

The background features a collage of medical and scientific imagery. At the top, hands are shown holding a red tablet. To the right, a cluster of hexagonal icons contains symbols for a clipboard, a heart rate monitor, a pill, a first aid kit, and a microscope. The lower portion of the image is filled with abstract white line art, including molecular structures, a brain, and various geometric patterns. The overall color palette is dominated by soft pinks, reds, and whites.

HBV-TAG

2021 CONFERENCE



What patients want out of new hepatitis B drug development

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Presentation objectives

1

Provide an overview of treatment-related experiences of people living with hepatitis B, including current challenges

2

Discuss the patient perspective on administration and outcomes of future treatments for hepatitis B

3

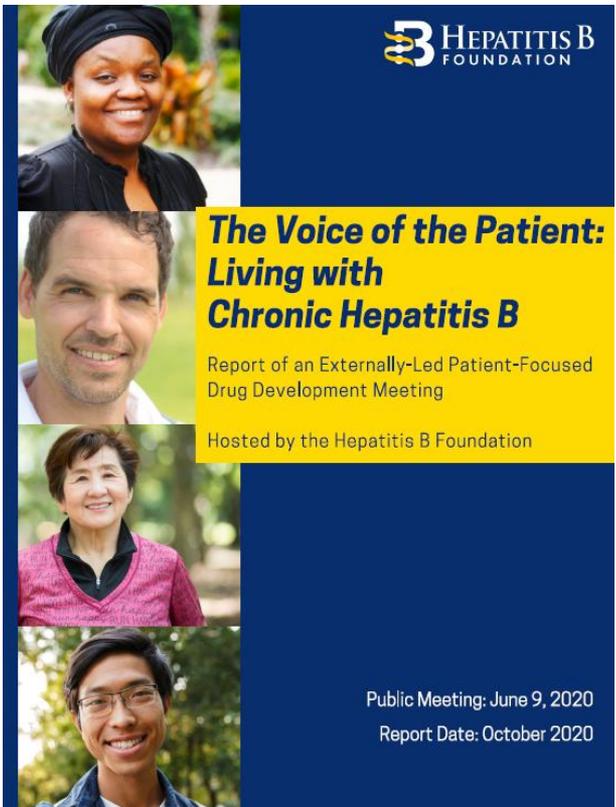
Understand patient perceptions of clinical trials for hepatitis B, including wants, needs and challenges

Including the patient voice in drug & clinical trial development

- What is the impact of living with chronic hepatitis B?
 - Physical, emotional, professional and social impact, stigma, discrimination
- What do people experience during treatment; what do they want/need from treatment?
- How can we use what we learn:
 - Include PROs into clinical trials and clinical management of hepatitis B, towards improving HRQoL
 - Improve clinical trial participation, and ensure diversity and inclusion



Including the patient voice in drug & clinical trial development



 HEPATITIS B
FOUNDATION

***The Voice of the Patient:
Living with
Chronic Hepatitis B***

Report of an Externally-Led Patient-Focused
Drug Development Meeting

Hosted by the Hepatitis B Foundation

Public Meeting: June 9, 2020
Report Date: October 2020

- Hosted Externally-Led Patient Focused Drug Development Meeting June 2020
 - 650 participants, 12 panelists, 300 email comments
- Online survey (U.S. and international) (n=1,707)
- 24 in-depth interviews - people living with hepatitis B
- Data mining and qualitative analysis of 10,000 email consults

<https://www.hepb.org/news-and-events/patient-focused-drug-development-meeting-virtual/>



Impact of chronic hepatitis B

There is significant physical and emotional impact for people living with hepatitis B that appears to reduce quality of life and enjoyment of daily life

- Fatigue, pain, shame, and fear of liver cancer/dying prematurely and & transmission to others

Living with chronic hepatitis B impacts familial and social relationships, as well as education and jobs/careers

- Anxiety, stress, decreased social interaction & isolation - harassment, discrimination, stigma
- Avoiding jobs that require disclosure
- Avoiding jobs that are physically taxing
- Job and immigration and family/marriage discrimination

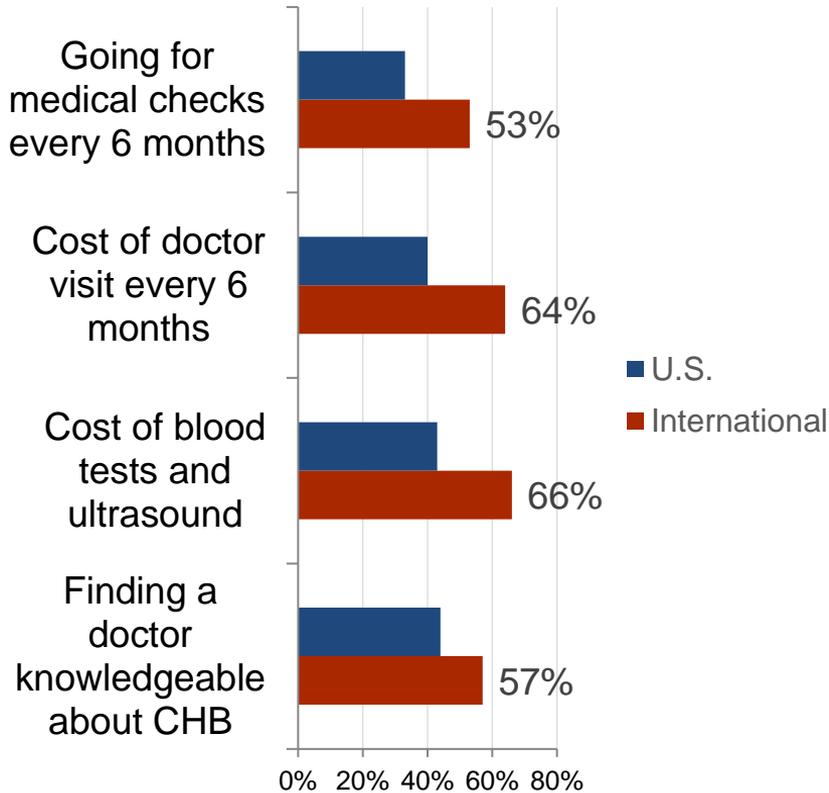
Current treatment experiences and challenges

Current treatments are effective in suppressing the virus, but they don't eliminate the virus, or the risks

- Have improved the quality of life for many patients, and somewhat decreased fear
- Generally easy to take with few side effects (but some do have side effects)
- Can be long-term or lifelong
- Even while being treated, still fear the possibility of disease progression and premature death
- Many do not meet the current criteria for treatment, and are them nervous and uncertain about the future
- Many have adopted healthy lifestyles in the hope of preventing negative outcomes



Reported challenges managing CHB



Additional challenges identified from PFDD/Interviews:

- Finding a right doctor knowledgeable about hepatitis B
- Concerns over treatment cost, even among those who have insurance
- Concerns about side effects and taking medication long-term
- Taking a daily pill



Positive outcomes of taking CHB medication



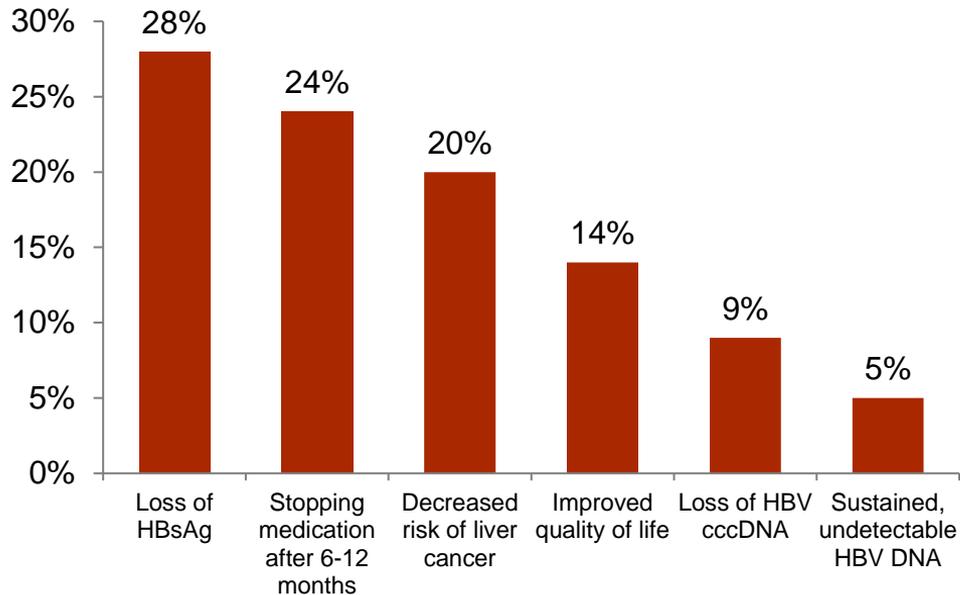
Future treatments and clinical trials

Above all, patients want a functional cure for chronic hepatitis B

- Finite-duration therapy
- Participants wanted treatments that:
 - Achieve and sustain undetectable levels of HBsAg
 - Achieve and sustain undetectable levels of HBV DNA
 - Significantly reduce the risk of cirrhosis, liver failure, and liver cancer
 - Improve quality of life and end stigma and discrimination



Ranking future treatment outcomes



U.S.

1. Decreased risk of HCC
2. Loss of HBsAg
3. Being able to stop meds after 6-12 months
4. Improving quality of life
5. Loss of cccDNA
6. Long-term DNA suppression

International

1. Loss of HBsAg
2. Being able to stop meds after 6-12 months
3. Decreased risk of HCC
4. Improving quality of life
5. Loss of cccDNA
6. Long-term DNA suppression



Future treatments and clinical trials

Preference for oral treatment, but injectables/IV infusion also acceptable by some, if they were limited frequency and duration

Participants favored convenience - some were willing to tolerate a greater level of inconvenience (e.g., longer course of treatment, side effects) for greater chance of functional cure

Mild, limited symptoms considered acceptable by most



Future treatments and clinical trials



Patients might participate in clinical trials of products that have a low risk of serious side effects and a high potential to provide a functional cure

- Risk of serious side effects was a key consideration in the decision to participate
 - Concern about a viral flare/serious liver damage or permanent damage to other organs
- Chance investigational treatment could provide a functional cure was a compelling factor for participation (>50%)
- Clear safety information about the investigational treatment

Future treatments and clinical trials

Burden of participation was a key factor - should not greatly interfere with daily life

- Time/amount of visits/distance to travel needed to participate
- Length of study participation
- Route of treatment administration
- Side effects

Those with children, and those who are older, are particularly cautious about participating in clinical trials

U.S. vs. international - differences in treatment access/challenges and clinical trial perceptions





Thank You

“Never doubt that a small group of thoughtful, committed, citizens can change the world. Indeed, it is the only thing that ever has.”

-Margaret Mead