2026

Informed

Hepatitis Delta
Patient Conference Report

HEPATITIS B FOUNDATION
A World Free of Hepatitis B, Hepatitis D and Liver Cancer

HEPATITIS DELTA CONNECT
A PROGRAM OF THE HEPATITIS B FOUNDATION

Table of Contents

1 Conference overview

2 Understanding the basics of hepatitis delta

3 Developments in hepatitis delta diagnostics and the therapeutic pipelines

4 Hepatitis delta clinical trials and what you need to know

5 Provider panel discussion: Best practices for hepatitis delta screening and management

6 Lived experiences of hepatitis delta

7 Group brainstorming activity

8 Conference key takeaways

Overview

The Hepatitis B Foundation hosted a virtual *B Informed Hepatitis Delta Patient Conference*, bringing together people living with hepatitis B and hepatitis delta (HDV), community leaders, researchers, and clinicians. The event fostered collaboration to raise awareness of hepatitis delta, share knowledge about HDV testing, and discuss advancements in the therapeutic pipeline. More than 110 people attended the live conference on September 22, 2026.

Presentations covered the basics of hepatitis delta, fundamentals of HDV clinical trials, and recent developments in the diagnostic and therapeutic pipelines for HDV infection. The event also featured a powerful lived-experience panel, during which individuals living with hepatitis delta shared their personal experiences, discussed what people living with hepatitis B and hepatitis delta should know about the disease, and offered recommendations for improving the hepatitis delta care cascade.



The global prevalence of hepatitis delta is estimated to be **12–72 million people**.

Watch the full conference recording HERE



01

Understanding the basics of hepatitis delta



Robert Gish, MD

Dr. Robert Gish is a Clinical Professor of Medicine at Loma Linda University and the Medical Director at the Hepatitis B Foundation.

Presentation Highlights:

- HDV occurs as a co-infection of hepatitis B (HBV).
- HDV infection is a serious condition which can cause major liver complications (cirrhosis, liver failure, liver cancer).
- HBV/HDV coinfection raises the risk of liver cancer compared to HBV infection alone. HBV/HDV/HIV co-infection is even more serious.
- The global prevalence of HDV as an active infection among people living with hepatitis B is ~3%. There is, however, wide country variability, with some countries having the biggest burden.
- In the U.S., ~75,000 people have HDV, although the data on the actual prevalence is still limited. This makes it difficult to establish whether it is a rare disease or if it is common.
- HDV testing has been inequitable in the U.S. The barriers contributing to low testing include low awareness of HDV, lack of an U.S. FDA approved test until recently and complexities in HDV guidelines.
- Risk-based testing has failed in the past, **so there is a need to test all people with HBV for HDV.**
- When testing for HDV, the first test should be the anti-HDV test. If the first test is positive, it should be followed with the second test is the HDV RNA quantitative test to confirm infection (referred to as double reflext testing).
- There is now an FDA approved treatment for hepatitis delta, bulevirtide. This should be an opportunity to improve routine testing for HDV.

HEPATITIS DELTA RESULTS IN

3–6×

higher risk of HCC than HBV alone

HCC = hepatocellular carcinoma

“ The goal at this time is to promote hepatitis delta double reflex testing. We hope to get to a point where all hepatitis B surface antigen positive people (HBsAg+) are automatically tested for anti-HDV, and all anti-HDV positive people are automatically tested for HDV RNA. We need to improve HDV testing from the ~ 20% U.S. testing rate to 100% ”

02

Developments in hepatitis delta diagnostics and the therapeutic pipeline

Theo Heller, MD

Dr. Theo Heller is a Senior Investigator in the Translational Hepatology Section, Liver Diseases Branch, National Institute of Diabetes and Digestive and Kidney Diseases at the NIH.

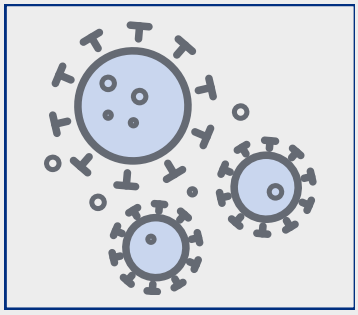


Presentation Highlights:

- The goal clinically should be to stop the progression from HDV infection to cirrhosis, and to prevent death from HDV.
- In HDV, the progression from a healthy liver to carcinoma can be fast, taking 6- 10 years which is more accelerated than what we seen in HBV/HCV coinfection.
- We have seen success in hepatitis B, with a decline in new cases and an increase in vaccination rates. Whereas for hepatitis delta we still need more data to determine if cases are increasing or if this is because we are testing more than before.

Why has it taken so long to find therapies for hepatitis delta?

- Structure of the virus: HDV is a small RNA virus with very few targets for developing therapeutics because it targets human DNA for replication.
- There has been difficulty in developing assays for measuring levels of the virus. There are also many HDV genotypes, which adds another layer of complexity in developing universal assays.



How will we ever find therapies?

- This is an exciting time for HDV. As of September 2026, there are ten drugs currently in the pipeline for HDV, eight of which are in phase II/III clinical trials.
- The approval of bulevirtide has bought a lot of positivity to the field.
- There has been a concerted effort between patients, academia, industry and advocates to advance the field. This will continue to be important as we work towards new treatments.
- There is a great opportunity for using combination therapies to manage hepatitis delta. There are multiple mechanisms for targetting the virus including entry inhibitors, prenylation inhibitors, monoclonal antibodies, siRNA and more.

“HDV is prevalent all over the world, if we do not see it, this is because we have not looked in those places.”

03

Hepatitis delta clinical trials and what you need to know

Joseph Lim, MD

Dr. Joseph Lim is a hepatologist, Professor of Medicine, Director of Clinical Hepatology and Vice Chief of the Digestive Diseases division at the Yale School of Medicine.



"In 2026, we have a standard of care for treatment of HDV through bulevirtide. This should be the first consideration for you and your clinician when deciding if you should be participating in a clinical trial"

Basics of Clinical Trials



Current U.S. Food and Drug Administration (FDA) Guidance on HDV drug development:

The U.S. FDA has guidelines on trial design, trial population and expected primary endpoints for HDV clinical trials:

Trial design (Phase 3):

- Double-blind placebo-controlled trial (preferred)
- Three-arm double-blind controlled trial with intervention, comparator, and placebo (acceptable)

Trial population:

- HDV antibody positive, HDV RNA positive for at least 6 months
- Receiving HBV treatment on stable regimen for at least 3 months with documented HBV DNA suppression

Primary endpoints

- Proportion with undetectable serum HDV RNA and ALT normalization (preferred)
- Proportion with 2 log10 decline in HDV RNA and ALT normalization on-treatment (acceptable)
- These represent reasonably likely surrogate endpoints (RLSE) for initial accelerated approval

In addition to this guidance, patient considerations are important for determining clinical trial endpoints, as an example, the 2022 AASLD-EASL HBV-HDV Treatment endpoints highlight these additional considerations:

- Patient experience data, including patient preference information.
- Patient reported outcomes in development of trials, including assessment of health-related quality of life.

Suggestions of questions to ask your clinician and/ or HDV trial site team



- How am I assigned to a treatment group in this trial?
- How effective and safe were these study drugs in the previous phase trial (e.g. phase 2b results if phase 3 trial)? Ask for the trial results or manuscript!
- Is there a chance my active treatment will be delayed?
- How are the study drugs administered? And is it administered in the office or at home?
- If I am randomized to a control group, am I guaranteed access to the study drug later?
- What are the main side effects of the study drug(s), how common are they, how are they monitored and treated, and am I at higher risk for these issues?
- How often do I have to travel to the trial office for evaluations or are some virtual? (every 2/4/8/12 weeks)
- What tests will be performed to assess the effectiveness and safety of the treatment?
- What happens if my liver tests or HDV tests actually worsen while on the study? (stopping rules)
- How long is the total treatment and post-treatment monitoring study? (1 year vs 3 years vs 5 years)
- Will all study medications, labs, and procedures be covered at no cost? How about parking, travel, lodging?
- What happens if I develop a complication or medical event during my participation in the study? Will this be paid for by the study or by my insurance company?
- What happens if things become difficult for me with other responsibilities and I need to stop participation after I start?
- How will you protect my personal health and genetic information during and after this study?
- If the study drugs work well for me, will I have access to the medication after the trial ends? (expanded access or compassionate use program)

04

Provider panel discussion

Tatyana Kushner MD, MSCE | Robert Wong, MD, MS



Tatyana Kushner MD, MSCE, Associate Professor of Medicine
Director of Outcomes Clinical Research, Department of Gastroenterology at Cornell University



Robert Wong, MD, MS, FACG, FAASLD
Clinical Associate Professor of Medicine, Division of Gastroenterology and Hepatology at Stanford University

Q: “Why should providers be testing for hepatitis delta, and why is timely testing so important?”

- HDV has faster disease progression compared to HBV alone, and people need to be diagnosed early and linked to care for better outcomes.
- We now have the first approved treatment for HDV, which makes it so critical to identify cases early.
- The treatment plan between HBV and HDV is distinct, so it would not be adequate to manage HBV without knowing the status of HDV infection.

Q: “What tests are being used for HDV testing in current practice?”

- There are two main tests for HDV. The first is an anti-HDV test - it is a screening test and a measure of exposure rather than active infection. The second test is an HDV RNA test, which helps detect active infection.
- Traditionally, the tests had to be done stepwise. Some labs now offer reflex or automatic HDV testing. Testing for delta using reflex testing should be the standard of care. If anti- HDV is positive, you do not need to have the patient come back, instead, test the same sample for HDV RNA.

Q & A HIGHLIGHTS

Q: “What are the barriers that make routine testing for hepatitis delta difficult?”

- Education and awareness – there is a need for education among providers.
- There were no approved treatment options for HDV, which discouraged testing among some providers. There is an opportunity to change that now that there is a treatment available.
- Patient barriers - people who live far from large academic centers or those with low socioeconomic status are less likely to receive testing for HDV.
- Lack of guidance for the U.S. population – current AASLD guidance still calls for risk-based testing. There is AGA guidance which recommends universal HDV testing and hopefully that can be adopted.
- Stigma which is associated with HDV - By adopting universal screening of all people living with hepatitis B rather than targeted testing, we address HDV associated stigma.

Q: “How should people living with hepatitis B approach the conversation about HDV testing when talking to their provider?”

- Arm yourself with knowledge about HDV, that way you can have points to help you talk to your provider about testing. Ask questions about HDV, whether that is with your primary care provider, gastroenterologist or hepatologist.

Q: “What does a management plan look like for people with HDV?”

- First, providers establish if there is active infection/ viremia. Further evaluation with imaging is then needed.
- Providers also determine the disease stage and determine treatment options - this discussion should help the individual understand available treatment options and there should be shared decision-making on current therapies that are prescribed, such as interferon and bulevirtide if eligible.
- Providers and people living with HDV should also discuss other important treatment elements, such as the treatment mode of administration, expected duration of treatment and discuss suitable clinical trials.

Q & A HIGHLIGHTS

Q: "What role do people living with HDV play in making decisions about the management of their condition?"

- People living with HDV should play an active role in the management of their condition. They must empower themselves with knowledge about their condition. To be an effective advocate for yourself, you have to be well informed.
- There can be conflicting data for HBV and HDV, and providers may treat cases slightly differently. It is good to ask your provider questions and ask them about the rationale of what they do.

Q: "How will the introduction of bulevirtide change health outcomes?"

- It is paradigm shifting to have this new treatment and many potential therapies in the pipeline. Pegylated interferon was rarely prescribed because of its side effects and low effectiveness. A lot of people living with HDV came up to ask if there were options for treatment given the severity of their condition, but there were no options. Now we have an option which will improve health outcomes.

Q: "What resources do providers need to ensure they are equipped to provide these new therapies?"

- There is a need for educational opportunities that will equip providers to use these new therapies.
- There needs to be a good infrastructure of doctors, nurses, pharmacists to support patients.
- Providers need to see people living with HDV regularly to monitor them closely for side effects, viral load response and to ensure the individual is feeling well emotionally too.
- Providers need to be aware that there are support programs for them too, such as the Gilead Support Path for providers.

Key takeaways from provider panel discussion

- HDV has faster disease progression compared to HBV alone, and people need to be diagnosed early and linked to care for better outcomes.
- It is good practice for providers to test for HDV among all people living with hepatitis B, using double reflex testing.
- People living with hepatitis B should not hesistate to start conversations with their clinicians about getting tested for HDV.
- There is now a new approved treatment for HDV in the U.S. This should be an opportunity for people with HDV to get treatment, and an opportunity for providers to improve HDV testing and management practices.

05 Lived experience panel

Joe Balestreri , Patient Advocate and #justB Storyteller
Ravshan Yakubov, Patient Advocate and #justB Storyteller
Dennis Barrett, Patient Advocate

Joe Balestreri , *Patient Advocate and #justB Storyteller*

Joe learned he had hepatitis delta during a routine test in 1998. His condition significantly impacted his life, forcing him to stop work. Joe learned to advocate for himself and has been highly involved in hepatitis delta clinical trials. He identifies himself as citizen scientist, and has made significant contributions to hepatitis delta research and raising awareness. He believes people with hepatitis delta are critical to improving hepatitis delta outcomes.



Joe's Story

Joe's recommendations

- Joe experienced difficulties during clinical trials, including long travel hours while struggling with severe side effects from treatment. Joe recommends that clinical trials are designed to be more accommodating for patients, including creating infrastructure for patients to be followed up and monitored outside main research centers.
- Joe recomends that people with hepatitis delta have a team of family and friends who can support them throughout their journey navigating HDV.
- Joe recommends compiling a list of questions you do not understand in order to ask your provider.
- When participating in a clinical trial, Joe recommends that you do not hesitate to call your doctor, nurses and ombudsman if you have concerns.

Ravshan Yakubov, *Patient Advocate and #justB Storyteller*

Rav was diagnosed with hepatitis B as a child, following accidental medical exposure. In 2012, Rav learned he also had hepatitis delta and cirrhosis. The diagnosis was heavy on him and significantly impacted his emotional wellbeing. Overtime, Rav has learned to advocate for himself and has benefited from new hepatitis delta treatments.



Rav's Story

Rav's recommendations

- Rav recommends that providers should balance the message they give to people living with HDV during a hepatitis delta diagnosis. He recommends that providers do not put a clock on the individual's life, while also not providing false hope.
- Rav recommends that providers learn more about hepatitis delta monitoring in order to provide people living with hepatitis delta the best care possible.
- Rav recommends that people do not simply 'google' their symptoms. There is a lot of information online and it is not always a one size fits all. Use trusted sources and your providers.
- Rav recommends that people with hepatitis delta learn as much as they can about their condition, so that they can have well informed conversations with their providers. **" Take the driver's seat, get real data and challenge your doctors".**
- Rav recommends that following your diagnosis, remember to take care of yourself - do not drink or smoke and make sure you follow a healthy diet.

Dennis Barrett, *Patient Advocate*

Dennis first learned he had hepatitis delta and cirrhosis in 2022, after living with hepatitis B for many years. Dennis started treatment with bulervitide and he described feeling improvement in his health and says he has gotten his strength back.

Dennis' recommendations

- Dennis main recommendation is for individuals to take care of their health after a hepatitis delta diagnosis, including abstaining from any substance use.
- Dennis also recommends advocating for yourself when you have unanswered questions. He describes moving between different centres in Carlifornia before understanding his diagnosis. He believes this saved his life.

06

Group Brainstorming Activity: How can we work together to fill gaps in the context of hepatitis delta?

- Testing everyone with hep B for delta
- Educating healthcare providers about hep delta
- Improve access to hepatitis delta diagnostics

Center our work around highlighting people with HDV as leaders - maybe they can lead us in putting together a list of priority questions that need to be answered (research, treatment, care, what they need and want).

Advocacy for testing all positive for Hep B for delta- and reflex testing

Update AASLD screening guidelines

Provider Education & Community Education!

Increasing access to testing for Delta and understanding of Delta test results

Conference key takeaways

1. Testing for hepatitis delta among all people with hepatitis B

A theme that came up from this conference was the need to shift from risk-based testing for hepatitis delta to universal testing for all people living with hepatitis B.

2. The new HDV treatment option represents a new paradigm for hepatitis delta

Bulevirtide was approved by the U.S FDA as the first treatment made for HDV. This presents an opportunity for people living with HDV to access treatment in the U.S. With a treatment now approved, providers, should also improve HDV testing.

3. The voices of people with lived experience should be integrated into hepatitis delta care and research

People living with hepatitis delta bring rich perspectives that can help improve the hepatitis delta care cascade, from diagnosis to treatment. It is important that the inputs of people living with hepatitis delta are integrated into hepatitis delta research and disease management decisions.

Action Items

- **Promote recorded event widely** - This event recording will be promoted widely to ensure education about HDV reaches new communities. The video will also be available in Mongolian and Spanish.

- **Continued education on HDV** - Through Hepatitis Delta Connect, the Hepatitis B Foundation will continue to educate communities about the basics of HDV and the importance of adopting double reflex testing, through webinars, provider-focused ECHO sessions and new fact sheets.

- **Engage people living with HDV in the development of new priorities -** The HDV diagnostic and therapeutic pipelines have made major advancements in 2026. In the age of new HDV diagnostics and therapies, new priorities will need to be set and people living with HDV will be engaged as key stakeholders.

Thank you to our conference sponsors

We would like to thank our conference sponsors for their generous support for this conference.



Diasorin

