



James Valentine ([00:13:56](#)):

Good afternoon. My name is James Valentine and welcome to the Externally Led Patient Focused Drug Development on Chronic Hepatitis B. We're coming live to you today from the Washington DC metropolitan area actually not too far from the US Food and Drug Administration's headquarters in Maryland. To open today's meeting, it is my pleasure to introduce Dr. Chari Cohen who's the senior vice president of the Hepatitis B Foundation. Dr. Cohen, take it away.

Chari Cohen ([00:14:24](#)):

Thank you very much, James. Hello and welcome to the Externally Led Patient Focused Drug Development meeting on Hepatitis B hosted by the Hepatitis B Foundation. My name is Chari Cohen and I am the senior vice president at the Hepatitis B Foundation. It is my pleasure to welcome you to the first ever completely virtual PFDD meeting today. We were honored that the FDA has been in support of us hosting this meeting, and we have been planning since July 2019.

Chari Cohen ([00:14:52](#)):

The goal today is to document the physical, psychosocial, and professional impacts of living with chronic hepatitis B and to hear perspectives on current and future treatment from those who are living with hepatitis B infection. We are at a critical juncture in hepatitis B research. There are 27 potential drugs moving through the development pipeline, and we will likely see the initiation of new clinical trials in the near future. It is imperative that we integrate the voice of those living with chronic hepatitis B into the drug development and clinical trial process.

Chari Cohen ([00:15:25](#)):

In addition to the meeting today, the foundation has been listening to the needs of people living with hepatitis B. In January, we initiated an online survey that has collected data from over 2000 people worldwide. We have also conducted over 25 in depth phone interviews and reviewed thousands of email and telephone consults. Those strategies have informed the design of our meeting today and will help us to build a robust picture of living with hepatitis B from the voices of those most impacted.

Chari Cohen ([00:15:54](#)):

The meeting today will result in a summary report that can be used by healthcare providers, federal partners, scientific researchers, coalitions, academics, and industry, to ensure that the voices of people living with Hep B play a role in hepatitis B elimination, programming, drug development, and clinical trial design.

Chari Cohen ([00:16:13](#)):

I am now going to hand it back over to James Valentine, who will be our moderator for today's meeting. James has worked for the last 12 years as a champion for the patient voice and drug development, starting with his time at FDA, where he was a patient liaison and help to establish the PFDD initiative. Since leaving FDA six years ago, James has been integral to the transition of the PFDD meetings to externally led and has worked with over 20 patient groups to organize and moderate their meetings. The Hepatitis B Foundation has been working closely with James over the past few months to plan this meeting, and we have benefited from his experience and expertise. I know we are in good hands. James, I turn it back over to you.



James Valentine ([00:16:54](#)):

Thank you, Chari. Next on our agenda, we have some additional welcoming remarks from another important person from the Hepatitis B Foundation, Dr. Timothy Block. Dr. Block is the president and co founder of the Hepatitis B Foundation and its research arm, the Baruch S. Blumberg Institute. He is a virologist who changed his area of focus 30 years ago when he learned that his wife had hepatitis B. Today, he is an internationally recognized leader in the field of hepatitis B scientific research and drug discovery and is a thought leader in this field. Dr. Block?

Timothy Block ([00:17:34](#)):

Thank you very much, Mr. Valentine. This is a big day for the Hepatitis B Foundation and for those of us who are concerned about hepatitis B. So I want to start by giving my thanks to the FDA and to Dr. Chari Cohen and Joan Block and all the speakers for making this important and exciting meeting possible and for helping keep our eye on hepatitis B and D at a time when obviously there's great demand for attention elsewhere. And I thank each of you for listening and participating in the middle of this pandemic. I know there are distractions.

Timothy Block ([00:18:09](#)):

So the Hepatitis B Foundation is very proud to help put this meeting together. Patient advocacy and linkage to care is what we're all about. When my wife and I and Janine and Paul Witte started the Hepatitis B Foundation 30 years ago, there were very few options for those who were affected by chronic hepatitis B. It was all about prevention and the use of vaccine at that time. Those are very important goals to be sure, but of little help to those who are already infected. So that's why we wanted new medicines. And that's why we created the Hepatitis B foundation and the Baruch S. Blumberg Institute.

Timothy Block ([00:18:47](#)):

The Blumberg Institute, where I'm sitting right now, is a research organization that was created to find a cure for hepatitis B and D. And we at the Blumberg Institute and other research organizations have been working hard for the past 20 years on drug discovery. So the good news is today, there is a wave of new what are called investigational therapeutics out there. As Dr. Cohen mentioned, there are more than 27 clinical trials or drugs I'm assuming up to clinical trials for hepatitis B right now, five for hepatitis D.

Timothy Block ([00:19:21](#)):

And the really important thing, a neat thing is that these new drugs are covering different mechanisms, not just what we have now. They're immune modulators, capsid inhibitors, siRNAs. Some drugs are given by injection, some orally. And that's why input from people who have hepatitis B and who will be taking these drugs is more important than ever. So again, I appreciate everybody's flexibility and adapting to this format, which by the way, has helped open up the meeting to almost a thousand people, something we wouldn't have been able to do before. And I congratulate the Hepatitis B Foundation for all the effort in putting this meeting together, which I observed from the sideline was quite a bit of work. So now I'll sign off and thank Mr. Valentine again, turn it back, and listen to what the community has to say. Thank you all very much.

James Valentine ([00:20:15](#)):

Great. Thank you, Dr. Block, so much for those remarks, and we're very much looking forward to the rest of this meeting and getting to hear the voices of the patients and their direct caregivers living with

chronic hepatitis B. But before we do that, a key partner in this program, and as you'll hear really the organization that developed this type of this initiative, this patient focused drug development initiative, is the Food and Drug Administration. And so we're pleased to have an official from the FDA here today to provide some opening remarks, which is Dr. Poonam Mishra. Dr. Mishra is the deputy director of safety in the division of antivirals within the office of infectious diseases within FDA Center for Drug Evaluation and Research. Dr. Mishra has been involved in the development and review of direct acting antiviral treatments for chronic hepatitis C. She is also actively engaged in drug development of novel therapies for the treatment of chronic hepatitis B and hepatitis D viral infection. Dr. Mishra, welcome to the program.

Poonam Mishra ([00:21:26](#)):

Thank you, James. Good afternoon, everybody. I would like to welcome everyone. Can you hear me? Good afternoon, everybody. I would like to welcome everyone to today's patient focused drug development meeting for hepatitis B. I want to start by thanking Hepatitis B Foundation for convening this meeting as we recognize we are all in this unprecedented and incredibly challenging time during an ongoing COVID-19 public health emergency. I'm happy to see that so many patients, caregivers, and advocates are able to join us virtually today. Thank you all for being part of this meeting and your willingness to share your experiences with us today.

Poonam Mishra ([00:22:24](#)):

Hepatitis B is a disease of global public health importance. It is a serious and life threatening condition that can have a significant impact on people's lives. According to the WHO, there are an estimated 257 million carriers of hepatitis B virus worldwide, of whom roughly 600,000 die annually from hepatitis B virus related liver disease complications. There are up to 2 million people in the United States living with chronic hepatitis B infection. The implementation of effective vaccination programs in many countries has resulted in a significant decrease in the incidence of new hepatitis B virus infections.

Poonam Mishra ([00:23:14](#)):

Nevertheless, hepatitis B remains an important cause of morbidity and mortality globally. FDA shares the patient community's commitment to facilitate the development of safe and effective therapies for hepatitis B to help millions of people that are affected with the disease. Shortly, we will hear from Dr. Anna Lok, who will discuss the current landscape of treatments for hepatitis B.

Poonam Mishra ([00:23:42](#)):

Currently available options for hepatitis B have benefits and can reduce long-term disease related complications. But these treatments do have limitations and potential risks. Most patients require long-term and often lifelong treatment for continued bile suppression with its associated potential risks of adverse reactions or side effects and emergence of drug resistance. Risk of hepatocellular carcinoma or liver cancer still persist in patients who are virally suppressed even though at a lower rate. And even in patients adhering to relatively long duration of treatment, hepatitis B surface antigen loss and surface antibody seroconversion is infrequently achieved.

Poonam Mishra ([00:24:36](#)):

So even though we have treatments currently available to manage chronic hepatitis B virus infection, we are here today recognizing that there is more progress to be made and more work to be done to further advance the treatment and management of hepatitis B. While FDA plays a critical role in medical

product development, we are just one part of the process. These meetings give FDA and other key stakeholders, including medical product developers, healthcare providers, and federal partners an important opportunity to hear directly from patients, their families, caregivers, and patient advocates about the symptoms that may matter most to them, the impact the disease has on patient's daily lives and patients' experiences with currently available treatments.

Poonam Mishra ([00:25:31](#)):

The meeting will also give us a chance to explore important issues as we look forward to research and development in the area of possible finite duration therapies for hepatitis B. These finite duration treatments are intended to control or eliminate hepatitis B virus infection so that no further medications are needed to maintain health. We would like to hear what specific things patients look for in an ideal treatment to manage their condition. This will help inform the focus of new drug development and future clinical trials. We look forward to the opportunity to listen and learn from your unique experiences living with hepatitis B, a lifelong condition. Having this kind of dialogue is extremely valuable for us to understand how patients view the benefits and risk of therapies for hepatitis B. Your input and perspectives really help us and would also help industry and academia to move the drug development process forward to ensure that new medications meet the needs of people living with chronic hepatitis B infection globally. 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. Together we can achieve hepatitis B elimination. Thank you. And I will hand over to you, James, now.

James Valentine ([00:27:15](#)):

Thank you so much, Dr. Mishra, for both explaining why it is so important that we hear the voice of the patient, particularly in chronic hepatitis B and the importance of the role that it plays for you and your colleagues at the FDA. So we really appreciate not only your participation today, but the participation of all of the FDA officials that are tuning in live to hear, listen, and learn from patients and caregivers.

James Valentine ([00:27:43](#)):

So before we move into the part of the agenda where we will start to hear from patients and caregivers, we wanted to give an overview of chronic hepatitis B and the current treatment landscape. And to do that, we're pleased to have Dr. Anna Lok. Dr. Lok is the assistant dean for clinical research, professor of hepatology, and director of clinical hepatology at the University of Michigan. She served as the 68th president of the American Association for the Study of Liver Disease, also known as AASLD, as well as coauthored the management and treatment guidelines for chronic hepatitis B, both for the AASLD as well as the World Health Organization, truly a thought leader in this space. So Dr. Lok, welcome to the program.

Anna Lok ([00:28:31](#)):

Well, thank you, James, for the very kind introduction. And I would like to also thank the Hepatitis B Foundation for organizing this very important meeting. So I was tasked to provide a brief background on hepatitis B, where we are with the current treatment, and where we will be going to.

Anna Lok ([00:28:52](#)):

So next slide. First of all, how common is hepatitis B? If you look at what percent of the US population affected, it seems to be a small proportion, 0.3%. However, if you look at the absolute number, it's just a

fairly substantial number, which ranges from less than 1 million to just over 2 million, depending on the source of the data. What is most important to know is that many people who are infected do not realize that they're infected. In fact, only roughly one third know that they are currently infected.

Anna Lok ([00:29:34](#)):

Next slide. So what happens when people get infected with hepatitis B? People get an acute infection, which may or may not have symptoms, but many go onto chronic infection, more so if they were infected at a younger age. Among the people with chronic infection, there are dreaded complications of progressing to cirrhosis, liver failure, and liver cancer. We all know that the most effective way of preventing or eliminating hepatitis B is to have everyone vaccinated.

Anna Lok ([00:30:11](#)):

However, as we've heard, among the people already infected, what can we do? Well, antiviral treatment can suppress the virus and prevent progression of the disease to cirrhosis and liver cancer. It also can contribute to reducing the number of infections because by reducing the viral load in these patients, they're less likely to transmit infection.

Anna Lok ([00:30:39](#)):

Next slide. So what do we hope to achieve when we treat patients? Well the best thing is if we can completely eliminate the virus. For those already infected, we want to be able to reverse the liver damage, prevent progression to cirrhosis and liver cancer, improve the quality of life, reduce the symptoms and remove the stigma of carrying hepatitis B infection.

Anna Lok ([00:31:11](#)):

Next slide. Well, what treatment do we have currently? Our current treatments are very limited. They fall into two large groups of drugs, one we call interferon. Pegylated interferon is just a long acting form of interferon, but it has to be given as injections once a week, generally speaking for one year. The problem is that it is associated to many side effects. And after one year of treatment, only roughly 20% of one in five would have a durable benefit.

Anna Lok ([00:31:52](#)):

The other group will be the oral antivirals, which currently are mainly two drugs, Entecavir and two different types of Tenofovir. They're taken by mouth once a day. The good news is that they're associated with very few side effects and they're very effective in suppressing the virus, but they don't completely get rid of the virus. And therefore, most patients require long term treatment because when you stop treatment, the virus would bounce back.

Anna Lok ([00:32:24](#)):

Next slide. How do we know if a treatment is working? Well because we used antiviral treatment, the first thing is to measure if the viral level goes down and down to undetectable. We want to see if the liver disease is getting better. So we want to know if the liver enzymes decrease back to normal. For patients who are also hepatitis B e antigen positive that usually represents an earlier stage of infection, we want that to go from positive to negative. Hepatitis B surface antigen is the primary...

Anna Lok ([00:33:00](#)):

Hepatitis B surface antigen is the primary marker of infection, and we also want that to go away. Ideally, we want to completely eradicate the virus. We want to also prevent progression to cirrhosis and liver cancer and prevent liver failure. Now you can see that indicate a number of checks and the size of the check. That indicates what we can accomplish with current feeds. We do a pretty good job in suppressing virus. Normalizing of the liver enzymes and we can prevent progression to cirrhosis and liver failure, but we don't do as good a job in getting rid of the virus protein, the S antigen, very, very small percentage. We hardly can say that we eradicate the virus. We do, with the current treatment, reduce the risk of liver cancer, but not completely. Next slide.

Anna Lok ([00:34:03](#)):

So, why is it so difficult to completely get rid of the virus? Hepatitis B Virus is a very smart virus. It can integrate into their patient's own DNA. So, once it gets into our own DNA, it becomes very difficult to completely get rid of it. The hepatitis B virus also exist in special form, which we call a CCC DNA. It hides in the liver cell nucleus, where it makes new virus and new virus proteins, and occurring treatment that we have does very little in suppressing this special form of CCC DNA. So, these special DNA live in the liver cells for many, many years. We also know that people chronically infected has impaired ability to mount a new response to hepatitis B. They're not generally immuno suppressed. They can fight COVID-19 just as far as other people, but they just don't manage to fight the hepatitis B virus. Next slide.

Anna Lok ([00:35:12](#)):

So, when we think about curing hepatitis B, we have to ask ourselves, is it really possible? Well, in the purest sense, it may be very difficult. The purest sense, would mean we get rid of every trace of the virus, including a virus that has already been integrated into the patient's own DNA. That probably is going to be very, very difficult, but we know, talking about a functional cure, which essentially means that we silence the virus, push it into a corner, keeping it in a corner so the virus is not completely gone. By that we mean that patients with hepatitis B surface antigen and I suppose hepatitis B virus DNA negative. After we finished the course of treatment, we stop the treatment and the virus still stays in a corner. Now, with current treatment, we can accomplish that, but in very small proportion. Actually, even without treatment, we sometimes see that the virus burns out and this functional cure can be accomplished in roughly 1% of patients every year.

Anna Lok ([00:36:29](#)):

So, sometimes jokingly tell the patients, "If you live to a hundred years, then a virus might be gone." But what was the current treatment, with interferon one year treatment, roughly five to 10% of patients might get there. With oral treatment, it takes longer. Even after five years of continuous treatment, roughly one to 8%. So, the goal of the new treatment is to push this up to maybe 30% at least, and with a short duration treatment, maybe one or two years. That's our call. Now whether we can get there would still requires a lot of hard work, but we know that if we can achieve functional cure, there's a decreased risk of liver cancer, and when patients become surface antigen negative, it removes the stigma of hepatitis B infection. Next slide.

Anna Lok ([00:37:22](#)):

So, what are the steps? But right now the current treatment is actually just blocked once they're in a hepatitis B lifecycle. Now, if we can get additional drugs, we might be able to block two or more steps in hepatitis B virus lifecycle, but we will also need to block the surface antigen production, and then

boosting immune response. If we do it, either step, or simultaneously, we might be able to achieve a cure. Next slide.

Anna Lok ([00:37:57](#)):

Well, I don't expect that some of you would read through the details, but this really shows that the hepatitis B virus life cycle is complicated then many, many different steps. We currently have treatment of the interferon and oral antiviral in a Brown box. So, we stopping just two steps in the virus by cycle, but the new boxes indicate the new drugs that are currently in clinical trials that have other steps in the virus life cycle. So. If we're able to pick the right combination, we might be able to achieve a better suppression of the virus and also reduce the virus protein production. Next slide.

Anna Lok ([00:38:44](#)):

Now, before I finish, I also want to briefly mention the hepatitis B virus or the Delta virus. This is a very unique virus. It only happens in patients with hepatitis B, and worldwide, it's been estimated that between 5% to 30% of people with hepatitis B also are infected with the hepatitis D virus and B + D = bad. It really is bad because increases your risk of cirrhosis and liver cancer. It's also bad because we currently have no approved treatment. Interferon has been shown to have some benefit, but not very high proportion of patients, and the oral antivirals [inaudible 00:39:28] are not effective, but what is so exciting is that some of the new drugs that are currently developed for hepatitis B may also be effective for the Delta virus by blocking virus entry into liver cells, and also by decreasing hepatitis B surface antigen production. Next slide.

Anna Lok ([00:39:50](#)):

So, there's a lot of excitement. We've heard that many new drugs are in development, but they're also a lot of challenges because the current oral antivirals are very safe. So, we need to make sure that these new drugs are just and safe. Not only do they need to be effective, but they need to be just and safe. The oral drugs are very convenient. You swallow a pill once a day, and these are drugs that are going generic so the cost is coming down. So, the new drugs, if they work better, they should also be convenient and they should not be a lot more expensive because we need these drugs to be accessible to patients. We need to make sure that they can be given to patients, whether they have milder of the disease or whether they have a decompensated state of cirrhosis, because the current oral antiviral drugs is so safe that you can use it in patients with liver cancer with advanced cirrhosis, and we need the new drug to be just as applicable.

Anna Lok ([00:40:54](#)):

The challenge, and this is the reason why we have adopted measure from FDA is how do we develop the most efficient way of testing these new drugs? What patient population should we study it in? What would be the right study design that can give us the answer that when it becomes available in the general population that it will work just as well? To have a patient perspective, how we also would need your help, because when I'm asked to test new drugs and I talk to my patients, many of them are very scared, and say to them, "I have a treatment that works very well. That is safe and is very convenient. So, I really take the risk of testing something new that you're not sure?" Well, if no one is willing to test new drugs or never get an answer. And so, we also need to figure out what would motivate patients to be willing to test new drugs so that we can make advancement compared to what we currently have.



Anna Lok ([00:41:58](#)):

And I'd like to thank Hepatitis B Foundation, again, for inviting me, and I look forward to hearing your perspective. Thank you very much.

James Valentine ([00:42:10](#)):

Great. Thank you so much, Anna Lok for providing that clinical overview of hepatitis B and framing some of the key issues that we want to hear from today. So, now we actually turned to that part of the meeting where we get to hear from you individuals living with hepatitis B, as well as the direct caregivers, family members of those persons living with hepatitis B to share your experiences and your perspectives on living with this condition, and as was forecasted, also understanding your current treatment approaches and what you would be looking for from future treatments. As well as what you would consider in making decisions or out about participating in clinical trials. So, as you've heard, and might have a sense of now, patient focused drug development is really a more systematic way of gathering patient perspectives on their condition and on available treatments.

James Valentine ([00:43:08](#)):

As you heard from FDA's Dr. Mishra, your input can really help inform the agency's understanding of chronic hepatitis B infection to help inform drug development and review, not only for the agency, but also for other stakeholders like academia, as well as drug developers. I would note that this really is a unique opportunity for your voices to be heard, and in fact, many patient communities have yet to have such an opportunity. I can tell you that FDA has held 26 of its own patient focused drug development meetings. Today marks the 33rd externally led patient focused drug development meeting, and due to the ongoing COVID-19 pandemic, this is the first fully virtual patient focused drug development meeting of any kind. So, we're very eager to have this truly be an interactive session and I'm going to share with you a little bit of an overview of how we're going to accomplish that together today.

James Valentine ([00:44:07](#)):

So, again, today's meeting is intended to be fully interactive with you, those individuals living with hepatitis B and caregivers that are tuned in today. We're going to break up today into two main topics. First, we're going to be exploring the patient and caregiver experience with living with hepatitis B, and the impacts that living with the disease has on your life daily. We're then going to build in a second discussion on, once we've understood a bit of the burdens and impacts in your life, to then explore the various treatment approaches that you have available to you. And get a sense of how well those are working, what might be the downsides, as well, we'll be asking you about your preferences for future treatment and about participation in clinical trials.

James Valentine ([00:44:58](#)):

So, within each of those two overarching discussions, we have a number of ways that we're going to be engaging with all of you, and they're really broken down into three main methods. First, we're going to be hearing from a panel in each of those two topics panel consists of patients it's and caregivers of individuals with hepatitis B. These panelists have prepared statements that will be displayed, that help set a good foundation for the discussion. They're going to be sharing their own personal experiences. They were selected to help represent a range of different experiences, and what we hope to do is use those panelist statements as a springboard to launch into a broader discussion. With the rest of you that are following long live, to help build on that, understand maybe things that you have in common with what the panel has shared, other experiences that weren't shared by any of our panelists, to really help





round out the day. So, once we've completed those panelist presentations, we're going to broaden our discussion with you through some polling questions.

James Valentine ([00:46:09](#)):

So, we'll be using a polling software, and I'll describe how you'll be able to do that, but you'll actually be able to use your phone. Your cell phone, if you have it right in front of you, you can open up a new web browser on your computer, and you'll be able to follow along, and answer and provide responses to the different polling questions that we have for you. And we'll be going to those polling questions throughout each of our different discussions to help get a sense of the different experiences and preferences that we have, but then we really want to drill down and get some of your personal experiences, hear some stories from you about those experiences. And we're going to do that through an actual live conversation today. You can think of it almost as like a tele town hall. I'll be posing some discussion questions to you, and we'll ask that if you have an experience or a perspective that you would like to share, we'd like for you to either telephone in and I'll be providing that phone number when we get to that time, and you'll be able to call in and actually speak with me and to the audience live.

James Valentine ([00:47:19](#)):

There's also an opportunity to provide written comments in real time. You'll see below your live stream on the webpage, that there's a little comment form that you can fill out, and we're monitoring those comments live, and I'll be sharing some of those throughout. But I should note that we may not be able to get to all of those written comments today. However, we will be capturing all of those, and importantly, all of the input from today will be taken into account when the Hepatitis B Foundation puts together its voice of the patient report, and this is the summary report that will capture all of the input from today and from some of the other ways that the Hepatitis B Foundation has been collecting the patient perspective. We'll also be extending the comment period. So, we'll keep that comment box open until the end of the month. So, June 30th. So, just know that today is not necessarily your only opportunity to provide input.

James Valentine ([00:48:17](#)):

If you walk away at the end of the day, feeling that there was something left unsaid, maybe you think of something later after having participated in the meeting, or maybe you're watching this recording on demand, you weren't able to attend the live meeting. If you watch this and you have a comment to share before June 30th, we would love for you to provide those comments in writing. So, before we get to our first set of polling questions, which are some demographic polling questions to get a sense of who we have in the audience, I want to provide a few ground rules for today. So, first and for most, this is a unique and important opportunity for you all in the hepatitis B patient community to share your perspectives. So, I do encourage you, both individuals living with hepatitis B as well as direct caregivers and family members, that you're a parent, a spouse, a child, anyone that has that close caring relationship to please participate in the polling questions. Please call in, please submit written comments.

James Valentine ([00:49:23](#)):

We are limiting this input to individuals with hepatitis B and their family members or direct caregivers. The FDA drug developers, clinicians, and researchers are here to listen. So, they won't be chiming via those different methods. They're going to be hearing the outputs and listening and learning. I will note that the views expressed today are inherently personal. We're asking you questions about your personal

experience with your condition, and we understand that the discussion may get emotional at times. So, we just ask that, as you're participating, you please respect one another. Respect is paramount for the success of this meeting, and to that end, I do ask that you try to be focused and concise in your comments so that way we can hear as many voices as possible throughout today. So, thank you for bearing with me while we just oriented you a little bit to this meeting format, but let's get to it.

James Valentine ([00:50:20](#)):

If we can go to our polling questions. This is going to be the time for you to pull out your cell phone, open up that new tab in your browser and type in [www.PollEV.com/HepB](http://www.PollEV.com/HepB) or H-E-P B. You can see this URL listed at the top of the slide that is being projected right now. So, I'll give you a moment to go ahead and enter in that website, pull out your phone. Again, we're asking just patients and their direct caregivers to respond to polling questions today. So, while everyone's doing that, I'll go ahead and read our first question. We want to know if you are either a person living with hepatitis B or if you're a family member or other direct caregiver of someone living with hepatitis B?

James Valentine ([00:51:16](#)):

So, you can enter your response options either A, if you're a patient, or B, if you are a caregiver. So, we'll give you some time, knowing this is the first polling question, to get oriented to the polling technology. Again, you can do it on your cell phone. You can do it in a web browser. You will be going back to this throughout the day, and I will remind you, as well as remind any new viewers that we might have on how to do this, but here we want to get a sense of the breakdown of our participants in terms of people living with hepatitis B versus those that are representing individuals with hepatitis B as a caregiver or family member. So, we'll give you just a few more moments to go ahead and respond to this. Some of these demographic polling questions will be, hopefully, a little simpler, and then we'll be asking you some harder questions to really consider later in the program, but here we're, we're hoping just to get a sense of who it is that we have represented today.

James Valentine ([00:52:37](#)):

So, while the final kind of polling results are coming in for this first question, it looks like around two thirds of our participants are persons living with hepatitis B and about a third of our participants are caregivers and family members. So, thank you. Can we go to our second polling question? So, here and throughout, we're going to be asking questions. They're framed for the patient, however, we would like if you're a caregiver to respond to these questions on behalf of the person living with hepatitis B. So, here, the question is where do you currently reside? Or if you're a caregiver, where does the person living with hepatitis B currently reside? More likely than not, that's going to be the same place if you're a direct caregiver, but the options are A, the United States, B, Europe, C, the Middle East, D, Africa, E Asia, F, Australia, G, Canada, H, South or central America, or I, some other not listed on this slide. So, again, please just let us know where you currently reside. We'll give you just a few more moments. It looks like, perhaps not surprisingly, we are by and far, most represented in the United States with about just over 80% of you being located in the United States. However, we do have representation from Europe, Asia, including India, Australia, and Canada, and we can go to our third demographic question. So, here we would like to know how you identify, or if you're a caregiver, how the patient that you care for identifies. The options are A, male, B female, C, gender variant or nonconforming, or D, if you prefer not to answer. So, please respond with how you, if you're a patient, or if you're a caregiver, of the patient that you care for, how do they identify? A, male, or B, a female, C, gender variant or nonconforming, or D, if you prefer not to answer. Looks like results are still trickling in. At this moment it seems a pretty

well distributed between male and female with no one representing a gender variant or nonconforming or anyone that would prefer not to answer.

James Valentine ([00:55:50](#)):

Okay, if we can move to our fourth polling question? So, this question is, how old are you? Or of course, if you're a caregiver, how old is the patient that you care for? The options are A, younger than 18 years, B, 18 to 30 years, C, 31 to 50 years, D, 51 to 60 years, or E, greater than 60 years of age. Again, we're asking how old are you the patient, or how old is the patient that you care for? All right, we'll give you just a few more moments to get into your response here. As it currently stands, it looks like our groups that are most represented our patients, the age 31 to 50, followed by those aged greater than 60. Though close behind that are those aged 51 to 60. We do have some representation from those in the patients that are aged 18 to 30, and as it stands, we have no patients represented that are younger than 18 years of age. Okay, if we can go to our next polling question?

James Valentine ([00:57:21](#)):

So, here we want to get a little bit of a sense in this, in our next polling question which will close out our demographic polling. A little bit of your experience with chronic hepatitis B. So, here we want to know when were you diagnosed? Or the patient that you care for, how long ago were they diagnosed? Less than one year ago for A, B between one and five years ago, C, six to 10 years ago, D, more than 10 years ago, or E, if you can't remember how long ago you are, the person you care for were diagnosed with chronic hepatitis B. I'll give you just a few more moments to do the math backwards a little bit and answer this question for us. As it stands, it looks like the greatest majority are those that were diagnosed more than 10 years ago, about three fourths, rather, with that experience. However, we do have just under 10% that were diagnosed less than a year ago. Same for between one to five years, and then a few in the six to 10 year range. No one is reporting that they don't remember.

James Valentine ([00:58:41](#)):

Okay, if we can go to our final demographic polling question? And so here, we would like to get a sense of your primary reason for you or the person you care for being tested for hepatitis B in the first place. So, please review this and select the one option that most closely resembles your primary reason for being tested, which is A, there was a free community screening event, B, you were tested during pregnancy, C, a family member was diagnosed with hepatitis B so you were worried that you may be infected, D, you were having symptoms, E, your doctor recommended it, F, you donated blood and received a letter that you had tested positive, G, it was a pre-work requirement, or H, some other primary reason for being tested that's not listed on this slide. Give you just a few more moments here. Please select the primary reason that you or your loved one was tested for hepatitis B. We can see already that there's a great deal of people listing other. So, there clearly is a wide range of reasons that people are tested for hepatitis B.

James Valentine ([01:00:05](#)):

Of some of the options given, the one with the highest proportion is a family member was diagnosed. So, you were worried. After that, it looks like because your doctor recommended it. However, there's good representation across each of these different reasons. Perhaps with the least common reason, being that there is a free community screening event, but again, I think these results really show that there's a wide range of primary reasons for being tested. So, with that, we're going to conclude our demographic polling, and thank you all so much for participating in that. Again, we'll be coming back to

this throughout all of our different discussions throughout today. So, now we're going to move into our first topic, which is living with chronic hepatitis B and a discussion of the symptoms and disease impacts. And so, in this session, we're going to be first hearing from a panel, but then have a discussion with all of you on a number of topics related to this.

James Valentine ([01:01:06](#)):

We're going to want to understand the different physical symptoms as well as disease progression and how that has impacted your daily life, and what are the most significant impacts? We're going to want to know what those impacts were in terms of your personal, your social and your professional life. Not only do we want to know, in this topic about what is currently most burdening you in daily life, but also what you're most worried about in terms of living with chronic hepatitis B, and perhaps thinking a little bit about your worries for the future. And then, an important topic in this community I know, is we wanted to have a discussion about any feelings of stigma or discrimination. You may have experienced as a result of this. And so, to get us kicked off on this topic, we have a panel of members of your community who have been very gracious in being willing to share their stories to help us get started here.

James Valentine ([01:02:06](#)):

And so, to lead us off today, we have a panel made up of Bright, David, Alice and Randy. So, we'll go ahead and get it started with Bright's statement first.

Bright ([01:02:21](#)):

The physical impact of hepatitis B, my experience. My name is Bright Ansa. I was born and raised in Ghana, West Africa for most of my life. I immigrated to the US in 2007. I currently live in Maryland. My journey with hepatitis B started in 2014. One of the first symptoms I experienced was fatigue, which is still impacting me today. In January of 2014, I noticed that I was feeling more tired than usual. I did not take it seriously because I was taking some college classes, working full time at a physically demanding job and serving in the AMA reserves at the same time, but the fatigue continued and the frequency began to affect most of my days. I consulted with my doctor about my concern, and that is when I was diagnosed with chronic hepatitis B. I wake up every morning tired, even before I try doing anything. Nothing helps not even 12 hours of sleep. I would still wake up feeling even more tired. Some days I wake up feeling a little better thinking I can get something accomplished, but guess what? I crash only an hour or two later.

Bright ([01:03:31](#)):

So, occasionally it feels as if something zaps or sucks the energy out of me. I immediately feel drained and have to find a bed to lie down or somewhere to sit. In addition to the chronic fatigue, I also have unexplained chronic muscular pain. I experienced this pain in my lower back, neck and on top of my shoulders to my upper back. No one medically really knows what is causing this pain. Many medical tests have been done, but the results have all been negative except for hepatitis B. The pain and the fatigue usually happen in tandem, and make it extremely hard to get anything accomplished. On days that I experienced this pain, the muscles around my neck, shoulders, and back will tighten up, ache and feel as if I have a hard road running along my spine. It is hard to drive some days, cook, or even to help with Clinton in and around the house, because most pain medications can be tough on the liver, I'm limited to what I can safely take. For me the physical impact of hepatitis V has been deliberating and huge.

Bright ([01:04:34](#)):

I've been unable to work since 2016 because of the fatigue and muscular pains. Yet I've been told that my condition is not serious enough, that I'm too young and should learn to adjust. I've been denied social security disability multiple times. I have been living at a friend's place for the last three plus years as I could not afford to keep my apartment since I was unable to work. I love playing sports but unfortunately I have not been able to do that anymore. In the process, I've also been diagnosed with asthma. With all this combined, I have not been able to play tennis, run, hike, or ride a bicycle for a while. My fatigue and pain have forced me to live a sedentary lifestyle, which is not like me at all. It is hard to tell how it is going to be from one day to another. So, I live by the moment. I have been struggling a lot these last two years because of my symptoms. They seem to have become less and are affecting my daily life more now than they did in the past years.

Bright ([01:05:33](#)):

I love cooking, but it takes time and my body just does not cooperate well. I'm not able to hang out with friends as much as I wish. So many times I make appointments to meet up with friends, but then I have to call and cancel because I do not have the energy to get out of bed, let alone to drive. I do not participate in any school extracurricular activities mostly because of chronic fatigue and pains. On my best days, I can drive to my medical appointments in Baltimore-

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

Bright ([01:06:00](#)):

My best days, I can drive to my medical appointments in Baltimore alone, or cook a complete meal at home. On my worst days, I can barely do simple tasks, such as dead and out of bed and walk into the bathroom or kitchen to get something to eat or drink. I'm currently studying for a degree in social work. And as part of the program, I'm required to do an eight month field placement starting in September of this year. I've been worried and concerned as to whether I can do it. At school, I've relied heavily on accommodations to get to this point. But my field place accommodations may be limited. I will need to complete 16 hours each week and I worry that even with any accommodations, this is going to be a tough eight months for me. Currently, it is more difficult not knowing and not having control over which days will be good or bad. It just happens.

Bright ([01:06:51](#)):

This has become a new headache and stress. It is an exhausting life when you are experiencing something this difficult. Feeling like you are the only person that fully understands what is going on, while some people around you or even those in position of authority like school instructors, doctors, government officials, or work supervisors think that it is all in your head and you are just being lazy. It robs you of the little dignity you have left. A million times, I've wished I had never had this virus, that it will live my body and never return again.

David ([01:07:33](#)):

Hello. My name is David Urick. I'm 31 years old and live in Ann Arbor, Michigan. I was adopted from Seoul, South Korea when I was five months old. I've lived with hepatitis B for most of my life, as my biological mother transmitted the virus to me when I was born. My adoptive parents knew about my hepatitis B status when they were given my adoption file, and in a huge show of unconditional love, they adopted me regardless and educated themselves as best they could about the disease. Throughout my

childhood, I was raised like most other children. The main difference was that I was taken to the doctor's office more often than most kids were and received blood draws on a semiannual basis. Not knowing any better, I never questioned these blood draws and I didn't talk about hepatitis B until years later. Thinking back on those times, it's extremely difficult to imagine my life without actively knowing about my hep B.

David ([01:08:23](#)):

When I was 13 years old, I remember being taken to the doctor by my parents one day after school. I cannot remember much specifically from this day. It seems like a series of blurry images with muffled audio. What I do remember is that I was given a crash course on hepatitis B and what it meant to be a chronic carrier. My body shivered in fear and confusion. My arms and legs went numb and I started to sweat while the doctor explained that it could be transmitted through blood. I remember feeling very disappointed when I was told to stay away from alcohol. I was in eighth grade at the time. I had a pretty diverse friend group and was becoming interested in dating. Drinking, sex and parties were starting to come up in conversation and I was excited about the prospects of my teenage years. I felt fairly comfortable in my skin, especially for being a teenager. That all changed after that day.

David ([01:09:10](#)):

When I got home from the doctor's office, I couldn't help but feel extreme dread about returning to school. How would I keep this secret and what if someone found out and told everyone? Would I be ostracized? How in the world would I tell any of my friends about this? The possibility of transmission and fear of others' reactions to my Hepatitis B, was the most impactful in my life. Having a chronic transmittable disease has led me to be very selective about who I tell my status and in what context I tell them. I waited until I was 18 years old to talk about my status with any of my friends. And it wasn't until my twenties, that I could talk openly with therapists about fears and worries related to hep B. You can never know exactly how someone else will react to you and that is painful to think about sometimes.

David ([01:09:51](#)):

I've made new friendships throughout my life where I've felt completely lost as to how to talk about hep B or even whether to talk about it at all. I've avoided potential friendships because of fear of rejection. Even with old friendships, it's been very difficult sometimes to explain the basics of this illness without making people very anxious. Treading the line between managing who knows about my status and how much I tell them is been very difficult for me. Dating has been a turbulent practice most of my life. I'm so grateful to have met a wonderful partner and best friend last year. But before that, the dating world was especially daunting for someone with a transmittable disease. When and how do I tell them about my status? How will they react? These are questions that don't have the same answers depending on who you are talking about.

David ([01:10:33](#)):

People have different expectations for things and I've learned throughout my experiences with dating, that it's different for different people. Clear and honest communication from my end, it seemed to work out the best overall. Positive depictions of hepatitis B in the media are few and far between. I've never seen anyone positively talk about hepatitis B in any commercial, movie or TV show I've ever watched. Hep A, B and C might as well be the same disease. Some people look at others with these diseases and think of them as less than human. I blame this on a glaring lack of empathy and sex education in the United States. If someone only it relates the word hepatitis with dirty filthy and disgusting, it's hard to



reeducate from there. Being on medication and not knowing if I'll be able to stop taking it is also a cause of worry for me. I've been taking Tenofovir Alafenamide or TAF since June of last year.

David ([01:11:24](#)):

I had gotten a liver biopsy done a few months earlier and was taking it another drug until switching. TAF is working very well in my body so far. My viral load has been reduced to undetectable levels, which gives me some relief knowing I'm potentially less contagious. Well, I do take medication. It does cause me anxiety from time to time. I don't know if I'll ever be able to stop. For now the side effects have been minimal but what if that changes? I still have a lot of good years ahead of me and thinking about taking this pill for the rest of my life doesn't exactly make me happy.

David ([01:11:55](#)):

I hope someday I can think of stopping the medication as a real possibility. Physically, my chronic hepatitis B has gotten better over time. The fear and anxiety I feel do vary quite a bit. Talking about concerns with my doctors and loved ones make me feel empowered but I don't always have that strength every day. Since I've gotten involved with the Hepatitis B Foundation, I can see a glaring lack of funding and need for more awareness. I can only hope that someday I can look and not see.

Alice ([01:12:29](#)):

My name is Alice. I live in Sacramento, California, and was born and raised in Hong Kong. I grew up in a traditional Chinese family where talking about illness is taboo. My parents always remind us not to talk about illness because it can change your wellbeing. When we were not feeling well, home and herbal remedies always came first. We could only visit a doctor if the illness get worse. As I recall, my family tends to feel shame for having a chronic illness. And we were afraid of being isolated from friends and relatives around us if they knew. So we usually did not disclose our health condition, always keeping it a secret among ourselves.

Alice ([01:13:29](#)):

I was first diagnosed with hepatitis B during my first pregnancy in the 1980s. I was shocked that I have been living with hep B and didn't know. I recall an incident that my friends has noticed jaundice in my eyes when I was a teenager but my parents did not express any concern and told me the jaundice will go away in a few days and it did. I then learned my mom also had the virus and that was probably transmitted to me at birth. My mother expressed that she was ashamed to tell me because hep B has been stigmatized throughout history. Her lack of knowledge about hep B put all of her children at risk from mother to child transmission and serious complication in life due to chronic hepatitis B. I also learned that some of my siblings have chronic hep B.

Alice ([01:14:41](#)):

My two children were protected from hep B infections because I was cared for by a dedicated OBGYN to provide full protocols to prevent mother-to-child transmission. My children received the first dose of hep B vaccine and immunoglobulin shot at birth. Then they completed the three-shot series. They tested negative for hep B at one year of age. As my oldest brother die of liver cancer in his middle age, I did not want to suffer the same fate as my brother. When my family doctor informed me that I have a 25% chance of getting liver cancer, I felt right distressed and depressed about the unknown in my future. I pursued if there's anything that I can do to slow the liver damage, to live a normal life without being discriminated against or isolated. Medications can help and stop the disease to progress so that I would

be able to raise my children to adulthood. My doctor, however, did not recommend any treatment or use of medications. I was monitored by blood tests every six months and ultrasound of the liver annually.

Alice ([01:16:20](#)):

So far, I have not taken any medications for hep B treatment. I have opted to adjust my lifestyle in the hope to build a strong body to fight against the chronic infection. I have been thinking positively that I can overcome the burden of a chronic hepatitis B infection by doing the right thing for myself. I believe all the activities have worked to improve my liver health because I have feel stronger and less fatigue. I am happy to know that my viral load has remained low. And my liver ultrasound continue to be normal. As a parent, I chose to be open with my family and my children on health related matters. I became involved in raising awareness in the local Asian communities. I believe knowledge is power. As my children attended Chinese language school during weekends, it gave me the opportunity to educate some parents about hep B facts, myths, vaccination and testing.

Alice ([01:17:48](#)):

To this end, it helped me to overcome the fear of isolation and focus on the positive because I wanted everyone to know that hep B can be prevented by testing and vaccination. Although we continue to do outreach to promote hepatitis B prevention in the community, I have not disclosed my liver status openly until 2018. At that time, I participated in a training to become a hep B storyteller in the #justB Campaign sponsored by the hep B foundation. During the three day storytelling workshop, I was empowered by the experience of engaging with other people living with HPV and family members impacted by the disease and seeing how everyone was able to share their stories without hesitation of feeling of shame. The #justB workshop sparked amazing changes in me to openly discuss my chronic hep B. I was full of hope that living with happy is not disgraceful and that I am grateful to be part of the hep B community working to find a cure and end the virus.

Randy ([01:19:31](#)):

Hello. My name is Randy Pendleton. I live in Port Orchard, Washington with my wife of 26 years. I met her while I was stationed in Anjeong-ri, South Korea in Camp Humphreys, from 1993 through 94. We met, fell in love and got married there. Then we moved on to England where we had two sons. I don't have hepatitis B but my wife does and my youngest son does. My deepest hope is that someday there will be a cure for hepatitis B. Thank you for this opportunity to share our family story. Both of our sons were vaccinated for hepatitis B. I wish I'd known that it wasn't necessarily foolproof. We just thought it was going to be okay. My wife contracted hepatitis B through the birthing process. All of her siblings have hepatitis B. In 2006, my wife's mom passed away. It was shortly after that that she took testing very seriously and found out that she needed to take both Entecavir and Adefovir to keep her levels in check. She's doing good right now with her levels and the doctor says her levels are almost nonexistent but she still takes the medicine today.

Randy ([01:20:47](#)):

Then in sixth grade, we had both sons tested for hepatitis B. Her oldest son showed signs of hepatitis B virus but was not sick and did not require medication. Our sons entered eighth grade and upon that timeframe, our youngest son showed signs that he was interested in attending the Naval Academy. This is an extremely difficult task to get into the Naval Academy. It requires exceptional grades and strong leadership qualities, but he started his journey at that time. His dream started. And at that point, he

really was working hard on his grades and he showed signs of interest in the local high school's Navy Junior ROTC program. They allowed him to start attending in ninth grade even though he still was in junior high. Our son excelled at the Navy Junior ROTC program. And then in his junior year, he was one of only three cadets who were selected to attend the Northwest Navy Junior ROTC Academy. Later, he eventually secured his nomination and we accompanied him to Maryland, where we saw him swearing in a grand ceremony. It was amazing. And then he was off for eight weeks of an extreme intense bootcamp.

Randy ([01:22:05](#)):

Phone calls were few and far between. We were already making plans to return to Maryland to see the graduation from basic training and as excited as they were to see him swear in, we were about to experience the absolute opposite feeling and have our lives rather complete changed. He called one day, we were so excited to talk to him. We were telling him of all our plans to come see him and bring his grandfather to see him. We were going to be so excited to be there for him. And he said, "Dad, don't get too excited about that." He says, "I pop solid for hepatitis B." We were in complete disbelief. We reminded him that he had tested negative for hepatitis B back in sixth grade. Later, that week, he had some more tests taken at Bethesda Naval hospital and they confirmed that result. He did in fact have hepatitis B. We later found out that you can't serve in any branch of the military, officer or enlisted, if you have hepatitis B.

Randy ([01:23:06](#)):

At this point, my wife was beside herself. There's been nothing I can say to take the pain away. She blames herself for killing her son's dream. I tell her that's not true and it's not for you to pick up. I hope no one ever has to go through what we did. The disappointment is devastating and we continually live with it. I believe that time does heal all wounds, but for us, it's just hard to move on. The other last year would have been our son's graduation from the Naval Academy. I just happened to be channel flipping that year, come across the graduation ceremony, where the guys were throwing their hats in the air, I just hung my head and cried. To think what could have been, is a constant thought that we have a difficult time letting go of. When others speak about their kids as accomplishments, we just find it difficult to participate in that kind of conversation or even be around others who would like to brag about their kids.

Randy ([01:24:05](#)):

Not necessarily because that's wrong, but if we share our story, it would be like pouring cold water on the conversation. We don't have very many friends and we don't go out very much. My wife doesn't even speak to her family all that much back in Korea. Although that has changed recently due to the coronavirus and I have been excited about that prospect. Not only for her, but for I as well. That's one positive thing that's happened as a result of this pandemic. Later, we had our whole family tested again for hepatitis B. At that point, we found out that our oldest son who we thought had the hepatitis B no longer shows any signs of hepatitis B whatsoever. And our younger son still has hepatitis B. The only explanation for that is that the test that we had the kids take back in sixth grade was somehow mixed up. After this, our son showed an amazing degree of maturity and decided to go back to his Naval Academy Preparatory School to finish his associate degree. After graduation, he came back home, he looked for work around the area but found none.

Randy ([01:25:14](#)):

He decided to move back to Alabama where he now has moved in with some other friends of his and he works at a local hospital where he's been handpicked to set up a surgical ward with supplies. He's working really hard to try to overcome the things that have happened to him and we're very proud of him. How amazing would it have been to have a pill, an injection, or some other kind of treatment that my son could have gotten at the Naval Academy? He could've continued on and he would have been a Naval officer today. Please put more effort, more resources into curing hepatitis B. So many lives depend upon it. Recently, we learned that my wife's brother had a portion of his liver removed due to hepatitis B and the effects of it. I thank you for this opportunity and I just hope that someday there will be a cure.

James Valentine ([01:26:21](#)):

I want to thank our panelists for being so brave to work and think about their personal experiences and putting that down onto paper and being willing to share that with our audience today. So truly Bright, David, Alice and Randy thank you so much for doing that.

James Valentine ([01:26:40](#)):

We're now going to continue this conversation about living with chronic hepatitis B. This is our first opportunity to do so with our live audience today. So for those of you that are following along, this is your chance to telephone in or submit written comments in the submission box below the livestream as I present various number of different discussion questions that we'll be working together today. You'll also see on the screen a number of familiar faces. Our panelists, as well as a couple of other individuals from your community that will also be participating in this live conversation. So if I could first have our discussion questions. So today these are the questions that you've just heard our panelists speak to but I'll also be asking you about. We are going to be asking you, how have the physical symptoms or liver disease associated with your chronic hepatitis B impacted your daily life? And importantly, what are the things that you view as being the most significant impacts in your life? Related to that, we want to know what the impact of your diagnosis and your experience with the disease has had on your personal, social and professional life. Related also is what worries you have about living with chronic hepatitis B, knowing that while you may have many day to day impacts, there may be some things that are in the future that are on the horizon that may worry you and that you may want to share with us today.

James Valentine ([01:28:23](#)):

And then I think a cross cutting element that certainly this community experiences is the stigma and discrimination as a result of this diagnosis. And that may be related to many of these topics we're talking about. So we'll certainly want to hear from all of you about this. I want to take this time to give you the phone number that you can call. If you have a comment to share related to one of these four questions, that number is +1 703-844-3231. Again, that's +1 703- 844-3231. So we will actually now start with our first discussion question, and I want to start with our discussion panel that we have. This question is of course, "How have the physical symptoms or the liver disease itself associated with your disease impacted your daily life, particularly what you think might be the most significant impact?" So I'd like to start with Joan and Joan, you were not one of our panelists, so perhaps you could just start by briefly introducing yourself to our audience today and then sharing your thoughts about the physical symptoms that have most impacted your life.

Joan ([01:29:45](#)):

Thank you, James. So my name's Joan Block. I'm one of the co-founders of the Hepatitis B Foundation. And two years ago when I retired as executive director, I publicly shared my story about living with hepatitis B. And as you heard in the introduction, that's the reason my husband, Tim Block and Paul and Janine Witte and myself started the foundation. But with that said, I would like to say that fatigue has been the primary symptom for living with chronic hepatitis B. It's something I didn't realize until we started hosting patient conferences and I was communicating with patients through email and telephone. But as a child, my mother always said I was lazy because I needed to sleep a lot. As a young woman, I thought it was the stress of having children, working full time, that I was just a rather low energy person. And now as a 60 year old, I feel like, well now it's my age. But in reality, having spoken to literally thousands of patients, I realized fatigue is probably the defining characteristic of living with chronic hepatitis B.

James Valentine ([01:30:52](#)):

Thank you, Joan. And I'm just curious if you could tell us a little bit about maybe how that fatigue may have changed over time in your life. It's kind of been lifelong but is it something that you know is ever present or do you for example, have better days and worst days? And is there anything that you've noticed that might impact that better versus worst day? It might predict that or is it completely unpredictable?

Joan ([01:31:24](#)):

Well, of course, as a child you have lots of energy, although I didn't have as much as the other children. As a young woman, you have to do what you have to do. You have children to raise, you have a husband to care for. I had a job as a nurse working, but I think the biggest impact is that I don't feel I was as productive as I could have been. After I worked, I was too tired at night to bake cupcakes for the kids, for their birthdays. I wasn't willing to participate in committee meetings because I was just too tired. And then when the kids went off to college, I did work 10, 12 hours a day but then I would crash over the weekend. I'd literally be on the sofa.

Joan ([01:32:04](#)):

And now that I finally retired in 60, I can sleep until eight. I can take a nap during the day. So it's not impacting my daily life as a 60 year old but I will say the biggest drawback is that I don't feel like I was as productive. I don't feel I was as involved in the children's lives as I could have been. And that's something I regret.

James Valentine ([01:32:27](#)):

Sure. Thank you so much Joan. I also want to give our other discussion group member who is not part of our panel, the chance to introduce herself and share what might be the most significant, either physical symptom or other aspect of liver disease that has the greatest impact on her life. And that is Maureen. So Maureen, if you want to introduce yourself.

Maureen ([01:32:51](#)):

Sure. Thank you, James. My name is Maureen [Kaminski 01:32:53] and my daughter who we adopted 22 years ago came from China and she had hepatitis B. We weren't aware of it at the time but she was very sick. Her symptoms, you know particularly, she was very fatigued. She had a lot of joint pain. She must've had some digestive issues because she really didn't eat. She had pretty extensive fibrosis but

the one thing... I worked with the Hepatitis B Foundation and over the last 10 years, I hear from thousands of people living with chronic hep B and I would say fatigue is probably the most common but it's everything from digestive system issues to more troubling issues like jaundice or bloating of the abdomen. But what I find most heartbreaking are those that are living with the terrible anxiety associated with hep B. And I think a lot of them are unable to say, be properly managed by a provider. So then they have no idea if their symptoms are due to their hep B or something totally unrelated. I find that, that's very hard for people.

James Valentine ([01:34:03](#)):

Sure. Well, thank you so much Maureen. So want to now go to our first phone caller, which is [SP 01:34:11] from Florida, who has some unique experiences to share relating to some of the physical symptoms being osteopenia and related, maybe you're not related, insomnia. So if we could have [SP 01:34:29] from Florida. [ SP 00:01:34:30], can you hear me?

Espi ([01:34:34](#)):

Yes. I can hear you. Thank you.

James ([01:34:36](#)):

Great. So [SP 00:28:36], if you could just briefly introduce yourself and tell us a little bit about the aspects of chronic hepatitis B that have most impacted your life.

Espi ([01:34:48](#)):

Well, I worry more about liver cancer even if I am on medication now, the risk is still there. The medication I understand reduces that risk. I worry about dying prematurely. I worry about transmitting it to my loved ones. Even if we have the vaccine now, I got my husband vaccinated and so is my son. I worry about my increased bone loss on my osteopenia. That's a very big concern for me and I experienced insomnia. I tried all other insomnia and sleep therapy, still I get it. There are odd times that I'll have a good night's sleep, very very few. And so those are the things that really bothers me the most.

James Valentine ([01:35:42](#)):

Sure. So could you maybe give me an example of a way either the osteopenia or the insomnia, maybe limits the activities that you're able to do in your daily life, maybe something that's important to you that you can't do?

Maureen ([01:35:56](#)):

Yeah, sure. The insomnia makes me tired, obviously when I don't get enough sleep. So I cannot do the things I wanted to do. I love to travel, I love dancing, I love to play tennis and those things I couldn't do as much as I used to because I am tired, most of the days anyway. So that really, it affects my lifestyle I would say. And of course the risk of liver cancer is always a big thing for me.

James Valentine ([01:36:37](#)):

It's an ever present worry. When you say you're tired most days, would you say that's five days a week? More than that? Less than that?



Maureen ([01:36:49](#)):

Probably maybe four to five days a week because I'm not getting a full... I don't get a quality sleep. I wake up in the middle of the night, two or three times in a night. And that really affects my sleep so I've gone to sleep therapy. And I feel like I tried whatever I learned from that therapy. It helps me improve a little better but the issue is still there. It's still not getting enough quality sleep. For whatever reason it wakes me up in the middle of the night and that makes me very, very tired most days.

James Valentine ([01:37:29](#)):

Wow. Well thank you so much for calling in and joining us, and showing-

Maureen ([01:37:33](#)):

The one that I always get concerned is about bone loss. I have osteopenia and I research about the medication and all the rest of it. Even if I'm on them [inaudible 01:37:43] a little less side effect I understand but it's still going to bone loss. The medication, being a lifetime one. So those are the things that really concerns me most about it.

James Valentine ([01:37:53](#)):

Sure. Well, I really appreciate that. And thank you so much for joining us today.

Maureen ([01:38:02](#)):

Thank you. Thank you for taking my call.

James Valentine ([01:38:05](#)):

I want to share a couple of comments that we're getting from the web. One, kind of along similar lines to what [SP 01:38:14] just shared with us, is actually Neha from Kenya and the effect of being tired, "I have been married for the past 10 years and was diagnosed with the disease seven years ago. It's impacted my daily life quite intensely. The main symptom was fatigue, weight loss, and body aches. I was tired the majority of the time. My social life was on a halt."

James Valentine ([01:38:41](#)):

I also want to... A couple of comments that have come in on another symptom that we haven't heard as much about in our discussion yet, which is pain. So we have [Sanchville 01:38:54] from Ghana who has said the joint pain fatigue associated with the disease is very painful. James from Hawaii...

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James Valentine ([01:39:00](#)):

This is very painful, James from Hawaii has shared that, "I have terrible pain, mainly in my abdomen. It impacts my work, and I have a very physical job." So, you can see that that symptom having an impact on James's ability to maintain a job. So, I'm curious if I could just see a quick show of hands from anyone from our discussion panel that has any experiences related to pain that they might want to share to add to that conversation. Yes, Bright.

Bright ([01:39:36](#)):

Yeah, so I happened to also deal with pain in addition to the chronic fatigue. So, when I started what actually led to my diagnosis was the chronic fatigue. But over the years, I've started also experiencing pain, and usually my pain when it started was all muscular pain. It wasn't much to the joint, but of late I've started noticing that it's radiating into my joints, and it's very, very unbearable, especially when it happens together the fatigue, it's impossible to do anything. So most of the time I spend my day in a house and it's just unbearable. There's nothing, I've tried everything from pain pills to pain creams and other stuff, but it's just impossible to get anything really to help. So in addition to the chronic fatigue, I think it makes life much more unbearable than anything I can compare to.

James Valentine ([01:40:42](#)):

Wow. Thank you so much, Bright. So in our second discussion question, which I think really is just a little bit of an evolution of the first one, we want to talk about the impact that diagnosis has had on personal, social, and professional life. And that may be from those direct symptoms and progression of the disease, but it could be from a wider range of impacts from the disease. And so I want to go to one of our phone callers, Gooksa from Minnesota, who wants to share some of the psychological and social aspects of living with hepatitis B. Gooksa, are you with us?

Gooksa ([01:41:29](#)):

Yes.

James Valentine ([01:41:30](#)):

Wonderful.

Gooksa ([01:41:31](#)):

It's really challenging to live with hepatitis B. Since I was diagnosed hepatitis B, I was living by my own with my family. I really want to just work home. I never go to the social life, like I never go to the public here like circus, sports venues. I was in fear, I never go to for [inaudible 01:42:11] or had a sign on them. And the fear I got another disease. Also emotionally, I was subject to prejudice, seen harassment from my coworkers, my roommates, I was rejected. I was telling them to get vaccinated. And I told them about the disease, but gradually they rejected me and I feel alone. At my workplaces, I was harassed and I [inaudible 01:43:03] I was like, womanized. I was called like bank robbers. I was probably [inaudible 00:01:43:21]. That's what I have to face in my work area and people close to me. I'm very much defenseless and I don't know how to defend myself of those emotional and psychological attacks. [crosstalk 01:43:44]

James Valentine ([01:43:44](#)):

Sure. And so does that social isolation that you felt as you described it in the workplace has that carried over into other areas of your life or is it primarily there?

Gooksa ([01:44:06](#)):

Yeah, it's highly affected me, my social life. Meeting people and working areas very much. I have a fear to get another disease and also a fear of rejection and a stigma, because as I told you, I said, rejection from people whom I told them about my condition. I told my roommates to get vaccinated. And then I go to the extent, take them to the vaccination areas to get vaccinated, but gradually they rejected me

and emotionally, verbally start to attack me at my workplace especially. It's very hard to, I got [inaudible 01:45:23] from my employers and because of that the difficult time, I'm always sad. I really never get an opportunity to talk about myself and this is my chance, and I can't stop silent, I have to talk and I have to defend myself because I feel defenseless, because there are people out there who try to benefit from someone's misery and put salt on the wound.

James Valentine ([01:46:10](#)):

I want to thank you so much for being a willing despite those life experiences to, to call in and being willing to share that actually today. So thank you so much. I actually have a comment from the web that I think also gets to this kind of social isolation related to the stigma. Raj from California says, "often I feel shame in sharing my diagnosis to friends, family, or coworkers, even though I understand that this disease is no fault of my own, as I've had it since birth, I still feel a stigma when sharing my story socializing can often be difficult. Also, as I often must explain why I'm not drinking alcohol." So I'd like to go to our discussion panel and see if there's additional experience to share here. And I'd like to ask David, if you'd be willing to speak to some of this, the impact on personal, social and professional life.

David ([01:47:14](#)):

Absolutely. I can relate with a lot of what the last caller was talking about, especially with social isolation. I've had hepatitis B since I was born. And when I was in puberty, 13 years old was when I realized I had it. And that sent me down a path of isolating in my mind, isolating physically from friends. And that turned into some very, very severe depressive spells, I've been diagnosed with clinical depression. And it's just very hard some days to know how to navigate your social life. A lot of people know the word hepatitis, but unfortunately that's where it ends for a lot of people, and there's a lot of misinformation in the world. There's a lot of fear based misinformation in the world, and it's been very hard for me sometimes to feel competent in talking about it or even feeling okay for having it.

David ([01:48:10](#)):

I remember when I was younger, I would just keep trying to find reasons why it was wrong for me to have it and why I needed to keep myself away from people and to not share my story. And unfortunately that just breeds more anxiety, more depression. It makes it so much harder to accomplish any goal you have in your life. And if I could just wish for anything, it would just be so much more education on the subject to get more people to be able to be comfortable enough with their situation to ask for help and to share their stories. Because for me that's just been such a lifesaver as far as being able to live confidently and be okay with the reality of my life.

James Valentine ([01:48:54](#)):

Sure, and I mean, I know that it probably effected so many different areas of social life, David, but if you had to pick one thing that maybe you really looking back wish you had been able to do, and maybe if you had been more confident then as you are now, you would have done that, that maybe you missed out on?

David ([01:49:18](#)):

Absolutely. I avoided a lot of very usually landmark events for people. I didn't attend any dances. I didn't attend any kind of big social gathering where I knew that there would be a lot of drinking involved because I succumbed to peer pressure when I was younger and drank alcohol. And it was just a nerve wracking experience being in the culture we are. And with young people, a lot of people like to get out

and drink and socialize that way. And it's just extremely difficult to be in that environment and be able to have your resolve. And if someone asks you why you're not drinking, it's sometimes very difficult to know what to do in that situation. So a lot of times I've skipped invites to birthdays or invites to weddings, things like that, just because of massive amount of fear that that generated.

James Valentine ([01:50:18](#)):

Sure, well, thank you so much, David, for sharing that. And I think one thing that I'm seeing is you all are not alone. There's a comment from someone with the initials WL from San Francisco, about isolation, "as someone living with hepatitis B for 26 years I feel like I'm going through it alone. The health community group emphasizes on public awareness, vaccination, and prevention, but little for people living with the disease. There's no dedicated support group for hep B, the ones found were for hep C and liver cancer, so I don't fit those "disease categories". Many organizations have information on hep C cancer and liver transplants, but little for hep B. So having hep B feels like a marginalized experience." So hopefully WL in San Francisco, you're hearing some of the stories today and know that you aren't alone and that many others have gone through this together.

James Valentine ([01:51:19](#)):

Also, it's clearly not just an experience here in the United States. Victor from Nigeria has written in and said that "in Africa, the stigma is very high and that's why people don't come out to speak about it." So clearly also being experienced around the world to just focus on one other symptom, that's come up. We do have a caller Daniel from Illinois who experienced joint pain. And I just wanted to maybe hear a little bit about that since we haven't heard specifically about joint pain yet, and the impact that that had on your life when you were experiencing it. So Daniel, are you with us?

Daniel ([01:52:04](#)):

Yes, I am.

James Valentine ([01:52:07](#)):

All right. Daniel, can you just tell us a little bit about yourself and your experience with the physical joint pain? Daniel, are you still with us? Okay, I think we lost Daniel, but we actually have another caller that wanted to talk about some of what I might call downstream effects of living with hepatitis B, the fatigue and the stress of it. And so that's Randall calling from the UK. So I'd love to hear Randall about a little bit about your journey and your experience, are you with us? Randall are you with us? Okay, so maybe while we're getting our phone caller lined up, I'll ask our discussion panel to weigh in a little bit on this notion that we were hearing about the social isolation and the many different drivers of that. So, Randy, maybe you might be able to add a little bit to this discussion.

Randy ([01:53:27](#)):

Hello, yeah, my wife has hepatitis B and, and she has never felt like being around other people. And I mean, initially it wasn't an issue when we were dating and things, and I don't think she really, I think she knew at the time, but she wasn't viral at the time. And so it wasn't as big an issue. And then of course, when we had our kids, we were told to get them vaccinated. We knew enough to do that. Not knowing that that's not necessarily a hundred percent foolproof was something that we were totally in the dark about and should have been more in the know about it and to watch more closely and have tests done more frequently, I think would have been a better thing. I guess if it works great, if it didn't then you know, but at least you could have planned your life accordingly and tried to navigate those things

because for us, for our son dedicating five years of his life towards a goal to become a Naval officer through the Naval Academy was a huge endeavor.

Randy ([01:54:51](#)):

And to get to the pinnacle of actually making it, and then having everything taken away from you, it was just totally horrendous for my wife. It just devastated her. She blames herself and there's nothing I can do to take that pain away. It's something that she lives with. And I just wish I could take that pain away and there's nothing I can do. And yeah, it's really difficult. So she, especially since that timeframe, she's really pulled back from a lot of people from church, from other friends that she's had for a long time.

Randy ([01:55:37](#)):

We have some very dear friends green. Her Korean friend that she grew up with just around the corner from us in our housing area. And she just doesn't talk with her that much, I mean her kids are grown up and doing things. And so we don't communicate much with them and I feel a loss because those are my friends too. But I, for respect of her, I try to respect that part of her life. And so I pulled back too, so it affects me as well. And so, yeah, it is difficult with regard to that.

James Valentine ([01:56:21](#)):

Sure, a real kind of family wide impact and quite a tragic scenario to hear about, but thank you so much, Randy, for sharing that there's a number of live comments that we're getting kind of talking about some range of other impacts that this diagnosis has had. Karen from California talks about the impact on professional life. You know, she has been unable to secure long-term care insurance and decided against making a job change, partly because of the increased challenge of obtaining adequate health insurance, especially with hepatitis B virus and at a reasonable cost in the private care sector compared to her government and employment.

James Valentine ([01:57:13](#)):

We also have Ricundo from Uganda who wrote in and said living with hepatitis B has greatly affected his life. He's not allowed to work in some organizations in Uganda, even in a job working in wildlife. And he can't work in the United Arab Emirates or other Gulf countries. And so he's even had to lie about his status to get a job. And can't freely associate with people when they come to know about his diagnosis. He's even the laughing object of some of his relatives. And then we have a Eduardo from the Philippines with a comment that just came in also along the same lines. One thing that bothers him is that his condition itself holds him back and continuing his teaching profession. He scared to be known by everybody. He wants to try applying for a teaching position abroad, but was turned away due to his condition.

James Valentine ([01:58:14](#)):

So I think we've heard a lot about the personal, social and professional impacts. I want to shift the discussion a little bit and talk about some of your worries about living with chronic hepatitis B. And for that, we're going to go to a polling question. So if I can get our third topic, one polling question. All right. So please again, go to your phones, go to that other tab on your web browser, go to [PollEV.com/HepB](https://PollEV.com/HepB). Again, it's at the top of this slide, if you need to see it written out. And so the question that we have here, so if I can go to our third polling question for topic one, that is the question that is, what are your top three worries about living with chronic hepatitis B?

James Valentine ([01:59:20](#)):

Okay, so here we want to ask you a little bit about your worries living with this condition, thinking about the future. And so here please select up to three responses that are your top three worries. Your options are A being able being unable to date or get married, B transmitting hepatitis B to loved ones, C the impact on school or work, D being unable to take care of your family, E dying prematurely from liver cancer or F some other worry that you have about living with chronic hepatitis B that is not listed on this slide. So please think about this a little bit, pick your top three responses. And these are your worries about the future with living with chronic hepatitis B.

James Valentine ([02:00:07](#)):

I'll give you just a few more moments here to get in your responses. What you're seeing here also since this is a poll that is allowing you to select more than one option is you're seeing percentages of responses. So these aren't percentages of individuals that are responding. So it's a percentage of the total responses and there's more than one per person. So kind of proportionally you're seeing the top worry that has the most votes being dying prematurely from liver cancer. Closely behind that see transmitting hepatitis B to loved ones as a worry. After that, maybe number three in the rank, we see being unable to take care of your family and being then unable to date or get married being number four.

James Valentine ([02:01:11](#)):

We also see responses on the impact on school and work as well as other worries. And so well, we encourage you to, again, to tune into or dial into that phone number +1 703-844-3231, to be able to share a little bit about your worries, if you're one of those that selected other certainly we'd be interested then to hear that, but we're going to take your calls now about what your worries are and for living with chronic hepatitis B. And so I'd like to first start back with our discussion panel, if we can go back to our panel and I'd like to ask Alice, if she could chime in a little bit on what might be her top worries for the future.

Alice ([02:02:06](#)):

Okay, so I went through quite a bit of things in the past, and now my worry for the future, since my kids is already grown up and I still worry about I might get hepatitis impact on my liver. So I kind of expect if one day I have cancer of the liver, I think I have done the best to myself to take care of myself or to care of the kids in the family. And so that's still my concern and worry. One day the cancer cell might get into me, [inaudible 00:23:57]. So that's my most worry, for the rest of my life.

James Valentine ([02:02:56](#)):

Sure. Thank you so much, Alice, and I think that probably resonates with a lot of people that are tuned in online because I'm seeing a number of written comments that we've had come in about worries for the future and about worries for developing cancer. I can't read them all, but I'll read just a few here. So Jason from New York wrote in that, what worries him about living with chronic hepatitis B is developing cancer or not being able to live a long enough for scientists to find a cure, although new exciting treatments to sustain healthy life are terrific a cure is much more satisfying. So he looks forward to the cure to help eradicate that particular fear. We have Raj from California who talks about his greatest fear is dying of liver cancer. His mother, who also had chronic hepatitis B passed away at 64 to liver cancer five years ago. And the idea of leaving his family behind and especially his young twins scares him deeply.



James Valentine ([02:03:57](#)):

You know, that that fear of death is recurring Abdul from Nigeria says, "I just fear I'm too close to my grave day after day, I sleep and wake up every day with so much fear." And again, liver cancer coming up, we have Yvonne from Australia, Sanjit from Ghana, SB from Florida, all reiterating that. SB saying, "I worry most liver cancer dying prematurely transmitting it to a loved one and increased bone loss from antiviral treatment due to osteopenia." So even when liver cancer is there as a fear, it's a fear amidst and a number of other fears at the same time. So we're starting to see that there's a great deal of different worries. I'd like to ask me to be more Maureen, if you would be able to share a little bit about worries for the future?

Maureen ([02:04:56](#)):

So for my daughter, our biggest worry at the time, because most kids don't have any symptoms, but she was very symptomatic, we worried that she was going to need a transplant before the age of five. She was fortunate enough to clear it, but I still worry about reactivation, but working with so many other people living with hep B, I feel their anguish. Some of them are just trying to get through daily life. So they haven't even gotten as far as thinking about liver cancer as much as they are worried about how they're going to support their children or meeting somebody that will accept them as they are. And the young mothers that find out after their second, third child that they have hep B and whether or not they transmitted it to others. That's a terrible burden for a mother to have to live with.

James Valentine ([02:05:53](#)):

Absolutely. Thank you so much, Maureen. So I want to go back to our phone lines Daniel, I know I had you on before from Illinois, you wanted to talk about joint pain. So I would love to give you that opportunity to do so, as well as share any thoughts that you might have about worries for living with hepatitis B moving forward. So Daniel, are you with us now?

Daniel ([02:06:18](#)):

Yes I'm still here. As was saying, in 2014, I've been diagnosed with hepatitis B, back then I wasn't taking any medication and in 2015 after taking tenofovir and I've been taking tenofovir I think for almost four years, and then I start feeling pain. I used to take the medication, once at night, like six or seven o'clock. But if I just take after 30 minutes, I would stay in bed because my leg between the pain. And then I spoke to my doctor I said, now we can change to a new one [inaudible 02:07:01] is 25 milligram it's safe.

Daniel ([02:07:06](#)):

So yeah, the worry it's like everybody, just who are worried about what will happen. And sometimes when you feel a little bit pain, you just start worrying is it cancer or what is it? And living with that every single day, you just know sometime it might happen that you will have the liver cancer and all that. So it's a challenge. And also we only discussed between family members, we don't just to avoid people being curious, how people trying to take advantage of you. We don't discuss it with people outside the house. So it's only inside the house we talk. If there's anything you can talk between family members and that's about it, worry. Every single day you are worried.

James Valentine ([02:07:56](#)):

Sure. Well, thank you so much for sharing those comments. I think we're hearing some common themes here for worries for the future. I do also want to go back to Randall who is calling in from the UK that

wanted to talk about fatigue and stress. And so I'd love to hear about that. And then again, Randall would also like to hear if you have any thoughts to share about worries. So are you with us?

Randall ([02:08:27](#)):

I am with us yeah, hi there. Yeah, first of all, my name's Randall, I'm from the UK. I got diagnosed with hepatitis B back in 2011, I think it was 2011, if memory serves me right. But still it doesn't feel that long ago, but when I first come on the scene, when I first got diagnosed, I was told by all the doctors, because I was in Thailand, I got it from having a tattoo. And I was told by all the doctors at the time [inaudible 00:29:58], it will clear blah, blah, blah, blah. And everyone's telling me it's fine. And it didn't, and then I turned into a chronic case. And I got onto the scene and I was told there's no cure and everything. And I think I was quite angry with the world. And I'd really just at this moment in time, just because I know Joan said to actually apologize for my behavior at the beginning, when I first came onto the scene.

Randall ([02:09:17](#)):

So Joan, if you're listening, I'm very, very sorry for the way I behaved towards you, I hope you do accept my apology. And it was out of order, but in terms of dealing with it, I just felt like, because I work as a fitness trainer, I do nutrition. It was the actual feeling of fatigue. The feeling of being alone as well was really a very lonely place. I've got to say I actually did feel like I'm in some dark places at times. And luckily I had some time friends around me who've had experience of dealing with chronic diseases and stuff. And one of them he was quite a positive guy had his issues and hepatitis C. And he said to me, he says, look, you know what, one day you'll look back at it and you'll say hepatitis B, the best thing that ever happened to you.

Randall ([02:10:00](#)):

And I thought to myself well, that really sounds to me, I can't agree with that at that moment in time. But looking back, it was because I've learned so much from it and I've met so many nice people through it as well. It's a very difficult condition to deal with. And I realized if you're not dealing with this thing, that's putting a lot of pressure on your liver at the best of times no one really understands how much energy it takes on you and all the feelings that you were left with to deal. You really do need people around you to support you and remind you that you're not alone. And it did kind of get me thinking to actually get some groups organized on Facebook and stuff and partnering with them. And it's quite like I met a lot of nice people.

Randall ([02:10:47](#)):

I ended up on the Gilead trial for the latest type of tenofovir that's out there, the latest 25 milligrams. And I've got a very good liver doctor. Fortunately I became surface antigen negative and surface antibody positive. And I'm very grateful to the whole team that actually helped me there. And I realize I'm very, very lucky, but when people say there's no chance of a cure, I think science is getting closer and closer. Every day that goes by is again a step closer in the right direction. And I don't see why people should die of hepatitis B leading to liver cancer when all it takes is testing and management as a start. And you can live a healthy life and anybody who's a bit clued up who is clued up about if you're undetectable and the other person's vaccinated, for example, you won't [inaudible 02:11:44].

Randall ([02:11:40](#)):

I remember when I got diagnosed, I was the last thing I was thinking about was dating. All I was obsessed about was getting better. I was thinking this can't happen to me, but guess what, things

happen to people. And this just happened to happen to me. But I do believe the future in terms of science is looking good. And I do think the treatments are out there are fantastic in terms of-

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Randall ([02:12:00](#)):

Treatments that are out there are fantastic, in terms of all of the ones that are available, especially the latest ones, but I believe the future is looking bright, but also I do understand that it is quite a burden for [inaudible 00:00:13]. It's not something you can just wake up, get out of bed in the morning and go, "Yeah, I've got Hep B." It doesn't work like that, but it is something that you will learn a lot from, if you choose to. You learn more about your body, what you can and can't do. And yeah, I'm very grateful.

James Valentine ([02:12:30](#)):

Wow. Well, thank you, Randall. We're grateful for having you join us and share those perspectives. I'm learning and understanding, and what you said, which is that, "It really takes it out of you to live with and manage this condition." So I have another phone caller on this particular topic, and then we'll move to our final discussion question. And that's Karen from California who wants to talk about her main worries for living with Hepatitis B and actually wants to talk about how they have changed as she has grown older. So Karen, are you with us?

Karen ([02:13:14](#)):

Yes, I'm here.

James Valentine ([02:13:16](#)):

Hi Karen.

Karen ([02:13:16](#)):

I just wanted to talk a little bit about how the process of aging has changed this for me, because much like the last caller, to most of my decades of living with Hepatitis B, took the attitude that it's an opportunity to learn more about what I can and can't do. And I educated myself and fortunately didn't have really any of the physical symptoms that some of the other people have described other than having to make some adjustments as I got older because of having osteopenia and osteoporosis. I had to give up my beloved hobby of speed skating for that, but I didn't dwell on that. And I just moved on to other things that are safer to do. And, it felt like if I just continue this way, I'm going to be fine. And I just avoid taking any medications and that I would be able to live out a normal life.

Karen ([02:14:08](#)):

And then I think I got a little bit, a wake up call when I was diagnosed with breast cancer and had to start juggling the treatment for breast cancer together with my Hepatitis B and started realizing that, as you get older, you start getting all sorts of other conditions. That's just the normal part of aging, that you get conditions that you're going to need to take medications for and how to juggle that with having a compromised liver. And also realizing that as you get older, you start suffering more pain and pain medications are not good for the liver. So I started becoming aware that that problem gets a little bigger as you get older, especially into advanced age, I'm 65 now and when I look at the future, it's a bit daunting to think about how to manage all of this.

James Valentine ([02:14:59](#)):

Wow. Thank you for sharing that perspective, especially that, what we haven't heard before, which is the development of other health conditions with aging and the complications of having Hepatitis B, along with that. So thank you so much, Karen. That's been great. So our final discussion question that I want to use our remaining time for in this particular topic session is really something we've we actually have been talking quite a bit about, but I want to hear some other experiences with this, which is the feeling of stigma and discrimination because of having your chronic Hepatitis B diagnosis. We'd like to hear your experiences with this, we've heard about some of this related to the dating life, a lot about this in terms of aspects of impacting jobs.

James Valentine ([02:15:57](#)):

We'd like to maybe hear some other experiences beyond that. I've been at least told that this is quite a large impact within this community. And so for all of us that are here to listen and learn today, we'd like to have some understanding of that. I do want to share a couple of comments that came in about worries before, as we were finishing out that section that were a little bit unique. So I wanted to share those. I believe one was about, these were both somewhat related to access. If I get those back, I'll share those with you. To get this discussion kicked off around stigma and discrimination. I want to come back to Joan and ask if Joan, you could share with us some of your examples of stigma or discrimination that you might be willing to share with us.

Joan ([02:17:02](#)):

Yeah. So when I was diagnosed at 30, I remember at that time that was the dark ages for all you young people that was in the 1990 and there wasn't a whole lot known about Hepatitis B. At that time, the HIV AIDS epidemic was raging. And so when I found that I had Hepatitis B first, I lost my job and my child was kicked out of daycare. And there was all this anxiety about had I affected my child, had I infected Tim my husband, would I be able to get my job back? It took a long time. And during those, it felt like years, I think it was months, but I felt really ashamed because it wasn't something, I was adopted also. So it's most likely I got it from my birth mother, but at the time you just think I'm a dirty person.

Joan ([02:17:56](#)):

I had to explain very quickly to people. I'm not a drug user. I'm not a prostitute. I'm not this, I'm not that. And so then I basically stopped. I shut up. And so for almost 30 years, I really didn't talk about it because it just became one of those things that just opens up too many boxes of questions and obviously helping to start the foundation for me, I had to literally put my personal diagnosis in a closet, locked, and I kept it very separated from what I was doing on the day to day basis, which is where I was hearing really heartbreaking stories of discrimination, children who were having to eat lunch with their teacher in the classroom, not the cafeteria, because they had Hepatitis B, children who couldn't join a school team. Wouldn't be invited to sleep overs. More recently, a woman whose husband left her because she had Hepatitis B and took their two year old son.

Joan ([02:18:58](#)):

So it's still a very current problem, the discrimination, but also the stigma that we've all sort of touched on. It's not just, there's also the feeling of, if you don't tell people, if you can't tell people it's a part of yourself that becomes secret and you don't feel authentic. And when I finally was able to tell people first, some of the reactions were, "Oh, I already knew." And then now that I've started to tell neighbors and stuff, it's no big deal. But 30 years ago it was a big deal. Even 20, even 10 years ago was a big deal.

Because as David said, people hear Hepatitis, they don't hear the B, they think about C and they immediately think you were a drug user, you were promiscuous. I agree with David. There's still a lot of education that needs to be done. And there is still a lot of shame around it, even though I'm a very well educated person. There is this feeling when I tell a new person, I feel this little anxiety about how are they going to react.

James Valentine ([02:20:09](#)):

So Joan I have a question for you, you talked about almost compartmentalizing it and blocking it off from the other aspects of your life and what people knew of you. And you described it as not being able to feel authentic with those people. Was there any particular direct impact that, that had you not being able to be authentic or not being able to engage as fully as you would have wanted that, that had limiting you in some activity or some other direct impact?

Joan ([02:20:45](#)):

Well, I always envied people who had diabetes or asthma, they could always say, "Oh, I can't eat this dessert because I have diabetes." Just like David, I don't drink alcohol. Everybody says, "Why don't you drink alcohol?" Well, part of it was, I was raised not to drink alcohol, but as a young adult, as soon as I found out I had Hepatitis B, I definitely didn't drink. And then that always became a thing. I think for women, it may be a little less peer pressure than for men, but there was always that everyone would always ask you at parties or events. "Why aren't you drinking?"

Joan ([02:21:21](#)):

And also in terms of the authenticity, there was always this fear. I know this is so ironic. There's always this fear when people would say, "Well, why do you work for the Hepatitis B foundation?" Or "Why did you join the foundation?" And I lied because I wasn't comfortable. And that felt really bad. And particularly when I would just talking to other patients, I felt like a fraud. And when I finally came out of the closet two years ago, it was such a huge relief. And also for the first time, I feel like I'm whole, because now everybody knows I don't have to keep it secret anymore. If I'm tired, I can say I'm tired because it's Hepatitis B.

James Valentine ([02:22:09](#)):

Right.

Joan ([02:22:10](#)):

So it's just an authenticity and being really connected to people.

James Valentine ([02:22:15](#)):

Sure. Well, thank you Joan so much for that. On the same lines, we have a caller [SP 02:22:21] from Florida who also wants to comment on this idea of stigma and discrimination. So if we could get SP, are you with us?

Espi ([02:22:31](#)):

Yes, hi.

James Valentine ([02:22:33](#)):

Hello.

Espi ([02:22:33](#)):

Hi. Yeah. I'd like to comment on about this stigma and discrimination.

James Valentine ([02:22:40](#)):

Yes.

Espi ([02:22:40](#)):

I have Hepatitis B since 2005. I'm almost 80 years old now, next year. I never felt it. I never experienced it because I don't share the information to anyone other than my family and a couple of close friends. And I feel strongly, nothing is to be feared in life. Now is the time to understand it. The more I understand it, I fear less. And I got that through the Hepatitis B Foundation many years ago.

James Valentine ([02:23:17](#)):

Sure. And for those that you don't share it with, can you tell us a little bit about that fear of facing the stigma and discrimination with those people?

Espi ([02:23:31](#)):

Yes, because I felt, I don't think generally speaking, the population is educated about the disease, because if you don't have any knowledge of it, then you fear it. Just like way back when they have, what is that one? The sexual transmitted disease? I can't remember right off hand. There was lack of knowledge. The people who have the knowledge of it, they don't have that fear. So I cannot educate the public, that's not my role. So I guess don't bother. And it's, for me, my personal information is not for public consumption.

James Valentine ([02:24:07](#)):

I see.

Espi ([02:24:08](#)):

So I take it for myself and people I want to share it. If I wanted to, I would do. I never experienced the stigma or any form of discrimination, any discrimination, of course, I'm out of the working world now. So I don't have experience that I'm retired.

James Valentine ([02:24:23](#)):

Well, thank you SP so much for calling in today and sharing that. We have a live comment from Ian, from the UK, also adding to this discussion of stigma and discrimination. He says, "I think we all put a stigma in our heads because of the virus. Feelings of being dirty and doing something wrong are hard to get rid of. It stopped me from applying for jobs over the years, hiding it for 25 years in my current employment. I'd love to come out." He said in quotes, "But people don't understand the disease and then you are stigmatized." So I think that's a really strong place as we're at the end of our time for this first topic, I do want to end. I actually think it's a perfect transition to our next topic, which we'll be talking about treatment approaches. Those two comments that had come in about other worries and they actually do relate to getting treatments.

James Valentine ([02:25:17](#)):

So James from Kenya said that, "He worries about being able to get treatment. It's a big problem here in Kenya. Many people die every day without being diagnosed in rural villages. I feel that the government doesn't have a plan for dealing with this condition. And I've seen many people turn to traditional medicine to deal with it." We also had Lynette from Massachusetts say that, "She worries because she has no insurance or money to continue to get the medicine for the rest of her life." So of course the worry of access, their worry of being able to get diagnosis. Those are underlying worries that of course will relate to how well available treatments will be useful to you.

James Valentine ([02:25:55](#)):

And we'll be talking about that in our next topic discussion. So with that, I want to thank our discussion panelists. I want to thank all of our callers and all of our commenters who have submitted comments in writing, we'll have another opportunity for everyone to contribute when we reconvene in 10 minutes for our topic two discussion. So thank you. We'll take a quick 10 minute break and we'll resume the program at that time. Welcome back. Everyone from break. This is the Externally Led Patient Focused Drug Development Meeting on Chronic Hepatitis B. And again, I'm James Valentine, your moderator. I want to thank everyone for tuning in earlier this afternoon and participating in the discussion around understanding the impacts and burdens of living with chronic Hepatitis B. Now we're at the part of the program where we're going to build on that earlier discussion and talk about your experiences, your preferences with current and future approaches to treatment. So in this topic, again, through our panelists polling and your live comments, we're going to be exploring the different ways that you're currently helping manage your symptoms and, and the disease itself. We want to get a sense of what those different things are that you're utilizing, how well they're working for you, or maybe where they're you feel there could be additional benefit as well as any downsides of those treatments approaches that you might experience.

James Valentine ([02:36:20](#)):

And I should mention that treatment experiences are broader than just prescription drugs, medical procedures, but really extend to the full range of different approaches, even diet, exercise, lifestyle, modifications that you might make in your lives. Anything you might do to try to help manage and make living with chronic Hepatitis B a little bit easier. We're also going to explore some of your preferences, both around future treatments. What an ideal next treatment might look like from your perspective, as well as your preferences for participating in clinical trials. We can't get to that. As we heard from Anna Lok this morning, we can't get to that next treatment without people being willing to volunteer and participate in clinical trials. And so we want to understand what is important to you as you're considering whether to participate in a clinical trial. So to get us kick off this discussion, we have a great panel of members from your community who are here to share their perspectives. We have Jacki, Peter, Wendy, and Joe. So we'll start off with Jacki.

Jacki ([02:37:33](#)):

Hi, my name is Jacki I'm from Princeton, New Jersey. I was born in Taiwan during the 1960s. In 1998 my elder brother was diagnosed with liver cirrhosis and liver cancer, Chronic Hepatitis B Infection. I decided to get tested at that time and found out that I also carry the virus. I didn't start treatment immediately. When I was first diagnosed at that time, I didn't have many symptoms except for elevated liver enzymes and sometimes feeling fatigue. I was also busy with my career, but most importantly, there were no good treatment at that time for Hepatitis B. The only available treatment were Interferon. And the first



generation you could [inaudible 02:38:26] in and out Lamivudine. Interferon is an injectable drug that has a high tendency of side effects while Lamivudine is known to cause drug resistance easily. However, due to a serious liver condition, my brother had no choice but to start Lamivudine treatment.

Jacki ([02:38:46](#)):

later on he was switched to Entecavir when it became available. So with my other family members with their encouragement and the fact that I also had severe fibrosis, I decided to take on this potentially life long journey for Hepatitis B treatments and with Entecavir in 2008. After starting the antiviral therapy, my Hep B viral load dropped quickly. Within three months, the virus had dropped to detectable [level 00:27:20]. My liver enzyme gradually returned to normal. Also I feel less fatigue and was able to walk with small energy and to enjoy my free time. However, it was not easy to take the medication every day for many years. Many times I forgot or purposely ignored the medication. My doctor gave me [honing 02:39:46] and sometimes my Hep B virus became detectable. Fortunately, I was able to keep up with routine doctor's visit and had laboratory tests and ultrasound exam regularly to monitor the condition of my liver.

Jacki ([02:40:04](#)):

My different enzyme level sometime exceeded normal range, which constantly reminded me of the importance of keeping up with the treatment. For now, I have continued my treatment with the most recent anti Hep B drug, Tenofovir alafenamide. The drug has a very low instance of drug resistance and a better safety profile for the bone and kidney. Currently my Hepatitis virus is undetectable and my liver enzymes are within normal range. However, even though this treatment might have lowered my risks of developing cirrhosis and liver cancer, they have not reduced the discomforts I experienced frequently, which might be a result of liver fibrosis as a damage caused by the virus or accumulated toxicity due to long-term use of the drug. Also, this treatment did not redeem my constant worry that I might go on to develop liver cirrhosis or liver cancer eventually, or one day the virus might fight back and become resistance to the antiviral drug.

Jacki ([02:41:16](#)):

So what's the ideal treatment I would like to see for Hepatitis B. Ideally, there should be a combination of oral drugs that target different stages of the virus life cycle. New candida is blocking different pathways of the viral replication cycle should be developed and tested quickly with the advent of new technologies and greater support for basic and translational research. I hope that one day soon, we can all take a simple pill for a short period of time, and finally be able to get rid of this virus from all of us. We should aim to eliminate Hepatitis B as early as possible. Hepatitis B is like a global pandemic that no one talks about or perhaps cares about. There are more than 250 million people affected by this deadly disease. And it can easily spread from human to human. Compare with the vigorous research and development for therapeutic agents against HIV and Hepatitis C and for the current Corona virus pandemic is clear that Hepatitis B has been ignored for too long. We need a cure for Hepatitis B now, and we need to stop the spread of this deadly virus. Thank you.

Peter ([02:42:46](#)):

All right. My name is Peter [Vo 02:42:49] and welcome to always sunny, Gilbert, Arizona. I promise you it's sunny outside. It's also 108 degrees. So that's why I'm inside. I'm currently 51 years old. I have Hepatitis B and was on oral medication, tenofovir for 12 years. The medicine had reduced my viral load to an undetectable level. And my GI doctor said at that time that I didn't need to take it anymore. He

said he would just review my blood work results about every six months. So I stopped about a year and a half later, shortly after new year, I was feeling very fatigued. My wife told me my skin and eyes like very yellow. I told her that my pee was very dark and my poop was very light in color. She immediately took me to the emergency room.

Peter ([02:43:44](#)):

I don't remember much after this because they placed me in a coma to keep me alive. But after 10 days I woke up and my wife told me the Hepatitis B virus had completely destroyed my liver and that I had a liver transplant. I remained in the hospital for another two weeks, for follow ups and therapies to regain my strength and speech. It has now been close to two and a half years since my liver transplant. I'm still within the three year recovery phase and being closely monitored by my post liver transplant team.

Peter ([02:44:28](#)):

My greatest health risk right now is organ rejection, bacteria and viral infections and Hepatitis B reactivation. The post liver transplant treatment regimen is very complicated and I have suffered a great deal, but that is a story for another day. Today I want to focus on the treatments, challenges I face for Hepatitis B virus condition. Immediately after my liver transplant I was given a treatments of tenofovir.

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

Peter ([02:45:00](#)):

Yeah. After my liver transplant, I was a treatments of Tenofovir Alafenamide, or TAF, and hepatitis B immunoglobulin or HBIG, which is done through IV infusion for seven days. I continued to take TAF daily, but the HBIG treatment is now only when my hepatitis B surface antibody is below 250 mIU per milliliter. Since I currently have stage three chronic kidney disease, as a result of my acute liver failure, I was switched to TAF since it has less renal toxicity.

Peter ([02:45:45](#)):

My hepatitis B virus condition and treatments are monitored every three months with blood work results. My hepatologist believes the combination of TAF and HBIG is the best treatment to prevent reactivation of the hepatitis B. One growth suppresses the hepatitis B while the other prevents it from attacking my new liver. I suffer from extreme heat, or extreme fatigue, or exhaustion, especially around the 5:00 PM hour, slightly as a side effect from my anti [inaudible 02:46:27] medications that I'm taking.

Peter ([02:46:29](#)):

However, I personally have observed a higher energy level as a positive side effect lasting up to about one week immediately after taking the HBIG medication. I do not notice any negative side effects while taking either the TAF or the HBIG medication, but this hepatitis B treatment combination is very costly, which I understood from the beginning as explained by my hepatologist. Even with the insurance, the cost of TAF is about 1100 each month. HBIG is also very expensive, and with my insurance, they cost about \$6,000.

Peter ([02:47:16](#)):

Currently with the intervals between HBIG treatment is about every six months or so. Because I have a very good insurance, the financial impact to me for hepatitis B is minimal, but I realized that that isn't necessarily true for everyone else. I would have to agree I'm currently very fortunate and blessed to

have an insurance plan that can offset the financial burden of taking a daily antiviral medication and undergoing an IV infusion of HBIG about every six months or so. Otherwise, the decisions of cost versus the weight and health benefit would have to be made very carefully.

Peter ([02:48:06](#)):

Other treatments options, such as the at home injectable syringe, HBIG alternative, a lower cost alternative to TAF, or clinical trials where new hepatitis B medications may be available. But I opted for the treatment combinations that have been proven most effective to me. Yet, a cure for hepatitis B would be wonderful so others don't have to experience the trauma that I went through before, during and after my liver transplant.

Peter ([02:48:42](#)):

Thank you for your audience and especially a big thank you to the hepatitis B foundation for being an anchor to all of us who have been affected by the hepatitis B. Thanks again.

Wendy ([02:48:58](#)):

My name is Wendy, and I live in Vancouver, British Columbia. I found out I had hepatitis B while in university, in the 1980s, and I had acquired it at birth as my mom was positive for HPV. I didn't know much about the disease, but I did know it was infectious. So other than assuring that my fiancé at the time was protected from transmission, I did not make any major changes to my lifestyle.

Wendy ([02:49:23](#)):

Then in 1998, my mom was diagnosed with advanced liver cancer and died six months later. It was horrible watching my beloved mom die of such a terrible disease. After her death, I did start to take my condition seriously and ask my doctor for regular blood tests and abdominal ultrasounds, which I did not have before my mom's diagnosis. Through these tests, I found out I was still in phase one of the disease, meaning I had a high viral load, no fibrosis, and my liver enzymes were within normal range. Hence, I did not receive antiviral treatment. My only treatment thus far has been to try to eat healthy foods, exercise regularly, And of course, to not drink alcohol. Due to fatigue caused by this disease, I also tried to get at least eight hours of sleep. As well, because of my fatigue, I was only able to work part-time. When I graduated from university, I had ambitions to advance my career by found I was too tired to work full time. Since my profession was in high demand, I was often asked if I was willing to work more shifts, but physically I was unable to, even after my children had grown up.

Wendy ([02:50:35](#)):

In fact, prior to retirement only work two days a week, which I found to be exhausting. My coworkers would often tease me about my part-time status as they did not know about my condition. Now, I am 57 years old. I'm still not on antivirals, but recently my liver enzymes having elevated. So I may need to start treatment soon, even though I am not on treatment, I have a close family member who is taking an HPV antiviral. So I'm familiar with how the medication suppresses viral replication, but unfortunately it does not cure the disease.

Wendy ([02:51:13](#)):

I am grateful that antivirals are available for Hep B and can prevent further liver damage. Nevertheless, every time my family member gets a blood test, I'm concerned that the virus will become resistant to the medication. And then what will be the treatment options? Am also worried for my family members

overall health because of the possible long-term side effects of being on a lifelong medication. It is very stressful, as I'm often concerned more about my relative than myself, especially since this person needed to go on medication because of fibrosis of the liver that was diagnosed at an early age.

Wendy ([02:51:54](#)):

So, I would hope that the future treatment of this disease would be viral suppression without having to take antivirals for a lifetime. I would also prefer though that there would be a treatment that leads to the loss of the hepatitis B surface antigen. My ultimate wish of course, would be the elimination of the cccDNA, which I know is a lofty go. If a treatment is discovered, my hope is that it has minimal side effects, has a finite treatment length, and can be taken early. I don't like needles or IV administration.

Wendy ([02:52:29](#)):

I have not been in a clinical trial, but if I was to participate one, safety and lack of adverse side effects would be my top priorities. I would need to know that the potential benefits such as a high probability of curing this disease would outweigh the risk of receiving an experimental treatment. I, of course don't want my liver to be damaged by the clinical trial. And I also want to be able to function and carry out my regular activities while participating in the trial. There is so much uncertainty when living with hepatitis B, it's an exhausting disease. And at times I feel like I have a ticking time bomb in my body, but having a cure would be so wonderful that I wouldn't have to have the fear of dying of liver cancer as my mom did, or developing life-threatening liver cirrhosis.

Wendy ([02:53:17](#)):

I know there are no guarantees in life, especially during these uncertain times, but it would be wonderful to have not have to constantly worried about my health or the health of those. I love. Thank you.

Joe Balistreri ([02:53:33](#)):

I'm Joe Balistreri, 67, a landscaper living in Santa Rosa, California, with my husband Wayne. I've had hepatitis B since 1977. I never felt ill when I contracted it. A friend noticed I was jaundice and I got tested. With the positive result, I was not told I could be infectious, or that it could lead to cancer. So I just forgot about it. Around '97, I was diagnosed with a co-infection of hepatitis D or Delta, a virus that only affects those with chronic Hep B. Around 2003, I was shocked to learn my liver was on the verge of cirrhosis. I remember crying. For years, I had kept myself safe from HIV while viral hepatitis was quietly damaging my liver. Fortunately, antiviral suppressed my Hep B, the Delta infection remained a curiosity rarely spoken of. In 2013, I was prescribed Entecavir when my first Hep B antivirals became ineffective.

Joe Balistreri ([02:54:41](#)):

My specialist told me that the Delta infection was more virulent than B and that there was no good treatment. Well, I didn't want to wait 20 years for something to come along. So I got online and I found the only act of trial to cure Hep Delta in the Western hemisphere. Although Hep B alone is very serious, Delta coinfections can speed up progression to survive fibrosis, cancer, and liver failure. Joining the three-part NIH clinical trial from 2013 to 2018, brought huge changes.

Joe Balistreri ([02:55:18](#)):

I hesitated because of the many cross country trips I'd have to make with the NIH. I could lose lots of work and income, and it meant being separated from my loved ones during scary medical procedures.

My fear of doing nothing was stronger. I made 70 round trips from California to the NIH. Most were overnight marathons of travel and procedures. I experienced very difficult symptoms for the first time since I'd contracted B. Sometimes I was so ill I couldn't face making another 4,000 mile round trip.

Joe Balistreri ([02:55:52](#)):

In December, 2018, I may have been the first patient for whom a Delta infection became undetectable through treatment. I wanted to kiss my doctor's feet, but by mid January, 2019, it was clear I couldn't tolerate Interferon. I had tolerated different combos of Lonafarnib and Ritonavir in phase one and two, but with the addition of Interferon Lambda in phase three, I reacted so severely, my doctors stopped all study drugs two months early. At that time, my MELD was 17.

Joe Balistreri ([02:56:28](#)):

MELD is a score that estimates a patient's chances of surviving their liver disease in the next three months. The higher the score, the more urgent the need for a liver transplant. My blood work was frightening to read. I had [inaudible 02:56:44], acid reflux hernias, depression, loss of appetite. I lost 25 pounds in three weeks. I wanted to this Delta study follow ups because quitting early meant incomplete wasted data and continued monitoring by the NIH was vital for my health. As a result of stopping the study drugs, I'm over all the symptoms. At the same time, my Delta viral load is slowly increasing. I try my best to eat healthy, exercise, I avoid alcohol pain meds, all recreational drugs. I take Entecavir, [inaudible 02:57:22], and the electrolyte supplements faithfully.

Joe Balistreri ([02:57:26](#)):

As of February, 2020, many of my blood tests are close to normal with a Hep B viral load of 10, and a Delta viral load of 4,500, both considered quite low. In the past, my Delta viral load has been in the millions. My GI doctor believes the clinical trial may have had some good effect after all. Today, because my blood tests have improved, my MELD score is at eight and I don't qualify for a liver transplant. As for future treatments, [Entecavir is ideal for controlling my Hep B. The next step would be a Hep B cure. It would be a twofer since Hep Delta can't survive without Hep B. And there's also the chance that my liver might reverse some of the cirrhosis.

Joe Balistreri ([02:58:16](#)):

Finally, for the huge numbers of hepatitis patients like myself, who can't tolerate it, we really need treatments free of interferon.

James Valentine ([02:58:34](#)):

Wow. Another incredible set up set of panelists' remarks from incredible individuals who were quite brave in sharing their treatment stories with all of us. Now we want to really, again, just like before, build on that and hear from all of you that are with us today and helping answer these questions. These are discussion questions that we'll be working with together over the next hour. We want to know what are you currently doing to help manage your symptoms and your condition?

James Valentine ([02:59:06](#)):

If you are currently taking a prescribed medication for hepatitis B, how do you feel it's affecting your daily life? We want you to consider what are the most important benefits of an ideal treatment. So thinking about not just what you're doing now, but what it is that you might want from that next treatment. We'll talk about those future treatment goals that you have as well as then end with a

discussion around your choice and decisions around enrolling in a clinical trial for an experimental hepatitis B medication. And what would you consider whether that be routes of administration you would be interested in, the length of treatment you would be willing to accept. What side effects, if any, you would be willing to tolerate in order to participate in a trial for one of these investigational products?

James Valentine ([02:59:54](#)):

So to start us off with this, I'd like to actually first go to a polling question. For those of you who may just be joining us. We were asking our patients, individuals with hepatitis B and their caregivers, family members that provide direct care giving to them to respond to these questions and to participate. You can pull out your phone, you can open a new tab in your web browser and go to [Pollev.com/hepb](http://Pollev.com/hepb). You can see that URL listed at the top of this slide, and we'll be coming back to some other polling questions throughout this session.

James Valentine ([03:00:35](#)):

Our question for you now is, in general, how much do you think your hepatitis B medications have helped improve your quality of life? So think about the treatment regimen that you've taken and let us know if you think, A, there's been no benefit at all, B, it has helped somewhat. C, see it has helped a lot, D, you're not sure how much it has really helped. E, other meaning that you have other thoughts about how well your hepatitis B's medications have improved your quality of life, but that has not listed on this slide.

James Valentine ([03:01:10](#)):

We'll give you a few moments to think about this select the response that is most appropriate, and you think best reflects your experience with how much you think your hepatitis B medications have helped improve your quality of life. And again, we're asking only that are individuals with hepatitis B and their caregivers, family members reply to these polling questions. Okay. It looks like responses are still just finishing trickling in, as it stands, it looks like the largest response is that is helped a lot. 42% of our patients represented today. Having had an experience where they, or their loved one feeling that their medications have helped a lot.

James Valentine ([03:02:01](#)):

We have about one fifth, 20% saying that it's helped somewhat. And then there's also a smaller proportion about four to 5% that say that there's no benefit at all. Meanwhile, there's another fifth of the group that's not quite sure how much their medications have actually helped improve their quality of life. And then we actually do have a proportion of the population represented 15% that are saying other something else that's not listed here. I think this is going to be a really important if we can go to our discussion group to talk about what this actually has meant in your lives, whether you think that medications that you've had have been able to help you a lot, whether you maybe not so much, or maybe if you're unsure. But any of those cases, we really want to get a sense of what is it that you've tried and how well has that worked for you?

James Valentine ([03:02:58](#)):

So again, to help in our conversation, we have a few ways for you to participate. We have with us a group of panelists who are here to participate in the discussion. We also invite you to dial in to 1 703-844-3231. Again, that's 1 703-844-3231. If you have any thoughts about your treatment experience that

you would like to share, we'd like to hear from you, and you can, of course continue to submit your written comments for us in that form. That's below the live stream that you can see on your webpage right now.

James Valentine ([03:03:42](#)):

We may not be able to read all of those. We will consider all of those as we put together the voice of the patient summary report, but we will be sharing some of those as we go throughout the program. We have two individuals with us today that were not part of that panel. So you have not heard from them. I'd like to start here first with Sue, to ask about what is your assessment of the treatment options that you have available? And what has been your thinking around decision making, around taking treatment options? We'd like to hear if you want to first start by introducing yourself a little bit and talking about your experience with the treatment options.

Sue Wong ([03:04:27](#)):

All right, thanks, James. My name is Sue Wong. I am living with hepatitis B, and I also happen to be a physician and I do primary care, but I also take care of a lot of patients with hepatitis B and I am involved with the world hepatitis Alliance, which is an organization that advocates for patients. For myself, I am currently in what we call the chronic inactive phase of hepatitis B. Meaning my viral load is under 2000. My liver enzymes have been normal, and so as per the AASLD/EASL guidelines, the professional liver society guidelines, I don't meet the requirements for treatment. So I'm not on anything.

Sue Wong ([03:05:10](#)):

That can be good and bad. I think we realize that at this point, we believe that the treatments don't benefit those of us who are in the chronic inactive phase, but I feel like I get nervous. I think many of us who are not on any medication sometimes feel anxious that we're kind of sitting on a ticking time bomb. And even though the data so far so that we may not be at tremendous [inaudible 03:05:38] more risk. There's also some data showing sometimes that viral load in itself and just the chronic inflammation from the virus could potentially increase our risk.

Sue Wong ([03:05:46](#)):

I'm eager to see data, and I also look at the history from HIV and Hep C, which show that at some point they also had cutoffs for treatment, but now for both of those diseases, we treat all. And so some of the history of those diseases kind of makes me think, are we evolving towards that and hepatitis B? So those are my current thoughts.

James Valentine ([03:06:08](#)):

Sure. Sue, thank you for sharing that and sharing the perspective of someone that does not yet qualify under treatment guidelines for current medications. But since we are covering different approaches to treatment beyond medicines and medical procedures themselves, I was wondering if you, at this point in your disease experience have done anything outside of medication, whether that be diet, or exercise, or anything else that you might be doing to try to help with your disease and its progression?

Sue Wong ([03:06:48](#)):

Sure. Yeah. That's a great question, whether or not some of these other lifestyle therapies we think helps with the liver. I think that's a great approach, I think, and this is what I often tell my patients and kind of my belief too, is just to keep the rest of your body healthy just the whole person approach,



protecting the liver obviously is important. So I make sure I had all my vaccinations like hepatitis A, fatty liver is a big issue nowadays.

Sue Wong ([03:07:14](#)):

Fatty liver is impacted by having diabetes being overweight, exercising. And so those are the things that are in my head of what I should do, because even doctors often aren't listening to their own advice and I've heard others say that too. But I don't take any herbals or supplements. I know there's a lot out there [inaudible 03:07:31] something that there's some studies on, I don't take any of that. I generally just try to have a healthy lifestyle.

James Valentine ([03:07:40](#)):

Sure. Thank you so much Sue. Our other discussion group member who you have not heard from yet is Thomas. And so I want to pose this same kind of opening question to you, Thomas. I'd like to get your thoughts on how well available treatments have been helping you manage your disease and the disease symptoms and any thoughts you have about what impact they have had.?

Thomas ([03:08:10](#)):

Just to introduce myself, I'm Thomas [inaudible 03:08:16], I'm a scientist who works on the molecular structures of hepatitis B and how it works, how it replicates, how to detect it, or this sort of thing. I found out I had hepatitis B in my teen years, and I sort of was upset then, but then I sort of tried to find out more and more about disease and found out that I could do something about it and got into this pathway to become a scientist. I've now been doing that for the last 13 years, concentrating only on hepatitis B. When I found out I was in the immune tolerance phase, as it was then called, I still am, but with some raised AOTs. I'm in that, in between phase and I'm currently on Tenofovir, that has been fine. In this phase, I haven't had many symptoms. So on the physical front, I don't know if the medication has helped at all, but on the mental front of not feeling like I'm infectious to family, and closer contacts, and particularly children has been such a weight off of my mind after taking this. And just the act of being able to do something against the virus has been sort of empowering. And I think that's a huge part of treatment and the benefits you do get from treatment.

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

In terms of... Did you ask about availability as well? Sorry.

James Valentine ([03:10:43](#)):

No. This was very helpful. Actually, you triggered a question for me. I have a follow up for you.

Thomas ([03:10:49](#)):

Yeah, sure.

James Valentine ([03:10:49](#)):

Which is, you talked about kind of the weight of knowing that you're not infectious and that that's allowed you to kind of feel liberated and maybe do more. So wondering if you could give an example of something that you're now doing or feel more comfortable doing that you weren't so much before, before you got that treatment.

Thomas ([03:11:14](#)):

Just being able to interact with younger family members, and hugging, or playing around with them, I'm a lot more comfortable with doing that now. I guess that's one of the good examples that [inaudible 03:11:36]-

James Valentine ([03:11:36](#)):

Sure. No, that's an important one. So thank you very much, Thomas. And we'll be coming back to this panel throughout. I want to read a couple of the live written comments that have come in, which are also talking about how well current treatments have been able to manage their conditions.

James Valentine ([03:11:58](#)):

We have Wen, from Tennessee, who wrote in that said, five people in her family have died from liver cancer due to hepatitis B, and she is infected herself. Her sister took interferon and died of liver cancer. Wen is on Tenofovir right now, and she's afraid to die prematurely like her family members. So she wanted to make the point that even though she is on treatment, there is still residual fear around that ultimate disease progression. Some other comments, Patrick, from the Philippines said that he manages his hepatitis B by eating healthy foods, but is currently not taking any medicine except for supplements. So certainly, there's others that maybe we are in that state where they're not yet eligible for available treatments, but they're working to stay healthy through other means. We have Joe, from California, who wrote that he's not sure that the hepatitis B meds have helped because he's coinfecting with hepatitis D, Delta, which suppresses his hepatitis B. And then finally, Bright, who you'll also recognize is one of our panelists from the first session noted that it's hard to really tell how the treatment has impacted his quality of life. His viral load is undetectable, but his liver enzymes fluctuate all the time and his physical symptoms have not improved. He actually thinks they have gotten worse after treatment for almost five years.

James Valentine ([03:13:47](#)):

So you can see there's a kind of a mixture of what people have tried. I can now see why there might be some of those "unsures", not sures that responded to that polling question, as well as some of that range of the different experiences. I want to kind of build on this. I think it's very interrelated, and again, encourage people to also call in to our phone line. If you'd like to share a comment over the air.

James Valentine ([03:14:21](#)):

Related to how well current symptoms are working... or current treatments are working to help manage symptoms. We also want to get a sense of how taking these different prescribed medications for hepatitis B are affecting your daily life. Now, this could be anything from different side effects of products, the burden to actually need to take these products or visit your doctor. Really anything that you might view as a burden or a downside of needing to take these treatments. I'd like to ask Wendy, if she might be willing to have a little bit of discussion around this? Wendy's on mute.

Wendy ([03:15:15](#)):

Yes. As I told people the other day, I actually just started treatment about a week ago. I started taking Entecavir because my liver enzymes after being fairly stable, all my life has recently elevated. And so my hepatologist thought that'd be a good time to start taking medication. I have to admit, I've only been on it for a week, so I don't know the effects of the entecavir. I have to say, I don't enjoy being on it. Even in

this first week, I'm already experiencing some mild side effects, that they're irritating such as itchy skin, just feeling off and not myself.

Wendy ([03:15:53](#)):

Time will tell whether or not this will be effective, but as Sue has said, I think that anyone with hepatitis B that is not on treatment, does feel a level of uncertainty as to what their future holds, because they feel like they're not able to take a proactive course other than healthy lifestyle. So it is definitely an unknown when you're not able to take medication. So at least now I know that being on medication I'll have hopefully a lower chance of getting liver cancer like my mom had.

James Valentine ([03:16:27](#)):

Sure. And Wendy, do you mind just sharing with us some of the side effects that you were referring to that you've been experiencing?

Wendy ([03:16:33](#)):

With Entecavir?

James Valentine ([03:16:33](#)):

Yes.

Wendy ([03:16:36](#)):

It's just, it makes me feel foggy and I don't feel like myself in this past week, and it could be just because I started it and my body might be reacting to it. I don't know, but it's also, I break out in rashes and it's inconvenient because I have to fast two hours before and two hours after. I do not like going four hours without eating because I'm very active person and I'm always hungry. So yeah, it's an inconvenience that way. And I have to go to bed very hungry because I have to fast before.

James Valentine ([03:17:10](#)):

Sure. Thank you so much. We're getting some live written comments about this question. Paul, from California wrote, I'm currently on Vemlidy for treatment and numerous other meds for issues related to hepatitis B and cirrhosis. Although I was told there would be little to no side effects, I was sort of 'brain dead' for three months afterward. I could not think, process, remember, was irrationally emotional, and couldn't even speak properly.

James Valentine ([03:17:42](#)):

It took another six months after the initial three to start getting back his memory and vocabulary, it also caused digestive issues. He still lives with these issues on a little less scale with the help of more medications. He's described as quality of life as having plummeted once he started treatment, he knows the treatment was necessary-

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James Valentine ([03:18:00](#)):

... plummeted once he started treatment. He knows the treatment was necessary and inevitable, but the issues and effects after the fact were just as detrimental. Not just physically, but mentally and

emotionally. Another comment that I'd like to share is Yvonne from Australia. She says that she had already had early cirrhosis by the time she made it to a specialist for the first time. She's been taking tenofovir for 10 years, which has literally saved her life. Being on tenofovir is not affecting her life much, and she has a positive attitude of gratitude. She has no side effects, and the six monthly visits to the specialist clinic are easy because she works at a hospital. Cost is also not an issue, because in Australia it's heavily subsidized by the government. She says she would much prefer a drug that could cure her, so she wouldn't have to be on medication long-term. She never says lifelong, because she believes a cure will be found in her lifetime.

James Valentine ([03:19:07](#)):

But you can see, I think from both Paul and Yvonne's comments, that there's a varied ability and side effects experienced. I think that probably is true for most any drug. But in either case there's still an unmet need that exists, something more that they would like from a future therapy. And we'll be talking about that shortly. I'd like to come back to our discussion panel, and ask Peter if he would be willing to share with us some of his thoughts about how these prescribed medications might affect his daily life.

Peter ([03:19:53](#)):

Hi.

James Valentine ([03:19:54](#)):

Hey Peter.

Peter ([03:19:59](#)):

The medications, I was diagnosed with hepatitis B since 2004, and admittedly I was taken or prescribed, actually it's called [epivir 00:03:20:12], and it didn't really help. It had a bad side effect and it didn't reduce my viral load. And it also [inaudible 03:20:25] about a year later my GI doctor changed me to TDF and that was effective. It reduced my viral load to undetectable. And I continue to taking it for over 10 years and it got so routine that I didn't really have any inverse side effect. And I just didn't really affect a bad quality [inaudible 03:20:58] I didn't have. My life was just normal, regular. I take medication every day. And I thought about that I even have hepatitis B, I just take this medication every night and don't think about it. But as seen from my video, I recently had a liver transplant because I had stopped the medication for a year and a half based on the advice from my GI doctor.

Peter ([03:21:36](#)):

But after my liver transplant, I was switched over to TAF, the [inaudible 03:21:47] because it's less infected on my kidney. I currently have stage three kidney disease as well. But [inaudible 03:21:59] I was given the immunoglobulin for seven days straight after my liver transplant. And now I only take this immunoglobulin I take about every six months. Only when my hepatitis B surface antibody is below 250 MIU per milliliter. And so once I get the treatment, it jumps up to 1000, but then it wears off after about six months or so, and it goes below 250 again and I would repeat the treatment. The [inaudible 03:22:54] is a very sooner to original [inaudible 03:23:01] side effect from taking it.

James Valentine ([03:23:04](#)):

Thank you so much, Peter.

Peter ([03:23:05](#)):

I take...

James Valentine ([03:23:07](#)):

Yeah. Thank you for sharing that. We have a live email comment that came in. Another example of just another treatment experience and how side effects might be a bit different from person to person, but Joan from Pennsylvania wrote in saying she started on [lamivudine 00:03:23:28], but develop drug resistance, so had to change to TDF, but then she developed osteoporosis as a result of TDF. So switched to TAF to decrease her risk of further bone loss. So she's currently on her third hepatitis B antiviral, and is worried that if there's no cure in the near future, she may run out of options. So I think this has been really useful conversation around the existing treatments. I want to go to a polling question as we evolve on this and build on this really, because I think our group here has been talking about what it is that they would want.

James Valentine ([03:24:16](#)):

And whether it's talking about the downsides of things that exist, or maybe their current treatment approach is not going as far as they would like to prevent disease progression or their fear of disease progression. We want to get a sense from you of what would be most important from a new ideal treatment. And so we're going to go to our polling questions here. If you can go to [pollev.com/hepb](http://pollev.com/hepb). Our question for you right now is, "What would be the top two most important benefits of an ideal treatment for chronic hepatitis B?" And here you can select up to two options.

James Valentine ([03:24:52](#)):

Your options are A, being able to stop taking medication after six to 12 months. B, experiencing an improved quality of daily life. For example, having less fatigue or joint pain or more energy. C, a loss of hepatitis B surface antigen. D, decreased risk of developing liver cancer. E, eliminate the possibility of transmission to others or F, some other important benefit that you would want from an ideal next treatment that would be important to you. And again, you can select up to two options here. Just give you a minute to think about this. What would be the most important benefits of an ideal new treatment? You can select up to two options.

James Valentine ([03:25:56](#)):

All right. So it looks like as it stands. And again, these are percentages of responses, not individuals, because again, here is an option where people are allowed to respond more than once. So that's the percentage of responses overall. But our greatest response is people would like to see a decreased risk of developing liver cancer. That maybe is not surprising given earlier that was one of the biggest worries that was voted. After that it looks like you'd like to see a loss of hepatitis B surface antigen. Ranked pretty close third and fourth are being able to stop taking medication after six to 12 months, and then experiencing an improved quality of life. Things like less fatigue and joint pain or more energy.

James Valentine ([03:26:44](#)):

There are individuals, a smaller group that would like to see the elimination of the possibility of transmission to others, and nobody ranked other. So something that wasn't listed on this slide is something that they would like to see from that next ideal treatment. So let's broaden this discussion and hear from you all about what it is you would like to see from future treatment. I'd like to go to our phones. We have Ross from California. He wants to talk a little bit about his treatment experience, but

how that can also relate that to what he's looking for from a better or ideal treatment. So Raj, are you with us?

Ross ([03:27:33](#)):

Yeah, I'm here. Thanks for taking the call. Yeah.

James Valentine ([03:27:33](#)):

Thank you, Ross, if you want to go ahead and introduce yourself and tell us a little bit about your treatments and what you're looking for?

Ross ([03:27:40](#)):

Sure. Yeah. So my name is Ross [inaudible 03:27:41], I'm based out of California and actually worked for a bio pharmaceutical company out here. So for me, an ideal treatment would be one that gives me a functional cure. So I've been taking Viread for, gosh, I almost forgot how long I've taken it now. Definitely over 10 years. So something for the future would be something that can certainly address the fears I think a lot of us have, which is really that it's something that could lower the probability of liver cancer. So something that would lower our viral load, detectable levels, something that would protect my liver from inflammation, scarring, fibrosis. Or anything that would lead to that end result, which I think a lot of us are fearful of would be what I would think of as an ideal treatment. So it's not necessarily clearing it out of my body, but essentially having a functional cure where I could have confidence of living a full life.

James Valentine ([03:28:37](#)):

Sure. No, that's a very, very precise and helpful Ross. So I really do appreciate that comment. Thank you very much. So we have a couple of live email comments that have come in that I'd like to share with you all as well. It's sharing some of treatment experiences, but I think it helps highlight some of what people might be looking for from future treatment. So we had a comment from Tim from the UK. He said he's actually worried about how treatment will impact his life. His latest blood tests have shown an increase in ALT and the doctor wants to put him on entecavir in order to decrease the viral load in his body. But he's worried about going on lifelong treatment because he learned this could cause life threatening damage to his liver condition called lactic acidosis. He's also trying to get around the benefits of... Still trying to get the benefits of this treatment. If it doesn't prevent the complication of chronic hepatitis B, things like cirrhosis or liver cancer. So very much focused on what Tim would like to see. I'd like to go to our discussion panel and actually want to come back to you, Sue, because I'd like to get the perspective of someone who's not yet eligible for medication and what you would have to say about what you're looking for from an ideal treatment for someone in your situation.

Sue ([03:30:10](#)):

Yeah, that's a good question. This is really important, I think, because we have such great oral medications that are safe, easy to take, they're once a day, very few side effects. And so to go to something, I mean, a lot of the medications, the treatments right now that are being researched are not oral. Some of them are injections, some of them may have side effects. And especially if they're trying to boost the immune system, you may actually not feel well. So we know one of the original treatments for Hep B was interferon, which had more of a potential to actually cure and where you would lose a surface antigen, but people felt ill often. And it was a one year treatment course. And so when the

question comes up, "Would you be willing, would I be willing? Would any of us be willing to do injections for a year?"

Sue ([03:31:03](#)):

Or would it be six months with a higher potential cure? Maybe not as high as the Hep C medications, which are like 95%. But when we do it for a 20% chance of cure, 50% chance of cure, these are all really important questions that we have to think about. And it's going to be different for every person, right? Depending on what you're doing in your job or what you need to do in life. And I would be willing to do something beyond oral treatment, injections. And I would probably be willing to not feel great, maybe not miserable, but still be able to function in my life. But if I actually knew there was some chance of actually losing the surface antigen, I think it is that important for most of us to eradicate.

Sue ([03:31:44](#)):

I feel it's a little bit like The Scarlet Letter. You've heard all these stories about stigma, even as a physician. I feel it when I go get testing, I'm embarrassed about it and I'm always trying to figure out do I disclose it to my dentist? That lives with us, even though my blood tests may look perfectly fine. And the researchers may not be measuring that part, that stigma. That part weighs very heavily on a lot of us. So I would be willing to endure longer treatments if there's some chance that I would be able to achieve that functional cure.

James Valentine ([03:32:16](#)):

Sure. And Sue, you also mentioned that you would be able to feel not that great, I think is how you put it. What were you thinking of when you said that? Is it fatigue, nausea, is there certain things you were thinking?

Sue ([03:32:25](#)):

Yeah, right, right. Of course, it's easier to say that when you're not feeling that, but I'm thinking how interferon I know for some people, the [inaudible 03:32:35] I feel malaise, they feel like they're flu ish. Not everybody does, so sometimes you may not know until you start it, but I know people have endured that for Hep B and for Hep C. And you do it, and at the end of the year, if you're cured it definitely makes it worth it. So, yeah. So I think a little malaise I could probably handle.

James Valentine ([03:32:55](#)):

Got you. Thank you so much, Sue. We have some comments from the web on what people are looking for from an ideal treatment that I'd like to read. So Julius from Uganda said that he would prefer the most important benefit of a Hep B treatment is the loss of surface antigen and only taking his pills for a limited period of time, like one year. So I think very consistent with what Sue just described. Lindsay from Kentucky wrote in saying that a cure would be ideal, but a functional cure would be welcome too. Something that would make passing hepatitis B on to others no longer a risk, and would also reduce the chance of cirrhosis and liver cancer, even if not completely removing the virus. It would also do so with limited side effects, whether you used long-term or short term. Preferably short term use, perhaps no longer than six months of treatment.

James Valentine ([03:33:57](#)):

We also heard Chris from Maine, who is a parent of a child with chronic hepatitis B. Says an ideal treatment for hepatitis B would act similarly to the current treatment for hepatitis C, completely



eradicating the virus. Any treatment that would require ongoing indefinite regimen of pills, similar to the current HIV treatment, would be ineffective in resource poor regions and countries.

James Valentine ([03:34:27](#)):

And then we have Ronald from California who said in his ideal treatment would be one pill taken only once, or if not possible then one pill taken daily for one month resulting in the loss of hepatitis B surface antigen and normalization of ALT AST and reversibility of any fibrosis, all of which are sustained as cure forever. So we're hearing a lot about a cure and different definitions, functional cure, complete cure. I'd like to go to Joe on our discussion group to maybe add to that discussion and give some of your thoughts around cure.

Joe ([03:35:15](#)):

Thank you. Yeah. Well, I was sort of chomping at the bit because I really want to get out the concerns about interferon as part of a cure or treatment. Okay. So I got interferon for hepatitis D in the clinical trial, and I reacted very, very badly. The only times that I've had real symptoms since I first got hepatitis B in the mid seventies, was from the interferon a little over a year ago in the clinical trial. And I have been able to talk to people working in research at VIR Biotechnology in San Francisco, and Janssen Pharmaceuticals. And one researcher said to me, this was her own opinion. She said that there are people who are really stuck on using interferon, and there are other people in research who feel we have to work on alternatives. And speaking as someone who really went to a frightening place with interferon, I just am hoping that research will go into treatments that don't include interferon.

James Valentine ([03:36:49](#)):

Thank you so much for adding to that, Joe. So I think we're at a point where I want to spend some time talking about how we get to that next ideal treatment. And again, Anna Lok set this out so beautifully early on where she said, "We need our patients, our community to come together and participate in trials because if nobody participates then there won't be those next treatments." And so we want to drill down on that and really understand what it is that those of you in this community would be willing to... What type of clinical trial you'd be willing to participate in. What would be key decision making factors for you about that. And so to help us get into that discussion, we have a series of polling questions.

James Valentine ([03:37:41](#)):

This would be our final polling questions for the day to help us get a sense of your experiences and your thoughts about clinical trial participation. So we have three questions for you. And our first is asking you about what are the top factors that would help you decide on whether to participate in a clinical trial for an experimental hepatitis B treatment. And here we're giving you the option to select up to three choices. So what are the top three things that would be a key decision making factor for you? Your options are A, how the treatment might improve your physical wellbeing. Things like fatigue, pain. We talked a lot about these earlier today. B, how the treatment might improve your emotional wellbeing, whether it be things like stigma or anxiety and depression. C, the distance and time it would take to travel to the study site.

James Valentine ([03:38:32](#)):

So that's where the clinical trial is being conducted. D, the risk of common or less severe side effects. So these would be things like headache or nausea. They might be more common, but less severe relative to

other types of side effects. E, the risk of rare, more serious side effects. Examples of this might include elevated liver enzymes, or ALT flares. F, would be the amount of time it would take to participate or impact your daily life. G, the way that treatments are administered. For example, whether it's a pill versus an injection. Or H, some other factor that's not listed on this slide that would be a top factor for you in deciding whether to participate in a clinical trial for an experimental hepatitis B treatment.

James Valentine ([03:39:26](#)):

I'll give you some time to think about this, please select up to three options. So while results are coming in, it looks like the top choice. Again, these are percentages of responses, so that the top ranked factor would be the risk of rare, more serious side effects. After that, it looks like how the treatment might improve your physical wellbeing, impacting things like fatigue. After that, those are, I think, by and large, the top first and second, that there's a little bit more of a clustering of a number of factors. The amount of time that it would take to participate or impact your daily life, the risk of common, less severe side effects, distance and time it takes to travel. And the way that treatments are administered. However, every single option has been selected by participants today. We do have some people saying that being able to treat or improve your emotional wellbeing would be important.

James Valentine ([03:40:38](#)):

And some people have said other as well. So we'll definitely want to explore why it is you chose the choices that you've made here in terms of your top three. We want to understand where maybe you would draw the line on any of these things, why you selected them as your top choices.

James Valentine ([03:40:55](#)):

So if we go to our next polling question. So here we're asking if you decided to enroll in a clinical trial for an experimental hepatitis B medication, would you be willing to accept the following routes of administration? And here you can select all that apply. So your options are A, an intravenous or IV infusion that's given over one hour weekly, and this would be for a duration of six to 12 months. A subcutaneous injection that is under your skin. It's not a muscle injection that's given weekly or monthly for up to one to two years. Two or three pills that are taken every day for up to six to 12 months. A combination, if you would only do A and C please select D. And then if you would only do a combination of B and C, which would be the subcutaneous injection and pills, but not IV, please select E.

James Valentine ([03:41:59](#)):

So think about this. I know we've given you a number of different options to consider, but we want to get a sense of what are the different routes of administration that you would be willing to have administered in a clinical trial. Right, I'll give you a few more moments to think about this. So it looks like the greatest responses, two or three pills taken every day for up to six to 12 months. A number of you would also be willing to take a subcutaneous injection under the skin, far fewer being willing to do an IV infusion that's given over an hour period of time weekly. A number of people are willing to do the subcutaneous injection and pills, and very few people would be willing to do the infusion plus pills. So thank you very much for your responses here. And then for our final polling question on this.

James Valentine ([03:43:18](#)):

So here we want to know if you decided to enroll in a clinical trial for an experimental hepatitis B medication, would you be willing to accept the following routes of administration? So this looks like it is a repeat. Is there by chance a next polling question? No, okay. So apologize for the repeat question.

We'll actually move now to the discussion. So here we want to get this sense from you of what were those key factors that would make a difference in your choice to participate in a clinical trial? And we actually have a phone caller, Chris from Maine who wants to talk about this very idea of what it is that she would be willing to do, what she views as important for participating in clinical trials. Chris, are you with us?

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

Yes, I am. Thank you.

James Valentine ([03:44:23](#)):

Thank you, Chris. Please do share. Introduce yourself and share your thoughts about clinical trial participation.

Chris ([03:44:32](#)):

I am the parent of a child with hepatitis B and what I would like, to date she has not required any treatment, but what concerns me most of all in clinical trials historically conducted in the United States is the historic short shrift that has been given to women, minority communities, low income people, and people for whom English is a second language. We have an abysmal track record on that. And so I want to underscore that any clinical trial needs to embrace and involve those communities, especially given the fact that most people living with chronic hepatitis B in this country are often immigrants, people in minority communities. And I would just like to seize on something the American Medical Association wrote when it talked about problems with health equity and one day developing a vaccine for COVID-19. They print out there's widespread and persistent under representation of minoritized communities in national clinical trials, despite growing evidence that whether for environmental or genetic reasons, drugs have different effects on different populations. Thus, the lack of representation could have direct implications on the efficacy of future hepatitis C treatments. Time and time again, we know that people who get involved in clinical trials have quality healthcare, have doctors that can connect them to clinical trials. They have resources, they have health insurance, which is why we have such a preponderance of white Americans participating in clinical trials. Going back to the AMA who's recommendation to increase representation, trusted sources must be enlisted to help educate and recruit underrepresented groups and barriers like transportation, time off work and childcare must be addressed to ensure full participation. I really believe that time and effort has to be made to involve physicians who serve these historically underserved communities and are at high risk of hepatitis B, including Asian Pacific Islanders and especially the African immigrant community. And again, these doctors need to have staff who speak languages to fully inform people of all aspects of clinical trial participation. So, that's it. Thank you for listening.

James Valentine ([03:47:25](#)):

Thank you, very poignant points that you made, and I think extremely relevant and important for us and for our colleagues at FDA and in drug development to hear. So thank you so much, Chris, for dialing in today to share that with us. We have another phone caller that I would like to go to. Karen from California who would like to discuss what it is that she would be willing to do to participate in a study and perhaps a little bit of how that might be different today than in the past. So Karen, are you with us?

Karen ([03:48:04](#)):

Yes, I am. Thank you. I guess I'm again talking about aging as an older person. So what I would be willing to tolerate in the way of trial and treatments during a trial, it's probably a little bit different now than it might've been when I was younger. I would have been willing to put up with more, maybe higher ALT flares or less comfortable side effects than I would know that I'm older. But it would also depend a lot, and this ties in a little bit with what Chris was just saying. It would have a lot to do with how well I was being monitored. And I think the area of monitoring is there's a big gaping hole there still. And the fact that people can now be on daily antivirals. I think in some ways hasn't helped because it kind of lulls us into the sense that if we just take our daily pill, the monitoring might not be so important.

Karen ([03:49:06](#)):

And I think Peter's story really hit me hard as far as how quickly he developed such a life threatening problem after discontinuing the treatment. And there's obviously with some kind of a gap in monitoring that happened there, or he would never have gotten into that situation. And of course you get concerned during a trial, participating in a trial, especially if you have to travel great distances to be monitored, or just generally how much, how thorough the monitoring would be. And there are a lot of barriers to this. And I think also we don't always necessarily have the best tools for monitoring yet.

Karen ([03:49:52](#)):

I personally experienced some problems with determining exactly how bad my cirrhosis is or was, and we've gone from needle biopsies or laparoscopic biopsies to doing more of the fibro scan now. But I think there are questions about how reliable that is. So one big concern I would have if I went into a trial is how well would I be, being monitored and how accurate would that monitoring be and what would be the effect of that on my future health?

James Valentine ([03:50:24](#)):

Sure. Thank you, Karen. A very, I think perhaps unique topic, one that would definitely fall into that other category. So I really appreciate you calling in and sharing that. We have one more phone caller, but before we go there, I actually want to come to Jackie on our discussion panel. We've talked a lot about some of these different considerations, key factors for participating in clinical trials. So, Jackie, I was wondering. When you were looking at that polling question, what was it that popped out to you as being most important? What factors do you consider, would you consider for clinical trial participation?

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James Valentine ([03:51:00](#)):

... factors would you consider for clinical trial participation?

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

All right. Sure. Thank you, James, for this opportunity and Hep B Foundation for giving us this opportunity to participate. When I look at the podium question, I think there's one thing missing, which is not an option, which is that you want a clinical trial that is sort of give you a high hope of a cure, functional cure or real cure, which I think is the most important. We are looking for a cure. All right. That's very important. So as long as it's effective. If you guarantee me that it's going to, you're going to get a cure after injection. Well, six months. Yeah, I will do it. You understand what I'm talking about? Because I don't want to take the medication for the rest of my life. However, there's also, I think their

promising point is that there are so many clinical trials, so many research and support going down for hepatitis B now. So I think we have a very good chance of getting a cure in the near future, probably. Hopefully within five or 10 years, or hopefully does.

Jackie ([03:52:08](#)):

Then ideally, obviously, we don't want an injection. I think the most important thing is that you have a Hep C cure. You have a single combination pill, a single pill that can be taken for 12 weeks and you can get rid of 99% would be cure. And now we have B we have been researched and study for much longer than Hep C and probably also not much longer than HIV. And therefore I think there's no excuse that the scientist has to find a cure, hopefully soon. I have been working as a scientist for the past 30 years. I've been doing research. I'm a very vigorous scientist. And I also know a professor in the medical school. I teach hepatitis and diabetes drugs in the past 10 years. And I also been involved in the social support groups on social media.

Jackie ([03:53:02](#)):

We have seen many, many patients and there's one point that I think is missing from this meeting is that there's one key point that everyone is missing is that, we are so lucky. I am lucky because my brother is not lucky because when he was diagnosed, he's already in diverse cirrhosis with liver cancer. And you don't want to live with diverse cirrhosis or liver cancer for the rest of the life. You want to give out a single medication like what we are doing now that I've been taking. I've been taking the antiviral. And that is ... I started with entecavir, which is low viral resistance. And then I now switched to a [inaudible 03:53:41] which is pretty safe. It's probably the most safe drug. I have no obvious side effects. [inaudible 03:53:47] is a really, really good medication for suppression happen already.

Jackie ([03:53:55](#)):

There's no excuse. If anyone is eligible for treatment, they should get on treatment. This drug has been there for decades.

James Valentine ([03:54:04](#)):

Sure.

Jackie ([03:54:04](#)):

You know, it's very, very cheap. And, obviously, the first thing of course, prevention, vaccination. I think there's still a big gap there. And then the people, if they have a hepatitis B with elevated liver enzyme.

James Valentine ([03:54:18](#)):

Yeah.

Jackie ([03:54:19](#)):

You should encourage them to get treatment as early as possible. And obviously if we research it, we can find a simple cure that we can take a short period of time to treat them.

James Valentine ([03:54:27](#)):

Yeah. Thank you.

Jackie ([03:54:27](#)):

Then that would be great. Yep.

James Valentine ([03:54:31](#)):

No, thank you, Jackie. And I think, wow, it's such a powerful place to end with, you know, we're right where you started, which was we should be, for you and probably many others, we should be thinking about what is that thing that's going to be that cure. And hope that a treatment could be, could have the effect that would be that ultimate or functional cure. So I think that ties everything very, kind of this back full circle to where we started of what are the burdens that still do exist for this community? And now what it is that we're looking for from future treatment and the fact that those same things that we're looking for from future treatment are the things that we're looking for from our clinical trials.

James Valentine ([03:55:22](#)):

So I want to thank our discussion panelists here for joining us, adding to the discussion. Thank all of you that tuned into this. This concludes our second topic, which is our wrapping up our patient input for the day. And we're about to transition to some final closing remarks. But before we do that, I just want to, as your moderator, and our collectively first virtual ever patient focused drug development meeting, thank each and every one of you that took the time out of your busy lives. I know you've told us today that you're juggling so much, there's so much to deal with that can be tiring from your own having to manage this condition. And there's so much direct physical impacts as well as the worry and stress of the future. And so I just want to thank you as your meeting moderator, for being so courageous today to pull back the curtain on what it is to live with chronic hepatitis B I think you've helped educate us all.

James Valentine ([03:56:34](#)):

Certainly even someone who's been involved with the planning today have learned so much. So truly, it's been my pleasure. Want to thank all of you for giving me this chance to be kind of hearing and working with you for over this period of time, as limited as it has been. It's a rare type of opportunity, not one that often where we bring together a patient community where we're really asking you to not necessarily perhaps focus on the positive or the hope, but really to teach us about what it really is like. And that takes a kind of that special commitment from all of you.

James Valentine ([03:57:27](#)):

So I want to, as we're moving in to the final closing remarks, just want to remind everybody that there is today. This is not the end. This is not the end of your ability to give us input. If right now you're thinking, "I wish there's this one additional comment I wish I could have said." Please, go into that comment box right now and type that in and send that to us. You'll be able to do so until the end of the month. If it will be there. You'll also here shortly, a way that you can email in comments. It won't end here because we're going to continue to look at everything that you've sent in throughout today. Everything that we haven't had that chance to read out loud, and we're going to look at it all. And we're going to summarize that in that voice of the patient report, that summary report that Hepatitis B Foundation will be putting together to submit to the FDA, to put on the web. So that way all of our drug developers and researchers and clinicians, and even all of you in the patient community, will have that chance, that opportunity to look and view that report and use it as a resource.

James Valentine ([03:58:52](#)):

And what I personally hope that that will be outdated shortly, I hope. I hope that we have those next therapies, that cure that comes for you. And so, hopefully we'll be needing to update the state of the burden of hepatitis B and the unmet medical needs that exist. And just a reminder also, if you tuned in at any point today, and didn't get to see the full program, we encourage you to come back. Know that we're going to post the link to the program here on this webpage. You'll be able to, or it will be archived here on this webpage. So you'll be able to watch it on demand any time at this same link. You can watch the full program. And again, through June 30th, you'll be able to enter in any additional comments that you might have.

James Valentine ([03:59:49](#)):

So with that I would like to introduce our first closing speaker who is going to be providing a summary of what he heard today. And I feel that I need to at least say that that's a tall task and it would not, is not actually possible to fully summarize all of what is heard. But hopefully you'll be hearing some of the key themes that came out from what all of you shared today. And so it's my pleasure to introduce our summary remarks speaker, Mr. Larry Bauer. He's a colleague of mine at Hyman, Phelps and McNamara, where he's a senior regulatory drug expert. Before that, Larry spent 17 years as a research nurse at the National Institutes of Health. After that, he went to the FDA where he was one of the co founders of the rare diseases program within the center for drug evaluation and research, where he worked for 10 years before retiring from the government and working with me in patient focused drug development. So there's probably not anyone better to do this summary. Larry, take it away.

Larry Bauer ([04:01:01](#)):

Thank you, James. I really appreciate this opportunity. I want to congratulate the Hepatitis B Foundation and the Baruch Blumberg Institute on being pioneers in this first, very first virtual patient focused drug development meeting that I think was incredibly successful. I'd also like to once again, thank Dr. Mishra from the FDA and all the FDA staff that are here. I know when I worked at the FDA that we would learn from these meetings and they would, they're very helpful, especially when trying to evaluate the benefit risk of any new drug treatment. It's important to understand what's important to patients and what they look for in treatments when trying to make that risk evaluation. So, like James said, I'm going to try in a few minutes to give a very high level overview of what, of some of the points I heard. We've heard that hepatitis B is a serious and life threatening disease that in the U.S. can affect up to 2 million people and worldwide, maybe 257 million people with 600,000 deaths annually. So this is a significant disease, a significant health problem.

Larry Bauer ([04:02:18](#)):

The goal of treatment overall is to eliminate the hepatitis B virus, to prevent cirrhosis and liver cancer, and improve quality of life for people that are living with, with hepatitis B. And importantly, to help reduce the stigma associated with the disease. There's several different treatments that are available right now. We've heard about peginterferon with the every week injections, but also that it has many side effects. And also about the antiviral treatments that are available - entecavir, tenofovir DF, and tenofovir AF. These are oral once a day meds with fewer side effects, but they require long-term, maybe lifelong use, and they might be effective in suppressing the virus, but they don't eliminate the virus.



Larry Bauer ([04:03:07](#)):

And it sounds like there's many new drugs in development, which is encouraging with possibly over 27 trials. And for hepatitis D, which we heard about, it's not as well known as hepatitis B. And it only occurs in people that already have a hepatitis B infection. It causes higher risk of cirrhosis and cancer. And the oral antivirals might not be as effective in treating this, but there are five trials currently going on for hepatitis D as well.

Larry Bauer ([04:03:39](#)):

So after hearing the first panel, this was about living with chronic hepatitis B, what are the symptoms and the impacts? It was interesting. Sometimes people weren't aware that they had hepatitis B and they didn't find out until maybe having a pregnancy or starting to develop side effects. We learned that in some cultures, there are taboos about talking about disease. And so this prevents people from communicating openly and honestly, with each other about the disease.

Larry Bauer ([04:04:08](#)):

We've also learned that hepatitis B is one of the common ways of transferring, this is during childbirth from mother to child. And that this can be prevented if the parents are aware and if they informed their OB GYN. Some of the symptoms that people reported were when there are liver problems, jaundice, and yellowing of the skin and eyes. There can be one of the primary symptoms people talked about was fatigue. One person said, "I wake up every morning, feeling tired before even trying to do anything. And even after 12 hours of sleep." We heard about muscular pain, the development of liver fibrosis and liver cancer. It sounded like several people had family members that developed cancer and said, "I don't want to suffer the same fate as my brother who died from liver cancer". And some of the other important symptoms we heard about were the psychosocial symptoms. A lot of talk about shame and embarrassment related to the diagnosis, the impacts of social isolation, worries about the future and kind of chronic anxiety, and a lot of discussion about fear of developing a liver cancer in the future sometime.

Larry Bauer ([04:05:26](#)):

The impacts. It affects people's jobs. We heard about even someone, their child being kicked out of daycare, which is unimaginable. Discrimination in the workplace. And people refer to the term coming out like they're fearful of coming out and the judgements that might come along with that.

Larry Bauer ([04:05:45](#)):

When it comes to the treatments there's many people are taking antivirals, but they can become ineffective over time. But they do lead to some people having an undetectable viral load. One of the issues of these treatments are that they're often lifelong and people, anytime you have to take a lifelong medication every day, it gets tiring. And sometimes people stop taking the medicine for a short period of time. And they can often develop consequences from that. It's hard to keep up this regimen. We heard from one gentleman who actually went into complete liver failure and was in a coma for 10 days, ending up in having to have a liver transplant. And that has its own medications and treatments to help prevent rejection. And those treatments are often toxic and can include renal toxicities.

Larry Bauer ([04:06:40](#)):

Some of the things that people said that they would like. They would like to have a pill that they could only take for a short time. So it wasn't every day. They'd like to see a finite length of treatment.

Everybody I think would like to see a cure, but they would be happy with a functional cure that suppressed the hepatitis B surface antigen. And for clinical trials, people want to make sure that the benefits outweigh the risks. I think that we heard some people would consider taking an injection or an IV treatment if they thought that it could help. And most importantly, people are very concerned about additional risks that a new treatment ... that they would not want to cause further problems than they already have. And yeah, some of the most important benefits were that they would, that it would decrease the risk of liver cancer and that they would test negative for the virus. Hence. So I think that was the summary of ... Some of the points I missed. I couldn't cover everything, but it was a very informative meeting. And I really thank all the panelists and all the participants from all over the world. This was a kind of a unique meeting in that way that we heard from people from Africa, from Europe, and it was good to have everybody included. So thank you.

James Valentine ([04:08:08](#)):

Great. Thank you, Larry. You know, great, quite a comprehensive summary and I think just a preview for what we'll see ultimately in that voice of the patient report. So now to offer some closing remarks, it's my pleasure to introduce Dr. Robert Gish. Dr. Gish is the medical director of the Hepatitis B Foundation, and a clinical professor at the University of Nevada School of Medicine, and the University of California Skaggs School of Pharmacy and Pharmaceutical Sciences. He previously served as the medical director of the liver transplant program at the California Pacific Medical Center, then as section chief of hepatology at the University of San Diego. Dr. Gish is truly an internationally renowned expert. So Dr. Gish take it away.

Robert Gish ([04:08:56](#)):

Great, thanks so much for having me and inviting me. And I've appreciated the Hepatitis B Foundation asking me to be their medical director. I think I'm seven years into this. I want to extend also most importantly, the thanks to all the patients for participating in this. This was a forum for patients to be here for us to listen. I really want to compliment the FDA for being so open for this patient advocate dialogue. Dr. Mishra has been fantastic and the rest of the FDA team has been incredible. I've been interacting with them through the HBV forum as well. Just incredible. Dr. Bauer, thank you for your closing comments. And of course, Chari, Maureen, Joan, what you communicate with so much, cause you listen to the patients that are here. Dr. Ana Lok unlocked the door by the introductory presentation and highlighted what we can do for hepatitis B today.

Robert Gish ([04:09:50](#)):

I really want to highlight, we can't manage hepatitis B if people aren't tested. And right now the testing recommendations are this risk based testing, which we know fails. That's why so few people know they have the diagnosis and our Hepatitis B Foundation efforts is to screen all adults for hepatitis B with this triple diagnostic panel. And it's really part of what we're trying to do is what we think all adults should know their ABCs, which you should know your hepatitis A, B, and C status, and put this together as a package. One thing I heard today that was very interesting was the issue of social distancing. I had not really gotten that concept about hepatitis B before. I've been hearing it about coronavirus, of course, for five months now. But this really is part of the hepatitis B world. And we really need to reduce stigma. So we don't have to have social distancing with hepatitis B and it doesn't impact people's interest in marriage and relationships and career and school and many of the other things that the patients brought forward today.

Robert Gish ([04:10:53](#)):

I learned so much about how symptomatic hepatitis B could be. I know I've heard it from Joan before, but hearing it again and again, really makes me a more, I think sensitive provider. I work in an FQHC. We have 42 languages and hepatitis B is a big part of my practice here in San Diego, as well as California and Nevada. So I think this was an incredibly successful forum. I think we got more input from people around the world cause we did it by Zoom instead of trying to fly everybody in from various places, which of course is logistically, even if we don't have a pandemic ongoing. So thank you, patients. Thank you, advocates. Thank you, FDA. Thank you. Hepatitis B Foundation and all the leaders and participants and moderators today. Thank you so much.

James Valentine ([04:11:40](#)):

Thank you, Dr. Gish. And now to close out the meeting, I'd like to invite back Dr. Chari Cohen.

Chari Cohen ([04:11:49](#)):

Thank you very much, James. I don't know if my slides are up. I can't see them, but Oh, there they are. Thank you very much. So just some concluding remarks. Thank you, everyone. I hope that all the panelists and attendees found this to be a worthwhile and engaging experience. It was for me. I learned an incredible amount. I think my hands are tired just from taking so many notes from the last four hours.

Chari Cohen ([04:12:14](#)):

But I wanted to inform you all about the next steps. Evaluation forms for the meeting are available now. They will be online until June 30th. So anyone who registered or participated will get an email with that link, or you can just click through from here. The email comment line will also be open until June 30th. So if anyone has any additional comments that they would like to share with us, you can email your comments to [comments@hepb.org](mailto:comments@hepb.org) until June 30th. A recording of today's meeting will be available soon at [hepb.org](http://hepb.org), and it will live on our website in perpetuity for people to be able to watch and share. Additionally, the Hepatitis B Foundation will be preparing a summary report from this meeting as James mentioned, and that report will also be available on our website probably by the fall of 2020. Next slide please.

Chari Cohen ([04:13:06](#)):

In addition to the thank you's that Dr. Gish offered, I just wanted to, thank all of the people who participated today. Thank you to Dr. Poonam Mishra. Sue Wong and I had this idea about two years ago and brought it up to Poonam and she, at the FDA, and she was really supportive. So thank you to all of the FDA officials and other drug development stakeholders that tuned in today to listen and to learn. We hope that you'll be able to take back what you learned today and help to put the patient perspective at the forefront. Thank you very much to the FDA Center for Drug Evaluation and Research, especially Meghana Chalasani and Shannon Cole for walking us through this process over the past year was very, very helpful. Thank you so much to our clinical experts who spoke today, Dr. Mishra, Dr. Lok, Dr. Gish, and Dr. Block, for adding your knowledge and your thoughts with us. A very special thank you to our 12 panelists and the amazing, the most amazing, just be storytellers who have shared so much time and dedication to this cause and who bravely and without reservation have shared their experiences with us.

Chari Cohen ([04:14:13](#)):

Thank you to the tireless and dedicated Hepatitis B Foundation team. I know that we together are eight people who do the work of about 800. So thank you for helping today become a reality. Thank you to



James Valentine at Valentine and Larry Bauer for helping us to plan this meeting. Really, your expertise has been incredible. James, thank you for sharing your moderator skills with us today. I don't know how you did it. I watched from behind the scenes. I couldn't do it. So thank you for doing it for us. And finally thank you to the team at Dudley Digital World, John, Eric, Kyle Corey, and others. I know there were lots of people behind the scenes.

Chari Cohen ([04:14:50](#)):

We weren't sure what we were going to do in March. Were we going to try and do this live and push it off until 2021? That wasn't a great option because patients need to be heard today. And so we decided to move this digital. Didn't have any idea how we would make it work, but with the team that we put together and James and Larry, and Dudley Digital, we were able to do it and couldn't have done it without you.

Chari Cohen ([04:15:13](#)):

So for everyone who joined today, thank you very much. If you don't want to wait for the official recording to be up there, you can actually relick on this live stream any time and you will be able to rewatch the meeting and just skip to the parts that you wanted to hear about. And I think we are, we are done at this point, so please keep stay tuned for the report and for the recording to be up on our website. And with that, I would like to close today's meeting. So on behalf of the Hepatitis B Foundation, thank you for joining us. We wish everyone the best. Stay safe and be well. Bye bye.

PART 8 OF 8 ENDS [04:16:40]