assessments into clinical studies. The information acquired directly from patients is key component of our overall benefit risk assessment at the time of a pre-marketing review or a marketing review. Once a therapy is approved, patient input continues to be essential to ensure that those needing or those

prescribing a treatment are able to make informed decisions when starting, continuing, or stopping a therapy. Now that we've covered the definition of patient focused drug development and the opportunities for patient input into all stages of drug development, I would like to talk briefly about FDA's patient focused drug development initiatives. So FDA recognized a need for more systematic ways of gathering patients perspectives on their conditions and on the treatment options available. As a result to date, FDA has conducted 26 patient focused drug development meetings, giving patients and caregivers a platform to contribute input that can help inform drug development and evaluation.

Erica Lyons, MD ([00:23:42](#)):

To highlight some of the findings from those meetings, we have learned that patients are experts on what it is like to live with their condition, that they are able to clearly articulate specific disease impacts in very concrete terms. They can also clearly articulate what is important to them regarding treatment benefit. We've also been able to share with patients that their chief complaints may not be factored explicitly into drug development plans, but they are very important for us to hear and understand. And now we have been reassured that patients want to be as active as possible in the work to develop new treatments, but that they aren't expecting FDA to address all of the gaps in current treatment or current approaches to drug development, but they do want FDA to help facilitate and identify the most effective pathway for them to play a major contributing role.

Erica Lyons, MD ([00:24:39](#)):

There is also growing interest and expanding efforts to gather patient input in support of drug development and evaluation from an external perspective. In 2015, we started welcoming patient organizations such as the National Pancreas Foundation to identify and organize their own patient focus collaborations. These externally led patient focused drug development meetings provide an opportunity to hear directly from patients, patient advocates and caregivers about the symptoms that matter most to them, the impact that a disease has on patient's daily lives and patients experiences with current available treatments. While the FDA is open and grateful to attending these patient led meetings that are externally led, the meeting and any resulting products like reports or surveys will not be considered FDA-sponsored or endorsed.

Erica Lyons, MD ([00:25:33](#)):

Meetings such as these externally led patient focused drug development meetings strengthen our understanding of the disease and treatment burden, which is what we call the therapeutic or clinical context. This patient input supports FDA staff as they conduct benefit risk assessments for products under review or advise drug sponsors on their development programs. We also believe that patient input collected from these meetings can have value to drug development in a broader context. For example, by helping to identify areas of unmet medical need and areas of patients conditions that are currently not being addressed by available therapies. This input may also help developers as they identify or create tools used to measure the benefit of potential therapies. A summary report from an externally led patient focused drug development meeting can be shared on FDA's website and I've included the link here in the presentation to the public website.

Erica Lyons, MD ([00:26:35](#)):

Patient focused drug development meetings are just one component of the agency's larger effort to enhance the incorporation of patient input into medical product development and evaluation. We are also working on a patient focused methodological guidance series, a pilot program grant for standard

clinical core outcome assessments, or COAs, that measure what matters most to patients as well as increasing patient focus into other existing FDA endeavors.

Erica Lyons, MD ([00:27:10](#)):

I would encourage you to visit the FDA CDER's Patient-Focused Drug Development website. And additionally you may contact the PFDD program staff at [patientfocused@fda.hhs.gov](mailto:patientfocused@fda.hhs.gov). Again, I would like to thank you for inviting us to participate in this meeting. We are so grateful for the opportunity to learn from you today and we are listening.

Dana K. Andersen, MD ([00:27:47](#)):

Thank you. Our next speaker this morning is Dr. Wahid Wassef and you can read his bio in the program. Wahid is one of this nation's leaders in the area of chronic pancreatitis. But I know Wahid because we had the pleasure, I had the pleasure of sharing many patients with him when I worked at the University of Massachusetts where he is the head of the pancreatitis clinic and directs the advanced endoscopy fellowship. And Wahid is an unusual gastroenterologist, because what he actually cares about, his patients and how they feel and their quality of life. And Wahid invested an enormous amount of time in developing a survey, a tool, that is now used internationally to assess the quality of life in patients with pancreatitis and for that he's internationally famous.

Dana K. Andersen, MD ([00:28:40](#)):

So Dr. Wassef, welcome.

Wahid Y. Wassef, MD ([00:28:50](#)):

Thank you, Dr. Anderson for these kind words.

Wahid Y. Wassef, MD ([00:28:54](#)):

What I'd like to talk about today is an introduction to chronic pancreatitis. Most of you really do not need that, so I'm just going to provide it as a framework for what we're going to be doing today. Before I start the presentation, though, I would like to thank Dr. Andersen and Jane Holt, cofounder of National Pancreas Foundation for their kind invitation to be with you. It's going to be a brief presentation. I cannot really tell you all about chronic pancreatitis in a few minutes. We're just going to share some background information. We're going to focus a little bit on current treatment modalities and then hopefully shed some light on future management focusing on pain in both of these areas.

Dana K. Andersen, MD ([00:30:05](#)):

Push that green button, the green triangle.

Wahid Y. Wassef, MD ([00:30:11](#)):

So chronic pancreatitis is not an uncommon disease. It is a significant worldwide medical problem in a number of studies. We see that in Copenhagen, for example, it's found in 13 out of 100,000 patients in the population. Male veterans in the United States, it's found at about 3%. In Japan, 17.4% of males and females have it. And in Southern India, 11 to 20%, so it's an international problem. And as you all know and you all have these symptoms, it presents with pain, diarrhea and diabetes.

Wahid Y. Wassef, MD ([00:30:50](#)):

In a study back in 1993, they did a natural history evaluation of these patients and over a 10-year period they found that most of the patients, about 65%, developed the pain, 45% developed the diarrhea and about 38% developed the diabetes. Now the diabetes is obviously something that is simpler to treat. There is insulin, there's oral hypoglycemics. The diarrhea, we have pancreatic enzymes for that, help absorbing the nutrients so they can get proximal absorption rather than getting to the colon and causing the diarrhea. But pain has always been a very difficult thing to address. With chronic pancreatitis. The first approach that we usually try for pain management is giving the patient pancreatic enzymes. Normally when the patients with chronic pancreatitis would eat food, the food would get down to the small bowel, it will release GI hormone called CCK, cholecystokinin, and that in turn would cause pain. When you give the patient pancreatic enzymes, the enzymes sort of short circuit that process so the food gets down there, but because there is pancreatic enzymes already down there, you do not activate the CCK. You do not release the CCK and hopefully you do not cause the pain. This is one approach. It's the simplest one that we usually start with, but it's not effective in everybody, as all of you are aware.

Wahid Y. Wassef, MD ([00:32:23](#)):

We then try to identify more specifically what is causing the pain. Is there something there, and this is where we do studies like an MRCP, magnetic resonance endoscopic pancreatography. Where we look the ducts, we look at the structures. In other words, is there a stricture, is there a narrowing in the pancreatic duct that's causing this problem? Is there a narrowing that will cause dilatation of the pancreatic duct, a ductal hypertension, pressure and discomfort. Is there a stone there? The stone can also cause the same process. Is there a pseudocyst? Is there a fluid collection that has leaked from-

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Wahid Y. Wassef, MD ([00:33:03](#)):

Is there a pseudocyst? Is there a fluid collection that has leaked from the pancreatic duct that led to fluid getting outside of the pancreas and causing inflammation and causing fluid collection? Is there neural inflammation? Some people think that chronic pancreatitis is associated with a neuropathy, where there is inflammation in the nerves leading to the pancreas.

Wahid Y. Wassef, MD ([00:33:23](#)):

Well, if we thought that there is an obstruction, if we thought that there is a stone in the pancreatic duct, a procedure known as ERCP is done endoscopic retrograde cholangiopancreatography. Where we would go down with the scope, and I'm sure a lot of you have had that and find the ampulla, find the opening to the pancreatic duct. Get to the pancreatic duct, cannulate it. And if there is a stricture, you dilate the stricture. If there is an area of narrowing, you can put a stent behind to try to decompress the system and that may provide some relief.

Wahid Y. Wassef, MD ([00:33:58](#)):

Every time I'm talking about pain management, I use the word may because none of this is 100% effective as you all know. If there is a stone there, we will put a basket in the pancreatic duct and remove that. If there is no anatomical problems, we do a procedure known as a celiac blockade. As you can see from the schema on the left side, we would go down with an endoscopic ultrasound scope. We advance a needle out into the ganglion which is located near the celiac artery. You have a cutter ski mount on the right side, but that's not what we usually use. And once we identify the area of the ganglion, we can inject it with medications to try to help relieve the pain.

Wahid Y. Wassef, MD ([00:34:49](#)):

But we usually start with epicanthine, which is a numbing medication like lidocaine. We usually follow that with either steroids or alcohol to cause some injury to the nerves in that area. By doing that, we're blocking the nerves, the sensory nerves that are innervating the pancreas. This has some success in some patients. We have done some studies looking at this, and about one third maybe to half of the population will benefit from this. And when it's beneficial, it's not really 100% either. It may provide some decrease in the pain management, it may provide less emergency room visits in this.

Wahid Y. Wassef, MD ([00:35:38](#)):

The last procedure that I talked about is doing something about a pseudocyst that develops. What we would usually do that is do something that I was told through years of fellowship never to do, and that is making a hole in the stomach. What we would do there is go down with the ultrasound scope, pass a wire using endoscopic ultrasound guidance into the area of the fluid collection. Dilate that with a balloon, and then eventually stent it. We usually stent that to provide drainage and to provide access. We usually have that initial approach to this called a step up approach, where initially you would do the drainage and drainage only. You go back a week, two weeks later to try to get into the area of the fluid collection and debride it if need be.

Wahid Y. Wassef, MD ([00:36:36](#)):

This is an image of what that area would look like. This is going into the stomach through to the back wall and debriding areas. These are old stents that have been there now for a couple of weeks, so their colors, initially greenish is now a little changed from all the debris that accumulated. And if there is a pseudocyst, that certainly will provide pain relief.

Wahid Y. Wassef, MD ([00:36:59](#)):

Now, the problem is that once we treat these patients, we're addressing the physical function. The diarrhea may go away, the pain sometimes it will go away, not always, and the diabetes would be addressed. But when we sit down and talk to our patients, we find out that's not enough, we're taking care of the physical function. But we also learned that chronic pancreatitis affects a lot of other things. It affects social function, patients cannot go out with friends, cannot interact with their significant others or with their kids. It impacts mental functions, emotions, depression, anxiety, stress.

Wahid Y. Wassef, MD ([00:37:43](#)):

And something that we developed or discussed or found out about really is cell function. One of the things that will happen with taking too many days off from work is losing the job, that has economic impact. Another thing that happens is medications are not cheap, another economic impact. And my patients always tell me healthy foods are more expensive than McDonald's, another economic impact. There's a lot of things that are impacting the patient that we do not address by just doing the CIS drainage, doing the celiac block or taking out the stones.

Wahid Y. Wassef, MD ([00:38:21](#)):

Because of that, we developed an instrument that Dr. Anderson referred to earlier. The pancreatitis, quality of life instrument PANQOLI for short. We developed first focus groups with patients at UMass to identify what the issues are that impacted their lives with chronic pancreatitis. We send these questions, these issues to physicians across the country to find out if there was anything else that we were missing. And then we did this study that was published a few years ago and funded by a grant from the American

Journal of Gastroenterology and from the National Pancreas Foundation to try to validate the instrument.

Wahid Y. Wassef, MD ([00:39:04](#)):

We had 175 patients out of 11 hospitals that did the study, and you do two things when you validate these instruments, you do a reevaluation of the instrument to make sure it's reproducible, and you look at its content validity. And on both accounts, this was a very useful instrument. It's the only one as Dr. Anderson alluded to earlier that was developed for chronic pancreatitis by chronic pancreatitis patients. It is also available on the National Pancreas Foundation website for free.

Wahid Y. Wassef, MD ([00:39:38](#)):

When we use that instrument and we applied it to patients in our clinic with chronic pancreatitis and compared it to the control population, how staff at UMass? you may argue that's not a controlled population, but that's what we used. You can see that the quality of life decreases with the chronic pancreatitis. We also compared this to a group of patients with inflammatory bowel disease. Now, you would think inflammatory bowel disease would be much more severe in its impact on its patients, and we found that the chronic pancreatitis had lower scores than inflammatory bowel disease patients did.

Wahid Y. Wassef, MD ([00:40:14](#)):

We then looked at it and interventions. If you look at the chronic pancreatitis patients, maybe their level is about 55 or so on average. Those that are smokers, their level is a little bit lower in the 50s. Those that quit, their levels actually get better, up to 60-ish, 61 so you can use it to evaluate treatment very nicely. Because of that, this has been introduced into four clinical trials that are currently ongoing in the United States. It is being translated into Chinese so that they can use it on their culture and in their culture to evaluate their chronic pancreatitis patient. And it's being used in the socialized system medicine in Denmark and in Sweden to evaluate their populations.

Wahid Y. Wassef, MD ([00:41:02](#)):

In closing, what I'd like to say is that we had treated diarrhea, diabetes, and pain specifically to treat the symptoms in the past. And I think as we look to new treatments these days and we go forward, I don't think that that's a sufficient point endpoint. I think we need to look at patients' experiences, patients' quality of life issues, and provide more personalized medicine if you will, as Dr. Whitcomb would say. Thank you.

Dana K. Andersen, MD ([00:41:48](#)):

Next on the program we're going to shift gears a little, and move to a real expert in this patient focused drug development process. James Valentine is an attorney who also received a Master's degree in health policy from Johns Hopkins Bloomberg school of Public Health. And he worked for the FDA for a number of years, and developed this patient focused drug development program. Now he's an attorney here in Washington who helps clients address issues related to drug development and patient advocacy. And James is here because he is the absolute expert in running these patient focused drug development meetings, so he's going to be at the controls from here on. James, thank you very much.

James Valentine, JD, MHS ([00:42:45](#)):

Thank you for that kind introduction, and it's really my pleasure to be here this morning to help moderate this externally-led, patient-focused drug development meeting on pancreatitis. As you heard

from Dr. Lyons, this meeting is really a way for us to systematically hear from and learn from all of you, patients and individuals that are caring for patients with pancreatitis. This is so key to be able to inform not only FDA's understanding, but really the entire drug development ecosystem. That way, decisions can be made that are anchored to what is really most important to you based off of your experiences and your preferences for future treatments.

James Valentine, JD, MHS ([00:43:35](#)):

I can say that this is a really unique opportunity for your community with many thousands of known conditions that exist. You heard from Dr. Lyons that there's been over 25 FDA-led PFDD meetings, and today marks, at least by my count, the 32nd externally-led PFDD meeting. Quite a unique opportunity to be able to convene and have all the stakeholders and here in the room to hear from you directly.

James Valentine, JD, MHS ([00:44:05](#)):

What will we be discussing today? You can see in the meeting programs that you have an agenda laid out, I'm going to talk through that very briefly. As you can see, the meeting is structured in a way that we're going to first this morning, talk about the adult experience with pancreatitis. And then we're going to come back after a quick break and dig a little into the pediatric experience in pancreatitis. Within each of those two topic sessions that we have, there's a number of issues that we want to explore with you. We're going to first be posing questions and getting your inputs on your experiences with the symptoms, health effects and impacts on daily life that you experience as a result of your pancreatitis itself. We'll be asking you not just what are those symptoms and health effects, but really ask you to help us understand which have the greatest burden and impact on your daily life. And related to that, help us understand which activities that are important to you are you not able to do either at all or as fully as you might want because of those symptoms and health effects. We'll also be asking you to help us understand the disease in day to day life, how much does it vary? Say from day to day, week to week, month to month or over the course of progression of the disease. As well as maybe what a best day versus a worst day might look like. And then of course knowing that not all of the diseases experienced at present day, knowing that progression may occur, we'd like to hear about your worries for the future of living with pancreatitis. We'll then build on that and have some questions for you related to your treatment experience, so we're going to want to understand what different approaches you take to treating and managing your condition. When I say treatments, I mean that in a very broad sense. We're going to be asking not only about prescription drugs and medical procedures, but things that you might employ in your daily life. Whether that be diet, exercise, even lifestyle modifications. Really think about that holistically, and helping us understand what it is you utilize. And then once we've got a sense of that, help us understand how well that's working as well as what are the downsides or trade-offs that you experienced as a result of those treatments.

James Valentine, JD, MHS ([00:46:49](#)):

And then finally, we're going to look towards the future and we're going to ask you to tell us about what it is you'd like to see from a future treatment. Of course, everybody in this room today would agree that we'd want a cure for pancreatitis. But short of that from that next therapy that might be coming down the pipeline, what is it that would specifically provide a benefit to you in your daily life? We'll explore that a little.

James Valentine, JD, MHS ([00:47:16](#)):

How are we going to draw all of that out? It's a hefty set of issues to explore. Well, we have three methods that are built into each of those two sessions we'll have. We're going to kick it off by first hearing from a panel of patients and caregivers, this is going to set a good foundation for the discussion that we'll have here in the room that will follow. The panelists were selected to reflect a range of experiences. Of course, they can't be fully representative, you can never have four people that fully represent a community. But it will at least help us get us kicked off and set the stage.

James Valentine, JD, MHS ([00:47:54](#)):

We'll then broaden the discussion with a combination of polling questions, so those in the room will be able to use their cell phones, or if you have a laptop or tablet you certainly can use that. And for those of you following along on the webcast, you'll be able to pull up a browser and answer those same questions for us. We'll get to see the results live, and those questions will give us a sense of who we have participating here in the room and on the web, and will give us then a launching point into an audience discussion that I'll facilitate with those of you here in the room, asking you many of those questions that I just previewed. During that period, I'll ask for questions. I'll ask you to just raise your hand, I'll call on you. And if you state your name, we'll be able to have you add to the conversation here in the room.

James Valentine, JD, MHS ([00:48:42](#)):

I want to say that today is not the only opportunity to provide your input, although we very much encourage you to share today. But if you leave the meeting today and feel that you just have something burning that you need to provide, that to be considered for that voice of the patient summary report that will be developed? Or if you're on the web, and you're not able to participate in the discussion here in the room? Or maybe you're watching this recording or you weren't able to attend the meeting today, and you want to provide your thoughts? We will be sending out a link to all of the registrants with a web form to be able to provide additional written comments. Which like all of the input today, will be considered in drafting that summary report, that voice of the patient report that will both be submitted to FDA as well as be available to those that are doing research and development.

James Valentine, JD, MHS ([00:49:39](#)):

One final thing before we get into our first round of polling questions, which are some demographic polling questions. I just want to cover a few ground rules. One, we are having this meeting because we want and need to hear from you, individuals with pancreatitis and their caregivers, family members, to be able to contribute to this dialogue. That being said, the different interactions that we'll be having today are limited to patients and their direct caregivers, family members, FDA, drug developers, and our clinician partners are here to listen. I also want to mention that the views today are inherently personal, you're sharing your personal experiences. And at times may get emotional. Because of that, respect for one another is paramount. To that end, I just ask that when you are providing your comments today to please try to be focused and concise, so that way we can try to hear as many voices as possible in the time that we do have allotted.

James Valentine, JD, MHS ([00:50:46](#)):

With that, let's go ahead and jump into our first set polling questions. For those of you in the room, please pull out your cell phones. Again, this is for caregivers and patients only. And for those of you on the web, please go ahead and open up a browser, and you can go to the URL [PollEV.com/pancreas](http://PollEV.com/pancreas). It's right here at the top of the slide that you're seeing right now. These questions, we would like for

caregivers to answer these for the patients that they're responding. For this question, where do you currently reside? Please respond in terms of where the patient resides at vary, wait. Well, maybe that you live in the same place, might be expected. But just from here and throughout, answer on behalf of the patient. Go ahead and answer this first question, where do you currently reside? These are your response options. If you're having any difficulty in the room accessing this polling, please raise your hand and we'll make sure to send someone to you to help you get in. Any issues accessing? We have one hand right here. That's one, Larry maybe. Help out right here. All right. It looks like we're everybody's into... One more right here Larry. We just want to make sure we get everybody into the system, so that we can follow all of your responses for and throughout the meeting. While we're getting that final responses in, just to report out on who we have represented today. Perhaps not surprisingly because of the time that we're starting and the location of the meeting itself, a little over half of our participants represented reside in US Eastern time zone. We have about a third of individuals from the central time zone, and just over 5% in the Pacific time zone. We do have representation from outside of North America, including some from the EU, Middle East and Asia. We go to the next question.

James Valentine, JD, MHS ([00:53:56](#)):

Our second question is, what is the gender of the individual you're representing today? If you're a patient, answer on behalf of yourself. If you're a caregiver, this is the gender of the individual that you care for with pancreatitis. Options are A, male, or B, female. Just give you a few moments. While final results are trickling in, it looks like the pattern here is clear. About three quarters of our participants are representing a female patient, and about a quarter of our participants are representing a male patient. And it looks like the gap between that is growing a little as more responses trickle in.

James Valentine, JD, MHS ([00:54:56](#)):

Next question. This question is how old are you? Again, we're talking about the patient. Is the patient younger than 18 years of age? B, between 18 and 30 years? C, between 31 and 50 years? D, between 51 and 60 years? Or E, greater than 60 years of age? While any final results are trickling in, it looks like our greatest group represented is the 31 to 50 year age group. However, we do have good representation across the different age ranges, with the next largest group being those over age 60, and the smallest group being those age 51 to 60. Next question.

James Valentine, JD, MHS ([00:56:08](#)):

Here, we'd like to know at which age did you or the patient you care for have their first symptoms of pancreatitis. And your options here A, before age five or earlier? B, between ages six and 18? C, between the ages 19 and 30? D, between ages 31 and 50? E, between ages 51 and 60? Or F, older than 60 years of age at time of first symptoms? It looks like the age at which most of the individuals we have represented today had their first symptoms of pancreatitis, with about 40% between the ages of 31 and 50. However, we do have quite a bit of representation of those that had their first symptoms during childhood, whether that be age zero to five, or six to 18. And then we also have a number of individuals just about 10% each that had their first symptoms between ages 19 and 30 or between 51 and 60. And no one present today had their first symptoms older than at older than age 60, or someone... I think that's probably one person just chimed in saying that they had that experience. Next question.

James Valentine, JD, MHS ([00:57:59](#)):

Here, we'd like you to answer what type of pancreatitis that you or your loved one have. Is it A, acute pancreatitis? B, recurrent acute pancreatitis? C, chronic pancreatitis? D, hereditary? E, acute

hemorrhagic? F, pancreas divism? G, auto-immune? Or H, related to some other disease? Please select the category that best applies to you or your loved one. All right. Well, final results are trickling in. It looks like just about half of our audience reports having chronic pancreatitis. We have about a fifth with hereditary, and then we do have representation from recurrent acute pancreas divism. Auto less so, but also representation from auto-immune and acute as well as related to another disease. It looks like no one has reported acute hemorrhagic. Next question.

James Valentine, JD, MHS ([00:59:27](#)):

Now, to just get a little bit more of a sense of your experience with pancreatitis, we want to know how many times have you been admitted to the hospital for your pancreatitis? Have you never been admitted to the hospital for your pancreatitis for option A? B, have you been admitted one to five times? C, six to 10 times? Or D, more than 10 times? It looks like just about half of you have been admitted to the hospital for your pancreatitis more than 10 times, I'm sure this will come out understanding the cause of those admissions as we dive into your experiences. And then we have good representation from those that have been admitted between one to five or six to 10, and just a few people have never been admitted to the hospital for their pancreatitis. And can we go to our final demographic polling question?

James Valentine, JD, MHS ([01:00:39](#)):

Here again, to get another sense of your experience with your pancreatitis, how many endoscopic or surgical procedures have you had to treat your pancreatitis? Same options as before. A, none? B, one to five? C, six to 10? Or D, more than 10 endoscopic or surgical procedures? During the discussion, we're certainly going to want to hear what procedures that you have had, how many of the different types and what impact that has had both good and bad on your experience? It's looking like about half of you have had between one and five procedures, another close to half have had more than that. And then again, a few people have had no procedures.

James Valentine, JD, MHS ([01:01:45](#)):

All right, well thank you for participating in those polling questions. It's great to have a sense of some of who we have in the room and some of your experience, and we're certainly going to be building on that quite a bit as we move on. I'd like to now invite our first panel up onto the stage. We're going to be diving into issues of the adult patient perspective on living with pancreatitis. And we're going to kick that off with a panel discussion. On this panel. We have June, Adriana, Eric and Hillary, who are going to be sharing both their experiences and preferences for treatment. And I'll ask June to get us started today. Or Jane, sorry.

Jane M. Holt ([01:02:39](#)):

Good morning everyone. As you just heard, my name is Jane Holt, and I'm a patient with chronic pancreatitis. As most of you know, our story really starts with a diagnosis. The beginning is more of a journey. My journey began in early January, 1988. I was at home asleep, my husband and four children were in the house with me. I woke up in the middle of the night in excruciating pain, it felt as though my insides were exploding. I knew immediately there was something terribly wrong, and I needed to go to the hospital. I had to drive myself and leave my husband at home with our younger children. There was a classic new England snowstorm going on, but luckily the hospital was not very far away. After blood work in an ultrasound, I was diagnosed with possible gallstones. They gave me heavy pain medication, set me up for an appointment with a surgeon and sent me home.

Jane M. Holt ([01:03:34](#)):

Now remember, I was alone. It was 4:00 AM in the morning and it was snowing heavily. They let me go out and drive my car home, but luckily I made it home safely. 10 days later, my gallbladder was removed. Things were different then, and I stayed overnight in the hospital. The next morning, the surgeon came to visit me. I remember so clearly telling him that I had some pain from the surgery but the original pain was still there. Many of us had had our gallbladder removed and the pain returns. I went back to the surgeon two weeks later, still in pain. He prescribed statins, and suggested I follow my GP. I did this for several months but continued to have the pain. But I was pretty lucky, I lived in Boston. I had friends that knew people in the best hospitals, and I was able to get an appointment with a gastroenterologist at BI Deaconess Hospital in Boston in October of 1988. After doing a medical history and blood work, my doctor said he thought I had pancreatitis. I had an ERCP that confirmed this diagnosis. Finally, I had a cause for the pain, and it only took several months to be diagnosed instead of years for some of the patients. In November, I had major surgery to open the ducts to my pancreas, and the journey continued. In the very beginning, my major symptoms were pain and nausea. I was always tired. My children were five, nine, and I had twins that were 11. They were my life, and I still tried to do everything for them but it became very difficult. The surgery held for a few months, but the pain returned. There was no treatment for pancreatitis. When the pain became intolerable, I had to be hospitalized. I would be NPO and put on IV fluids and heavy pain medication.

Jane M. Holt ([01:05:19](#)):

Early on, I couldn't go home until I could eat solid food. I was hospitalized at least four times a year, and sometimes more. There was one year where I spent the entire month of June in the hospital. Every time I advanced to food, the excruciating pain would return. My youngest son spent a whole day in the hospital visiting me because it was his birthday. We went downstairs for lunch in the cafeteria, a trip to the gift store. After school, the family came in and we had a birthday party with birthday cake. It totally exhausted me, but I had to be with my son on his birthday. My symptoms would improve after hospitalizations. My pain level was sometimes be as low as three. I stayed on my very low fat diet, I never drank alcohol and I took my enzymes. I never cheated because it wasn't worth it. I learned...

PART 2 OF 8 ENDS [01:06:04]

Jane M. Holt ([01:06:03](#)):

[inaudible 01:06:00]. I never cheated because it wasn't worth it. I learned very early that if I ate too much fat, within 45 minutes to an hour, I would be in pain. I had nausea medication I could take when I was vomiting that helped sometimes. I was always hospitalized in the fall and I never quite figured out why.

Jane M. Holt ([01:06:18](#)):

At first, I thought it was the stress of getting the kids back to school and back to a regular schedule after a very relaxing summer, but now I realize my attacks had nothing to do with stress. To this day, my pancreas always flares in the fall.

Jane M. Holt ([01:06:33](#)):

As time went on, I was hospitalized less. The surgeons put in ports so I could have TPN at home. To begin with, I had a big IV pole at home. It would take 10 hours every night to infuse a TPN. I have

pictures of Christmas morning with me and my pole enjoying the gifts that Santa Claus brought the children.

Jane M. Holt ([01:06:50](#)):

Later, I was able to use a backpack, which made me much more mobile. The kids were getting older, so it meant that I could go to school plays and concerts and sporting events, hooked up to my TPN. Then I had problems with the port. I developed blood clots and then one time when I was in the hospital, I developed sepsis, which was from an infection in the line. The port was removed and after that when I went home, I had to have a PICC line.

Jane M. Holt ([01:07:14](#)):

Luckily, I've been off TPN for about 10 years. I've never used pain medication on a regular basis. It was only when I had flare ups, but can go for long periods of time when I don't need it. I can always feel my pancreas. I always have a mild pain, at least, I can feel it always, right here.

Jane M. Holt ([01:07:33](#)):

My times of very bad pain had been less in the last six years and I've been hospitalized less. I've had a few ERCPs, many MRCPs, cat scans, ultrasounds, and thousands and thousands of blood tests. I've traveled to Mayo Clinic, Lahey Clinic, George Washington Hospital, for second opinions.

Jane M. Holt ([01:07:50](#)):

My doctors has brought my records to many medical meetings for input from other physicians. 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. For most patients, treatments haven't changed. It's now even getting harder to get one of the things that can help the most, which is pain medication. I hope this meeting is the beginning of a change. We can't ignore patients like me. We have to do something to make a difference for all of our patients.

Adriana Llamas Cowdin ([01:08:28](#)):

Good morning, my name is Adriana Llamas Cowdin. I'm a 43 year old married woman from Indianapolis, Indiana. My struggle with chronic pancreatitis started in 2015. I had recently relocated to Indianapolis to take a new job as a Chief Marketing Officer and had just started to date a man that would later become my husband. To say I was excited about the future was an understatement.

Adriana Llamas Cowdin ([01:08:49](#)):

I was in a new city with a new job, a new relationship, and a new home, and I was just doing it all. And then I took a sip of a water, nothing fancy like Pellegrino, just some tap water, and I doubled over into the worst pain of my life. My assistant came running into my office and immediately called the emergency room to have me taken over.

Adriana Llamas Cowdin ([01:09:09](#)):

They initially thought it was my gallbladder, so that was removed. They were wrong. It was an acute pancreatitis attack. That cleared up and I went back to work. Two weeks later it happened again, only this time it was a sip of coffee. Back to the ER and back into the hospital. I was admitted this time for three weeks. Forget dinner and a movie, our new dates were to the ER, and our movie nights were bedside as I laid in the hospital and learned about lipase, amylase, and feeding tubes.

Adriana Llames Cowdin ([01:09:37](#)):

Between 2015 and 2016, 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 pancreatic divisum and was living on and off feeding tubes.

Adriana Llames Cowdin ([01:09:57](#)):

We tried as many variations of medications possible and I'd learned how to live on Creon, a digestive enzyme that can cost a small fortune.

Adriana Llames Cowdin ([01:10:05](#)):

In this time I spent a total of six months in the hospital, lost my new job, my new home, and my livelihood. I regularly lived on strong narcotics for the pain. My now fiance's father passed away unexpectedly in November 2016. We flew to the remote part of Nebraska for the funeral and halfway through the funeral I had to find a quiet corner. A severe attack came on and I was crumbling into a doubled over pain on the floor. I was in a ball whimpering and I thought, why now? Why when he needs me most, is my body failing me?

Adriana Llames Cowdin ([01:10:38](#)):

We called my doctors and they asked how fast I could get to a hospital. The nearest hospital was two hours away and they didn't even have an MRI machine. The next morning we packed up and flew to Chicago where my new medical team was and I was admitted to the University of Chicago Medical Center.

Adriana Llames Cowdin ([01:10:54](#)):

Two days later I was told I had to have the Whipple procedure or I would die. I asked how long I had to make the decision and they told me they had a surgery date available on December 15th. They released me to spend Thanksgiving with my family and on December 15th 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.

Adriana Llames Cowdin ([01:11:19](#)):

I spent three weeks in the hospital with infections, complications, and was released home with three drains and it wound vac. 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.

Adriana Llames Cowdin ([01:11:47](#)):

I was still getting flares with debilitating pain, awful nausea and vomiting, and more long stays in the hospital with nothing but fluids to allow for organ rest. I'd lost my career, many of my friends, and I was down to 86 pounds.

Adriana Llames Cowdin ([01:12:02](#)):

By the grace room above, my fiance stood by me and we were married. He spent every night that I was hospitalized next to me sleeping, eating, and bathing in the hospital, and being my best advocate.

Adriana Llames Cowdin ([01:12:14](#)):

By 2019 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. My pancreas had a stone, a full blockage in the doc, and I had a hernia. I was taking narcotics four times a day, three types of nausea medications, and spending most of my days in bed. Things had to change.

Adriana Llames Cowdin ([01:12:39](#)):

November 14th of 2019 I had a total pancreatectomy auto islet transplant surgery. During a 14 hour surgery, they removed my pancreas, harvested islet cells, which produce insulin in your body and transplanted them into my liver. This highly skilled surgery was done with five surgical teams and was my last option.

Adriana Llames Cowdin ([01:12:58](#)):

I came out of surgery and was in ICU for three days and then on a transplant floor for four days. Seven days after surgery. I was released from the hospital. I'm now 90 days out from surgery and pain free, and workout four days a week, and I'm off all narcotics.

Adriana Llames Cowdin ([01:13:15](#)):

So I wouldn't say life is perfect, but in my mind it's as close as it can be. And that said, I'm an insulin dependent diabetic. I fight some low sugars and was almost hospitalized once for that. I still take Creon for digestion and I'm living on nausea meds four times a day. But I have my life back and I'm looking forward to working again, enjoying real dates with my husband outside of the hospital, traveling and spending time with my family, and I would say that this disease can rob you of your entire life, but with the right medications and care you can absolutely get it back.

Eric Golden ([01:13:47](#)):

Good morning, my name's Eric Golden. I'm 51 years old and live in Santa Monica, California with my wife and three children. 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.

Eric Golden ([01:14:15](#)):

To give you some perspective, before my symptoms became unbearable, I had essentially no patience for being sick. I once almost went six years without a sick day at work and simply pushed through the illnesses that would send most people home. It is impossible to do so with chronic pancreatitis.

Eric Golden ([01:14:32](#)):

Through genetic testing, I learned I have two CFTR mutations and one CASR mutation that my doctors believe are the primary cause of the disease. 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.

Eric Golden ([01:14:54](#)):

I consider myself one of the lucky ones with this disease. I have a wonderful supportive family. I'm able to be well informed, serving on the board of several nonprofits involved with pancreatic disease. I am

rarely hospitalized. Many people with this disease, including many you will hear from today, have it much worse, but I want to tell you what being one of the lucky ones means with chronic pancreatitis.

Eric Golden ([01:15:19](#)):

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. I've had severe shoulder dislocations, broken bones, and plenty of other painful mishaps, and none of them come close to this pain. You cannot fall asleep in that much pain and getting to sleep often takes hours and a combination of pain medication and sleep aides.

Eric Golden ([01:15:52](#)):

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. While I am too stubborn to stop working, many days I fight to make it to the end of the work day. When I get often I am done, in bed and not able to be the parent or husband I would like to be.

Eric Golden ([01:16:15](#)):

When you feel this way for a long time it is difficult not to experience at least some hopelessness and depression. 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.

Eric Golden ([01:16:43](#)):

If you had not experienced this before, you would take yourself to the emergency room right away since you feel that your body is simply shutting down. Sometimes these flareups are months apart, but other times they are weeks apart. It takes up to two weeks to recover from a flareup, so that means being debilitated for large parts of your life.

Eric Golden ([01:17:05](#)):

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 at the time, and even with constant vigilance you suffer almost daily.

Eric Golden ([01:17:32](#)):

For years I was on daily oxycodone. While I tried constantly to manage my dose, it increased over time just to have the same effectiveness. This fall I decided to stop daily opioid use. With the help of the Stanford Pain Clinic, I reduced my dose from 15 milligrams to zero over the course of 75 days.

Eric Golden ([01:17:53](#)):

This was exceedingly challenging and I'm concerned whether most people could do this without very serious help. I will say that it would be dangerous and cruel for physicians to cut off patients without a very gradual taper, but I hear about this all the time in the pancreatitis community.

Eric Golden ([01:18:09](#)):

In some ways I feel better without opioids. My energy level seems higher and I've had fewer flareups, though I cannot say whether this is causation or coincidence. But the medication I've been given as a substitute, including Gabapentin and Clonidine rarely comes close to stopping the pain and many nights I'm in too much pain to fall asleep without a sleep aid like Ambien.

Eric Golden ([01:18:33](#)):

Because of this, opioids remain an essential daily need for many patients. Two things that have been effective for me, not to sound like a stereotypical Californian, have been meditation and cannabis. For cannabis I take equal parts CBD and THC. I've meditated seriously for two years, and while it does not reduce symptoms, it can allow you to approach your condition with equanimity rather than hopelessness.

Eric Golden ([01:18:59](#)):

Cannabis for me does not reduce the pain, but makes it much easier to bear. I would urge this body to take cannabis very seriously as a treatment for conditions like this and to give very serious consideration to newer treatments like psilocybin, which I know from clinical trials has helped patients with terminal cancer cope with depression and hopelessness.

Eric Golden ([01:19:21](#)):

But I want to stress that none of this is enough right now. This is a degenerative disease that will get worse with dangerous complications, not all of which are well understood. For example, a laparoscopic procedure found extensive adhesions in my abdomen and one of the nonprofits I work with, Mission: Cure, subsequently learned that a large proportion of patients receiving the TPIAT procedure also have adhesions, presumably from the constant inflammation.

Eric Golden ([01:19:50](#)):

I believe these adhesions exacerbate digestive problems for me since they can contort or constrict my intestines. And in terms of life impact, this disease can be devastating. I cannot imagine how patients with more severe pancreatitis are able to make it through the day. And I am heartbroken to think that any child should have to go through such intense pain and suffering.

Eric Golden ([01:20:13](#)):

But as you will hear from the next panel, many of them do. It is essential an effective treatment be found for this debilitating, costly disease. I thank the FDA for its interest and attention, and am available to provide any additional information that would be helpful.

Hillary Mendelsohn ([01:20:34](#)):

Good morning, my name is Hillary Mendelsohn and I'm 54 years old. I'm a Los Angeles native. I have four kids, three in college and one recent graduate, and I'm a very happy newlywed.

Hillary Mendelsohn ([01:20:47](#)):

I was diagnosed with pancreatic cancer in February of 2002 at the age of 36. I had been experiencing a dull persistent ache in the middle of my back being caused by a large tumor on the head of my pancreas.

I had a Whipple procedure 10 days after diagnosis. The surgery was difficult and only three of four margins were clear. One still showed cancer cells.

Hillary Mendelsohn ([01:21:12](#)):

Post surgery, I had complications and infections which were supposed to take my life. After several months of hospitalization, home nursing, and the challenge of reintegrating solid food, I began to try and regain my strength. At 92 pounds, two small children and a marriage ending, I was a daughter, a single parent, a breadwinner, an entrepreneur, and a cancer survivor.

Hillary Mendelsohn ([01:21:40](#)):

When I was diagnosed, my doctor gave me the odds, 60 to 90 days without surgery and best case 10 to 24 months with surgery, based upon the type of my cancer and the size of my tumor. No matter the odds or the facts, I was determined to be the one to survive. I had too much to live for.

Hillary Mendelsohn ([01:22:02](#)):

But my journey wouldn't be an easy one. My motto became whatever it takes. I began to gain weight slowly, but I now had new adjustments. I had dietary restrictions due to my streamlined digestive system and as I would soon learn if I ate something that didn't work, it wasn't just a stomachache, but acute pancreatitis would ensue.

Hillary Mendelsohn ([01:22:25](#)):

Over the last 16 years, I've had eight surgeries related to my pancreas, seen doctors all over the country, as well as in Canada and Germany, and endured more pain than anyone should have to know.

Hillary Mendelsohn ([01:22:40](#)):

But I have lived each day to the fullest and made the most of my good days and figured out how to reduce my bad days. And even figured out how to better endure those bad days. When I would ask medical professionals about pancreatitis, they would always discuss it related to alcoholism, smoking, obesity, or diabetes. As a competitive gymnast from the age of seven through college, I was never a drinker, never smoked cigarettes or used drugs, never overweight, lived a clean, healthy life, and had no family history of pancreatic cancer or pancreatitis.

Hillary Mendelsohn ([01:23:17](#)):

The first attack of acute pancreatitis, I thought I was having a heart attack and went to the emergency room. No one had told me this was a potential side effect of pancreatic cancer. I was hospitalized and put on morphine drip and NPO for a week. After experiencing episodes of acute pancreatitis, most medical professionals I encountered assumed it was alcohol related before I told them about my medical history.

Hillary Mendelsohn ([01:23:47](#)):

It is so frustrating to be admitted a hospital and have most assume that I'm there with pancreatitis because of the consequence of my own hard living. And even when they do know the reason that I'm afflicted with this painful, disruptive, and destructive condition, many tell me there is very little I can do.

Hillary Mendelsohn ([01:24:08](#)):

I sometimes wish they could feel the pain just for a brief moment so at least empathy could enter the equation. Acute pancreatitis interrupts, makes you accommodate, and changes day to day life. It sets parameters on your life and affects those around you. When you combine that with being a pancreatic cancer survivor, things get even more complicated.

Hillary Mendelsohn ([01:24:34](#)):

Travel is part of my work and I have to figure out how to have what I need when I'm on the road. A restrictive diet means I go to the market so I have things I know I can eat. The hotel room I stay in must have a bathtub. I need to make sure I have a surplus of medications that I need, which stay with me in my backpack at all times and never in check luggage. I'm traveling alone, driving hundreds of miles a day, so I must be self aware of how I'm feeling at all times so that I can be safe and sensible should I feel an episode of acute pancreatitis coming on.

Hillary Mendelsohn ([01:25:13](#)):

I've learned to deal with the last decade of acute pancreatitis episodes on my own without pain medication, IVs, or hospitals. Over the past few years, with my streamlined digestive system, my liver is now overworked and underpaid and has begun to show signs of atrophy.

Hillary Mendelsohn ([01:25:33](#)):

Since then, I've made further accommodations knowing that there isn't someone like me who's had a liver transplant and trying to protect what I have. I have had many doctors and medical professionals tell me variations of, I can't help you with your issues, but frankly, you're just lucky to have been alive this long.

Hillary Mendelsohn ([01:25:56](#)):

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. Luck is the smallest factor of my existence in the face of difficult odds. I have fought to be here, endured much pain, and conquered fear. I have looked for answers where others said there were none. I have listened to my body, learned about physiology and come up with my own set of answers, truths, tricks, and methods.

Hillary Mendelsohn ([01:26:42](#)):

Knowing quality of life is the most paramount issue, even with all of my struggle, I'm thankful to have a life to live. To that end, I am hopeful and prepared to work towards making sure that more is learned and more can be done.

Hillary Mendelsohn ([01:26:59](#)):

Other than my beautiful family, I hope my legacy is to be part of the change, encouraging compassionate care and inspiring innovation in pancreatic studies and helping those afflicted find more daily quality of life.

James Valentine, JD, MHS ([01:27:17](#)):

Wow. It's a incredibly brave to get up and speak first in front of everyone. So I just would like to ask everyone to join me in another round of applause for the whole panel.

James Valentine, JD, MHS ([01:27:40](#)):

So now we're going to build on what we just heard from the excellent panel through some intermixed polling questions with audience discussion. So you can go ahead and pull out your phones again, we're going to ask our patients and caregivers in the room to answer a few questions, and then we're going to dig a little deeper with some facilitated dialogue.

James Valentine, JD, MHS ([01:28:03](#)):

So if we can have our first topic one question. So here we'd like to know which of the following pancreatitis related health concerns that you or your child recently have had and please check all that apply.

James Valentine, JD, MHS ([01:28:19](#)):

I should note that for this set of polling questions, even if you're here for to represent a pediatric patient, we would like you to respond to those at this time. These are going to be the polling questions that we'll use for the full group today.

James Valentine, JD, MHS ([01:28:37](#)):

So which of the following health concerns do you or your child have or have recently had? The options are A, pain, B, nausea or lack of appetite, C, fatigue, D, abnormal bowel movements, E, weight loss or malabsorption, F, bloating, G, dizziness, H diet restriction, I, thirst or dehydration, J, irritability, K, worry for the future, L, anxiety or depression, or, M, some other health concern related to your pancreatitis that's not listed on this slide.

James Valentine, JD, MHS ([01:29:18](#)):

Again, please check all that apply. So I think there might be a question about the percentages. Is that what it is? Yes. So this is not a percentage of patients and caregivers that are responding. It's a percentage of the total responses. So what's important is to look at the relative weighting of the different responses. It's just the way that the polling system displays it. We're able to actually look at the total percentage of everybody for each on the backend. But that's a great question. So while final results are trickling in, it looks like the pancreatitis related health concern that has been experienced most by our participants today is pain closely followed, I would say, by a cluster of nausea and lack of appetite, fatigue, abnormal bowel movements, and worry for the future.

James Valentine, JD, MHS ([01:30:28](#)):

However, there's quite a bit of experience across every single other health concern, perhaps dizziness being one of the ones that's less frequently experienced, and there's a good amount of experience with other health concerns. So we'll, as we go to the audience discussion, definitely want to hear about what those other health concerns are. Can we go to the second question?

James Valentine, JD, MHS ([01:30:54](#)):

So here we want you to... The previous question we asked about all of the health concerns that you have and it was quite a great burden across many, almost every actually every single one of the ones

listed here. We want you to pick the top three health concerns that you have. Your options are, A, pain, B, nausea or lack of appetite, C, fatigue, D, abnormal bowel movements, E, weight loss or malabsorption, F, bloating, G, dizziness, H, the diet restrictions, I, thirst or dehydration, J, irritability, K, worry for the future, L anxiety or depression, M, one of your top three pancreatitis health related concerns is something not listed on this slide. So please select your top three. So give you just a few more moments to get your responses in. It looks like pain is by and large the top, top three pancreatitis related health concern that those represented today have. A little bit distant behind that are nausea and lack of appetite. Worry for the future and fatigue. However, individuals did pick every other response option except for dizziness, not falling in anyone's top three,

James Valentine, JD, MHS ([01:32:42](#)):

and a number of other health concerns that aren't listed on this slide being top three. So certainly we'll want to hear about those. And if we'll do one more polling question at this point.

James Valentine, JD, MHS ([01:32:58](#)):

So here we've asked about the direct health concerns and now we want to get a sense of what the impacts are on activities in your daily life. So what specific activities of daily life are most important to you that you are not able to do when experiencing your pancreatitis? Please select your top three. Your options are walking, exercising, participation in sports and activities, social interaction and participation, attending school or having a job, or F some other activity in your daily life that's important to you that you're not able to do because of your pancreatitis. So it looks like the top two responses that have been flipping a little bit have been social interaction and participation, and attending school or having a job. So we'll definitely want to hear your experiences and what is made it so that you're not able to do those. Next together are exercising and participating in sports or activities, physical activities, more rigorous physical activities.

James Valentine, JD, MHS ([01:34:27](#)):

But some of you noted a top three impact is an impact on not being able to even walk. And then there's other activities that were listed, or that were not listed, that you report not being able to do that are a top activity you're not able to do. So we'll want to hear about that so that let's turn it to you in the audience to talk about the direct health concerns related to your pancreatitis. And so let's maybe start, we heard that the top concern is pain following that, it was nausea, but there were others like fatigue. And then we heard, although not listed explicitly that you have attacks and flare ups that happen. We heard that from the panel.

James Valentine, JD, MHS ([01:35:16](#)):

So we'd like to hear about what is maybe your top one or two health concerns and tell us why it is that you view that as a top health concern. Yes. And just remember, please say your name before you speak.

Carolyn Bloom ([01:35:29](#)):

Hello, my name is Carolyn Bloom and I am 72 years old, probably older than anyone up there in the panel. I was born, although I didn't know it, with pancreas divisum. So 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. So from 22 to 50 I could do my job, but I was in the hospital seven times.

Carolyn Bloom ([01:36:14](#)):

Then when I was a 47 I had a stent put in by a noted person and the day after the stent went in, I was in horrendous pain. The noted person had left town and they would not take the stent out. So I had to be in pain, like having a knife in me for two weeks. And after that it turned out that the stent, because we we're talking about quite a while ago, 1997, the stent had slipped and made my deformity even more deformed. So I became chronic.

Carolyn Bloom ([01:36:52](#)):

So from the time 1997 to, actually earlier, '96 to 2008, I was in the hospital 250 times. 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. And I was in the hospital the average of about eight months out of 12 months a year for 13 years.

Carolyn Bloom ([01:37:25](#)):

So I would say that I'm very knowledgeable on this topic. And then I was ready to kill myself actually. I was on Dilaudid, Fentanyl, Ketamine. They told me I couldn't have any more ERCPs and there was no more pain medicine. And so that's when I found the hotline, thank God. It used to be on yahoo.com it's now on Facebook, and I found out the... I went to every major medical center in this country, every single one, Mass General, Johns Hopkins, Mayo, I won't go into the rest. But then I heard about the one place in the country that did do this TPAIT. And so in 2008 I had it and it was my only choice, even though every institution poo-pooed it, and now every one of the institutions, including the doctors in this room today, everyone poo-pooed it. They said, you shouldn't do it. It's experimental and you'll become a type one diabetic, which I am. Who cares? I am here now 12 years later. I was told that I and one other person, I was told about this, are the oldest living survivors of the TPAIT, and I am probably one of the oldest living survivors of pancreatitis, period, being that I'm 72 and was born with it. So all I can say is that I do, if your pain gets really horrible, the TPAIT does...

PART 3 OF 8 ENDS [01:39:04]

Carolyn Bloom ([01:39:03](#)):

Really horrible. The TPAIT does stop the pain. I have learned the Whipple doesn't stop the pain and some of the Whipple candidates are not candidates for the TPAIT but some are. And so all I can say is thank you to university of Minnesota, Dr. David Sutherland who created this and Dr. Bellan who was part of my team when I had this. And I've tried for years to be a spokesperson for this because I don't think anyone as old as I has gone through what I've gone to, but I have not been able to break through. But I am happy to talk to anyone because I really unfortunately know a lot.

James Valentine, JD, MHS ([01:39:47](#)):

Yeah. So I have just a follow up question for you. So you talked about, I think it was age 47 where you had the stent in your pancreatitis became chronic. Could you kind of contrast for us a little bit, what was the driving symptoms and frequency of those symptoms before that time versus after?

Carolyn Bloom ([01:40:11](#)):

The pain when you're acute is many people said you get a horrible attack, you're in the hospital for two weeks. You don't eat anything but you're lucky. An ice cube is a filling [inaudible 01:40:25] and then you live in a very bland fat-free diet. But once I became chronic at 47 after that, I am again stenting by the way, because of mine. And I've been told that... Well of course I had my stent in the olden days. Now

that they have made the stenting more, probably better. But I'm anti stenting because I try to stand one other time and the same thing happened.

Carolyn Bloom ([01:40:54](#)):

But once you're chronic and become as chronic as I did, it's excruciating. Even when I was in the hospital eight months a year, I'd go home and I couldn't eat. I couldn't get out of bed. So then I'd end up back in the hospital eight months a year for 13 years, is a long time in the hospital. And I hope, I am so happy now that I hear that they are doing this surgery on people as young as five and if only I had been alive in the period, because I lived most of my life in excruciating pain. Anyone have a question or that's it? Okay.

James Valentine, JD, MHS ([01:41:41](#)):

Thank you so much. And you can just... yeah there. So who else would like to share about their top symptom or symptoms?

Holly Watson ([01:41:50](#)):

Hi, my name is Holly Watson.

James Valentine, JD, MHS ([01:41:52](#)):

Hi.

Holly Watson ([01:41:52](#)):

I'm 34 and I have hereditary chronic pancreatitis. I was diagnosed when I was 21 I think, I had my first attack that I remember that being what this was at about 19. And I was told when I was 21 at James Madison university in Harrisonburg, Virginia. They were like, "Wow." And I was like, "I know what it is. It's pancreatitis." And he's like, "How do you know that?" And I was like, "My whole family has this since they were three years old. My cousins, my aunts, my uncles, my sister, my mother, just I knew." And it to me at that moment was a death sentence because nobody knew what to do. They were, "We can't help you." And I was devastated. I mean, what do I do with that information? I'm 21. They tell you don't drink alcohol, don't eat large meals, don't get stressed out. I'm like, you just named my life in a nutshell. I don't have anyone to relate to. I have no one to talk to.

Holly Watson ([01:42:47](#)):

The pain was ongoing for so long and it started in my back. I thought I had kidney problems, and I kept going for months and months trying to get him to no fix my kidneys and there was nothing there. And it came to a head and I drove myself to the hospital too. And now I'm 21 weeks pregnant with my third son and all I can think of is my future or lack thereof. It's to me still the only option I have is the TPAIT potentially, I mean if you're a candidate, which I would hope I am, but I haven't gone through that process and that just sounds overwhelming to me. So anybody who has done that as a warrior, in my opinion, good for you. It is terrifying, but it is lifesaving. I'm not there yet. I thank God, every second of every day, I'm not in pain, but like some of them have said a sip of water, will put you into the hospital.

Holly Watson ([01:43:37](#)):

How terrible is that? What am I supposed to do there? I went 36 weeks pregnant with my last pregnancy and the ER admitting doctor was like, "Oh, you have pancreatitis and you're pregnant. I don't know what

to do with you. I won't touch you." And literally walked out of the room. Great, that hopelessness is one of my biggest symptoms. Pain, but everyone's pain is different. I bring it up to GI doctors, when I tell them dehydration is a big factor. If I get dehydrated, even the slightest bit it flares immediately and he was like, "Well that's interesting." I'm like, "You've never heard that before. That's so scary." I started going to Hopkins, I started seeing a specialist. My hope for that is somebody, I won't have to go to the ER where doctors don't understand it and I will have someone who has my back.

Holly Watson ([01:44:25](#)):

But that's a complicated relationship in and of itself. The pain is so scary to miss out on your kids' lives. They have three, four children up there and I'm on my third and now, 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. If I'm in pain in a hospital or in bed, I'm missing it. Then what's the point? So my future, I need to have hope for the future. Treating the symptoms is not enough. The symptoms have long gone. My chance for pancreatic cancer is so sky high. It's more of a chance of when will it happen not if, unless I get this radical surgery. It's radical.

Holly Watson ([01:45:11](#)):

I mean, you tell some doctors that you don't have a pancreas, they [inaudible 01:45:15] "You can't live without a pancreas." Well, that's scary too. Yes you can, I've seen it. But I can't work with you if that's what you think. Or type three diabetes is what they call it. Well that doesn't exist. Well then I don't know what to call it, but if I don't have a pancreas to counteract the blood sugar highs and the pendulum swing of the lows, what do you want to call it? Name it something else, but that's scary, especially in the middle of the night. Who's... I mean if you're sleeping, all of these things are so scary to me and it has been in my genes. Is it in my kid's DNA? I need hope for the future for them.

Holly Watson ([01:45:47](#)):

My history is set. I'm going to get this TPAIT. I just don't know when someone can talk me into it or my pain is on a daily basis and it is worth it. You want to cut it out yourself at that point. So my hope is to be here and to do things like this that we can start to get a dialogue going of the future hope for the generations, for the kids, for the next panel, for my kids. Not necessarily for me, I don't care so much about myself as much as I care about the future. So thank you.

James Valentine, JD, MHS ([01:46:16](#)):

Yeah. Thank you. I do have a question for you. So I think you're so articulate about your worries for the future. Just to give us a little bit of grounding in your current experience. The one thing that you was note worthy was you kind of had the onset of symptoms to the degree you knew it was the pancreatitis at age 19, you talked about the thing that maybe is the most common experience is flaring due to dehydration. How often does that occur and how debilitating is that when you do experience it now?

Holly Watson ([01:46:51](#)):

I haven't had, luckily a flare since I was 36 weeks pregnant about almost two years ago. And I'm one who luckily I kind of eat whatever I want. I take that, I'm going to eat all of the things that I can now before search hurting because a sip of water could do it or it could be a cheeseburger, I don't know. Or it could be the dehydration. But the symptoms... And I only knew this was what it was because my family members had, had it. I didn't know really the symptoms since mine started in my back and nobody else

had, had that. Can you repeat your question one more time, to make sure I'm going to answer it all the way?

James Valentine, JD, MHS ([01:47:28](#)):

Just how often since age 19 have you had those types of flares?

Holly Watson ([01:47:33](#)):

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.

James Valentine, JD, MHS ([01:47:48](#)):

Sure.

Holly Watson ([01:47:48](#)):

Is it really worth it? So I've probably, in all of those years probably had over 45 flares, but gone to the hospital about 20 times. You self-medicate Ibuprofen if you can, if you have something else. But 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 too. So part of me just wants to stay at home with all of that if I can, but it's more the dehydration, I need an IV. That's why I go.

James Valentine, JD, MHS ([01:48:22](#)):

Yeah. Thank you so much for sharing.

Holly Watson ([01:48:23](#)):

Thank you.

James Valentine, JD, MHS ([01:48:28](#)):

Others? Yeah.

Linda Martin ([01:48:29](#)):

I'll step over here in just a second.

James Valentine, JD, MHS ([01:48:34](#)):

Sure.

Linda Martin ([01:48:36](#)):

My name is Linda Martin and I'm the mother of an adult daughter with a chronic pancreatitis and I'm going to speak on behalf of her. She had hoped to be here, but was not feeling well and decided not to get on a plane and make the trip, so I'll tell her story best I can. It started really when she was diagnosed with chronic pancreatitis in 2015. She had a big job with an international company, had a whole team of software developers and engineers working for her around the world, was doing great in her career. Clients loved her and she loved her job. Was she sick more often than most people? Yes. In retrospect,

she had had a lot of stomach issues. Amy had been six since a little girl. We just all in the family said, "Oh, that's just Amy being Amy."

Linda Martin ([01:49:32](#)):

Every time there was a big event, every time there was a big school event, whether it was Christmas, some other big family event or holiday. Excitement, stress, change of routine, all brought on what we called Amy's sensitive stomach. And a little do we know till 2015 that there was actually a name for this sensitive stomach that was accompanied by pain. I took her to the doctor over and over again and it was constipation, acid, stomach sensitive stomach. She just didn't want to go to school, which was my favorite excuse and I would do the, "Oh, you don't have a fever, go to school." And I really underestimated the amount of pain and suffering that she was in as a child.

Linda Martin ([01:50:20](#)):

So fast forward to 2015 and the symptoms got remarkably worse. Very quickly. She was sicker and sicker all the time. Started missing more and more work. She could cover up for it for a while because she worked remotely from her house and was on online with her team, but she was offered a big promotion to go to Toronto and head up, be a vice president of the company. She had to turn it down and eventually they said, "You know what, you seem to be missing a lot of work. We're going to move on without you." And from that day on, she has not been able to be gainfully employed. Continued to get sicker and sicker over the next few months, lost about 70 pounds. My older daughter went with her to a doctor's appointment and came back and called me and said, "Mom, you have to do something about Amy. She is dying before our very eyes." And from that point I dropped everything I was doing and we went from hospital to hospital doctor to doctor searching for somebody with answers.

Linda Martin ([01:51:22](#)):

Eventually someone said it's pancreatitis. Never had heard of pancreatitis, like a lot of people didn't exactly know what the pancreas did, but we soon learned it was pancreatitis and one of the first visits after hearing the word pancreatitis, she was asked, "Have you ever had any alcohol?" She said, "Well, I'm 40 years old, so yes, I have had some alcohol. I've never been a big drinker. I don't drink a lot. In fact, for the last couple of years I haven't had a drink because when I drink it makes me really sick." And so nonetheless, her medical chart to this day does say alcoholic pancreatitis and so continued to search and search and search. In the meantime she was getting sicker and sicker and on top of everything else and in part because of the extreme and constant inflammation, she had numerous cancer biomarkers that were elevated.

Linda Martin ([01:52:23](#)):

So there was also a search and a lot of fear over does she have liver cancer? Does she have colon cancer? Does she have pancreatic cancer? She had tested positive for chronic amyloid leukemia, so had to go through bone marrow biopsy to rule out that she didn't actually have leukemia. Eventually and her GI at a very well known institution said, "Don't worry, you're eating a low fat diet. You're doing everything you can do. There's nothing else we can do for you. Don't worry, your pancreas is actually healing itself. You just don't realize it." And so by that point, she had done enough research. We had done enough research to learn that chronic pancreatitis does not heal itself. It is impossible to heal itself. But little by little she was saying, "Mom, I'm not really vomiting very much anymore. I'm not vomiting food because I really can't eat food. I'm only vomiting bile." She goes, "I'm just vomiting stomach vile, that's no big deal." Like, "Amy, that is not normal."

Linda Martin ([01:53:28](#)):

So continued our search and we were very frustrated about finding anyone who knew anything about this disease, let alone what to do about it. Quickly learn there was very little, no medications, no therapies. And about a year later we learned about TPAIT and at that point, even though numerous doctors, including the one that says she was somehow quietly healing herself, said it would be malpractice for anyone to do TPAIT she had only had three stents by that point and had not had chronic pancreatitis long enough to be qualified for TPAIT. She said, thank you very much. See you later. Referred herself to the university of Minnesota where she was evaluated and within six weeks had a TPAIT surgery, not before one more scare with possible pancreatic cancer with a mass in her pancreas that thankfully turned out to be benign and she went through with the TPAIT.

Linda Martin ([01:54:32](#)):

However, not knowing that she had chronic pancreatitis for all those years and what we thought was just these Amy being Amy attacks, were actually acute pancreatitis attacks. Her pancreas was pretty well destroyed by the time she got to TPAIT and there weren't many healthy eyelids to transplant into the liver, although they did the very best they could. So Amy is a fully insulin dependent diabetic, similar to the woman who spoke a few minutes ago. She would say if she was here, that's no big deal. Being a diabetic is a fully manageable disease and a chronic pancreatitis is not.

James Valentine, JD, MHS ([01:55:13](#)):

Sure.

Linda Martin ([01:55:14](#)):

So that's my daughter's story. Thank you for listening.

James Valentine, JD, MHS ([01:55:17](#)):

Thank you for sharing.

James Valentine, JD, MHS ([01:55:24](#)):

So Dr. Wassef had talked about first line treatment being enzymes and you know, we've heard about some of the more invasive kind of later surgical and other procedures. I wanted to get your experience with that enzyme treatment and you could describe how that might've helped or your views on the role that that played in your pancreatitis progression. So any views or experiences with enzymes? Yes right here.

Speaker 1 ([01:56:05](#)):

Sorry, getting there fast.

Michelle Canoy ([01:56:10](#)):

My name's Michelle Canoy, I'm from Indiana. I had my first incident probably in first grade. And this is my daughter Hope.

James Valentine, JD, MHS ([01:56:19](#)):

Hi Hope.

Michelle Canoy ([01:56:20](#)):

In first grade we didn't know what it was. Wasn't diagnosed actually until I was 30 after I'd had her with Creon, this was a lipase that I take. For three years, I was told we're not even going to try to prescribe it because it's too expensive, not even given a chance. When I was prescribed, the insurance I had, it was \$0. So physicians I think have a worry, a concern, and they just kind of write it off automatically due to the expense. However, if I'd had that opportunity, my chronic pancreatitis might not have gone to the progression that it has. They do help me eat, but I have to balance it out with a dehydration effect, so it's either be severely dehydrated and be able to eat or not be able to eat and then be very weak and malnourished.

James Valentine, JD, MHS ([01:57:12](#)):

Okay. Thank you for sharing. Eric, did you have something to add on that?

Eric Golden ([01:57:21](#)):

Yes. I'm not enzyme insufficient so I don't need enzymes for that purpose, but I have taken Creon for a number of years and I just wanted to comment that I have not seen any discernible effect on the level of pain. I know there was a comment in the talk earlier that it can, but it certainly does not help everybody in that respect.

James Valentine, JD, MHS ([01:57:43](#)):

Sure. So, oh, yeah Hillary.

Hillary Mendelsohn ([01:57:47](#)):

I started taking the enzymes after the Whipple because I did not have pancreatitis prior to the pancreatic cancer prior to the Whipple. I didn't know that it was supposed to help with pancreatitis. Once I did start getting the acute pancreatitis, it didn't change anything.

James Valentine, JD, MHS ([01:58:08](#)):

Okay, sure. Thank you. So we'll take another comment from Holly, but I'll also before you say that broaden it to other treatment approaches that maybe we haven't heard a lot about so far. Again, I know a number of come up repeatedly and some of the comments so far, but we'll go to Holly and then we'll take this comment over here.

Holly Watson ([01:58:31](#)):

Sure. I don't personally take the enzymes. My mom just recently started and she was very against this, will not have the TPAIT. She was a smoker for all these years, has the gene and all of that, but she then was told she wasn't really a candidate because she has COPD and all lot of other issues she has going on, but she was dead set against taking the enzymes. Dead set, "It's not going to do anything for me. It's the reason that I'm that I'm doing it. She started taking it and has seen major progressions really. She has more energy. She can digest food, she can eat. It doesn't run right through her. She's seen a gain of... she's gained five pounds in a week almost. I mean it's been really been life changing for her. I personally don't take them. I'm not there yet, and I don't know if you can take them pregnant. That's probably something I should look into. But yeah, it's really helped her a lot.

James Valentine, JD, MHS ([01:59:16](#)):

Sure. Thank you Holly. Over here.

Martin Cole ([01:59:25](#)):

Martin Cole. I'm a caregiver for an 18 year old. I think it's, Eric talked about good work with the cannabis, and my son has a more of a problem more recently with stones and he actually went through pain for nine months, Creon and everything else under the sun that they could think of to work. And for the most part, all it did was make him nauseous. So we went along and we got him a med mal card, med whatever card. And the cannabis has worked very well. Of course, that's brought along other potential issues as not a lot of parents in here probably say you want to go get some pot with your son? But that's the situation we're in. Thanks.

James Valentine, JD, MHS ([02:00:10](#)):

Thank you. So while we're exploring now, treatment approaches, I'm going to ask you guys to pull out your phones again. We're going to do some questions to get an idea of the experience that we have in the room with different treatments. all right. So I know this is a long list, but this is a, because we know you guys have to juggle a lot of different treatment approaches. So here, please select all of the different things that you're currently doing to help manage the symptoms of pancreatitis. Note that the next question we'll be asking you about what you've done in the past, but here we're asking you about what you are currently doing.

Speaker 2 ([02:00:57](#)):

[inaudible 00:22: 03].

James Valentine, JD, MHS ([02:01:05](#)):

These are-

Speaker 2 ([02:01:06](#)):

Percentages of the total responses.

James Valentine, JD, MHS ([02:01:10](#)):

Thank you for the clarifying question again. So anytime we have opportunity to have you provide more than one response, we're seeing the percentage of responses, not the percentage of individuals that have that experience. So not going to read the whole list here, but we have quite a few options of different things that you have done to help manage your symptoms of pancreatitis. Many that we've started to hear about, but some others that we haven't heard about quite yet.

James Valentine, JD, MHS ([02:01:57](#)):

So it looks like the leading current approaches to treatment include non-opioid pain meds as well as diet and dietary changes. I think we've heard a little bit about those so far. We just talked about digestive enzymes, haven't heard much about nausea medication and whether that is at all helpful in managing day to day nausea of symptoms. After that we hear about opioids and narcotics and other common treatment approach that we've heard about, but there's quite a bit of experience in other areas, different lifestyle changes. We'd be very interested if you have one of those to share for you to think about raising your hand, as well as hydration and heating or cooling.

James Valentine, JD, MHS ([02:02:45](#)):

I think maybe those are some good ones for us to talk about here in just a minute, but again, a lot of experience with almost every single one here as well as some others. So we wanted to put this up to get you thinking about sharing some of the maybe less common treatment approaches or maybe ones that just aren't as top of mind. Do we have a comment on hydration or heating and cooling? Let's just go down the line real quick. We'll start with Jane.

Jane M. Holt ([02:03:09](#)):

Oh real well. So I wanted to mention one thing that I did many years ago, which was part of a research project and it was a mind body program that was run by Dr. Benson up at BI Deaconess hospital and it was a six week program and we learned all sorts of things. We learned meditation, which is very helpful journaling. And I remember very clearly going through the whole program, we had to respond after each meeting, whether it helped or not, and saying, no, it didn't help me. I'm just saying as I always am. But the reality is it helped me tremendously because I realized right soon afterwards, which was after the time I was reporting that it really made a difference when I had a real flair, if I could, bring myself back to that really peaceful place. Or if I'm having an MRI or if I'm having a procedure, it helps me tremendously and I see other people doing journaling, which is very effective. It doesn't cure the problem, but it helps me deal with it better. And I thought it was very helpful.

Speaker 3 ([02:04:09](#)):

I just wanted to talk to a couple of different therapies around the nausea medications. I take composition three times a day and then I take a nausea medication that's for cancer patients called amend or app repentant. 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 longterm effects of that. I don't know how great that is, but it works very well for me. And so if you struggle with nausea and the regular kind of Zofran, Finnegan's don't work for you, I would recommend talking about that. Around heating and cooling-

James Valentine, JD, MHS ([02:04:43](#)):

And just how well is that regimen of nausea meds working?

Speaker 3 ([02:04:48](#)):

It works great. So I live on that, that regimen of nausea medication, and we've tried to cut back the composition to twice a day, half to three times a day. We tried to go after the TPAIT, we tried to take me off of the amend and that did not work. So.

James Valentine, JD, MHS ([02:05:04](#)):

And when you say great, are you still experiencing nausea at all?

Speaker 3 ([02:05:08](#)):

No, I don't experience any nausea, no. And very rarely do I vomit anymore. Now without those medications, I would be back on a feeding tube.

James Valentine, JD, MHS ([02:05:17](#)):

Sure.

Speaker 3 ([02:05:17](#)):

So with those medications I'm able to eat on my own without them I live on a feeding tube.

James Valentine, JD, MHS ([02:05:22](#)):

Got you.

Speaker 3 ([02:05:23](#)):

So they enable me to function and eat.

James Valentine, JD, MHS ([02:05:27](#)):

Sure.

Speaker 3 ([02:05:29](#)):

For heating and cooling, I travel with my heating pad. I mean it is my life blood because otherwise I'm just too cold to function and around anxiety, I do a lot of meditation also. Even that picture of like being in the MRI machine, I do a lot of meditation just to kind of get through things and get through pain. And I have a weighted blanket so it's a gravity blanket that really helps me stay calm when I'm having a flare or when I'm having pain or anything like that. I've noticed the weighted blanket is actually something that's come in real handy.

James Valentine, JD, MHS ([02:06:05](#)):

Wow. Thank you Adriana. Hillary, did you have something to-

Hillary Mendelsohn ([02:06:10](#)):

The bathtub is incredible for me. When I start to get a flare of pancreatitis, if I, there's things that I start have, I've started to do ritually when I start to feel that, and I have a product called Chelidonium Magis. It's a homeopathic medication used for indigestion, but somehow if I start to feel the pressure right in my sternum, I take that first. There's over the counter nausea medicine called Nausea. You can get at any drug store rather than taking the prescription. I take that first. I take two of those with the Chelidonium Magis. I get in the bathtub. Sometimes I can stave off a full episode. If I do that, I can cut it.

Hillary Mendelsohn ([02:07:04](#)):

I want to say first for me the most important thing is how I choose to deal with all this mentally. If you decide that you're going to get through this, that you need to have a positive attitude to help heal yourself, to get through every day, to be with those around you and not have this become your life. You have to have a framework in your mind of how to deal with it. And that's been the most significant part of all of this for me, including the cancer. So.

James Valentine, JD, MHS ([02:07:37](#)):

Thank you. Eric, one more point and then we're going to go to... We'll take actually a comment here, then we'll go to the next polling question.

Eric Golden ([02:07:44](#)):

I just want to make one more quick comment about cannabis. I live in California where it's fully legal, not federally, but on a state level and doctors and patients both accepted as a completely legitimate option. But I encounter people all the time around the country who kind of just get a little freaked out by it. And I want to say for me, it does not reduce the pain, but it can easily take me from being in bed feeling like absolute trash to be an up and walking around. And it just, as Hillary was saying, it kind of takes away the emotional response to your physical situation from the physical situation.

Eric Golden ([02:08:18](#)):

So you may actually say to yourself, wow, I'm really in a just a notable amount of pain, but it's not taking you down on a daily basis. So I'm happy to talk to anybody who wants to, but I think it's something, especially compared to opioids, considering it's infinitely safer and has fewer side effects, I think it's something that deserves very serious consideration.

Hillary Mendelsohn ([02:08:41](#)):

And in addition to that, 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.

James Valentine, JD, MHS ([02:08:53](#)):

Thank you, Hillary.

John Mahalchick ([02:08:56](#)):

My name's John Mahalchick. And just briefly from my history I had my first episode of acute pancreatitis in 2006 I was a freshman in college, a week before finals when I had my first debt attack in 2009 it switched over to chronic. And then in 2013 I had the total pancreatectomy with auto islet. And then just recently in the first week of December echoing the adhesions, I had a revision surgery to take care of adhesions and some other things. And I saw some improvement with that. But I was excited to hear about the focus on mental health from the folks in the panel. And that's kind of just what I wanted to echo as well throughout all of that.

John Mahalchick ([02:09:37](#)):

I definitely, looking back at underlying depression and didn't realize it and that's something I was able to start working with a therapist about two years ago and that has made... Like I said, it doesn't help with the pain. It doesn't help with the nausea and those kinds of things. But it definitely helps with management and I'm just excited to hear more focused on the mental health aspects, because I feel like there's a stigma associated with that sometimes and patients are reluctant to talk about it. But I definitely think that that needs to be a priority for folks with any chronic illness. But definitely with this as well.

James Valentine, JD, MHS ([02:10:11](#)):

Sure. And so for you, that type of talk therapy has been able to help a lot with that.

John Mahalchick ([02:10:18](#)):

Yeah that and has low dose anti-depressant as well, but it definitely, looking back my therapist her favorite line is, someone going through all this stuff. If you don't have some underlying depression, there's probably something else wrong with you. So that's her line, she gives.

James Valentine, JD, MHS ([02:10:34](#)):

Thank you so much for sharing.

John Mahalchick ([02:10:35](#)):

Thank you.

James Valentine, JD, MHS ([02:10:35](#)):

All right, if we can go to the next polling question. So here we want to understand a little bit about how your treatment regimen has changed over time. So you just told us about what you currently use, but we'd like to get a sense of what you've used in the past but no longer use. And again, please select anything that you've used before but no longer. So all results are trickling in. It looks like the top medication or treatment that you've used in the past, but no longer are non-opioid pain medicines. Following that, it looks like endoscopic procedures and digestive enzymes followed by opioids or narco...

PART 4 OF 8 ENDS [02:12:04]

James Valentine, JD, MHS ([02:12:03](#)):

... list of enzymes, followed by opioids or narcotics, surgeries and nausea medication, although pretty much every other... Well, every other category has been used in the past, but not currently.

James Valentine, JD, MHS ([02:12:16](#)):

Like to hear from anyone that has had an experience where you've stopped using one of these medications or treatments because it just wasn't working for you, and that's why you stopped using that.

James Valentine, JD, MHS ([02:12:31](#)):

It can be anything on this list. It may not be, or maybe it was because you weren't sure it was working for you, even if it wasn't certain. Yes, come right here.

Speaker 4 ([02:12:43](#)):

Who wants a microphone?

James Valentine, JD, MHS ([02:12:44](#)):

Can we get a microphone, just for the webcast?

Speaker 5 ([02:12:48](#)):

Sure. So my son was on the gabapentin for... seemed like somewhere between four and seven months, and all it was getting him was nauseous and it wasn't relieving the pain. So that's how we came upon the medical marijuana suggestion, and we switched that out, and it obviously worked much better.

James Valentine, JD, MHS ([02:13:06](#)):

So you're saying that, in that case, it was a side effect? It was nausea from the medicine, from the gabapentin?

Speaker 5 ([02:13:15](#)):

It wasn't working to relieve the pain either, so there was no upside to it for him.

James Valentine, JD, MHS ([02:13:20](#)):

Sure, thank you. Any other experiences where... Yes, I see a hand in the back.

Tara ([02:13:31](#)):

Hi, I'm Tara. I have acute pancreatitis and I used to live in Portland, Oregon. So I was smoking a lot of cannabis, and then my doctor told me that smoking might affect the pancreas as well.

Tara ([02:13:44](#)):

So I'm just kind of wondering how you guys use treatment if it's in the form of edible or smoking, because I was nervous and I removed it from my diet, kind of.

James Valentine, JD, MHS ([02:13:55](#)):

Sure. Are you now taking anything? What are you taking for pain management now?

Tara ([02:14:01](#)):

I'm a yoga teacher. I was doing yoga before I had pancreatitis, and I kind of fully grasped on to yoga and more natural ways of healing after I got my first spout of acute pancreatitis.

Tara ([02:14:19](#)):

It's happened twice now, and it was been about four years since my first hospitalization. So it's kind of a treatment process, but it's mostly digestive enzymes, meditation, diet restrictions. I haven't had a drink in four years.

James Valentine, JD, MHS ([02:14:36](#)):

And how frequent are your acute attacks?

Tara ([02:14:39](#)):

I've only been hospitalized twice, but I do have pain outside of going to the hospital. The times I was hospitalized was full-blown. I was in there for a week or two on just fluids. Severe case, yeah.

James Valentine, JD, MHS ([02:14:56](#)):

Sure. Thank you so much for... Oh, did you have something else to-

Tara ([02:14:59](#)):

Yeah, but I don't know if anyone had an answer to the-

James Valentine, JD, MHS ([02:15:03](#)):

Sure, just-

Tara ([02:15:03](#)):

... edible, slash, smoking question.

James Valentine, JD, MHS ([02:15:05](#)):

... really quick if Eric and Hillary can say what forms they're on.

Hillary Mendelsohn ([02:15:07](#)):

I was using the oils and a vape pen. I've since slowed down on that because there's no regulation, and I don't want to cause secondary problems until we know more about that.

Hillary Mendelsohn ([02:15:22](#)):

I use a Pax. Technologically, it's more advanced than most of the devices and uses flower. And edibles is a problem for me because of my digestive system.

James Valentine, JD, MHS ([02:15:44](#)):

Eric?

Eric Golden ([02:15:45](#)):

I thought that vapes was the healthy way to do it, but turns out it's not true.

Eric Golden ([02:15:49](#)):

There are tinctures, and the only thing you have to be careful of is, some of them are alcohol-based, which I think folks like us want to avoid, even any risk of.

Eric Golden ([02:15:59](#)):

But there are ones that are suspended in oil with medium-chain triglycerides, which are supposed to not be as bad for you.

James Valentine, JD, MHS ([02:16:09](#)):

[inaudible 00:04:06].

Tara ([02:16:09](#)):

Thank you.

James Valentine, JD, MHS ([02:16:09](#)):

Welcome. Do you have a comment?

Male ([02:16:09](#)):

[inaudible 02:16:10].

Dana K. Andersen, MD ([02:16:18](#)):

Just to provide a point of information for everybody, because I know this is a frequently discussed and poorly understood topic. 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.

Dana K. Andersen, MD ([02:16:44](#)):

NIDDK, our institute, is also interested in this. We happen to be sponsoring a workshop this July in Pittsburgh, which is entitled, Pancreatic Pain.

Dana K. Andersen, MD ([02:16:55](#)):

One of our faculty speakers in that workshop is a neurophysiologist from the University of California at Irvine who, in fact, has studied the mechanisms of cannabis and how they affect pain responses and pain transmission.

Dana K. Andersen, MD ([02:17:12](#)):

The difficulty, as you realize, is just, as Eric mentioned, the use of cannabis is legal in some states and not legal in other states. And that has complicated the scientist's ability to gather data about the use of cannabis and the effectiveness of cannabis.

Dana K. Andersen, MD ([02:17:28](#)):

And we hope that by virtue of holding workshops, like the one that's planned in July and other activities, that we can actually expand the research into this drug.

Dana K. Andersen, MD ([02:17:39](#)):

Currently, only the National Institute on Drug Abuse, NIDA, is able to sponsor clinical trials or studies that involve cannabis use.

Dana K. Andersen, MD ([02:17:50](#)):

But others of us, particularly those of us in the digestive disease division of NIDDK, are obviously very interested in this topic because we realize this may be very important for patients that we're concerned about.

Dana K. Andersen, MD ([02:18:02](#)):

So we're pushing the ball down the field, so to speak, from our end, and we're trying to learn more about this through programs, such as the workshop that we're going to put on this summer.

James Valentine, JD, MHS ([02:18:13](#)):

Great. Thank you, Dr. Andersen. So I want to put it out there. We have just one more minute for our first session here today. Of course, we'll have time to pick up the discussion. And really, the pediatric adult experience, I think is, in some ways, a spectrum, so we'll be able to continue to have this discussion when we come back from break.

James Valentine, JD, MHS ([02:18:35](#)):

But any other final experiences with treatments that you've had, whether you've stopped them or are using them currently? Yes, our final comment.

Melinda Mahalik-Fry ([02:18:48](#)):

My name is [Melinda Mahalik-Fry 00:02:18:48], and I've had chronic pancreatitis for at least five years with acute flareups. My story is like everybody else's here.

Melinda Mahalik-Fry ([02:18:57](#)):

So some of the things that my doctors have put me on are amitriptyline, pantoprazole, what else is it, Zofran, 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 mean, you're on the floor, you can't get up.

Melinda Mahalik-Fry ([02:19:22](#)):

So the other thing that I'm kind of curious of is, there's no medication that seems to keep our pancreas intact. You have calcifications and atrophy that occurs over time, and so I don't know if there's ever a possibility of anything like that being developed, but...

James Valentine, JD, MHS ([02:19:39](#)):

But that would be a priority for you?

Melinda Mahalik-Fry ([02:19:40](#)):

It would be. Thank you.

James Valentine, JD, MHS ([02:19:41](#)):

That's a great comment, thank you. All right. Well, with that, we're going to take a 15 minute break. We're going to come back at 10:50 and dive into our pediatric pancreatitis session. Thank you all.

Dana K. Andersen, MD ([02:35:34](#)):

Welcome back to our next session of this patient-focused drug development meeting. It's my honor to introduce our next speaker, Dr. Melena Bellin from the University of Minnesota.

Dana K. Andersen, MD ([02:35:47](#)):

Melena is neither a gastroenterologist nor a surgeon, but she's become absolutely expert in the treatment of pancreatic disease, and particularly, pancreatic diseases in children.

Dana K. Andersen, MD ([02:35:59](#)):

She's a pediatric endocrinologist, who also happens to have a joint appointment in the Department of Surgery because she leads the research program in total pancreatectomy and islet autotransplantation.

Dana K. Andersen, MD ([02:36:11](#)):

You've already heard about this from many of the patients who've spoken already today, but Melena's going to give you her perspective, as she sees many, many patients, only a few of which are candidates for this surgery. Dr Bellin.

Melena D. Bellin, MD ([02:36:32](#)):

Thank you. Well, it's really an honor to be here today. I have had about 14 years of opportunity to work with patients who have recurrent acute or chronic pancreatitis, and I think they're a very inspiring group, so I'm really honored to be able to present with them today.

Melena D. Bellin, MD ([02:36:48](#)):

So I'm going to focus on pancreatitis, as it pertains to children. I think what we heard, statistically, earlier this morning, is about 40% of the attendees at this conference had onset of symptoms in childhood. So obviously, this is an important pediatric disease, as well as an adult disease.

Melena D. Bellin, MD ([02:37:03](#)):

So when we're talking about pancreatitis in children, it's really a long spectrum of what we see in adult disease. But there are some unique features in children.

Melena D. Bellin, MD ([02:37:12](#)):

So first of all, what causes pancreatitis in children? Well, most of the data I'm going to talk to you about today comes from, what we call, Inspire. It's a study group for pediatric pancreatitis that was started by Dr. [Alia Uche 00:02:37:22] and Dr. Mark Lowe about a decade ago.

Melena D. Bellin, MD ([02:37:26](#)):

And so we know from now studying kids across the U.S. and internationally who have pancreatitis, that about 50 to 75% of them, depending on whether you're talking about recurrent acute or chronic pancreatitis, will actually have a genetic risk factor. I don't have all the genetic risk factors listed on this slide.

Melena D. Bellin, MD ([02:37:43](#)):

But the main ones have to do with either a problem in the trypsinogen trypsin pathway, in which trypsin becomes abnormally activated within the pancreas and causes inflammation, or a ductal problem, like a problem with the cystic fibrosis gene or the CFTR gene, that prevents... or abnormally mediates bicarb secretion from the pancreatic duct, so you get some sludging obstruction.

Melena D. Bellin, MD ([02:38:08](#)):

Now, I should say that genetic risk factors aren't mutually exclusive to other risk factors, so we actually see a number of kids who have more than one risk factor for disease.

Melena D. Bellin, MD ([02:38:17](#)):

But about a third of the kids we see in Inspire have some sort of obstruction, usually a congenital malformation of the pancreatic duct, like pancreas divisum, either alone or in combination with genetic risk factors. And sometimes, in this population, we see toxic exposures like medications that precipitated acute pancreatitis, hypertriglyceridemia, not typically things like alcohol that you might think of with some adult patients with pancreatitis.

Melena D. Bellin, MD ([02:38:44](#)):

But really, primarily, you're talking about genetic disease and congenital anatomic disease in this population. For a few, we never find a cause, and we call them idiopathic chronic pancreatitis.

Melena D. Bellin, MD ([02:38:57](#)):

So these patients, these children who have chronic pancreatitis or recurrent acute pancreatitis, have both acute symptoms and complications of disease, and long-term risks from the disease.

Melena D. Bellin, MD ([02:39:08](#)):

And I think the feature that comes out most often when patients come to clinic is complaints of abdominal pain. This can be episodic, it can be constant, it can be both, some constant pain with episodic flares, and it is very severe pain. I think that was reflected very well in the adult panel this morning.

Melena D. Bellin, MD ([02:39:26](#)):

Oftentimes, this pain may need opioid medications for treatment when it's very severe. Unfortunately, pain may go undertreated because, particularly in today's culture, with worry about opioid abuse and now you're talking about children, there can be some reluctance of pediatric providers to prescribe opioid pain medications, even when the pain is severe.

Melena D. Bellin, MD ([02:39:48](#)):

And then this is all in the studying of also nausea, vomiting, that I think you heard a little bit about earlier this morning.

Melena D. Bellin, MD ([02:39:55](#)):

The symptoms of recurrent pain certainly interfere with normal life. I think you'll hear that better from the panel than from me.

Melena D. Bellin, MD ([02:40:03](#)):

But statistically, when we look at patients at Inspire, they're frequently hospitalized. If we look at patients who have recurrent acute or chronic pancreatitis, they have an average of about two ED visits per year and one hospitalization per year.

Melena D. Bellin, MD ([02:40:15](#)):

But some patients are really, severely affected and have dozens of hospitalizations. As you might imagine, that can interfere with normal childhood and going to school.

Melena D. Bellin, MD ([02:40:25](#)):

So on average, children who have recurrent acute or chronic pancreatitis miss two or three days of school per month, but some patients are unable to even attend regular school. They miss so many days that the school says, "You have to do homebound school because you're not able to attend often enough."

Melena D. Bellin, MD ([02:40:42](#)):

I hear families say very often to me... I think this is hard data, objective data to collect, but they will say, "We can't plan a vacation. We're afraid of planning... for this child to go off to college because we just don't know what the future is going to hold, when they're going to have an attack of acute pancreatitis."

Melena D. Bellin, MD ([02:40:59](#)):

And I think we heard a lot about psychological impact of this kind of chronic disease state. Naturally, if you're having pain, you're being hospitalized, you're missing school. This can also be associated with depression, anxiety, because you don't know when this severe pain is going to come up.

Melena D. Bellin, MD ([02:41:15](#)):

That can lead to social isolation because you're not at school. And then, that just makes depression worse, so you have this whole psychological impact of the disease state.

Melena D. Bellin, MD ([02:41:24](#)):

Now, long-term, these patients, because they get progressive fibrosis through the pancreas with chronic pancreatitis, so in other words, scarring through the pancreas, are at risk for losing the functionality of the pancreas.

Melena D. Bellin, MD ([02:41:37](#)):

And if we look at kids during childhood in Inspire, about a third of them have digestive problems, with exocrine pancreatic insufficiency, and 6% have diabetes.

Melena D. Bellin, MD ([02:41:47](#)):

But of course, those risks increase lifelong. So those kids with chronic pancreatitis are invariably going to become adults with chronic pancreatitis, who are going to have more and more increased risk of diabetes and exocrine insufficiency as adults.

Melena D. Bellin, MD ([02:42:03](#)):

So what can we do right now to treat kids with chronic pancreatitis or recurrent acute pancreatitis? I think the reason that we're here is that our treatments... Although we can offer treatments, none of them are that great, and none of them stop or just cure the disease.

Melena D. Bellin, MD ([02:42:19](#)):

So we can offer a number of medical treatments, but they're really directed at symptom management more than anything else. So when these patients have episodes of pain, we can give them pain medications, non-opioid pain medications, opioid pain medications.

Melena D. Bellin, MD ([02:42:32](#)):

For the complications like dehydration, you can treat them with IV fluids. For chronic pain, we really encourage a comprehensive pain management program that can be geographically challenging to find.

Melena D. Bellin, MD ([02:42:45](#)):

But a good pain management program has ongoing care with both pharmacologic and non-pharmacologic aspects to pain management, health psychology, physical therapy, and then there's some treatments that might or might not decrease pancreatic stimulation, and reduce attacks.

Melena D. Bellin, MD ([02:43:04](#)):

We hear a little bit about diet restriction in adults and fat restriction. There's a lot of controversy about that, I would say, in children, and many providers would advocate not to restrict fat too heavily in children because they need that. They're growing, so they need their nutrients, including their essential fatty acids.

Melena D. Bellin, MD ([02:43:22](#)):

You can give feeds and kind of bypass the pancreas by doing enteral feeds or jejunal tube feeds, where the food is actually going past the point where the pancreas is, to try to decrease that theoretic pancreatic stimulation.

Melena D. Bellin, MD ([02:43:34](#)):

And pancreatic enzymes might be used for malabsorption, but they might also be used to try to calm down or suppress the pancreas. They're definitely effective for malabsorption. Whether or not they're effective to actually suppress the pancreas, I think is debatable.

Melena D. Bellin, MD ([02:43:48](#)):

And there are some trials with antioxidants in adults, just a calm pancreatic inflammation. There are mixed results and they haven't been tried in children.

Melena D. Bellin, MD ([02:43:57](#)):

So we have a lot of medical treatments we can offer to treat symptoms of disease, but not so clear that any of them actually prevent disease or reduce episodes of disease.

Melena D. Bellin, MD ([02:44:07](#)):

So for kids who really are having a lot of symptoms on medical treatment, we might consider stepping up to something that is a procedure or a surgery. And really, the main procedure, non-surgical procedure, that would be done in pediatrics is an ERCP, endoscopic retrograde cholangiopancreatography, as a treatment to try to remove any pancreatic duct stones or treat any strictures.

Melena D. Bellin, MD ([02:44:32](#)):

Unfortunately, if a patient has strictures all the way through the pancreas duct, this starts to become ineffective. And some patients have recurrent acute pancreatitis with no stones, no strictures, and an ERCP probably isn't going to be very effective in that circumstance. So while it may help some people, it doesn't necessarily halt the disease, and recurrence may still be a frequent complication.

Melena D. Bellin, MD ([02:44:54](#)):

So the other thing we can do is pancreas surgery. There are different ways you can do pancreas surgery. You can do a Whipple, which we heard about, you can do a procedure like a Puestow.

PART 5 OF 8 ENDS [02:45:04]

Melena D. Bellin, MD ([02:45:03](#)):

Heard about, you can do a procedure like a Puestow or a Frey that basically open up the pancreatic duct, but we don't really do a lot of those in children these days mainly because children usually have genetic forms of disease and we think there's a high rate of recurrence with those sort of what we might call lesser type of surgeries. Usually the surgical approach for these kids, if they get to the point of severe disease where they need surgery is to do that total pancreatectomy with islet auto transplant that you heard about. And that is a really extreme procedure. It can be very effective at treating pain, yes, but it involves a lot both in terms of the surgery and the longterm complications. The surgery itself involves removing the pancreas and because of the blood supply, removing the duodenum, a little piece of the

small intestine, putting the intestine back together and usually removing the spleen. You're talking about quite a significant and involved surgery process and you have exocrine insufficiency always after that procedure and usually some form of diabetes. What are the barriers that I see to treatment and children other than having few treatment options? The other thing that I see patients complain about in patients probably can speak to this much better than I can, but pediatric pancreatitis is not a common thing to show up, say in the community ER. If you're at a place where there aren't providers, so they're primarily adult providers, they haven't seen pancreatitis in children, even with a family history of disease, I've seen parents bring their kids in saying, "I think this is pancreatitis." And are told, "Well, children don't get pancreatitis. We don't need to test for that because children don't get pancreatitis." It can lead to some delays in diagnosis. And especially if you have no family history and no one's thinking of pancreatitis.

Melena D. Bellin, MD ([02:46:43](#)):

When kids get to the stage of chronic pancreatitis, they can have chronic pain without enzymes going up. Another thing that people will do is they'll come into the ER and they'll be told, "Well we checked your labs, your lipase is fine. This isn't pancreatitis pain." And that's not necessarily true, of course. There is kind of the stigma that we've heard about in adults. If you have a teenager that goes in, well are you sure they weren't drinking alcohol or he or she, your child, probably just wants pain medications. They're probably just drug seeking. And there is the, especially if you have chronic disease and you're in the clinic, well you look really good, you don't look like a sick person so you don't look like you're in pain.

Melena D. Bellin, MD ([02:47:25](#)):

I think all of those are hurdles that I hear my patients saying. This is where it's really tough sometimes for us to get care, unless it's a provider who knows me and they've sent me up with the infusion center and I'm not going to the ED, but going to a new provider can be really challenging. And for pediatric pancreatitis, I think really since I started in this field, I've seen so many gastroenterologists who have developed, pediatric gastroenterologists, develop an interest in pancreatitis, but they're still at academic medical centers. They're still geographically sparse. If you are a patient who lives in, it doesn't live by a center that cares for children with chronic pancreatitis, it can be a really a financial and geographic burden to get to a place that can provide appropriate care.

Melena D. Bellin, MD ([02:48:05](#)):

And finally, I just to set the session of treatments with for pancreatitis for recurrent acute or chronic pancreatitis, just want to summarize by saying that the options I talked about are really to either treat the symptoms or remove the pancreas to treat the pain. Neither of these, I hope, are the end all of pancreatitis treatment because all of these treatments are associated with lifelong morbidities. Either you're treating symptoms and the disease persists and progresses or you're talking about removing the pancreas, which might treat the pancreatitis pain, but obviously still carries some lifelong implications in terms of exocrine insufficiency and diabetes. At that I will turn it over to our panel.

James Valentine, JD, MHS ([02:48:45](#)):

Thank you for that wonderful clinical overview of pediatric pancreatitis. Now I'll invite our pediatric panel to the stage. They are going to be, come on right on up everybody. They're going to be sharing their experiences and perspectives on the same topics that we were discussing earlier today, but of course from the pediatric patient experience, both covering their experiences with the disease symptoms and health concerns as well as their experiences with current treatments, current treatment

approaches, how well those are working and what they'd like to see from future therapy from their perspectives. Here today we have Rebecca, we have Logan and Logan's mom, Erica, Gracie and Addie. I'll ask Rebecca to go ahead and take it away.

Rebecca Taylor ([02:49:50](#)):

My name is Rebecca Taylor. I'm a 17 year old high school junior from San Antonio, Texas. Learning is everything to me and I pour all of my time, even my free time, into school. You learn to love it when you had it taken away from you as I did when I was seven. I was diagnosed with chronic pancreatitis, caused from an unknown immunologic disorder that is still being studied today. I have since spent over 1,300 nights in a hospital bed, have had over 85 anesthetic procedures, 22 of which were ER CPs. My search for a cure led me to eight of the major hospitals across the United States, none of which provided an answer. When I was 12 I had to have the total pancreatectomy and auto islet cell transplant to save my life from the pancreatitis, but the transplant left behind many problems of its own.

Rebecca Taylor ([02:50:39](#)):

I have not experienced the pain of pancreatitis in over five years since my pancreas was removed, yet it still has a firm grasp on the way that I have to live life today. The pain of pancreatitis is unparalleled. None of my other 18 plus afflictions even come close to the level on which pancreatitis tormented me. The pain was similar to a knife actively stabbing in my abdomen, but that's not where it ended. The extent of the pain reached to ripple across my entire body until I couldn't help but shake. Every square centimeter ached and nothing alleviated it, not even high dosage narcotics. This kind of pain is debilitating and meant that I had to miss out on everyday activities such as school and seeing family members and friends. It kept me constrained to a bedside where my new life revolved around pain. Pain that is not only physical but mental.

Rebecca Taylor ([02:51:27](#)):

Each day I discover a new scar, a mental scar that pancreatitis has created and left behind. Certain moments of PTSD affect my everyday life, such as hearing certain words in a hospital setting that brings tears to my eyes where I have to clutch my stomach in an attempt to protect it. The worst procedure I've ever endured once kept me up for 72 hours straight screaming from the pain. I was 10 when I received this procedure and it still wakes me up in the middle of the night from a deep sleep with phantom pain. Even my dreams to this day are still filled with pain. 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.

Rebecca Taylor ([02:52:15](#)):

The options for treatment for this are limited and scarce and finding someone who knows how to help is nearly impossible. The transplant was not an option for me but was necessary. It is not a cure. Instead, it is an exchange of one set of problems for the next. I now have a failed colon in massive amounts of scar tissue that are wrapped around my intestines. I have to take three to nine cups of MiraLAX every single day just to keep me out of a hospital bed and the pain attached to it leads to narcotic usage. 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.

Rebecca Taylor ([02:52:59](#)):

Scar tissue provides issues of its own that creates incredibly severe pain that halt nearly every aspect of my life during its pain spells. Yet it is very difficult to remove considering the lack of surgeons willing to attempt such a procedure on a unique anatomy that the transplant leaves behind. The transplant is a time buyer. Islet cells don't live forever. After my islet cells have all died at the 10 to 15 year mark, I will become a brittle diabetic and we'll have to carefully monitor sugar highs and lows. I will have to navigate life completely without the use of a pancreas, which is considered a vital organ. Even the missing spleen takes a toll and requires extra precautions to be taken by those around me such as all of my friends and family members now have to get vaccinated early and have to avoid everyone around them who is sick.

Rebecca Taylor ([02:53:49](#)):

The school won't allow me to attend when certain number of students are absent due to sickness and which means more missed school on my behalf and even a slight temperature that I contract leads to yet another hospital stay and the days of missed school piles up. This disease is not a disease that anyone should have to endure, but especially not children. No child needs to be in debilitating pain that is this bad and they don't need to have their life taken away from them too soon. For this, we need a cure so that we can have a better option than the transplant that is just an exchange of problems, so that we can finally have a cure that will treat pancreatitis as a whole instead of just trying to remove the pancreas.

Erica Williams ([02:54:38](#)):

Good morning. Logan is an amazing and resilient seven year old boy in the second grade. Logan was first diagnosed with acute pancreatitis in March 27, 17 at the age of four. At that time, it was also discovered that he had a choledochal cyst. This was surgically removed in April of 2017 and deemed the cause of his pancreatitis. We were told it was an event and it was over. Logan was again admitted in October of 2017. The attending stated this wasn't supposed to happen. They placed him on a low fat diet and started him on CREON, digestive enzymes. At that time, the process of genetic testing began. He was again hospitalized in February of 2018 and at that time it became known that he had a SPINK1 mutation. It was homozygotic on two variants. Once the genetic mutation was discovered, they stopped the CREON and stated low fat diet would not make a difference.

Erica Williams ([02:55:38](#)):

We had spent months learning and measuring fat grams, teaching him his new food rules, consoling him through the changes and adjustment and supporting him in taking a medication with every meal. Then just like that, the rules changed. It was a whiplash for us, but even more so for him. He had learned eating a certain way kept him well. Now he learned that is not the case. It creates doubt in the mind of a child and impacts their buy in into the next set of rules that we have to teach him. Logan is hospitalized two to three times a year with acute recurrent pancreatitis. They are clear there is no treatment for him, only management of symptoms. When this journey first started, hospital management included nothing by mouth for days. Then all of a sudden a few stays in, they decided food as soon as possible was better. Again, we taught him one thing and then changed it. It is confusing to a child. It is confusing to adults.

Erica Williams ([02:56:35](#)):

This past summer 2019, Logan was evaluated by the TPAIT team of University of Minnesota. We are instantly comfortable with their role as leading experts. We left informed and impressed. After completion of the evaluation, the team recommended him to have the pancreatectomy and islet auto

transplant. Logan is treated at a children's hospital that vies for the number one spot every year and never drops below the number two. We have access to the best and what we were told is, "Your son has a progressive disease and there is no treatment." As we begin down the path of progression, the symptoms increase in severity and frequency. He identifies struggling most with the intensity of the pain, nausea and fatigue. We will have to abruptly leave activities. We have carried him off the soccer field and after a morning of activity he has to rest and recover.

Erica Williams ([02:57:31](#)):

When he's in a subacute flare, he is couch bound and not able or willing to engage in activity. When it becomes an acute flare, he stops being able to walk upright. He will tell us every step his punches to my pancreas. He stops eating, stops drinking and the pain creates a desperation for him. He is hunched when he walks and it is a telltale sign that we are on our way to an admission. Providers explain that they can manage his pancreatitis but there is no prevention or prediction. There are many theories as to what may precipitate an acute attack for him. However, he's had attacks with no precipitator identified. Logan wakes up, goes through his day and goes to bed with the potential of the extraordinary pain coming at any moment. Since his last acute pancreatitis diagnosis, his recovery has been slow and stagnant. Prior he would rebound. This time he faces daily nausea, fatigue, pain and difficulty after meals.

Erica Williams ([02:58:33](#)):

As a family. 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. Our only option is a drastic and invasive operation. It is terrifying and comes with substantial risks. Unlike his first major surgery, everything moved fast and we were not given a choice. We're left to determine the timing for this surgery. We are stuck in a game of guessing when he is sick enough but not too sick. It is a terrifying place to be. We're beginning to see the compounding toll this is taking on Logan. It is affecting his soul and his light. He's beginning to have times of defeat and the only option we have is to move our family out of state and for him to undergo an invasive complicated surgery. So many aspects of the surgery terrify us. Sometimes it's details that really impact you. In order for Logan to have his islets transplanted, his pancreas will be brought to a lab. This lab is in a different city than the surgery will happen in. Our child will lay in the operating room while his pancreas is driven to another city, islets harvested and then returned. There is no other option on the horizon. We are acutely aware that there are other families that would trade with us in a moment. We have an identified problem and an identified solution. We may not like the solution but we understand how lucky we are to have one.

Erica Williams ([03:00:10](#)):

We are also certain there are solutions or at least treatments already in existence. The cure could be sitting on a shelf waiting to be labeled for this fight. Inflammation is a trigger for Logan's pancreatitis. Medications can target this, raise the threshold or at least minimize it once it begins. This may limit damage if we can find those medications. If we limit damage, we limit progression. Slowing this down creates a wealth of time and opportunity to find the next step towards a cure. A cure much less invasive and risky than the one that we are offered now. Great job.

Gracie Jamison ([03:00:54](#)):

My name is Gracie Jamison. I'm 16 years old from Muskogee, Oklahoma. My sister Addie, my dad and my grandmother all have hereditary pancreatitis. On my 16th birthday, I was practicing for my driver's test, I told my parents that my chest was hurting, but we thought it may be due to nerves about parallel parking. I started crying from the intense pain, which is not normal for me at all. My parents took me to the emergency room and because of the family history with hereditary pancreatitis, they requested the hospital run lipase and amylase counts. They started an IV with morphine and did blood work right away. My lipase was over 900 and I had to be admitted into the hospital two hours from home. I spent three days in the hospital. At first I couldn't eat. Then I went on a clear diet to try to ease the pancreas back to functioning pain free. Soon after the diagnosis of hereditary pancreatitis, in April of 2019, I went to OU Children's in Oklahoma City to have an MRCP. They collaborated with my sister's team of doctors from Cincinnati Children's to make certain the scan was able to show the doctors the best results. Looking back, I'm certain I was having attacks earlier in life, but we attributed the pain to lactose intolerance or food allergies. Each time I feel pain, I get blood work done at the lab. Doctors want me to track my lipase and amylase counts. This has mandated many trips to the hospital lab forcing us to leave whatever activity we're doing.

Gracie Jamison ([03:02:25](#)):

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. It's even more discouraging when the counts would come back low, even though the pain had been high. I know the difference between a stomach ache and pancreas pain. 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. It is intense and relentless. 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. It's hard to tell others what is happening and what I need when the pain is. When the pain is the most intense, it is debilitating to the point of crying.

Gracie Jamison ([03:03:14](#)):

The severe pain generally lasts for 30 minutes or until the narcotics begin to take effect. In October of 2019, I had an ERCP done at Cincinnati Children's Hospital. A stent was placed into the duct to widen it since it was a little narrow. I had begun to notice a pattern with the pancreatitis attacks coming about one to two days before my menstrual cycle would start. I kept track on my phone calendar. When we were in Cincinnati for the ERCP, we mentioned the connection to Dr. Harsha who told us of a study she recently heard presented on this very condition. At this time, genetic testing was administered and it was determined that I had the PRSS1 gene mutation. In December 2019, I had a full TPIAT evaluation. It was determined we would review and re-examine in six months. We opted to start birth control in an attempt to regulate periods and determine if pancreatitis attacks are directly related.

Gracie Jamison ([03:04:12](#)):

Since starting birth controls, I've still had attacks with my periods. The main downside of this treatment is more frequent and heavier periods and I feel more emotional, discouraged and mad when experiencing pain. 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. Besides hormones through the birth control, I do not take daily medications. I rely on ibuprofen for pain until it isn't effective. Then I take oxycodone. After taking the strong medicine, my day is spent in bed because it makes me exhausted. I stopped eating for a while because of the pain that

comes right after eating to allow my pancreas time to rest. I increase fluids for nutrients and hydration. The doctors have described to me as an science experiment.

Gracie Jamison ([03:05:06](#)):

I'm figuring out when I must take the narcotics versus ibuprofen, learning how to make myself comfortable when I hurt, what the protocol is at school in order to be excused from class, tracking periods and pancreas pain, learning how to determine whether I should drive myself or have someone come get me, learning when and what I should or should not eat. Even though I have watched my sister deal with this disease my whole life, I now have to learn the effects of this disease on my body and determine how I can best deal with the pain and life changes.

Attie Jamison ([03:05:47](#)):

Good morning. I'm Attie Jamison. You all just heard from my sister Gracie. I'm 15 years old from northeast Oklahoma. At four years old, I complained to my pre-K teacher that my chest was hurting. She called my dad who also has chronic hereditary pancreatitis. The way I had shivered from pain looked all too familiar to him, and then he took me to the doctor requesting they run a lipase and amylase count. My numbers were so high, the test couldn't accurately count them. They confirmed I had pancreatitis. I was the youngest pancreatitis patient our doctor had ever seen. We then drove two hours to see a pediatric GI doctor. She sent us to the Mayo Clinic in Minnesota where they did an ERCP IH6. As I grew older, the attacks became more frequent and more painful. Being sick would mean missing out on dance, school and church.

Attie Jamison ([03:06:37](#)):

The pain, hospital stays, and narcotics made school very challenging. 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. The nausea was so bad that I couldn't function. I was given phenergan pills and gels for it. 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. The agonizing pain. I would first feel like I had pressure on my chest. I would stop eating, taking ibuprofen, and warm up the corn bag. 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.

Attie Jamison ([03:07:26](#)):

The pain would subside, then come back, but worse. It felt like I was being stabbed in the abdomen repeatedly. At that point, I would take hydrocodone. 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. I remember begging nurses to start the IV one time so I could just get some relief. 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 and because of strange insert issues and God's plan, I was admitted to St. Francis Children's Hospital. There, they referred me to a GI specialist in Oklahoma City who had just learned of a surgery that corrected pancreatitis.

Attie Jamison ([03:08:24](#)):

The surgery involved the removal of the pancreas, spleen, gallbladder, and appendix. The insulin producing islet cells would then be translated into the liver to control blood sugars. After a bit of a fight, my parents temporarily moved us to Cincinnati where I had a total pancreatectomy with islet cell auto transplantation in December of 2017. I woke up from the surgery not only in pain but scared. I was on about 25 IV drips, but there was still the pain and the nausea. For days I laid in bed and sat in a chair, hardly moving because of the nausea. The trauma to my body or the drugs were causing violent nightmares, which lasted about six months after the surgery and still happen sometimes. I took Seroquel, neurontin, antibiotics, and CREON because my liver clotted after the transplant of the islet cells. I required a second surgery to break up the clotting, which resulted in heparin and lovenox for weeks after the surgery. Because my blood sugars were so unstable, I went through hourly finger sticks for days.

Attie Jamison ([03:09:33](#)):

The biggest thing that I can remember is the nausea. I was vomiting frequently, which was not good given that my abdomen had just been sliced open. Nothing helped the nausea. Eventually I was given medication for patients on chemo. It made me feel better, but only for a short time. Didn't return, but I couldn't have any more medicine, days of nausea were finally cured by a tiny pink pill, phenadryl. At one point I was taking around 30 pills per day as well as managing an insulin pump and a Dexcom, but miraculously, within 12 weeks of the surgery, my islet cells begin to fully function and today I take no insulin to control blood sugars.

Attie Jamison ([03:10:16](#)):

I was on an antibiotic for the first year after surgery as well as aspirin and blood thinners to help control my platelet counts. Since the surgery, I've been hospitalized one time for fever because I am asplenic. the TPIAT was intense. The recovery was harder than anything I could have ever imagined. The second surgery was the worst case scenario, the nausea and night terrors were long lasting and hard on my entire family. However, the absence of pancreatitis and chronic pain is worth it. After the surgery, I have grown six to seven inches and gained around 40 pounds because I don't have a faulty pancreas draining every nutrient out of me. Hopefully I can be a small part of the changes I wish to see in the development of a cure for pediatric pancreatitis.

James Valentine, JD, MHS ([03:11:10](#)):

Rebecca, Logan, Gracie and Attie. Thank you for your courage of sharing your stories today. Join me in thanking the whole panel again.

James Valentine, JD, MHS ([03:11:24](#)):

Now we have the opportunity to broaden the discussion as we did in the earlier session to hear about the pediatric patient experience with pancreatitis. Like before, we'll be asking, I'll be asking some questions and asking you to raise your hand to please share. We know that pancreatitis as was mentioned, is quite a spectrum of a disease. And so even some of you that may have been sharing your experiences during the adult session, we know from the polling that 40% of you had your first symptoms in childhood. We welcome you to also share your pediatric specific experiences as well.

James Valentine, JD, MHS ([03:12:07](#)):

I'll start us off with one question. We heard from a number of our panelists that they had different frequencies of kind of what I would call worst days and that there might be certain things that they

noticed preceding those worst days, something that might trigger those severe symptoms, perhaps even an acute attack. And so I was just curious for those in our audience, if you'd be able to share, if you're able to notice either in your child or in yourself, those kind of either triggering events or some way of knowing that you might be having the onset of a worse day. Just raise your hand and we'll have a mike to you.

Speaker 6 ([03:13:01](#)):

Well as I said, I'm quite old right now, but I do remember being in elementary school and having stabbing pains and bending over and they would call my mother and she would come get me. And this went on from elementary school right through, forever. But anyway, I was told I had the stomach flu then they would give me, they didn't have endoscopy's in those days for pancreases, but they would do GI tract x-rays and colonoscopies and they would give me Valium and then they'd say I had an ulcer and they'd give me ice cream and cream. The worst possible thing for pancreatitis. I have to say until I was diagnosed at 22, I was in camp, I was in high school, I was in college. I spent a lot of time in college in the hospital at college. And it just lasted from the time I can practically remember, five or six. It was torture.

James Valentine, JD, MHS ([03:14:29](#)):

Did you ever notice anything that would trigger those events? Or is it just pretty random?

Speaker 6 ([03:14:34](#)):

No, it would just sort of happen. And I'd go to the nurse at school and I'd sit there for a while and then they'd call my mother and say, "Oh, she has stomach flu." I remember being in camp one summer and they taught for two weeks, I was in the infirmary. They said I had stomach flow and then in college that was the worst. They told me I had an ulcer and they gave me everything you shouldn't have for pancreatitis. And as I said before, I was finally diagnosed at 22, which is when I sort of knew how to control low fat and all that. But it was, this was a different time and I'm so glad these young people, even though they've suffered, have better, there's better understanding of it because it was pretty bad.

James Valentine, JD, MHS ([03:15:28](#)):

Thank you so much. Other experiences on this? Yes. Jane. You all can raise your hand at any time too.

Jane M. Holt ([03:15:41](#)):

I just want to say I've spent 32 years trying to figure out what triggers my pancreatitis and I can't figure out anything. It just happens. I think I said, I try to be very careful of what I eat. I do what I'm supposed to do. It doesn't make any difference. I just get the pancreatitis and nothing I can do to change it.

James Valentine, JD, MHS ([03:16:01](#)):

Sure. Thank you so much. Just pass that right there. Yes, Attie?

Attie Jamison ([03:16:07](#)):

Yeah I know for me specifically, nothing really triggered it. I could be fine one minute and the next minute in excruciating pain, but once an attack would be over, and even after the surgery, we could sit back and kind of look. The more dehydrated I was, the worst the attack would be. We finally noticed a pattern after several years that the attacks became worse in the summer whenever I was outside

playing, going, going, going, not drinking water. For me, I would say one of the things that, not necessarily triggered it, but probably was a factor was the dehydration.

James Valentine, JD, MHS ([03:16:46](#)):

Thank you so much. I know earlier in the day we heard a little bit about food. Does anyone have experience where specific foods might trigger or even just eating, obviously eating is a common thing, but any patterns noticed there? Hilary did you want to? Right here.

Hillary Mendelsohn ([03:17:11](#)):

It can happen at any time, but there are certainly triggers that when I look back, I know what triggered it. The first time I had acute pancreatitis, I had been eating granola and nuts, like a trail mix and had no idea I wasn't supposed to eat nuts. Stress is also, when I am under severe stress, I try whatever I can do to calm myself down because I know that that can lead to an attack as well.

James Valentine, JD, MHS ([03:17:40](#)):

Absolutely. Thank you, Hillary. You also heard, so we've heard about stress, dehydration and we heard a little bit about food. Anybody else have a experience where hormone changes triggered pancreatitis attacks? We have a couple of hands we'll come here and then we'll go to Holly.

Speaker 7 ([03:18:02](#)):

Yeah, I can relate to...

PART 6 OF 8 ENDS [03:18:04]

James Valentine, JD, MHS ([03:18:03](#)):

[inaudible 03:18:00] Holly.

Adriana Llamas Cowdin ([03:18:03](#)):

Yeah, I can relate to Gracie every month that I would get my menstrual cycle, I would end up hospitalized. The attacks would be so bad. And so I'd be in the hospital for about a week, every single month. And so they ended up putting me on an IUD to stop the menstrual cycle from happening just so that they could stop that cycle from recurring every single month.

James Valentine, JD, MHS ([03:18:23](#)):

Sure. Thank you Adriana. Holly?

Holly Watson ([03:18:30](#)):

I have noticed with being pregnant now for the third time that it's gotten, it didn't happen in my first pregnancy, but the second one at 36 weeks, it was like the more the hormone surge, the worse it got. And it could have also been the smashing all of your organs inside, the pancreas does not like to be crushed. Don't touch it, don't put pressure on it. But now this time around, I feel like I'm just waiting for the inevitable. It's going to happen and I can kind of feel it almost now.

Holly Watson ([03:18:59](#)):

And I don't know if it's a stress, sometimes speaking in public makes you nervous or hearing these things being emotional and crying, which I can't seem to stop doing right now, really, it's like it tenses up almost like a cramp in a muscle and I just, I know the hormones with being pregnant is something to take into consideration when you think about it, just to kind of try to relax as much as possible because the stress and the hormones altogether and with your menstrual cycle is just, I have noticed it more in women in my family than I have in men, and I'm wondering if that's playing a factor. I don't know. I've heard it's not gender specific but it just seems to affect in my family specifically more women than men. And I'm wondering if it's hormone related.

James Valentine, JD, MHS ([03:19:41](#)):

Interesting. And did you in your past pregnancies have kind of increased frequency of that feeling or even the onset of the symptoms themselves?

Holly Watson ([03:19:54](#)):

It did. The bigger that I seem to get and the less room to pancreas had, I would notice it more. And then with breastfeeding, that's when I had the worst pancreatitis attack that lasted for the longest, probably it lasted for nine months, it never went away. And I want to say it was Jane who had said that you noticed you have a pancreas. It's weird to notice that you have a pancreas and to feel it working. And I do, I notice my pancreas is actively working, that's not something that is normal, you shouldn't notice that. Kind of like your liver, you shouldn't know it's working or your kidneys, but with your pancreas I had noticed that as well, and yip the bigger you get the more you feel it and the frequency is more intense.

James Valentine, JD, MHS ([03:20:34](#)):

Absolutely. Thank you. Any other noticeable patterns? Do you want to? Yep.

Speaker ([03:20:46](#)):

Okay. I'll talk about the noticeable patterns and then I'm going to give another few words on behalf of children that I see on a regular basis. We happen to have the privilege of starting a charity for children with pancreatitis, but we see dozens and dozens and dozens and dozens of children that come in with this disease path. So we've done so many studies now on the children and their diseases. The triggers are one into the next.

Speaker ([03:21:10](#)):

We do have a lot of children that are triggered by fat still, and I know there's a lot of research that say no, no fat or not, but a tremendous amount of children including my daughter Rebecca, who was the first to speak there that are triggered by fat. So I get a little nervous when everybody's like, oh, don't worry about the fat, it's not a big deal because we have so many children that are coming in with that. Again, that doesn't mean that that's always the case, but we do have a lot of the fat triggers. There's a lot of the stress triggers, especially for children who have a lot of stress from school and from academics or things that are coming. So that runs the gamut.

Speaker ([03:21:44](#)):

But I also want to just speak to the broader issue of thank you for hosting this meeting because I think it is paramount in the world of pancreatitis, but especially in the world I see with children. Because again, adults get it, they get effected and that's just horrific, but to see a young child who has their entire

childhood taken away from them because of this disease path is something that's excruciating, and I see that all the time. A huge portion of our children don't even attend school, they have all had to drop out and have some form of homeschool because they cannot keep up with the rigorous education, and the education portion itself does not understand why they're missing so many days because it's not a known disease path.

Speaker ([03:22:29](#)):

The second I wanted to be able to bring up is the lack of education that we have about this disease path means that children, again, as Dr. Bellin attested to go to the hospital and we get children all the time. One example, two weeks ago we 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.

Speaker ([03:22:58](#)):

So the psychological ramifications that are coming 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. And so it's not just as you had mentioned the pain factors and so forth, but it's also the emotional side. We have children, many that have attempted suicide, some that have committed suicide, and a lot of that is actually based upon the pain factor.

Speaker ([03:23:32](#)):

And because you have doctors that say, I'm not going to give you opioids ... Rebecca is a 10 year old child, I'll never forget a doctor calling me outside the room, her amylase and lipase had not risen, it was lagging because she had had so many attacks by that point, he pulled me outside the room and said, your child is just drug seeking. 10 years old. My child had not had a drug in her system and nine months and yet she was a 10 year old that's drug seeking. And you're being told that as a parent and the child's being told that what they're is not right and that their pain is wrong. We had a nurse that would say, what's your pain factor, and we have this happen all the time, and Rebecca would say seven eight and then all of a sudden the nurse would say, eh, you don't look like it's seven eight so I'm going to put a two down. So after a few days, Rebecca just stopped saying her pain factor. Why did she stop saying her pain factor, because she wasn't being listened to. And the doctors were fearful a lot of giving the opioids because of the new opioid crisis that we're having. We are from Texas, which 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.

Speaker ([03:24:36](#)):

So to have something that's an alternative outside of removing multiple organs, again, we're thankful for the TPIT, it saved my child's life, but the ramifications we're having in a lot of other children we're seeing it's about 50/50, 50 have terrible repercussions after the TPIT, from scar tissue and other posts splenectomies and so forth, the others do really well, but if you're in that 50% as a child that's growing, it's very difficult. The fact that we could actually start conversations for the first time about addressing the pancreas and healing from itself without something radical will be not just life changing from a

physical perspective but will be life changing from an emotional, mental, and cognitive standpoint too. And I'm very thankful to be actually opening up conversations about that. Thank you.

James Valentine, JD, MHS ([03:25:20](#)):

Yeah, thank you for those comments. A lot to unpack there and actually would like to explore some of those exact issues with the audience and hope to draw out some more of the experiences of those we have in the room today. So, kind of getting maybe first to the point of stealing the childhood, these people living with pancreatitis in these early years, childhood, teenage years, and the impact that these symptoms, these health effects, even the health care treatment and the burden related to that that we've heard about, the long hospital stays, what have the impacts of that been on the pediatric patient, so the child or the teenagers activities in daily life. What are the things that are most important to our pediatric patients that have been limited or maybe impossible, because of having to live with pancreatitis. So I'd like to hear any examples, stories that you might have that might exemplify those losses. Yes.

Michelle Canoy ([03:26:49](#)):

Again, my name is Michelle. I did not have a diagnosis. I mentioned earlier, my first round was at seven years old. We had no idea of what it was. I had no idea. I was just told it was in my head. I was just sick all the time. Didn't get to do anything enjoyable, didn't go to summer camps, couldn't go anything like that. It actually even changed my track in life. 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. Went a safe route, started as a teacher, it just wasn't it. So then got into business and that just wasn't it.

Michelle Canoy ([03:27:27](#)):

Finally when I was 30 I got my diagnosis, had a laparotomy, was told things were going to be fixed. If anything, it did help my psychological factor because then I did go into firefighting. I did firefighter one and two, am now a basic EMT as well. Was on a truck, found out I wasn't fixed and was having increased problems. So I've had to come off of a truck and now I actually work as a fire marshal, so I'm still on fire prevention, still doing something, and it has fulfilled a part of me to be able to do something that I wanted to do all those years ago.

Michelle Canoy ([03:28:00](#)):

I joke and I say I'm going through my second childhood because for so long I was so worried about what was going to happen. You couldn't eat it, didn't know, couldn't eat too much, but I'd eat too little, couldn't hydrate, would be dehydrated, did not know that balance till I finally stopped and I listened to my body and now I know what's right for me. And to have people here and the FDA and other doctors to listen to the patients say what's right for them, there's no cookie cutter for any patient and [inaudible 03:28:35] you're going to have a whole gamut of things, but to have a quality of life is priceless. I mean it is just, there's nothing that can replace being able to smile, being able to be happy, being able to do something that fulfills something in you, which I'm 39 years old and I'm just getting.

James Valentine, JD, MHS ([03:28:55](#)):

Wonderful. If you don't mind me just asking a question. You gave as an example not being able to go to summer camp and so that's something that clearly was a decision that had to be made well in advance,

you didn't sign up, was there certain fears of certain symptoms on setting or was there, you just knew you had a chronic level of symptoms that wouldn't allow that? What kind of-

Michelle Canoy ([03:29:22](#)):

Pretty much. A lot of it just being lethargic, tired all the time. I always wanted to be active, but then there's a lot of GI issues and again, did not have a diagnosis with it. This is 30 some years ago. So it was the fear of, and then what would happen if, I mean we have the one extreme to the other with bowel movements and that sort of thing. What am I going to do when we're out on a hike and something like that happens.

Michelle Canoy ([03:29:47](#)):

So even now I have to deal with that. Do I eat before I go to work? Do I try to snack? Do I just wait until the end of the day? What do I need to do? Now as an adult I have more choices and I have more freedom, but the children don't have that, especially when they don't know what's going on.

James Valentine, JD, MHS ([03:30:03](#)):

Sure. Thank you so much for sharing. Other experiences? Yes. Right here.

John Mahalchick ([03:30:14](#)):

Just to echo something that I've heard a couple of times, I was 18 when I had my first attack, so I was already in college, but being told it's all in your head. I'm sure most of us have heard that many times before. And I think part of the issue with that is, you have these symptoms that are going on. You see doctors, that doctor probably send you to another doctor, to another specialist or something like that. After you get a nice six month workup, they say, okay, well now we're going to send you to a mental health professional because we can't find anything wrong physically. And it's just, I think that the effect that those kinds of comments have can be pretty tough on somebody, especially children. So, I just think, again, that's probably one of the reasons that mental health professionals could be involved from the very beginning of the process and not kind of as an afterthought thrown in at the end.

James Valentine, JD, MHS ([03:31:06](#)):

Yeah. And kind of that mental psychological burden, have you noticed that in your own life, having downstream effects in daily life?

John Mahalchick ([03:31:16](#)):

I think initially so, but then I was able to get connected with some resources two and a half, three years ago and it's been life changing.

James Valentine, JD, MHS ([03:31:24](#)):

Sure. Thank you so much Jean. Other experiences in life, impacts on activities, Rebecca?

Rebecca Taylor ([03:31:39](#)):

Because I'm a high schooler you want to be normal in high school and be able to go to school, but when I'm at home I can only attend school for an average of three days a week. Sometimes three and a half if I'm lucky. And 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 who are telling you who think you're just seeking attention. So you try to hide it all so that other people don't see that.

Rebecca Taylor ([03:32:10](#)):

And for example, last August I went to a summer camp and I had very bad stomach pain that just kept piling up, but I wanted to be normal for once so I didn't tell anybody. And I stopped eating so that it wouldn't cause pain and eventually halfway through the camp I ended up passing out one night in front of everybody and had to be taken by an ambulance to the emergency department. So you have to try to maintain this balance to be seen as normal by everybody else when clearly everything is wrong and it's not.

James Valentine, JD, MHS ([03:32:42](#)):

Sure. Thank you so much Rebecca. Okay, so I'm going to maybe transition the conversation a little bit to talking about treatment approaches, something that's come up a number of times on our panel and throughout the discussion. Maybe to start that off, we'll go to our second to last polling question and I encourage everybody, all our patients and caregivers to respond to this both here in the room and online. So here earlier in the day we asked you about the different treatment approaches that you've used.

James Valentine, JD, MHS ([03:33:19](#)):

Here we want to get a sense of, in general, how much have those medications and other treatment approaches helped to improve your quality of life. Options are A, you've had no benefit at all. B, they've helped somewhat. C, they've helped a lot. D, they've had a very significant benefit. Or E, you're not sure the benefit that they've provided. Please select the one that most closely reflects your experience with medications and treatments and how much they've helped improve your quality of life.

James Valentine, JD, MHS ([03:33:50](#)):

We'll give you just another moment to get in your response here. As it stands, I would say a vast majority of people, around just under two thirds, have said that those treatments and medications that they do have available have helped somewhat. We have about a quarter of people saying that they've helped a lot, just under 10% saying no benefit at all. And a small proportion of people saying they've had a very significant benefit. No one reported that they were unsure. And so of course this all depends on what treatments that you've had and we want to explore those treatments that you've experienced and how well they've worked. Which of these categories essentially it's fallen into.

James Valentine, JD, MHS ([03:35:06](#)):

So maybe a place to start in that category, because we heard that there, Erica shared a little bit about this, there could be some unique considerations for a disease management in childhood and maybe perhaps more so in early childhood, but maybe also into teenage high school years.

James Valentine, JD, MHS ([03:35:27](#)):

So I was wondering if anyone had any examples where maybe some of the treatment approaches we talked about in the adult section have had either you've had difficulty in implementing them during childhood years, maybe they weren't available to you for some reason because of being in childhood years or maybe there's just some issues with even being able to comply given the nature of childhood

years. So any experiences, unique experiences with difficulty in managing the condition because of childhood. Any thoughts on that. Yes.

Speaker ([03:36:14](#)):

We found in the pediatric world it's really difficult getting doctors to take pediatric patients with this disease path. So that's one of our biggest problems that we're having. There'll be probably 10 to one adult doctors that will take on pancreatitis patients versus the one child and a lot of adult doctors don't want to delve into the field of pediatrics. I'm sorry, I'm blocking half your view.

Speaker ([03:36:36](#)):

Some of the doctors don't want to dive into the world of pediatrics, which is understandable, but we're having a hard time with children coming from all different portions of the US actually even pinpointing a hospital that will take children with this disease path and not just outside of the NPO, stick an IV in, give them some opioids and let them rest. What happens beyond that next step? We have one patient in particular that spent six years, went to four major university hospitals, hospital to hospital to hospital, large hospitals and would never take her as a child patient outside of sitting in the hospital with IVs.

Speaker ([03:37:10](#)):

So I think an awareness, of course, of this disease path that trickles down is helpful, but also educating and training pediatric doctors themselves or adult doctors to take on the pediatrics is something that needs to be addressed for the welfare of these children.

James Valentine, JD, MHS ([03:37:25](#)):

Yeah. So to help me maybe understand the impact of that lack of access to kind of care is there ... Are people not getting on the right diets, are they not getting on the right medicines?

Speaker ([03:37:37](#)):

Oh, they are having severe damage by the time we actually see a lot of our children in San Antonio or at other institutions where that will take them, they're already at a severe chronic pancreatitis state because they've spent years traveling from place to place to place and have had no help. What would have happened, and there's no way to have a crystal ball to look, but if they had had intervention that was appropriate from either medication, and again, that's assuming that we get medication that can help that, I'm not just discussing opioids, from medication intervention or even an ERCP.

Speaker ([03:38:07](#)):

We have some of our patients that needed one ERCP, a very simple fix. Not that you would say ERCP if you don't need it, but a simple fix and they're in remission for nine, 10 years, but because they didn't get that and their inflammation continued year after year after year, by the time that we get them at kind of a last stop resort, these children already have so much damage it's irreversible. And when you have a young child with growing organs and irreversible damage that's affecting their health, it's affecting their physicality, it's affecting their growth rates, it's affecting their liver, it's really a severe process.

James Valentine, JD, MHS ([03:38:41](#)):

Sure. Thank you very much. Other unique challenges or barriers to treating pediatric pancreatitis?

Speaker 8 ([03:38:50](#)):

Yes, so one success story we had from Dr Lowe was, my son's first three attacks were time regulated for some reason, every hundred days give or take, and Dr Lowe suggested that the combination of Centrum silver and methionine, I know I said that wrong, you have to excuse me, but I have absolutely no doubt at his earlier ages that completely expanded the time between attacks as well as the duration of, and as it started to wear down, we figured out that because he was a growing boy, we needed to increase the dosage and I still believe that that contributes in some factor to those well periods, although they are a little bit shorter in between now.

James Valentine, JD, MHS ([03:39:36](#)):

Sure. Thank you. Any other, kind of broadening it, unique treatment experiences? Maybe not ... This isn't a manifestation of being a kid, making it harder to comply with learning a diet, staying on a diet, same with changing medical or medicine regimens, but anything in terms of treatments that you might have tried in childhood that really haven't been talked about yet. And again, treatments being thought of broadly, not necessarily just medicines, medical procedures, but anything, maybe management within the school system or special categories of care, like physical therapy that might be leveraged in childhood. Yes.

Jenny ([03:40:37](#)):

My name is Jenny and I am Attie and Gracie's mom, and I would just say that some of the things that we've dealt with in that, well a few things actually. One, we've, when you put your teenage daughter on birth control, that's a conversation that you have to have. She wears a patch and so people see it, and so that, it just brings it up. But it's also we can use it however we want to and we choose to just use it to educate. So that is one factor.

Jenny ([03:41:04](#)):

The other thing that I would say too, we worked with Attie. So Attie was diagnosed at four and I was a teacher so she actually would just rather than her missing school, she came to my classroom. So we spent a lot of time with her in my classroom trying to get her to feel better and if we could push her through then we would send her back to class.

Jenny ([03:41:25](#)):

So those were my friends who were her teachers. But that's just one thing that I would say definitely is as much as you can communicate with the people that you have in your school, if you've got children with pancreatitis, is as much communication as you can give upfront, that is best. Attie now has had the TPIT and she does take the enzymes, but the bathroom is a situation for her. They're loving, I'm talking menstrual cycle and diarrhea. So they've never been more proud for me to be their mom. But she is ... So we have to have that conversation with teachers that the bathroom is a situation, she is in high school, she does not want to be embarrassed.

Jenny ([03:42:11](#)):

And so we have education plans for both girls in place, 504s, and we have not done an IEP just yet for the girls, but it is something that I would definitely recommend you do if you have a child that's facing this because of the absences and things like that. And so that plan can follow them even into college so that they would be taken care of so that they don't have to be dismissed because they have an illness. And so I would say that that's definitely something for children that you need to advocate for.

Jenny ([03:42:41](#)):

And then again, just as much communication as you can give to the teachers, as much education as you can give to them as well, things like this, if they could watch ... If you could get the teachers to just have a short little ... I know there are so many things out there, but any little session that you could give them will really help them to help your children. And you just have to advocate for them, but the way that you go about it too.

Jenny ([03:43:01](#)):

We tried to not pull Attie 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. And so there were times that we would ... She was trying out for a competitive team, she ended up missing the tryout. She was hospitalized, but as soon as she was out of the hospital, that team allowed her a special try out. And so we didn't have to really pull her from all the things. There were times [inaudible 03:43:31]. 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. But we tried to just sort of keep her involved and active as much as possible, as well as, you're sick, but we have choices that we have to make. And so those were just ways that we tried to deal with it as well.

James Valentine, JD, MHS ([03:43:52](#)):

Sure. Thank you. Yeah. In the back.

Patrick ([03:44:01](#)):

I'm Patrick Salami from the foundation. We've had a number of schools approach us with questions about how they support children with chronic pancreatitis in school. So over the last nine months we've started developing a toolkit based on conversations with some children. Once we have something we can work with, we're going to put it out for consultation with parents and students and then hopefully have it on our website to support schools and to support parents and students as well. But it's going to help them when they're going into school so the teachers are prepared to understand the needs and how to support the child with chronic pancreatitis. Thank you.

James Valentine, JD, MHS ([03:44:42](#)):

Yeah, thank you.

Speaker 9 ([03:44:43](#)):

[inaudible 00:26:45].

Speaker 6 ([03:44:46](#)):

Yes, there is one topic that whether it's adults or pediatrics that we haven't really addressed, is that when of course when I was young, no doctor wanted to discuss pain medication and then as an adult, as the years went by, your internist, your GI, they didn't really want to discuss that because they were afraid of ramifications. They didn't want to discuss pain management other than maybe Percocet. And then a number of years ago, maybe eight years ago, it became law that if you want pain management, you go to a pain management doctor. And I think this applies whether you're an adult or a kid because there are times when you need adequate pain management and your doctor and your surgeon are just not going to deal with it.

Speaker 6 ([03:45:48](#)):

And so my advise would be if you had a kid or you were an adult like me, because what happened is when I had my surgery, I had been doing pain management in San Francisco. The fellow that treated me wouldn't give me pain management and I was in agony. I was in the hospital for a month because I got [inaudible 03:46:10] and pneumonia. I had to call San Francisco to the pain management doctor and have him call the hospital so I could get pain management. So I think that this is for people of all age is a major topic and that if you're suffering, you go to a pain management doctor. That's it.

James Valentine, JD, MHS ([03:46:34](#)):

Thank you. So one topic that while we're talking about treatments, I saw that a quarter of people said that their treatments have helped a lot. And just from hearing the different testimonies of people from throughout today, probably a lot of that response is driven by TPIT procedure. And so what we also heard though is that there are trade offs that come after having that procedure, kind of lasting effects. And they were varied in what we've heard.

James Valentine, JD, MHS ([03:47:14](#)):

So I wanted to see, of those that have had that procedure, how has that ... Has that helped a lot in fact. And then also, what have been those lasting perhaps trade offs that have had the greatest impact on you specifically. So any experiences with that procedure. And it's okay if it's, we've heard it come up a number of times, we want to both understand kind of common experiences as well as unique experiences, but your personal take on those. So yes, Attie?

Attie Jamison ([03:47:57](#)):

I would definitely say I feel very lucky that I can say I'm one of the success stories in which I know pancreatitis is never a good thing and it's a horrible thing to have to say that you feel good, that you feel that it's better about having something so terrible. But the lack of pancreatitis I would say is worth it even though there is other things you're facing. And for me it's not as severe as some people, which I know and I thank God for, I have friends that I've met through the surgery that have different issues and we're all, I was telling Rebecca last night, we're all the same, but we're also different.

Attie Jamison ([03:48:39](#)):

So for me some of the things that have been more impactful are mainly the uncontrollable bowel movements. That's big for me. And one of the things was specifically right after the surgery, the getting tired so easily and I lost so much weight after the surgery and things like that. Just things that as a kid, I don't want to slow it down. I don't want to. And that's, it was kind of an argument between me and my parents, I was like, well I'm not doing it if I'm not going to get to do dance competitions and things like that. So more the, I don't know the word for it, but psychological I guess impact of it, I would say, is one of the greater things of the, I don't want to get slowed down but my body won't allow that.

James Valentine, JD, MHS ([03:49:25](#)):

Sure. And was that slowing down something that was kind of temporary even if it lasted a little while or have you bounced back from that or is it still kind of [inaudible 03:49:34].

Attie Jamison ([03:49:35](#)):

I would say it is temporary, the severe part, but there is still times that I might have to leave an event or can't go as long as other people, or can't do this because of the surgery, even though it's not as bad as it was, maybe three months, two- ... After the surgery, it's still there.

James Valentine, JD, MHS ([03:49:57](#)):

Sure. Thank you so much. Other experiences in the room? Go ahead. Yeah. Okay.

Linda Martin ([03:50:08](#)):

So, as I said before, my daughter had TPIT about 15 months ago. It's been a complete life changer. It's completely saved her life. She has no pain. She can eat anything she wants without any digestive issues or pain. Yes, 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. She calls having TPIT her midlife crisis and everything is changing and she's on her way. So complete success story.

James Valentine, JD, MHS ([03:51:00](#)):

Sure. Thank you.

PART 7 OF 8 ENDS [03:51:04]

Jane M. Holt ([03:51:01](#)):

Sure.

James Valentine, JD, MHS ([03:51:01](#)):

Thank you. Yeah?

Speaker ([03:51:05](#)):

Sorry, I feel like I'm talking too much. I'll just give a brief something.

Speaker ([03:51:10](#)):

I see both sides because we've sent a lot of children through for the TPIAT and of course I have Rebecca. Rebecca has not been the most great, wonderful story, but she's alive, so we're thankful. So I think a lot of that comes with two fold. 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... I see a lot of nods of understanding... This huge, enormous surgery and yet they still have a lot of complications.

Speaker ([03:51:45](#)):

And so I do think what Hillary was saying, it's a big mindset. Know that you're going to have complications and if you have that set, but a lot of parents have the thought process in patients that I'm going to do the surgery and everything's going to be great, and for 80-90% their life is irreversibly changed one way or another. And that's a big step that they're embarking on.

Speaker ([03:52:06](#)):

I do also think with the TPIAT, one of the negative sides of it, there's so many positive sides and we've addressed that 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 and it's ripping and tearing, and we're having lots of repercussions and lots of children hospitalized afterward for that.

Speaker ([03:52:34](#)):

There's not a really good answer on what to do because a prime example, for Rebecca's situation, there's no surgeon in Texas as of right now that will take her to go and clean up the scar tissue. So she just lives in this constant state of pain. A lot of nods, again. This is not a problem that's uncommon, we're finding, especially in children.

Speaker ([03:52:53](#)):

So you know when you're at the same size and you're not growing and you're not having those issues as an adult, it's a very different story. But you've got a five-year-old, six-year-old body, 12-year-old body and they're still continually growing and we are having a lack of post TPIAT care. That's our biggest issue we're having right now for the pediatric population.

Speaker ([03:53:14](#)):

Again, adults are different, but we're having a lack of post TPIAT care. It's like we've done the TPIAT... Now the endocrinology side has it down to a science. Dr Bellin is one of the most brilliant doctors I have ever been around, hands down. The endocrinology we have down to a science.

Speaker ([03:53:28](#)):

The other repercussions, because we're kind of entering into new territory... We're really struggling with what to do for any complications and we don't even know where to send these children, or my daughter prime example, to be able to get the help that they need after that. So a big word of caution for both sides.

James Valentine, JD, MHS ([03:53:45](#)):

Sure. Thank you. Comment here with John.

John Mahalchick ([03:53:57](#)):

I know we've discussed all the pros for the total pancreatectomy so I'll skip over that. But I had my surgery in 2013 and did really, really well for a period of time afterwards, but then I started to get some gastroparesis type symptoms. I was getting constant nausea and vomiting, lots of pain again, and it was like, "What's going on?"

John Mahalchick ([03:54:17](#)):

I'll preface this by saying I absolutely love my doctors. I wouldn't trade them for anything in the world and they take great care of me. But throughout this, I've been able to travel to different medical conferences around the country and one of these conferences I ended up at, I was talking to a physician afterwards and he's was like hearing similar stories from other patients. He actually is not a total pancreatectomy surgeon.

John Mahalchick ([03:54:41](#)):

So I was able to travel to their facility to get kind of checked out again. And that's when 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. So because of that situation, I was able to find a surgeon back in my hometown. Just the first week of December, I had another revision surgery.

John Mahalchick ([03:55:05](#)):

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 kind of thing. So...

James Valentine, JD, MHS ([03:55:19](#)):

Great. Thank you. So I want to move to a question and I'm going to broaden this to both the pediatric and adult perspectives. I'm going to start it off with our final polling question.

James Valentine, JD, MHS ([03:55:35](#)):

So here we're going to kind of spend the last time we have together talking about your preferences, your priorities for a future treatment. And so we're going to start that with this polling question, which is asking you which ability or symptom would you rank as most important for a possible drug treatment today? And you can select your top three.

James Valentine, JD, MHS ([03:55:57](#)):

The options here are: A) Decreased pain.

James Valentine, JD, MHS ([03:56:01](#)):

B) Improved digestion.

James Valentine, JD, MHS ([03:56:03](#)):

C) Improve the ability to participate in sports or activities.

James Valentine, JD, MHS ([03:56:07](#)):

D) Improve the ability to work and engage in social activities.

James Valentine, JD, MHS ([03:56:12](#)):

E) Fatigue.

James Valentine, JD, MHS ([03:56:14](#)):

F) Anxiety/depression.

James Valentine, JD, MHS ([03:56:16](#)):

G) Some other ability or symptom that would be most important for a possible drug treatment to treat.

James Valentine, JD, MHS ([03:56:26](#)):

I'll give you a moment to think about this. Pick up to three responses. All right. I'll give you another moment. Pick your top three symptoms or abilities that you would rank as most important for possible drug treatment today.

James Valentine, JD, MHS ([03:57:02](#)):

As it stands, it looks like the top... And again these are percentages of responses, not total of people answering. The top ability or symptom that you would rank as most important to treat is the pain. After that, next most important would be an improved ability to work and engage in social activities. Number three would be improved digestion, though fatigue, anxiety/depression and other were all rated by a number of you as being a top three priority. It looks like maybe a one or two people might've selected improved ability to participate in sports and other physical activities.

James Valentine, JD, MHS ([03:57:51](#)):

So with this in mind and don't feel limited to the responses that we gave you as options... We want to think about again, as I mentioned at the outset of the meeting, we would all want a cure; but short of that, we want a pipeline of treatments that might be able to help you improve upon what you have today, which we've talked a lot about.

James Valentine, JD, MHS ([03:58:21](#)):

There weren't a lot of responses, actually, maybe one or zero responses that said that the current treatments gave you the greatest level of benefit of the options that we provided. So clearly, there's room for improvement, and we want to understand what that improvement could look like.

James Valentine, JD, MHS ([03:58:39](#)):

So the question is, short of a cure, what specifically would you look for from that next future treatment? Something that would provide a meaningful benefit in your life and Hillary, do you want to start us off?

Hillary Mendelsohn ([03:59:00](#)):

I spent about 10 years of my journey as a single mom. And the use of opioids before my liver started to atrophy was not an option most of the time because I had to pick my kids up from school, I had to be with them. And so I think there has to be some focus on being an adult and responsible for other lives around you.

Hillary Mendelsohn ([03:59:32](#)):

My kids hated seeing me on pain medicine because I wasn't me. So the ability to still be me and still manage to do what I needed to do while not being knocked out on pain medication.

Hillary Mendelsohn ([03:59:46](#)):

And I also want to say that most of the people who are experiencing any form of pancreatitis, their pain threshold, I guarantee you, is among the highest of anybody that you'll ever know. So when they tell you that they are a six, seven, or eight... And for the people who've never experienced that kind of pain, it's off the charts because you learn to tolerate a certain amount of pain. You learn to live with it every single day and that becomes your normal.

Hillary Mendelsohn ([04:00:17](#)):

So when you're saying you're in pain, it's crazy amounts of pain. I think it's important for practitioners, medical professionals, doctors to understand that when they're dealing with it.

James Valentine, JD, MHS ([04:00:32](#)):

So, Hillary, I have a question for you. A beautiful articulation of avoiding the side effects of opioids and other painkillers kind of you not being you.

James Valentine, JD, MHS ([04:00:43](#)):

You were talking about second, pain tolerance and the high pain tolerance of patients with pancreatitis. Would there be a benefit to even knocking that down just one or two notches on that pain scale from that seven or six you described to a six or a five?

Hillary Mendelsohn ([04:01:03](#)):

Any relief that you can still be you is worth it. Any. And that's why I think a lot of us use alternative things. It's why heat is so important.

Hillary Mendelsohn ([04:01:15](#)):

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 and those psychological ramifications are coming out.

Hillary Mendelsohn ([04:01:45](#)):

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 as well. And the fear of, "Could this happen to me? Is what you have genetic? Am I going to get this?" That fear alone is intense.

James Valentine, JD, MHS ([04:02:10](#)):

Thank you. We'll go to Jane and then Eric.

Jane M. Holt ([04:02:19](#)):

I think it's really important right now with all of the emphasis on opioids and getting rid of opioid drugs, there is an increase in research on alternative things for pain medication. And I think it's really important that our patients get included in some of these studies or at least find out.

Jane M. Holt ([04:02:38](#)):

I don't know if the FDA can help us to find out when there are new pain medications coming in. I don't know how we can access this information. But there's a lot going on.

Jane M. Holt ([04:02:47](#)):

I know you have the workshop going, which will be very helpful, but how do we as patients, how do we make sure that when new pain medications come in, not all of our physicians are going to hear about it. How do we find out about it and how do we get those available to us?

James Valentine, JD, MHS ([04:03:02](#)):

Sure. Let me put a question back to you. We'll make sure that the foundation takes that as an action item.

Jane M. Holt ([04:03:10](#)):

We've been working on it.

James Valentine, JD, MHS ([04:03:13](#)):

So for those pancreatitis patients that make it into those trials, they were successful at getting them enrolled in those studies for new pain treatments, what would be an improvement? How would you define improvement for them? What amount of benefit would you need for them to see, to say that they're really getting a real treatment effect when they're participating in those studies?

Jane M. Holt ([04:03:39](#)):

So that's a very important question and obviously something that has to be determined, but I feel that an improvement in quality of life, even if it's three points, would be better.

James Valentine, JD, MHS ([04:03:51](#)):

What do you mean by quality of life? Because I think people use that term a little differently.

Jane M. Holt ([04:03:56](#)):

If you look at quality of life questions, whether it's PROMIS-29 or if it's [PANGOLAY 04:04:02] or what it is, they ask you more than just your pain level. They ask you, are you able to sleep at night? Are you able to socialize? In the last seven days, has your pain affected you in this way, that way or another way. It not only is doing just your level of pain, but how it's affecting you in your life.

James Valentine, JD, MHS ([04:04:22](#)):

Sure.

Jane M. Holt ([04:04:23](#)):

And 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.

James Valentine, JD, MHS ([04:04:34](#)):

Sure. Thank you. And maybe one way, what people said is a quality of life includes the ability to work and engage in social activities. That was number two to pain. Yes?

Hillary Mendelsohn ([04:04:47](#)):

[inaudible 04:04:50].

James Valentine, JD, MHS ([04:04:47](#)):

Hillary noted not compromise other organs. But Eric, I would love to hear your thoughts on this question.

Eric Golden ([04:04:52](#)):

So I'm going to present a slightly different perspective on that. Dealing with pain is critical, especially in the short term and nobody should have to deal with this much pain on a regular basis. But pain is a signal that's telling your body something for a very good reason.

Eric Golden ([04:05:08](#)):

If you have this disease, you just have to trust me, there's an underlying inflammation that affects you across the board. And the fatigue, again... Like to be at 10% or 20% of your usual energy level. That is almost for me as noteworthy as the pain, right? I can fight through pain, but you can't fight through having zero energy.

Eric Golden ([04:05:29](#)):

And there are a whole bunch of other complications that we haven't discussed and won't have time to discuss that affect a ton of other organs. And if you get a bunch of patients like us together, we start talking about the effects on your hands and your arms and your eyes and other things.

Eric Golden ([04:05:44](#)):

And what keeps me going... I can deal with the pain, but I need to know that within five to 10 years like us are going to have some treatment for the underlying inflammation. And Erica said that, too. And we're all trying to do that.

Eric Golden ([04:05:59](#)):

I want to stress if we're going to prioritize things, pain modulation is incredibly important, but we have to go beyond that because there is a ticking time bomb that we're all facing and we have to address it before it goes off.

James Valentine, JD, MHS ([04:06:12](#)):

And what's the ultimate outcome that you... If something were to treat your underlying inflammation, what would you hope that would do for you and the pancreatitis and the disease?

Eric Golden ([04:06:22](#)):

You know, so I'm going to give you a slightly longer answer. For me, one of the most important things is for a lot of patients, you go in and they don't give you a plan. There is no plan.

Eric Golden ([04:06:35](#)):

Psychologically knowing, "Okay, we're going to try this and then we're going to try this. Then I'm going to try this. Then I'm going to try this."

Eric Golden ([04:06:41](#)):

Or, "Here's how it's going to progress and here's what we're going to do with that." That, from a psychological perspective, is critical. I think it's not happening except maybe among the very, very top pancreatic specialists and they just don't have the tool set.

Eric Golden ([04:06:56](#)):

So yes, there are daily quality of life impacts that need to be addressed like fatigue and pain, but 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.

James Valentine, JD, MHS ([04:07:18](#)):

And just to ask because you mentioned it, that it is a degenerative disease; would it be meaningful if that treatment helps slow that degeneration?

Eric Golden ([04:07:27](#)):

Absolutely. Absolutely. For me, it doesn't necessarily have to get better, but to know that the underlying inflammation is not just going to snowball is really the important thing.

James Valentine, JD, MHS ([04:07:36](#)):

Sure. Thank you. All right. Yep. Sorry. Here. Come over here and you'll be the closing comment.

Michelle Canoy ([04:07:49](#)):

I don't know if it would be an approachable thing and I might be ignorant but hydration, if there could be a focus on hydration because I think I've heard a theme of other people. Then also as being a first responder, a lot of medical traumas, a lot of issues that I go on are contributing to dehydration. So that could be a focus as well.

Michelle Canoy ([04:08:09](#)):

I know there's a lot of things being thrown at the wall for pain, but that might be able to treat and get to the core of the matter instead of just treating one of the symptoms that everybody else is kind of focusing on. But if there was a way to get hydration easier, how many ER trips would be saved? I know myself, some of my ER trips I would go and they wouldn't even give me fluids because I was a "Drug seeker." Sometimes it would take two to three hours to get the fluids.

Michelle Canoy ([04:08:34](#)):

So if there could be a pill, if there could be some kind of way to be able to get the hydration easier, FDA approved, I think that could go a long way to improving all of these things.

James Valentine, JD, MHS ([04:08:43](#)):

Sure. Thank you. And the last comment?

Linda Martin ([04:08:46](#)):

I just want to add on because I think it would be remiss to leave this meeting with having everyone think that while this is a terrible disease with terrible symptoms and it is degenerative and so many people, children and adults suffer, there is hope. There is hope.

Linda Martin ([04:09:08](#)):

There is a lot of work going on. Numerous people have mentioned in their answers that they have genetic variants or mutations, hereditary pancreatitis, commonly PRSS1 or SPINK, CFTR which is also the

mutation that is associated with cystic fibrosis is now appearing in more probably more than 50% of patients with chronic pancreatitis. Much more study needs to happen with that.

Linda Martin ([04:09:41](#)):

But finally, through the advances in genomic sequencing and other technologies like artificial intelligence and machine learning, we now have tools to be able to target what is actually going on that causes all these symptoms and can start to have researchers and developers working on treatments that if they don't cure, they slow or prevent progression of the disease.

Linda Martin ([04:10:09](#)):

And we're not there yet and it's still going to take years. But I don't want to leave here having this kind of common... None of us believe we'll ever have a cure. I don't believe that. I believe in less than 10 years, we will have a cure or at least effective treatments that make you forget about pancreatitis. And for me that's good enough. Thank you.

James Valentine, JD, MHS ([04:10:29](#)):

Sure. Thank you. As you could probably tell with the podium kind of collapsing on me a little bit, we're getting towards the end of the meeting here.

James Valentine, JD, MHS ([04:10:45](#)):

Before we close out the meeting and I introduce our next speaker when I say personally for me as your moderator, thank you. I know it's difficult. The questions that I asked were difficult and pulling back the curtain on your own experiences and shedding light into what are very difficult things; I mean, obviously the pain alone being tremendous... Incredible impacts on your lives and a whole snowball effect I think I heard it referred to multiple times.

James Valentine, JD, MHS ([04:11:23](#)):

It takes a lot to be able to share that and I just feel so honored to have been able to work with you all today, to come into your community as an outsider and have you share all of that. I think it's going to make a huge impact on that pipeline of treatments to make sure that they're really being developed for things that are important to patients and caregivers. And so I just want to have you all give yourselves a round of applause cause it's truly incredible what you've done today.

James Valentine, JD, MHS ([04:11:58](#)):

So without further ado, I'm going to introduce our speaker who is going to be providing some brief summary remarks on some of the themes and comments that were heard today. My friend and firm colleague, Larry Bauer, who joined our firm after over 10 years at the Food & Drug Administration. He worked within the rare diseases program within the Drug Center at FDA, not only working on drug development programs, but working directly with patients stakeholders in that time; and even before that, served many years as a research nurse at NIH. So comes the perfect person to give some summary remarks. So please welcome to the stage Larry Bauer.

Larry Bauer ([04:12:52](#)):

I'd like to reiterate some of what James said as far as, thank you. I don't think there's anyone in the room who has not learned and had their knowledge about pancreatitis expanded even amongst the patients. I'm sure that you guys have learned from hearing from each other.

Larry Bauer ([04:13:08](#)):

I studied pancreatitis when I was in school and stuff, but today has just been a total shift in my understanding that can only come from us taking the time to be together for this a half a day with doing nothing but listening. This is a very unusual and rare thing that we have done. And I hope that when we publish the Voice of the Patient report, it will be filled with direct quotes from all of you with the knowledge, with the results from the polling. And this report will be in the public domain available for anyone that wants to learn more about pancreatitis. So I think that what we have done here today is going to definitely move the field forward.

Larry Bauer ([04:13:57](#)):

I was asked to give a summary. There is no way that I can say everything that's been discussed today. So I'm just going to mention a few of the high points that I heard. Please forgive me if there was any high point that you thought was significant that I don't include in my remarks.

Larry Bauer ([04:14:15](#)):

So some of the takeaways for me was that pancreatitis is an incredibly complex disease, that it affects people in many different ways. There is not just one form of pancreatitis. The management is also extremely complex as you've heard. No single one of you has been managed in the same way. So we need qualified medical staff to be able to manage this condition and to work with patients.

Larry Bauer ([04:14:44](#)):

Even though there's many treatments available for symptoms, we still do not have any approved drugs for pancreatitis, which I think is a huge hole that needs to be worked on. Many of you talked about the diagnostic odyssey that you've been on. We heard from some of the kids or even from some of our older folks that are here. They had symptoms early on that were just being written off as stomachaches, as diarrhea... That people are physicians are not catching this early. And then people that were told that they had gallstones went through surgery... It took years sometimes to get to a diagnosis. Of course, one of the main symptoms that everybody talked about was the pain. The pain of pancreatitis is unlike any other pain. We've heard descriptions of stabbing knives, of acid, unlike anything else, that the pain scales are not measuring it accurately. The worst pain of your life and it's like a heart attack.

Larry Bauer ([04:15:52](#)):

It has also impressed me how people are dealing with this all the time. So even if they're not having a flare, that sometimes people are having mild levels of symptoms.

Larry Bauer ([04:16:04](#)):

Treating the pain, people having to take narcotics; longterm use of even nonsteroidal drugs has side effects. Gabapentin, Clonidine, cannabis, Ambien, oxycodone, hydrocodone all these drugs.

Larry Bauer ([04:16:22](#)):

And especially, it got my attention thinking about the use of narcotics in children. I understand that that's what's required for this level of pain, but I also know that that's a serious impact on children's lives and their quality of life. So I do hope that that's an area of future research.

Larry Bauer ([04:16:43](#)):

We've heard a lot about the GI symptoms, chronic nausea and vomiting, going back and forth between diarrhea, constipation; adhesions in the bowel, just all kinds of situations. The fatigue is significant. Over and over again, we've heard quality of life. What I want is quality of life. I think we heard from a couple of people that when you're in chronic fatigue or if you're have fatigue related to having surgery or to a flare, that this seriously impacts your lives.

Larry Bauer ([04:17:23](#)):

I was also impressed by the number of hospitalizations that people have gone through. It's unlike... There's very few illnesses where people are hospitalized as frequently and for some of the lengths of time. It's really almost unheard of.

Larry Bauer ([04:17:39](#)):

Let's see what else... I thought one of the quotes from Gracie was that she "Felt like a science experiment." I thought that really captured what each of your journeys... They actually sound like each of you is a science experiment; that you're working with your physicians and your healthcare teams to try to figure out how to approach this. We heard a lot about the total pancreatectomy procedure, the pluses and the minuses of that. One of the things that stuck in my mind was that I think it might've been Rebecca that said it "Exchanges one problem for another." And then it leaves you with a unique anatomy postop so that postoperatively, if you develop additional symptoms, it's going to take a specialist to know how to treat that because you don't look the same inside anymore. There's issues with scar tissue and other things.

Larry Bauer ([04:18:34](#)):

So I think you're a courageous group. I appreciate everything that was said today. You all have such stamina and grace in this disease. And even like, I remember Eric, you said "I'm one of the lucky ones," but you're still also one of the suffering ones.

Larry Bauer ([04:18:55](#)):

So I wish you all the best and I hope that this meeting really moves the field of pancreatitis and research and treatments forward. So congratulations to you all.

Larry Bauer ([04:19:07](#)):

So to close the meeting, I would like to introduce Jane Holt. Jane was one of the co-founders of the National Pancreas Foundation. Jane, I also wanted to thank her. She stepped in... Someone couldn't attend, one of the panelists, and Jane stepped in to be a panelist at the last minute. So we really appreciated that. So Jane.

Jane M. Holt ([04:19:32](#)):

Hi. So as Larry said, I'm one of the co-founders of the National Pancreas Foundation, but I also really wanted to introduce my other co-founder Patter Birsic who is sitting in the back of the room and

without Patter, this foundation wouldn't have happened. So we have to thank both of us equally. It was definitely a joint effort and a wonderful process.

Jane M. Holt ([04:19:56](#)):

So, wow. You know it's very hard to conclude this meeting because this has just been an absolutely amazing meeting. But I want to say that from my bottom of my heart, I want to thank all of you for being here.

Jane M. Holt ([04:20:09](#)):

I know how hard it is, as James said, how hard it is to tell our stories. When I started to write my story, I had to think back 32 years and suddenly all the things that had happened started popping into my head. I knew I had had a tough time, but I had pushed away a lot of the details. I would suddenly remember being an emergency room rolled up in a ball because my pain was so bad or driving to pick up my kids at school and having to stop and vomit.

Jane M. Holt ([04:20:38](#)):

It was very hard for all of us to write this story and it was even harder for all of us to come and tell the world about it. But I have to say that each and every one of us did it for one reason. We all want something to happen that will change the treatment of patients with pancreatitis. We all want a better life for all of these patients and we're hoping that we were able to help the FDA today and we hope we are able to let you understand more about this disease and it will help you in the future helping us to get a change.

Jane M. Holt ([04:21:12](#)):

We did this as a partnership. Without Mission Cure, Rebecca's Wish and the FCS Foundation, who have brought in patients and have given us assistance and guidance along the way, having them join the cause has been very important to all of us. We want to thank all of the patients who have spent all their time on the webinar and answering our questions because everything that you have done is also just as important as what we are doing here. And please listen to James and if you have thoughts or questions or things that you want to add to it, please you are going to give us an email address, right? Or some place to respond?

James Valentine, JD, MHS ([04:21:49](#)):

[inaudible 04:21:52].

Jane M. Holt ([04:21:50](#)):

Okay. We're going to get information on how to respond back, so please do that. So in ending, again, I want to thank everybody for being here. I want to say thank James and Larry for all of their help. And of course, [Sakpaul 04:22:02], you did an amazing job and the meeting has been fantastic, so thanks everybody.

PART 8 OF 8 ENDS [04:23:15]