

2021

THE VOICE OF INDIVIDUALS LIVING WITH HEPATITIS B

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



Hosted by the Hepatitis B
Foundation
Public Meeting: June 9th, 2020



THE VOICE OF THE PATIENT

Living With Chronic Hepatitis B

The most common serious liver infection worldwide

Hepatitis B is a serious and potentially life-threatening infection of the liver caused by the hepatitis B virus (HBV). Chronic hepatitis B infections are those which persist beyond 6 months. HBV-related complications include liver cancer, liver failure, and cirrhosis. Hepatitis B is a "silent disease:" most infected individuals are asymptomatic and can remain undetected for decades.

There is no cure for HBV

There are treatments available- interferons and oral antiviral drugs- that suppress the replication of the virus in the body and slow the progression of long-term complications. These have limitations are not without risk.

Barriers to elimination exist and a functional cure is needed

HBV has a complex life cycle that's not yet fully understood. A functional cure would silence the virus and reduce liver cancer risk with finite treatment, even if HBV is not completely eliminated from the body. Input from people who will be using future treatments is necessary to ensure that their experiences, perspectives, needs, and priorities are factored into hepatitis B programming, product development, and clinical trial design. This meeting aimed to document the impacts of living with chronic hepatitis B and to hear perspectives on treatment needs and priorities from those living with chronic hepatitis B.

**>2
BILLION**

Number of people infected with HBV at some point in their life worldwide

Number of people worldwide infected with chronic hepatitis B

**300
MILLION**

**>880
THOUSAND**

Number of people that die annually due to HBV-related complications

Estimated number of people in the U.S. living with chronic hepatitis B

**2.4
MILLION**

66%

Estimated percent of people with chronic hepatitis B in the U.S. who aren't aware they're infected

This report was prepared by the Hepatitis B Foundation (HBF) as a summary of the input shared by patients living with chronic hepatitis B during an externally-led Patient-Focused Drug Development (PFDD) meeting hosted by HBF on June 9th, 2020. It was designed to complement the work of the FDA's PFDD initiative. The input collected will inform the development and regulatory review of new hepatitis B drugs.

TOPIC 1: LIVING WITH CHRONIC HEPATITIS B- SYMPTOMS AND DISEASE IMPACTS

The first topic discussed at the PFFD meeting was how those living with hepatitis B are physically and mentally impacted by the disease. The Hepatitis B Foundation conducted phone interviews and an online survey from over 2,100 people in 102 countries to gain insight for the PFDD meeting. At the PFDD meeting, we heard testimony from several people living with hepatitis B that helped explain what day-to-day life was like with hepatitis B. We then led a robust moderated discussion with the panelists, encouraging participants to call-in and email comments. Many of the participants described similar experiences to the survey results.

They survey results and group discussion had several common themes such as social isolation, need for a strong support system, and the difficulty doing activities of daily living while living with hepatitis B. 58% of people with hepatitis B felt they were discriminated against due to their condition and 62% of those living with hepatitis B find their life less enjoyable due to their disease.

Themes from Topic 1

1

Hepatitis B's physical symptoms can be debilitating, with fatigue being the most common symptom.

2

Those living with hepatitis B suffer emotionally and are often stigmatized due to their disease.

3

Hepatitis B can cause social isolation and constant fear, stress and anxiety.

TOPIC 2: PERSPECTIVES ON CURRENT AND FUTURE APPROACHES TO TREATMENT

A panel discussion identified challenges in current treatment experiences in the management of chronic hepatitis B, hopes for future treatment options, and factors that contribute to their decision to participate in clinical trials. Persistent underrepresentation of minorities in clinical trials and the need for more thorough and accurate monitoring were also concerns that were raised.

CURRENT CHALLENGES

- Lifetime of treatment without cure
- High cost of antiviral medication
- Detrimental physical and cognitive side effects
- Experience of symptoms even with treatment

DESIRED ASPECTS & OUTCOMES

- A functional cure for HBV infection
- Decreased risk of developing liver cancer
- Improved quality of life
- Elimination the risk of transmission to others
- Finite course treatment
- Convenient administration (oral medication)
- Elimination of the need for interferon

FACTORS AFFECTING PARTICIPATION IN CLINICAL TRIALS

- Concern about the risk of serious side effects
- Quality of long-term monitoring
- Potential of trial treatment to provide a functional cure
- Accessibility of clinical trial sites
- Route of treatment administration