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Findings from the Externally Led Patient Focused Drug Development Meeting on Chronic Hepatitis B

Chari Cohen, DrPH, MPH

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Voices of the Patient

As we move through a new era of hepatitis B treatment and cure research, we must ask:

- What is the impact of living with hepatitis B on the lives of those chronically infected?
- How do people feel about current and future treatment options?
- How do people feel about participating in clinical trials for chronic hepatitis B?
- Can we use what we learn to make treatment and clinical trials more patient-focused, and can we improve clinical trial participation, and ensure diversity?

Why a PFDD for hepatitis B?

- The Patient Focused Drug Development program: definition and history
- Importance of hosting a PFDD meeting for chronic hepatitis B in 2020

Our PFDD Goal:

- Document the experience of living with CHB to help with design of elimination programming, drug development and clinical trials.
- What we learn should inform the development and regulatory review of new drugs for CHB that will have a meaningful impact on patients' lives.
- Understanding patient wants and needs should result in improved clinical trial design and participation and increase uptake and adherence of new FDA-approved drugs.

Hepatitis B PFDD Objectives

1

Better understand the physical, psychological, professional and social impact of living with CHB.

2

Document what people with CHB want and need for new treatments; Understand what the ideal hepatitis B treatment looks like for people with CHB.

3

Document what people with CHB are willing to accept with future treatments and clinical trial participation, including treatment duration, route of administration and side effects.

4

Better understand barriers to CHB treatment, including stigma, discrimination and access challenges.

PFDD Planning Process

Communicating with FDA

Submission and approval of LOI

Transition from in-person to fully virtual platform

Positive and negative implications

Virtual meeting format

- Panel speakers
- Open discussion
- live call-ins
- Polling questions
- Email comments

Session Themes and Participants

Four overall session themes

1. Individual impact of living with CHB
2. Societal impact of living with CHB
3. Current CHB treatment experiences
4. Thoughts on future treatment and clinical trials

Attendance/participation

- 650 live/online participants
- Of patient participants, 2/3 were living with CHB and 1/3 were family members
- 15% were age 18-30, 30% were 31-50 years of age, and 50% were aged 51 or older
- 80% were living in the U.S.
- 56% of 144 comments were from people in 14 countries outside the US

Discussion

Theme 1: Physical impact

The physical health effects of living with chronic hepatitis B span the range from asymptomatic to end-stage liver disease and liver cancer

Unrelenting chronic fatigue

- Primary concern expressed by most participants
- A defining characteristic of their disease experience
- Debilitating, impacting productivity and ability to care for children, as well as professional (work/school) lives
- Led to regret about missing out on life

Joint pain, muscle pain, and body aches: Significant impact on daily life

- Impacting ability to work, socialize, and attend to necessary life tasks
- Managing pain is a challenge (many pain meds are harmful to the liver)
- Range of digestive issues, including abdominal bloating and weight loss
- Bone loss and osteopenia/osteoporosis were a concern, as possible side effect of antiviral therapy

Discussion

Theme 2: Personal and social impact

Anxiety, fear and stress

- All were pervasive: worry about long-term health impacts, especially cirrhosis, liver cancer and premature death
- Fear of transmitting the disease to others (especially one's children)
- The need for life-long treatment and not being able to afford or access care and treatment

Decreased social interaction and isolation

- Participants limit social interactions to avoid potential harassment, discrimination, and stigma, and for fear of transmitting to others
- Social interactions with alcohol were a burden
- Dating and finding a life partner was a particular challenge for young people
- Some have been rejected by family, friends, or coworkers - leading to isolation, loneliness, anxiety, and depression
- Some noted the importance of making connections with others living with hepatitis B to help overcome isolation

Discussion

Theme 2: Personal and social impact

Harassment and discrimination

- Losing jobs, being prohibited from getting jobs, being discharged from military service, and having children expelled from daycare
- Fear of discrimination led to people choosing not to share their status with others

Stigma

- Some noted being ridiculed by relatives, others felt that stigma impacted their entire family
- Described the need to raise public awareness and counter fear-based misinformation

Shame

- Feeling “dirty” or at fault; blaming themselves for transmitting to loved ones
- Need for more education and support for those who have hepatitis B, so they can move beyond the stigma and shame and ask for help
- Hearing stories of others living with hepatitis B has given hope and reassured them that they are not alone

Discussion Theme 3: Current treatments

Current treatments are effective in suppressing the virus, but they don't eliminate the virus, and there are other 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, which made them nervous and uncertain about the future
- Many have adopted healthy lifestyles to stay strong in the hope of preventing a disease flare

Discussion Theme 4: Future Treatments

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
- Participants favored convenience and preferred oral treatments over injections/IV infusion
- Injectable medications were acceptable to some, if they were limited frequency and duration
- Some were willing to tolerate a greater level of inconvenience (e.g., longer course of treatment, side effects) if there was a greater chance for achieving a functional cure

Discussion

Theme 4: 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
- Chance that the investigational treatment could provide a functional cure was a compelling factor for participation
- Burden of participation was also a key factor
 - Time needed to participate or the travel distance
 - Route of treatment administration
 - Side effects that might impact daily life



Overview of what we learned

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

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

Current treatment challenges include cost/access, and taking a daily pill for many years

There is a strong desire for loss of HBsAg and reduction of risk for liver cancer, with a finite treatment



Overview of what we learned

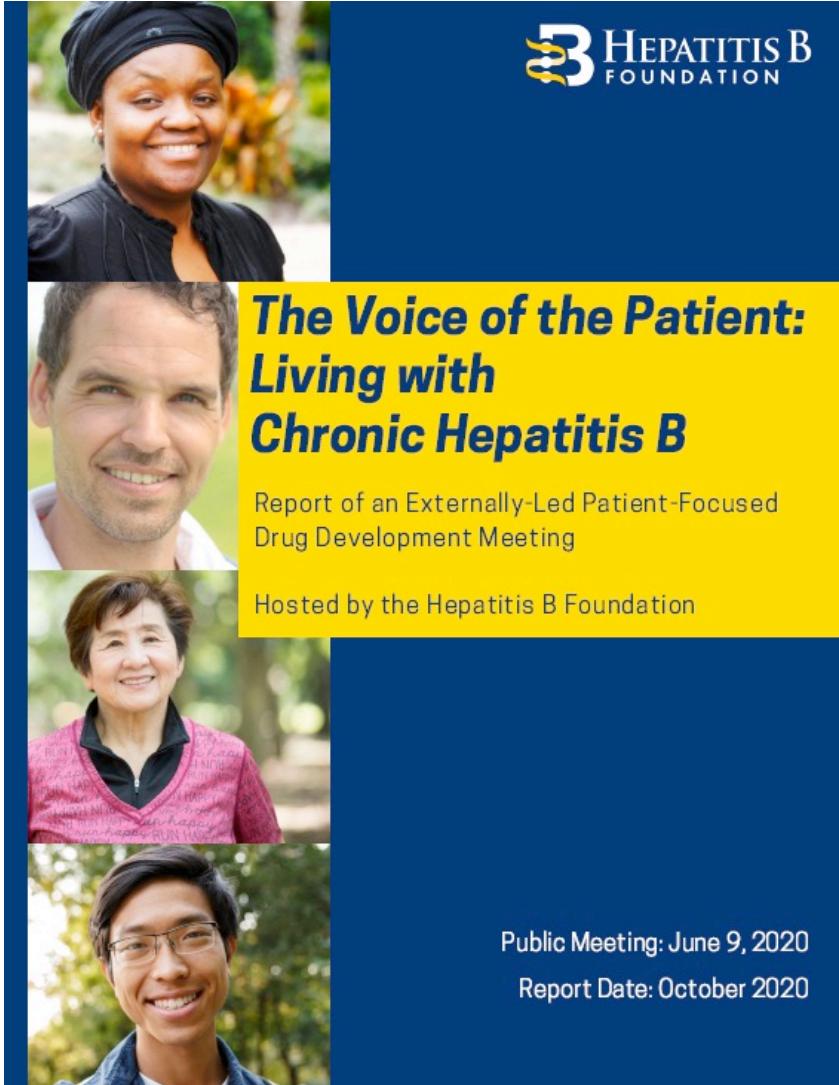
Preference for oral treatment, but injectables also acceptable by many


Mild, limited symptoms considered acceptable by most

Willingness to participate in clinical trials with high chance of functional cure and limited side effects/impact on daily life

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



 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

HBF is grateful to the more than 600 people around the world who participated in the 2020 PFDD meeting.

The voices of the people heard at this meeting provide a window into the challenges and triumphs they face daily in living with chronic hepatitis B and highlight their unmet treatment needs.

HBF thanks the FDA for partnering on this project and prioritizing the voice of the patient in playing a role in the clinical trial development and regulatory process.



#justB



Learning from people living with CHB through personal stories