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Original Article

Boosting Diverse Communities Participation in Clinical Trials: What People Living with Hepatitis B Must Know

Yasmin Ibrahim[1], Tanya Machado[1], Fiona Borondy-Jenkins[1], Shreya Koirala[1*], Mi Dong[2], Ibrahima Sankare[3], Mohamed Ali[4], Dung Hua[5], Ashley Che[6], Chari Cohen[1]

[1]Hepatitis B Foundation, Doylestown, Pennsylvania, 18902, United States
[2]Asian Center of Southeast Michigan, Southfield, Michigan, 48075, United States
[3]African Services Committee, New York, New York, 10027, United States
[4]Somali Health Board, Tukwila, Washinton, 98188, United States
[5]Vital Access Care Foundation, Fountain Valley, California, 92708, United States
[6]Public health professional, Maryland, United States

***Corresponding Author:** Shreya Koirala, Email: Shreya.koirala@hepb.org

Abstract

Introduction: Globally, people from African, Asian and Western Pacific regions are disproportionately affected by hepatitis B virus (HBV) and are underrepresented in HBV clinical trials (trials). This study explored trial knowledge and misconceptions, sources of information, and community recommendations to enhance hepatitis B trial participation.

Methods: This mixed-methods study combined an online global survey followed by semi-structured interviews and focus groups (FGs) across 10 diverse communities in the U.S. Qualitative data collection was informed by initial survey insights. Participants were ≥ 18 years old and living with HBV.

Results: In total, there were 680 survey respondents and 36 qualitative participants (30 FG participants, 6 interviewees). Survey respondents reported some of the classical challenges to trial participation including limited awareness of trials (73%) and concerns about trial safety (41%). Qualitative participants elaborated on these challenges, discussing difficulties accessing reliable information and misinformation about their eligibility. Despite these challenges, survey (85%) and qualitative participants expressed a high willingness to participate in HBV trials if they were properly informed. Participants identified community-specific strategies to enhance trial awareness, provide accurate information, and address common misperceptions. While healthcare providers and local community organizations were recognized as trusted sources of information, they were among the least frequently reported sources for learning about trials.

Conclusion: This study shows that with accurate and accessible information, people living with HBV are more likely to consider participating in clinical trials. However, they are often not exposed to informative trial communications. This limited access fosters misperceptions and fear, hindering hepatitis B trial participation. Community-informed outreach strategies, such as engaging healthcare providers and community-based organizations to deliver culturally tailored and linguistically appropriate education, can enhance community engagement in trials, ensuring diverse and representative participation in HBV trials.

Keywords: Hepatitis B virus, Clinical trial participation, Patient recruitment, Ethnic and racial minorities, Diversity, Equity, Inclusion

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Introduction

Hepatitis B virus (HBV) is a significant global public health challenge. The World Health Organization's (WHO) 2024 Global Hepatitis Report estimates that there are 254 million People Living With Hepatitis B (PLWHB), and the number of HBV-related deaths increased from 820,000 in 2019 to 1.1 million in 2022.[1] In the U.S., up to 2.4 million PLWHB, predominantly foreign-born from HBV-endemic regions in Africa, South-East Asia, and the Western Pacific, are disproportionately affected.[2,3]

Effective HBV treatments are essential to reduce mortality.[4] However, participants in HBV clinical trials (referred hereafter as trials) do not reflect the global demographic distribution of HBV prevalence.[5,6,7] Most HBV trials are conducted in countries with existing trial infrastructure. Therefore, many of the countries heavily burdened by HBV in Africa, South-East Asia and the Western Pacific are underrepresented in trials.[6,7] Africa is deprived of HBV trials, with only 18 out of the 1,804 trials conducted on the continent since 1983.[6] Trials in Asia are concentrated in certain countries including China, Japan, and Korea, but are lacking in other countries with high HBV endemicity like Vietnam, Indonesia, Philippines, Thailand and Melanesia, Micronesia.[7]

These global disparities are mirrored in the U.S., where trial diversity remains limited. In 2023, the U.S. Food & Drug Administration's (FDA) Center for Drug Evaluation and Research approved 55 novel therapies for various diseases, involving 44,000 study participants.[8] While most programs were multinational, the report

presents data specifically for U.S. participants. Summary data reveals that Whites comprised > 50% of the trial population across all programs, while Asians, Blacks, and Hispanics were underrepresented. Despite the FDA's emphasis on diversity,[9] participation of minority populations in the U.S. remains low, especially among those from regions with a high HBV burden. Barriers to minority participation in trials include mistrust, lack of comfort with the trial process, insufficient information, time and resource constraints, and lack of awareness about trials.[10] Underrepresentation of highly impacted populations can hinder generalizability of trial results and negatively impact the confidence in the efficacy of the trial treatment.[11]

This study sought to understand existing knowledge and perceptions about trials, identify trusted information sources, and preferred communication platforms, and outline informational needs among PLWHB representing diverse minority communities.

The study used the Ford conceptual framework to frame the results (Figure 1), to demonstrate the facilitators and barriers that influence an individual's decision to accept or refuse trial participation.[12] The Ford framework facilitates the translation of research findings into practical strategies for researchers and academic institutions. This framework presents three critical factors influencing one's decision to participate in a trial: awareness, opportunity, and acceptance.[12] For diverse communities to participate in trials, they first must be made aware of opportunities to participate, then have access to the necessary information about trials to make an informed decision on whether they will participate if given the opportunity.

This study adapts the Ford framework to elucidate how low awareness of trials, including limited existing knowledge and resulting misconceptions, can be a barrier to individuals' decision to participate. The results present these barriers, across diverse communities, along with participants' identified informational needs and recruitment recommendations to overcome these barriers and increase their communities' awareness and acceptance of trials.[12]

The insights gained from this study can inform trial developers on how to communicate trial information to diverse PLWHB, to improve recruitment and enrollment efforts, to ultimately improve trial diversity and inclusion among PLWHB.

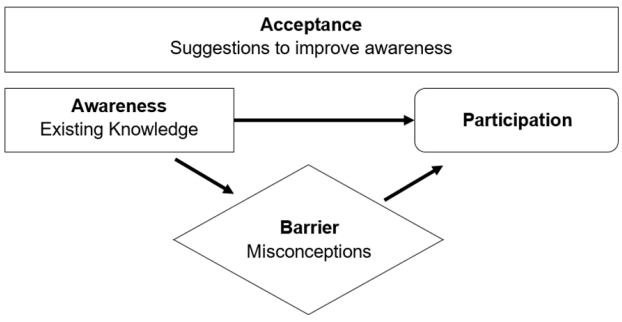

Figure 1. The modified Ford conceptual framework demonstrating the facilitators and barriers of clinical trial participation

Methods

This was a mixed-methods study consisting of two arms: a quantitative arm comprised of an online global survey, and a qualitative arm comprised of virtual in-depth interviews and focus groups. A panel of experts, including PLWHB, public health researchers, and an epidemiologist, developed and reviewed the global survey tool (Appendix A) and semi-structured interview/focus group guide (Appendix B). Questions explored trial participation perceptions, barriers, and decision-making factors. The two study arms were conducted consecutively. The quantitative and qualitative data collection tools were developed complementary to each other. Quantitative data collection was initiated first, with initial survey insights informing the refinement of the qualitative guide. The integration of findings from both arms provided a comprehensive understanding and helped identify key insights relevant to the study objectives.

Global Online Survey

The anonymous, cross-sectional online survey ran from January to October 2023 via SurveyMonkey.[13] To ensure linguistic inclusivity, the survey was available in nine languages: French, Korean, Tagalog, Chinese, Marshallese, Vietnamese, Spanish, English, and Amharic. The survey was professionally translated by a translation company with expertise in biomedical and social research. To ensure understandability and cultural relevance, native-speaking community partners subsequently reviewed each translation, providing feedback to enhance clarity and cultural accuracy.

The study used convenience sampling. Recruitment strategies involved in-language social media posts (Facebook, Twitter), distribution of the survey link by community partners through their local networks, and promotion via the Hepatitis B Foundation's e-newsletter, which reaches approximately 12,000 subscribers.

Quantitative data were exported from SurveyMonkey to Microsoft Excel and analyzed using the Statistical Package for the Social Sciences (SPSS), Version 25.0 (SPSS Inc., Chicago, IL, USA).[14] Descriptive statistical analysis was used to analyze sociodemographic data. Categorical variables were reported as frequencies and percentages.

Eligibility required participants to be aged ≥ 18 with a self-reported chronic HBV diagnosis. A decision-tree algorithm tailored question sets: prior trial participants received questions on experiences, while trial non-participants or ineligible respondents answered queries on reasons for non-participation or ineligibility, minimizing missing data.

Participants who only completed the demographic section and did not answer additional survey questions were excluded from the analysis. A complete survey submission was defined as reaching the final page of the survey and selecting the "submit survey" button. Among those who completed the survey, some individual questions were left unanswered. No survey item had a missing response rate exceeding 20%. Furthermore, visual inspection and descriptive analyses of the data revealed no systematic patterns in missing responses.

Interviews and Focus Group Discussions

Eligibility criteria for participation in the qualitative component mirrored those of the survey and included being 18 years of age or older, having a self-reported diagnosis of chronic hepatitis B, and residing within the United States. While the survey recruited participants globally, the qualitative arm specifically focused on individuals living in the U.S. to better understand trial knowledge and perceptions among people from minority populations representing foreign-born communities that are highly impacted by hepatitis B.

Participant recruitment occurred between January and August 2023 using purposive sampling to ensure representation across key demographics of PLWHB, including Africans, Asians and Pacific Islanders. A purposive sampling strategy was used to ensure representation from each of the target communities of interest. Saturation was reached after five focus groups, and six interviews were completed. This strategy for saturation assessment was confirmed in the literature.[15]

Recruitment materials—including informational flyers and digital announcements—were disseminated by partner community-based organizations through organizational e-newsletters and social media platforms, collectively reaching an estimated 45,000 individuals. Interested respondents completed an online intake form to express their willingness to participate. Trained community navigators conducted outreach via email or telephone to provide prospective participants with detailed information about the study, including its objectives, procedures, and ethical safeguards related to confidentiality and voluntary participation. The researchers collaborated with community-based organizations (CBOs), with whom they have long-standing partnerships. These organizations possess deep knowledge of the communities they serve and have extensive experience working with PLWHB. Trusted community navigators, who were integral to this study, were key personnel at the partnering CBOs. They were culturally and linguistically competent, and were trained to conduct the focus groups in participants' preferred language, if participants indicated this as a preference. All this has played a key role in ensuring the cultural appropriateness of the study. In instances where recruitment fell short of the threshold necessary for a focus group or when individuals expressed privacy concerns, one-on-one interviews were offered as an alternative. PLWHB participated in either focus groups or interviews (hereinafter referred to as "participants"); no one participated in both.

A total of five semi-structured focus group discussions and six individual interviews were conducted virtually via Zoom between February and August 2023. One focus group discussion was conducted in-person, as preferred by participants of that community. Each session lasted between 60 and 90 minutes and were recorded and transcribed. Discussions were conducted in either English or participants' native language, based on participants' preference. All participants received a $75 honorarium as recognition for their time and contributions. Throughout this manuscript, both focus group and interview findings are reported together.

A directed content analysis approach was used to generate and organize codes into a codebook (Appendix C). Thematic saturation was achieved during the data collection phase by weekly meetings between researchers to discuss the codebook, themes, and coding of transcripts. Once no new themes emerged within the coding process, the researchers agreed that saturation was met, no further data were collected, and the thematic codes and codebook were finalized. Each code was clearly defined to improve coding accuracy and inter-coder reliability. Two trained researchers independently coded all transcripts using NVivo Version 13, with regular meetings held to discuss emerging patterns, clarify code definitions, and resolve discrepancies.[16] A third senior researcher provided oversight and facilitated consensus in cases of coding disagreement. Inter-coder reliability was assessed using NVivo's Kappa coefficient tool, with a final coefficient of 0.81, indicating substantial agreement and high consistency in coding practices. The research team continued code refinement and theme development until thematic saturation was achieved.

Ethical Considerations

No personally identifiable information was collected in either arm of the study. Prior to participation, focus group and interview participants were provided confidentiality details and they signed an informed consent form. If participants were not comfortable reading or understanding English, the trained community navigator read the forms to them in their native language, and they provided verbal consent that was recorded during the interviews and focus group discussions. Additionally, participants were guided to change their names to participant 1, participant 2, ... etc. during the virtual discussions to further ensure confidentiality. All data are stored on a password protected computer. This study was approved by the Heartland Institutional Review Board (IRB) (HIRB Project No. 081122-407).

Results

A total of 1,064 individuals initiated the survey. Of these, 848 respondents met the inclusion criteria. After data cleaning, the final analytic sample comprised 680 respondents. The survey completion rate was calculated at 80% (680/848).

Participant Characteristics

Most survey respondents were male (70%, $n=476$) and self-identified as Black or African American (63%, $n=431$). Over half (53%) were between the ages of 31 and 45 (IQR = 13 years). The most frequently reported country of residence was Nigeria (34%), followed by the United States (12%) and the Philippines (7%). Table 1 provides a comprehensive overview of the survey respondents' demographic characteristics.

Table 2 outlines respondents' hepatitis B-related clinical characteristics. Approximately one-quarter of participants reported not having access to a healthcare provider for hepatitis B management, and just over half indicated that they were either currently receiving or had previously received treatment for hepatitis B. Although 34% of respondents had been living with an HBV diagnosis for more than ten years, only 5% reported prior participation in a trial.

For the qualitative arm, there were 36 PLWHB participants. There were 30 participants across six community focus groups: Vietnamese, West African (Senegalese, Burkinabé (Burkina Faso), Cameroonian), Somali, Korean, Chinese, and Caucasian. Six individual interviews were conducted with Filipino, Black, Marshallese, and Chuukese participants. Further demographic details are provided in Table 3. Qualitative participants' hepatitis B-related data can be found in Table 4.

Table 1. Survey Respondents' Demographics, 2023

Survey Respondents' Demographics (N = 680)	N (%)
Gender	
Male	476 (70%)
Female	184 (27%)
Prefer not to answer	13 (2%)
Missing	7 (1%)
Race	
White (Caucasian)	83 (12%)
Black or African American	431 (63.4%)
Asian	139 (20%)
American Indian /Alaskan Native /Native Hawaiian / Pacific Islander	3 (0.4%)
Prefer not to answer	1 (0.2%)
More than one race	10 (2%)
Missing	13 (2%)
Ethnicity	
Hispanic or Latino	28 (4%)
Not Hispanic or Latino	456 (67%)
Prefer not to answer	184 (27%)
Missing	12 (2%)
Age Group	
18-30 years	140 (21%)
31-45 years	362 (53%)
46-60 years	108 (16%)
61 years and above	40 (6%)
Missing	30 (4%)
Previous Clinical Trial Participation	
Yes	31 (5%)
No	597 (95%)

Factors Influencing Trial Willingness and Suggestions to Increase Acceptance

Awareness: Existing Knowledge

Limited Existing Knowledge

Diverse communities are receptive to learning about hepatitis B trials. For example, 68% of survey respondents wanted to learn more about participating in future trials. Yet only 27% of respondents had received information about trials. Participants of the Chinese, Somali, White and Black communities revealed they had some existing knowledge of trials. However, participants in the Vietnamese, West African, Marshallese, Chuukese and Filipino communities had limited trial knowledge. One West African participant stated, *"I have never participated, seen, or done it before, and I don't know how it works and how it ends."*

Some Korean participants had some understanding of trials, others were unaware of the purpose of trials, as one participant asked, *"What is a clinical trial or [the] subject of clinical trials? I'm just curious. What's the clinical trial about?"* This indicates the need to inform the broader communities about trials in general.

Despite low awareness, 85% of survey respondents were willing to participate if offered the opportunity, with 13.4% undecided and only 1.4% unwilling, highlighting potential for engagement with proper outreach.

Perceived Importance & Patient Safety

Participants demonstrated a wide range of perceptions regarding the purpose and importance of trials, with notable variability both within and across community groups. For example, a Black participant discussed their understanding of trials, stating, *"it's carried out for us to get data, information about a certain disease or certain sickness so as to be able to develop drugs or develop medication or vaccines to tackle it."* One White participant was familiar with trial timelines, *"I hear clinical trials, I think research, I think a long period of time from start to finish, years."* Some participants also explained their understanding of the purpose of trials, with one Chinese participant saying, *"To determine the risks. What are the side effects, the success rate."* A Somali participant also added, *"You can't use anything that didn't go through clinical trials."*

Table 2. Survey Respondents' Hepatitis B Data, 2023

Survey Respondents' Hepatitis B Characteristics (N = 680)	N (%)
Time Since Hepatitis B Diagnosis	
Less than 5 years	285 (42%)
6-10 years	144 (21%)
More than 10 years	231 (34%)
I don't remember	16 (2%)
Missing	4 (1%)
Currently or Previously on Prescribed Antiviral Medication	
Yes, I'm currently taking medication	205 (30%)
No, but I used to take medication	151 (22%)
No, I have never taken medication for HBV*	319 (47%)
Missing	5 (1%)
Frequency of Hepatitis B Medical Visits	
Every 6-12 months	281 (41%)
Every 1-2 years	111 (16%)
When I have a new symptom	64 (9%)
I don't have access to a medical provider	153 (23%)
Consult with a natural healer or an herbalist	23 (3%)
Other	24 (4%)
Missing	24 (4%)

*HBV refers to hepatitis B virus.

Survey data reveals that 79% of respondents believed that trials are conducted according to stringent regulations aimed at safeguarding the well-being of participants. Similarly, Black, Korean, West African and Vietnamese participants agreed that trial participants must be kept safe.

Some participants of the same community had differing opinions about their participation in a trial, even if they perceived them to be safe. For example, one White participant stated, *"I assume that there are lots of guard rails in place, that safety is the number one concern during any clinical trial."* However, another White participant added:

> *I agree with that but I'm not going to be the lab rat to do it, so I agree that we need people, but I'm just not going to be the first one to jump in unless I had no other choice.*

With this, participants from other communities discussed the risks and benefits of participating in a trial when asked about their understanding of the safety regulations for trials. As one Chinese participant noted, *"Yeah, there's some benefits, right? You cannot totally see it's dangerous. There is some risk but still you can benefit from there."* With this, when asked if they believe participating in a trial is dangerous, one Korean participant stated, *"I do not think so. After hearing about the goal of clinical trials and importance of trials, why they [researchers] will do the trials to harm people?"*

Lack of information and awareness about trial processes, and an inability to gain more information, appeared to impact perceptions of participation among participants.

Table 3. Focus Group and Interview Participant Demographics, 2023

Focus Group Demographics (N = 36)	N (%)
Gender	
Male	16 (44%)
Female	20 (56%)
Race/Ethnicity	
Black or African American*	**13 (37%)**
Black	2 (6%)
Somali	6 (17%)
West African	5 (14%)
White (Caucasian)	**3 (8%)**
Asian	**17 (47%)**
Chinese	5 (14%)
Filipino	1 (3%)
Korean	3 (8%)
Vietnamese	8 (22%)
Native Hawaiian or Other Pacific Islander	**3 (8%)**
Chuukese (Micronesia)	2 (6%)
Marshallese	1 (3%)
Age group	
18-30 years	2 (5%)
31-45 years	9 (25%)
46-60 years	15 (42%)
61 years and above	10 (28%)
Previous Clinical Trial Participation	
Yes	4 (11%)
No	32 (89%)

*None of the focus group or interview participants self-identified as African American.

Table 4. Focus Group and Interview Participants' Hepatitis B-Related Characteristics, 2023

Focus Group, Interview Participants' Hepatitis Characteristics (N = 36)	N (%)
Time Since Hepatitis B Diagnosis	
Less than 5 years	11 (30.5%)
6-10 years	1 (2.7%)
More than 10 years	20 (55.6%)
I don't remember	4 (11.1%)
Currently or Previously on Prescribed Antiviral Medication	
Yes, I'm currently taking medication	17 (47.2%)
No, but I used to take medication	3 (8.3%)
No, I have never taken medication for HBV*	16 (44.4%)
Frequency of Hepatitis B Medical Visits	
Every 6-12 months	26 (72.2%)
Every 1-2 years	3 (8.3%)
When I have a new symptom	1 (2.7%)
I don't have access to a medical provider	2 (5.6%)
Consult with a natural healer or an herbalist	2 (5.6%)
Other	1 (2.7%)
Missing	1 (2.7%)

*HBV refers to hepatitis B virus.

For example, a Somali participant explained, *"There is a lack of information and awareness about the clinical trial. I would not have participated as I would need more information."* This sentiment was supported by the online survey results, as 30% of respondents who have reported their willingness to participate in a trial said they were unable to reach anyone from the trial team to get more information or discuss patient enrollment.

Sources of Information

Results reveal that both survey respondents and participants who had some existing knowledge learned about trials through digital sources, including online and news-related media, and in-person sources, including healthcare providers and trusted community organizations.

Digital sources: Among survey respondents who received information about trials, 71% received information from the internet, 19% got information from social media and 4% indicated government websites.

Participants also said that they gained trial information by searching on the internet. Vietnamese participants indicated they learned about trials from searching online: *"I searched the information about it on the internet..."* A Black participant explained how they have *"read about clinical trials, I've read even on the internet, during my visit to the hospital or my care provider. I got a link from different sources both online and offline."* Other sources of information included news media, as identified by some of the participants who stated they learned about trials through *"the media, the TV, and movies."* A Korean participant also noted how they learned about trials when living in Korea, *"I saw leaflets to recruit participants in clinical trials"* while taking the subway.

In-person sources: Of the survey respondents who had received information about trials, 27% said they received this information from their healthcare providers. Similarly, Vietnamese, West African, Chinese and Black participants had learned about trials from their regular providers, particularly because their doctors were aware of active trials, and were inquiring about their patients' willingness to participate. As one Chinese participant explained, *"I used to see a doctor in New York and I remember a long time ago he updated me, there was some kind of clinical trial going on right now [and he asked] if I'm interested."* One Black participant mentioned, *"My doctor once talked to me about participating in a clinical trial."*

While doctors are often regarded as a trusted source of information, there remains a significant gap in patient awareness of trials through their healthcare providers. When asked, 'Has your doctor ever talked to you about participating in a clinical trial?' most survey respondents (83%) reported that their healthcare provider had never discussed this option with them.

This was also evident across community participants. Participants from Filipino, Marshallese, Chuukese, Korean, and White communities shared that they had not received information about trials from their treating physicians. As one White participant recounted:

> *I go to a Hepatologist at the [name of institution], and they do research, but I've never been steered into any sort of a clinical trial of either through them or through a pharmaceutical company. So, I guess it just seems like there's not a lot of pressure or there's not a lot of motivation to join a clinical trial unless you take your own initiative.*

Importantly, only 13% of survey respondents reported learning about trials from faith leaders and trusted community and patient organizations. Somali and West African participants also indicated they learned about trials from these sources. One Somali participant stated:

> *...we will not use a medicine that we just saw somewhere, we need our community, the Somali Health Board, to make us understand its usage and the diseases it cures and its level of certification. Then it is possible for us to participate...*

Barriers: Misconceptions

General Misconceptions

Some participants held misconceptions about trials, confusing trials with other types of research or clinical studies. For example, one West African participant incorrectly believed that trials are the same as routine clinical surveillance, stating: *"To see if the disease improves in your body. For example, they told me to come for tests every six months to get checked. In my opinion, I think that's what a clinical trial is."* Similarly, a Marshallese participant equated trials with focus groups, describing them as *"Some kind of opinion gathering from individuals or groups of people to gather information about particular medicines."* Additionally, a Chuukese participant perceived trials as preclinical research, explaining: *"My own understanding it's carried out for us to get data information about a certain disease or sickness so as to be able to develop drugs or medication or vaccines to tackle it."*

Eligibility Misconceptions

Misconceptions regarding trial eligibility were substantial within both participants and survey respondents. More than half of survey respondents did not have a correct understanding of trial eligibility related to prior use of HBV medications. Approximately 15% incorrectly believed that individuals taking HBV medication were ineligible to participate in trials, while 38% were unsure about this statement. Participants also expressed confusion about eligibility requirements. One White participant speculated, *"Somebody who's already on medication might not necessarily be the best candidate for it."* Conversely, a West African participant shared

that one should be allowed to participate despite being on medication, because they might benefit from a new treatment, "*(If) the treatment that they are taking is not working for them, I do not think they should be disqualified because they might need something else.*" Notably, a White participant had prior experience with a trial for [a different health condition], so they had some understanding of eligibility criteria, stating: *"I didn't qualify for it because I was already being treated for hepatitis."*

Both survey respondents and participants were asked if they agree or disagree with the statement: 'People who have liver disease (fibrosis, or cirrhosis, or liver cancer) are not eligible to participate in clinical trials for new medications for hepatitis B.' Among survey respondents, 14% assumed people living with progressive liver conditions are ineligible to participate in trials, and 37% were unsure. Similarly, a Black participant answered, *"I am really confused. I don't know whether I should agree or disagree, because people with the liver disease, they really need to take part in clinical trials to get new drugs, to start to try new things out."*

Finally, age was perceived as a factor influencing trial eligibility; 17% of survey respondents believed people who are 60 years or older are ineligible to participate, and 36% were unsure. With this, one Filipino participant noted, *"I'm old already, I'm not going to be participating."*

Importantly, some Vietnamese, West African, and Korean participants had some understanding of eligibility criteria. A Korean participant stated, *"Everyone should be able to [participate in] clinical trials if [they] meet protocol profiles."* A West African participant explained their understanding of eligibility requirements based on what they have seen from televised medical advertisements:

> *Let's say I participated [in a] clinical trial for another disease other than hepatitis B, that will be an issue for me at some point, like you see some medicine, when they make advertisements about it, they say people with this disease cannot use this... I think before you participate [in] any clinical trial, you have to do like a screening to know what diseases you have and what you don't have.*

Fear-Related Misconceptions

Both survey respondents and participants reported fear-related misconceptions of trials. Amongst survey respondents, 41% believed that participating in a trial seems scary. This fear may stem from thinking that they will be testing medications that are new and have not yet received regulatory approval, as well as concerns about the unpredictability of potential adverse reactions. A Somali participant highlighted this issue, stating, "*I think the biggest problem is the fear of the side effects of the medication since no one knows what the outcome would be, where the side effects will affect the most.*" A West African participant also echoed these sentiments by expressing that they would be concerned about the effects of the medications as they will be the first one taking it.

Interestingly, when asked if they had ever participated in a trial for hepatitis B, about 15% of survey respondents said they chose not to participate and provided their reasons for declining participation. More than one third of respondents (39%) indicated they chose not to participate because they were concerned about their safety during the trial and potential side effects.

Acceptance: Suggestions to Improve Awareness

Survey respondents and participants showed lack of awareness and held numerous misconceptions, which served as barriers to their participation in trials. Despite these challenges, the data revealed that willingness to participate increased significantly when proper information was provided. A particularly insightful quote from a West African participant emphasized this point: *"Information matters, information plays an important role. You must be informed to participate, if you are not informed, how will you participate?"*

Providing Specific Information

Specific information is pertinent to a participant's decision regarding trial enrollment. Amongst survey respondents who chose not to participate in a trial, 49% stated they made this decision because they were not given enough information about the trial.

Additionally, participants discussed the type of information they wished to see, if ever approached to participate in a trial. Trial details shared with potential participants should include the primary objectives and targets of the intervention, the specific phase of the trial, its anticipated duration, findings from previous research and the ethnic makeup of other enrolled participants. Participants also want to know how their personal lives would be impacted by study participation, such as the impact on daily and work activities, time commitment, and their anonymity during participation. As summarized by a White participant:

> *I want to know what research has been done. What steps [have] they already taken? What level of the trial it's at, … if they had tested on anybody else … what their hypothesis is, what it entails... I want a breakdown of exactly the length of time, what's going to be required of me when I'm doing it, how much of my time like, am I restricted on eating certain things or doing certain things?*

Information about the trial drug should also address participants' health-related questions, as posed by a Marshallese participant, *"How will it affect my health or what would it be like if I take more medication that I've never taken before? What will be the pros and cons? What will be the impact negatively on my health?"*

One Black participant brought up concerns related to potential interactions between the trial drug and their regular medication. Given that potential participants could

already be on other medications for other comorbidities, the distinction between adverse effects caused by the trial drug and those secondary to pre-existing illness should be explicitly explained. Each community group had a specific focus as to what information was most relevant in their decision to participate in a trial. Further details are offered in Table 5.

Tailored Recruitment Strategies

Participants highlighted that trial communications should use diverse dissemination methods for different age groups. For example, one Vietnamese participant shared, *"For young people, media channels work better. For older audiences, they trust family doctors so if the doctors promote it, it will be more effective than TV, radio, and newspapers."*

Recruitment strategies discussed included community-specific channels such as radio, newspapers, social media and other messaging platforms (Zalo, KakaoTalk, Line, WeChat) to reach diverse racial and ethnic groups. One Vietnamese participant suggested to, *"post in a Vietnamese newspaper and post the phone number for anyone who needs it."* A Chinese participant shared, *"I would say community events. Like for me, my kids go to Chinese school (where) we get a lot of information."*

Table 5. Community-Identified Informational Needs

Clinical Trial Information: What People Want to Know	Community Group
Clinical Trial Procedure	
Study Objectives	West African, Chinese, White
Study Outcomes, Goals	West African
Phase of trial	Chinese, White
Duration	Korean, Chinese, White, Black
Location	Vietnamese, West African
Research Team & Doctors	Vietnamese
Previous Research Results	White
Number of Participants	Chinese, Black
Personal Commitments	Chinese, White, Black
Trial Medication	
Medications' intended purpose (cure versus treatment)	West African, Somali
Function of medicine	Korean, Chinese, Filipino, Marshallese
Safety profile	Vietnamese, Korean, Filipino
Side effects	Vietnamese, Korean, Filipino, Marshallese, Black
Health affects	West African
Potential harms	Korean, Marshallese, Black
Benefits	Somali
Instructions to take the medication	West African
Has medication been tested (certified for human use)	Somali
Success of medicine in other patients with similar health conditions	Marshallese

Participants emphasized the importance of receiving trial information and opportunities from trusted sources. One Somali participant added that word of mouth through a trusted messenger would be the best way to inform their community of trials, explaining, *"I would have also participated and shared with the people so that they can know about it since it's for all the people and the community at large."* Similarly, medical providers were often mentioned as one of the most trusted sources of information. As shared by a Vietnamese participant, *"It is best if it is a doctor's office, a medical office, or a hospital, the people who participate in the experiment will trust them more."*

To reduce knowledge gaps and misconceptions about trials, participants suggested distributing clear participant-oriented, in-language communication that details the clinical process, trial duration, trial medication specifics, participant roles, time commitment, and the racial/ethnic makeup of study participants. Further details are offered in Table 5.

Tools to Enhance Trial Experience

Survey respondents shared several key suggestions to enhance the enrollment process for trials.

A user-friendly app: The importance of a user-friendly application or tool was strongly emphasized, with 55% of respondents stating that such a resource would be very important to help them navigate and understand the various steps and phases of a trial. An additional 21% rated this feature as somewhat important, indicating a significant demand for accessible and clear guidance throughout the trial process. With this, one Chuukese participant said that for appointment reminders, *"an app will [be] handy to remind me of such events."*

Support groups: The significance of support networks during trials was clear, with 58% of respondents identifying the presence of a support group or program as "very important", and another 18% considering this "somewhat important" in their decision to participate in a trial. To this point, a Chinese participant said, *"it would be great to have a support group where you can ask questions, and you have something to relate to."*

Additionally, a notable 35% of respondents emphasized the importance of communicating with individuals with whom they have a shared identity, who had previously participated in a trial, with an additional 27% considering this somewhat important. This highlights the value placed on firsthand experiences and peer insights during the decision-making process.

A summary of the study findings can be found in Table 6.

Discussion

This mixed-methods study, informed by the Ford

Model elucidates how low awareness of trials, including limited existing knowledge, related misconceptions, and difficulty accessing trial-related information, can serve as barriers to an individual's decision to participate.[11] The results present these factors, across diverse communities, along with tailored informational needs and recruitment recommendations to overcome these barriers. Participants' suggestions can help to increase their communities' awareness of and willingness to consider participating in trials.

Existing Knowledge Gaps and Associated Misconceptions: Barriers to Trial Participation

Participants in this study demonstrated a strong willingness to participate in trials, consistent with findings from previous research.[17,18,19] However, willingness alone is not enough, it must be supported with key pillars such as awareness, access to accurate information, effective communication, and reliable access to care to ensure meaningful participation.[17] Lack of access and exposure to trial information is a barrier to PLWHB participation in trials.[10,20,21] In the present study, only a few participants had prior knowledge of trials, and awareness and understanding varied across diverse communities. This lack of knowledge and minimal understanding of trials and their processes may be due to a general lack of patient education about trials, either from the research teams themselves or the patient's primary care providers.[22]

Participants in this study expressed confusion around trial terminology and enrollment processes, a barrier that has also been well documented.[22,23] This study also demonstrates challenges in communicating with trial sponsors when seeking information about specific trial opportunities. This barrier prevented participants from gaining accurate trial information and often left many with misconceptions about eligibility.[24] A commonly held

Table 6. Summary of Survey Findings and Corresponding Qualitative Quotes

Summary of Survey Findings and Corresponding Qualitative Quotes		
Main Themes	**Survey Findings (N = 680)**	**Qualitative Quotes (N = 36)**
Awareness (Existing Knowledge)		
Limited Existing Knowledge	27% had received information about trials	*"I never learned about a clinical trial. I don't have any idea [about] clinical trial."* - Marshallese participant
Sources of Information (among 27% of respondents who had learned of trials)	Digital sources: 75% online 19% social media	*"The website, hepb.org. I really get my info from there."* - Black participant
	In-person: 27% healthcare providers 13% faith leaders, trusted community or patient organizations	*"I've never been suggested by my specialist for a clinical trial, but I do get emails but it's some of the work that I've done that I think my name has gotten out there."* - White participant
Barriers (Misconceptions)		
Eligibility Misconceptions	Current Treatment: 53% did not have the right information about the trial eligibility of people receiving antivirals	*"I'm old already, I'm not going to be participating."* - Filipino participant
	Comorbidity: 51% did not have the right information about the trial eligibility of people living with comorbidities	
	Age: 53% did not have the right information about the trial eligibility of people over the age of 60 years	
Fear-related Misconceptions	41% believed trial participation is scary	*"I'm not really going to participate for taking any medication that is not approved yet."* - Filipino participant
	39% had concerns about their safety during trial, fear of side effects (among those not willing to participate)	*"Because it's something that hasn't been tested before. And I'll be the first one. So, what if there is a component in the actual medication that doesn't agree with my system?"* - West African participant
Acceptance: Suggestions to improve awareness		
Tailored Recruitment Strategies	Specific Information: 49% of those who declined trial participation said it's because they were not given enough trial information	*"The things I need to do, all these appointments... and the whole progress, [the] whole picture of this clinical trial. Like what kind of stage [it is] in right now and how long I need to participate... about the research and about my personal participation, the details."* - Chinese participant *"For young people, media channels work better. For older audiences, they trust family doctors so if the doctors promote it, it will be more effective than TV, radio, and newspapers."* - Vietnamese participant
Tools to enhance trial experience	User-friendly app: 76% said having a user-friendly app to navigate trial is important	*"In terms of reminders or maybe something like ads, or an app that will have [the ability] to remind me of such events."* - Black participant
	Support Groups: 76% said support groups are important	*"I think support groups are great, you know, and having the support of other people."* - White participant

belief was that certain health conditions or demographic factors, such as co-existing medical conditions, older age, or current use of hepatitis B medications, were automatic grounds for disqualification. These misconceptions significantly hindered trial consideration and reinforced participants' perception that trials were not intended for individuals like themselves.

Fear was another salient barrier. A lack of exposure to accurate, accessible information contributed to concerns about unknown side effects and general distrust of the research process. Participants expressed apprehension about being treated as "guinea pigs," reflecting longstanding fears documented in the literature.[25,26] These concerns, coupled with limited understanding of trial safety protocols, led many to view clinical research as risky or untrustworthy. Addressing these fears through transparent, community-specific education is essential to improving trial engagement.

Engaging Healthcare Providers and Community-Based Organizations to Improve Trial Awareness

Trusted sources of information, including healthcare providers and community-based organizations (CBOs), are often gatekeepers to patients, and therefore, they are the key to bringing trial information to potential participants. Lack of provider awareness of actively recruiting trials is a barrier to recruiting and enrolling diverse participants into trials, as identified in this and previous studies.[20,22] In the present study, most survey respondents and many community participants indicated that they had never discussed trials, including participation opportunities, with their healthcare providers, with whom many have a long-term physician-patient relationship. Only a handful of the Vietnamese, West African, Chinese and Black participants had learned about trial opportunities from their healthcare providers.

This highlights gaps in providers' knowledge about active trials, and may explain, to some extent, why many diverse communities are unaware of trials and do not participate in them. As healthcare providers are trusted sources of information for diverse patient populations, trial teams must plan to share culturally appropriate information with providers to expand trial awareness among both provider and patient populations, to help drive recruitment and enrollment efforts of diverse communities.[10,22]

Increasing the role of CBOs and leaders in educating the public about health topics, specifically trials, is equally important, as they are vital sources of information for immigrant groups.[27] In this study, a small number of Somali, West African and Korean participants discussed how they learned about trials from their local CBOs and community leaders and survey results indicate that only a few respondents said they gained trial information from CBOs and leaders. These findings highlight an important yet often missed channel to effectively recruit diverse participants into trials.

Drug developers must partner with CBOs and involve them early, from the trial's onset to develop effective outreach plans to ensure that all study procedures, including recruitment and enrollment strategies, are culturally appropriate and responsive to the needs of the communities.[28,29] Trial teams should establish continuous communication with CBOs and leaders, inform them of potential participation opportunities and provide them with access to accurate information about the trials. Creating strong ongoing partnerships with CBOs can prove beneficial to trial developers' efforts to engage underrepresented communities, as CBOs can inform their participants about the importance of research participation before recruitment efforts begin.[10,22,28,30] With an established partnership, CBOs and leaders can inform their community members and promote participant recruitment and enrollment efforts.

Increasing Trial Acceptance: Suggestions to Improve Awareness and Reduce Barriers

Support Groups

Shared experiences can unite individuals and serve as a powerful source of empowerment. Offering access to support groups for potential trial participants can foster connections with others facing similar experiences, offering both emotional and practical support. This highlights a significant need for community and support networks in trial participation, which can enhance the willingness to participate among diverse racial and ethnic groups. Participants in this study expressed the need to communicate with others who have been through a similar trial journey as a tool to know what to expect and encourage them to participate in trials. This supports previous findings.[27,31]

User-Friendly Applications to Enhance Trial Experience

In recent years, the integration of cutting-edge technologies, like user-friendly apps, into trials has significantly influenced the successful and expedited conduct of various trial stages, especially the recruitment process.[32] For potential participants, these digital tools can be an important factor that influences enrollment into trials by making it easier for participants to find information about trial opportunities around them. Apps also allow trial participants to schedule appointments, track their progress, and receive timely reminders. Ultimately, such innovations could enhance accessibility, engagement, and increase participation throughout the trial process.

Engaging Trusted Community-Based Organizations and Healthcare Providers

Participants suggested that effective recruitment and

retention efforts should focus on involving trusted personnel and accessible information sources for different communities. Results indicate that few respondents obtained trial information from CBOs and healthcare providers. To drive recruitment and enrollment of diverse populations into trials, healthcare providers and CBOs must be informed of trials taking place, at national, regional and local levels, as well as granted access to basic and understandable information about the trial.[20] Providing these messengers with adequate educational and informational materials can enhance participant understanding and willingness to participate in trials, as providers and CBOs are often the most trusted source of information.[10,21] There is significant potential for improving trust and engagement through better integration of providers and CBOs into the recruitment process, which may entail on-ground engagement between trial teams and these trusted voices, to establish collaborative relationships between the research community and those serving diverse PLWHB. Trial teams can also create ongoing and specialized educational programs, or training materials for providers and CBO staff who serve diverse populations, [33] so they can more easily relay the clinical and ethical aspects of trials, as well as benefits of participating, which can increase participants' willingness to participate in future trials.[20,23]

Delivering Clear, Community-Specific Insights for Better Understanding

To increase trial acceptance, study participants emphasized the need for culturally appropriate, in-language, patient-facing resources to reduce mistrust in research and improve understanding of the trial process. This suggestion is supported by other studies.[34,35] Previous programs have been successful in recruiting and enrolling diverse patient populations in trials when using culturally sensitive methods, like in-language materials, to educate diverse communities about trials and research processes.[23] Previous studies have also found that providing culturally tailored educational materials to diverse racial and ethnic participants improved their attitudes towards trials and general willingness towards future participation.[20,21,22,25,36,37]

Transparency and clear comprehension of trial processes and medications are crucial for informed decision-making, as seen in this and other studies. [22,29] This may require restructuring beyond a generic consent form so it is more catered towards diverse populations.[38,39] Participants stressed the importance of offering clear information that reassures patients about their health and safety. This includes sharing details about prior testing of trial treatments and ongoing health monitoring. Specific trial information should also include the study's goals and protocols, eligibility requirements, patient safety measures, and scientific values, in lay language that CBOs and providers can easily relay to their participants.[22,29] This can significantly enhance patients' educational awareness which could increase the likelihood of their participation in the trial. This finding is supported by previous literature.[10,29] Trial teams can create informational materials for diverse communities and tailor them according to the preferences identified by the communities most impacted by HBV, to promote acceptance of trial participation.

Diverse groups of PLWHB must be provided with culturally appropriate information to increase their knowledge and understanding of trials and allow them the opportunity to consider participating. When PLHWB have access to clear and accurate information, there will likely be less fear and misconceptions, as communities have greater trial awareness. As diverse communities gain trial awareness and have trusted avenues where they can learn more information, their trust in trials strengthens, allowing them to make an informed decision about enrollment when made aware of existing trials, ultimately leading to increased participation.

Limitations

This study has several strengths, including highlighting the needs of PLWHB to participate in clinical trials and offering actionable strategies to improve communication with underserved communities. However, it also has limitations.

For the qualitative component, findings are not generalizable to the broader U.S. population, as participants were drawn from specific racial and ethnic minority communities with existing access to healthcare services or relationships with community-based organizations. However, the results are transferable to similar populations at risk for hepatitis B who reside in the U.S. and have comparable levels of healthcare access and community support.

For both study arms, due to the virtual nature of the survey and majority of the focus groups/interviews, potential participants with low digital literacy and those without access to the required technology may not be appropriately represented in study results. The virtual nature of both study arms may have introduced the potential for selection bias. However, methodological precautions, including survey translation into nine distinct languages including English, and focus group recruitment through trusted community navigators and considerable sample sizing ensured consistency and credibility of the findings.

Despite these efforts, in-language survey response rates remained low. Future studies should consider more targeted outreach approaches to promote multilingual participation, including culturally relevant dissemination channels and trusted community partners. While this limitation impacted the in-language response rate, the study's successful outreach and recruitment achieved

robust online survey participation spanning a wide range of racial and ethnic groups.

Additionally, certain demographic groups were underrepresented in the online survey, including Asian and female participants. Approximately 30% of respondents identified as female, and 20% of all female participants identified as Asian. These imbalances may limit capturing the perspectives, experiences, and preferences of Asians and women living with hepatitis B. However, the study overcame this through purposeful recruitment for the focus groups to ensure a balanced gender and racial representation, with similar numbers of male and female participants, and nearly half of all focus group participants identifying as Asian.

Future research should continue to prioritize equitable inclusion across all study components to ensure a comprehensive understanding of the needs and experiences of all affected populations.

Conclusion

Clinical trials are essential for advancing the understanding and treatment of chronic diseases, including hepatitis B. However, equitable participation remains a challenge. This study identifies critical barriers to trial enrollment among diverse communities affected by hepatitis B, particularly related to knowledge gaps, misinformation, and lack of access to accurate and culturally appropriate trial information.

By incorporating community-informed recommendations, this research offers actionable strategies to support more inclusive and representative trials. Key strategies to ensuring diverse trial participation include: early engagement of healthcare providers and community organizations in clinical trial recruitment and retention efforts; tailored educational resources for providers, organizations and PLWHB; improved communication of eligibility criteria; the integration of culturally sensitive outreach and digital support tools.

Implementing these approaches can enable researchers, sponsors, and institutions to build trust, improve awareness, and foster greater inclusion of underrepresented populations in hepatitis B trials. In doing so, the trial enterprise will move closer to producing treatments that reflect and serve the needs of those most affected.

Future research is needed to build upon the findings of this study, to better understand how to enhance the collaboration of healthcare providers and community organizations in clinical trial recruitment and retention of diverse communities living with hepatitis B. This can further enhance and refine the operationalization of the proposed strategies. Ongoing collaboration with PLWHB communities will be essential to sustaining progress and ensuring that clinical trials are accessible, understandable, and responsive to the priorities of diverse populations.

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Authors' Contribution

Conceptualization: Yasmin Ibrahim.
Data curation: Yasmin Ibrahim.
Formal analysis: Yasmin Ibrahim, Tanya Machado, Fiona Borondy-Jenkins.
Funding acquisition: Yasmin Ibrahim, Chari Cohen.
Investigation: Yasmin Ibrahim, Tanya Machado.
Methodology: Yasmin Ibrahim.
Supervision: Yasmin Ibrahim, Chari Cohen.
Project administration: Tanya Machado.
Writing–original draft: Yasmin Ibrahim, Tanya Machado, Fiona Borondy-Jenkins, Shreya Koirala.
Writing–review & editing: Yasmin Ibrahim, Tanya Machado, Fiona Borondy-Jenkins, Shreya Koirala, Mi Dong, Ibrahima Sankare, Mohamed Ali, Dung Hua, Ashley Che, Chari Cohen.

Competing Interests

The Hepatitis B Foundation receives public health program and research grants from BMS, GSK, Gilead Sciences, Vir Biotechnology, and Dynavax Technologies. Chari Cohen serves on a patient/advocacy advisory committee for GSK and Gilead Sciences, with funds being distributed to the Hepatitis B Foundation. Yasmin Ibrahim serves on a patient/advocacy advisory committee for Roche/Genentech, with funds being distributed to the Hepatitis B Foundation. No corporate funds supported this research.

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Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki and approved by the Heartland IRB (HIRB project No. 081122-407 and 04/26/2023). Informed consent was obtained from all participants involved in the study.

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