CLINICAL TRIAL PARTICIPATION
Among People Living With Hepatitis B

Yasmin Ibrahim, MD, PhD
Patient Engagement Program

- Patient-Focused Drug Development Meeting (PFDD)
- Global online survey
- One-on-one Interviews with PLHB
Patient Engagement Survey

- Document the physical, emotional, and social impact of living with chronic hepatitis B (CHB)
- Treatment experiences, challenges and perceived value of current treatments
- Perspectives on future treatments and clinical trial participation

1,700 Survey Participants

- 15% Were tested they were having symptoms
  - Less than 45 yo: 32%
  - 31-45 years old: 49%
- 81% Male
- 67% Lived outside the U.S.
- 83% Black
  - 29% AAPI
  - 13% White
- 50% Diagnosed in the past 5 years
- 53% Experience with CHB medication
- 56%
Telephone Interviews

- 24 telephone interviews
- 50% Female
- 21% Black
- 46% Asian descent
- 33% White
- 63% were currently taking medication
Patient-Focused Drug Development Meeting (PFDD)

- Externally-Led Patient Focused Drug Development Meeting June 2020
  - 650 participants, 12 panelists, 300 email comments
Important Outcomes of Future Treatments

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
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Preferred Outcomes for Future Hepatitis B Treatments
Willingness to Participate in Hepatitis B Clinical Trials

Journal of Translational Science

Research Article

Attitudes towards clinical trial participation among people living with chronic hepatitis B

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Would you be interested in participating in a future clinical trial for a new hepatitis B treatment?

Willingness to participate in clinical trials for new hepatitis B medication (all respondents). Three possible responses (n): yes (563), undecided (162), no (46)
Participants living outside U.S. were more willing to participate in a new hepatitis B clinical trial.

Willingness to participate in clinical trials for new hepatitis B treatment by location (U.S. vs. international)
Black participants living outside U.S. showed the highest rate of willingness to participate in a new hepatitis B clinical trial.

Those willing to participate in clinical trials by race and location (U.S. vs. international)
Age is an important factor in willingness to participate in hepatitis B clinical trials.

Those willing to participate in clinical trials by age group and location (U.S. vs. international)
Male participants were more willing to participate in a new hepatitis B clinical trial.

Those willing to participate in clinical trials by gender and location (U.S. vs. international)
What Did We Learn?

▷ Willingness to participate in CHB clinical trials vary by race, gender, age, and geographical location

▷ In U.S., there is need for culturally competent efforts to recruit minority populations to participate in clinical trials.

▷ Globally, there is need to work closely with local authorities
  ○ The legal environment
  ○ Research infrastructure
What We Still Need to Learn is..

▷ How do the different barriers to clinical trial participation interplay in the hepatitis B space:
  ○ Incorporating the new treatment in current hep B management
  ○ Disease-related stigma
  ○ Immigration and Socio-cultural status of people living with hepatitis B

▷ It is important to understand
  ○ how to reach those who are willing but not participating?
  ○ why there are 34% of respondents from U.S. were undecided?
Thank You!