Clinical and Economic Burden of Hepatitis Delta Infection in the U.S.

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Hepatitis Delta Connect – Hepatitis B Foundation

November 30, 2023

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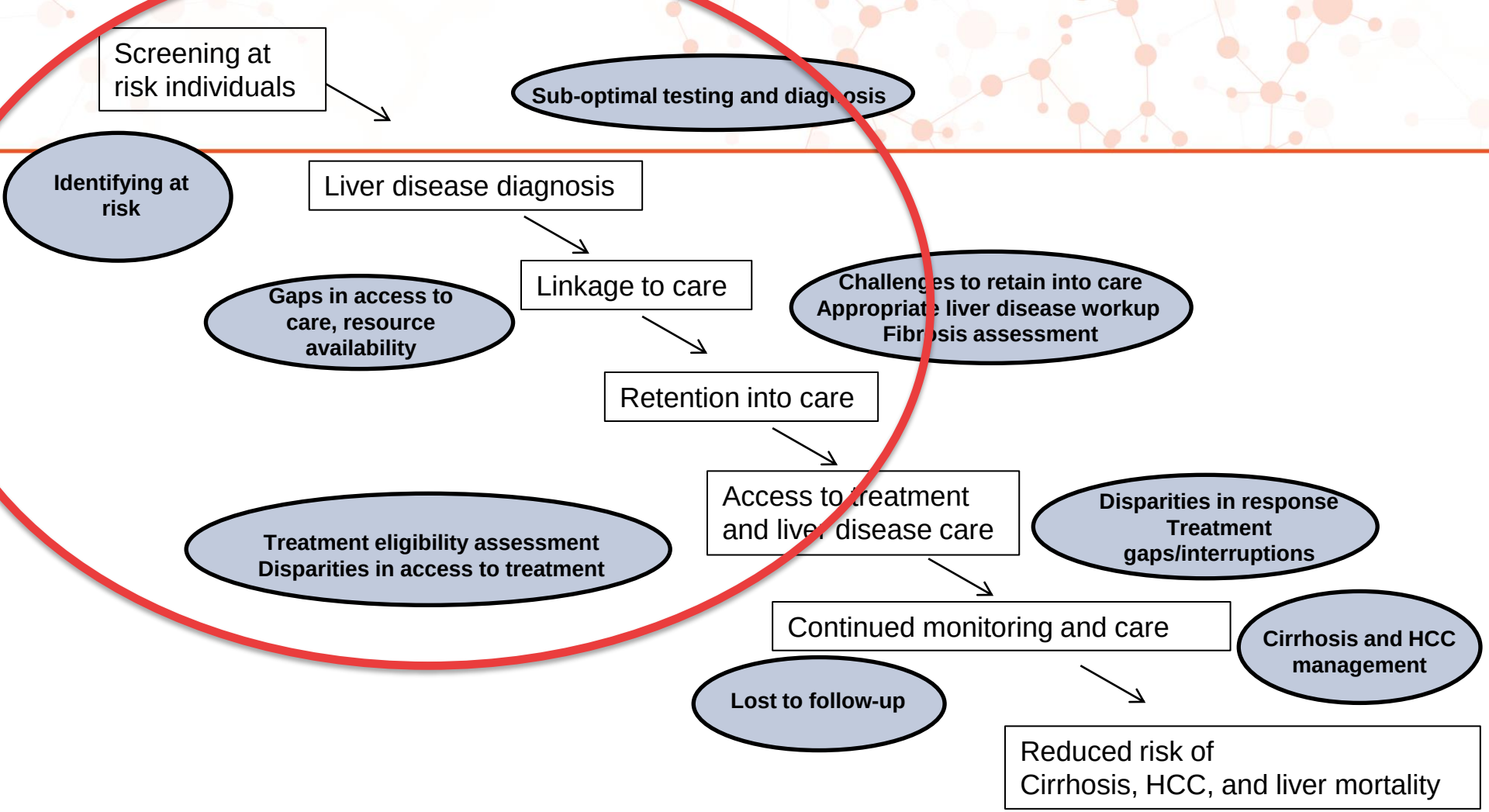
VA | U.S. Department of Veterans Affairs

Disclosures

- Research funding (to my institution) from Gilead Sciences, Exact Sciences, Theratechnologies, Durect Corportation

Objectives

- Brief overview of HBV epidemiology updates and the importance of the chronic HBV cascade of care
- Review recent updates on epidemiology of HDV in the U.S. with a focus on highlighting the clinical and economic burden


Screening at risk individuals
Sub-optimal testing and diagnosis
Identifying at risk
Liver disease diagnosis
Linkage to care
Gaps in access to care, resource availability
Challenges to retain into care
Appropriate liver disease workup
Fibrosis assessment
Retention into care
Access to treatment and liver disease care
Treatment eligibility assessment
Disparities in access to treatment
Disparities in response
Treatment gaps/interruptions
Continued monitoring and care
Cirrhosis and HCC management
Lost to follow-up
Reduced risk of Cirrhosis, HCC, and liver mortality

HBV Cascade of Care – Global Estimates

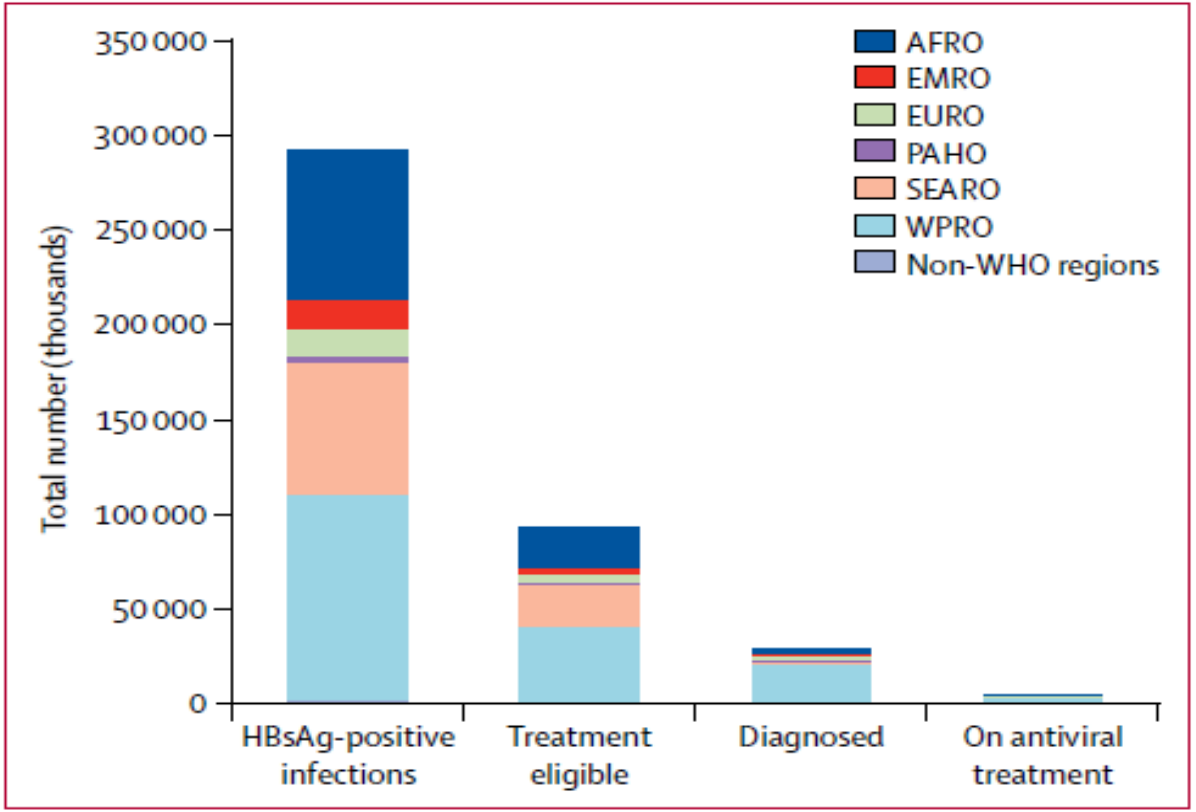
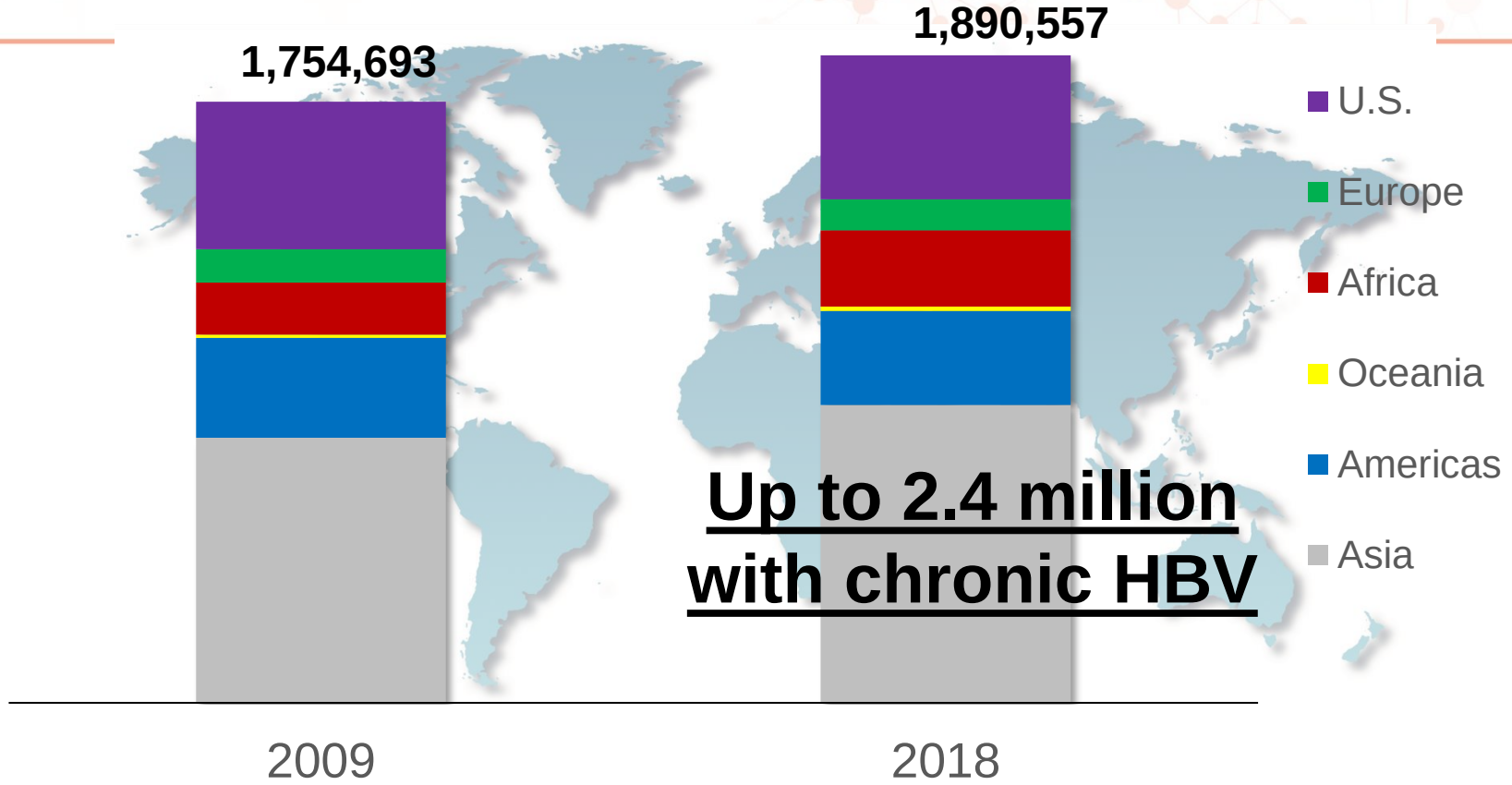


Figure 2: **Global and regional hepatitis B virus cascade of care in 2016**
AFRO=Regional Office for Africa. EMRO=Eastern Mediterranean Regional Office. EURO=Regional Office for Europe. PAHO=Pan American Health Organization. SEARO=South-East Asia Regional Office. WPRO=Western Pacific Regional Office.

Polaris collaborators, Lancet 2018;3:383-403

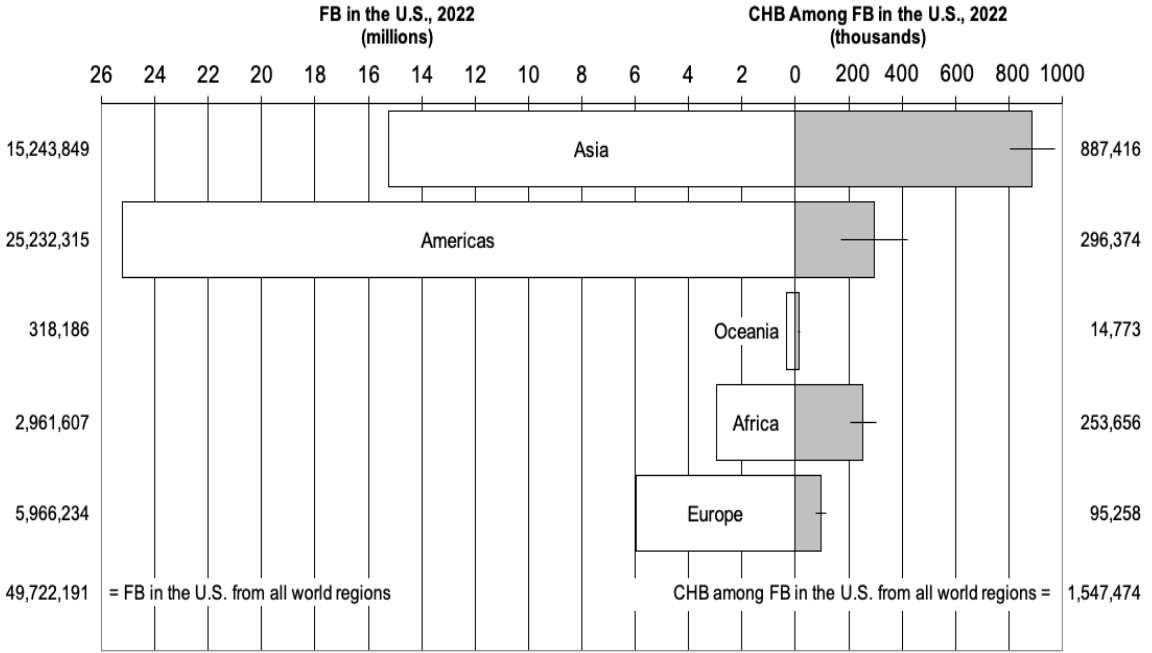
HBV Prevalence in the United States



Wong, et al. Hepatology 2021;74:607-26

HBV Prevalence in 2022 – Up to 2.5 Million

- In 2022, we estimated **1.971 million** (M) (95% CI 1.547–2.508) persons with CHB
- **1.547M** (95% CI 1.264–1.831) were FB
- **0.424M** (95% CI: 0.282–0.678) were U.S.-born
- Based on updated meta-analyses and incorporation of most recent 2022 US Census data

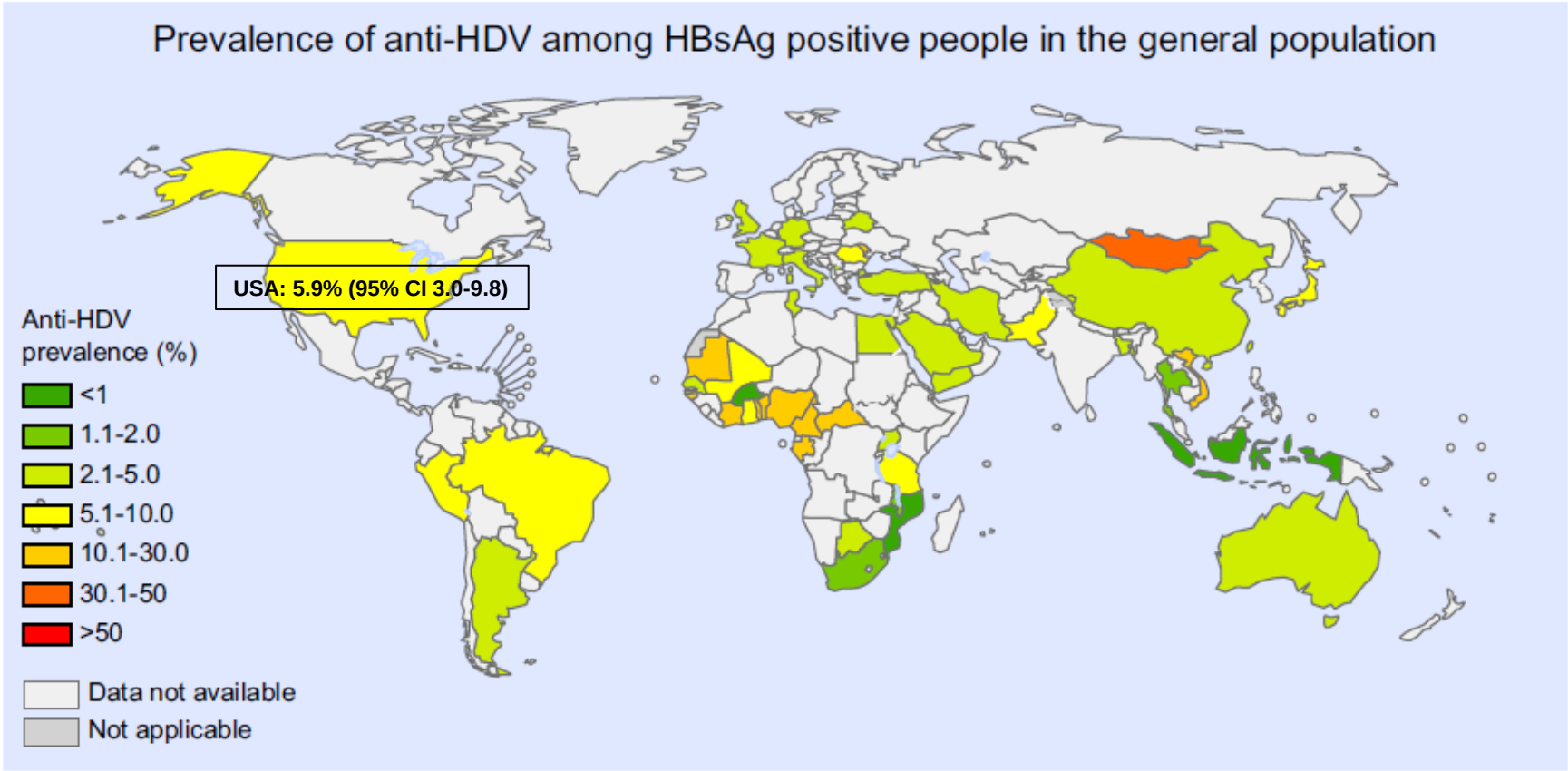


Under Review

Hepatitis Delta Virus

- Hepatitis Delta virus (HDV) infection, occurring as a super-infection in patients with chronic HBV, or concurrently as co-infection together with HBV is associated with increased risks of liver disease progression to cirrhosis, hepatocellular carcinoma (HCC), and liver related morbidity and mortality.
- Sub-optimal awareness of and non-routine testing for HDV among patients with chronic HBV contributes to low rates of HDV testing and gaps in our understanding of HDV epidemiology in the U.S.
- Global studies have estimated HDV prevalence ranging from 12 to 74 million, reflecting the heterogeneity of existing HDV epidemiology studies
- Studies specifically focusing on HDV epidemiology in the U.S. are lacking, and there is a need for large high-quality studies to improve our understanding of HDV testing and prevalence patterns among U.S. populations

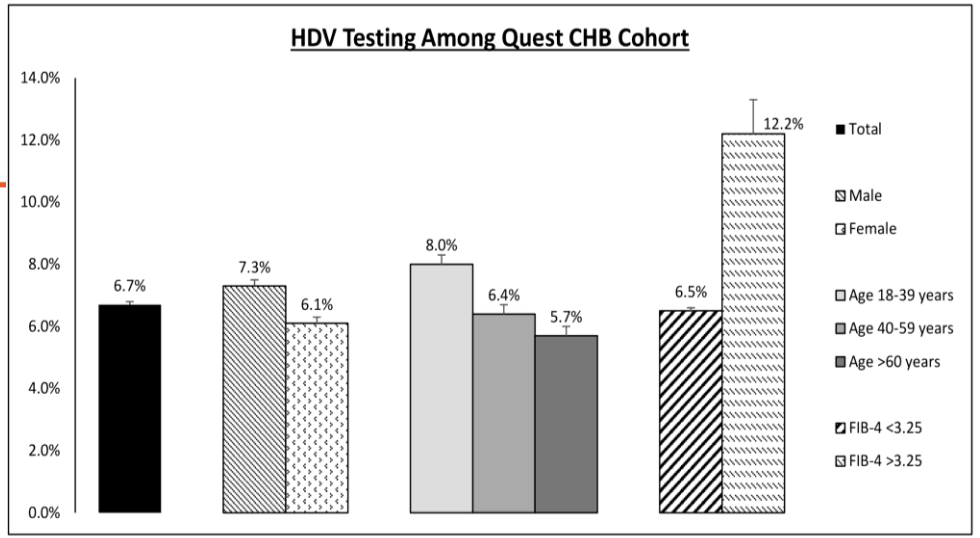
Stockdale, et al. J Hepatol 2020;73:523-32; Chen et al. Gut 2019;68:512-521; Miao, et al. J Infect Dis 2020;221:1677-1687

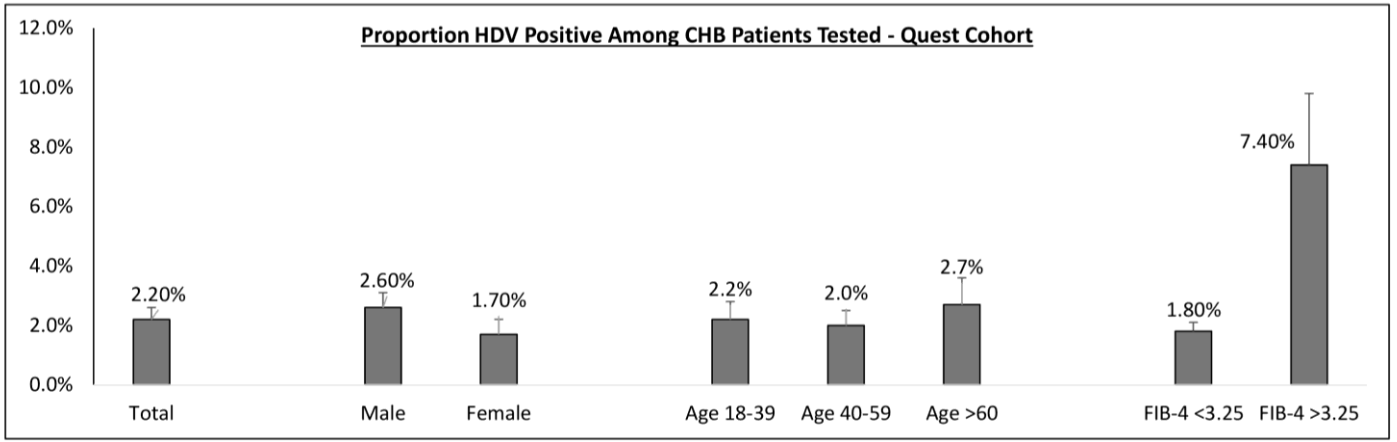


Stockdale, et al. J Hepatol 2020;73:523-32

HDV testing in the U.S.

- Among 157,333 chronic HBV patients identified in the Quest 2016-2020 cohort, 6.7% underwent testing for HDV.
- Among those tested, 2.2% were positive

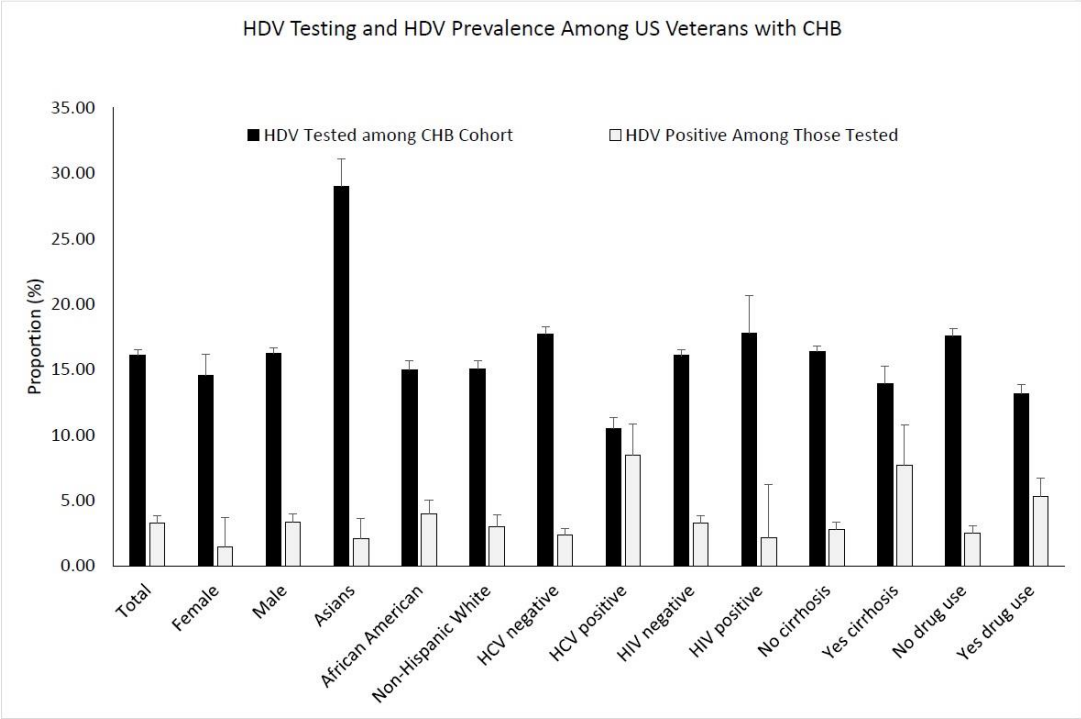




Wong RJ, et al. Am J Gastroenerol 2022.

HDV Testing and Prevalence – National VA Data

- Among 27,548 CHB patients
  - 93.2% male, 92.5% non-Asian
  - 2.8% HIV, 22.3% HCV
- Overall, ***16.1% completed HDV testing***, among whom **3.25% were positive**.
- HDV testing was higher among
  - Asians vs. non-Hispanic white (29.0% vs. 14.9%, aOR 1.49, 95%CI 1.32-1.68)
  - men vs. women (16.2% vs. 14.5%, aOR 1.24, 95%CI 1.07-1.43)
  - HIV positive vs. negative (17.8% vs. 16.1%, aOR 1.32, 95%CI 1.07-1.64), p<0.01 for all.
- Among those tested, HDV positive was higher in
  - HCV-positive vs. HCV-negative (8.45% vs. 2.35%, aOR 3.24, 95%CI 1.94-5.42)
  - cirrhosis vs. non-cirrhosis (7.71% vs. 2.80%, aOR 2.27, 95%CI 1.47-3.53)
  - drug use vs. non-drug use (5.30% vs. 2.49%, aOR 2.04, 95%CI 1.14-3.63), p<0.01 for all



Under Review

National and Regional Prevalence of Hepatitis Delta Virus Among Commercially Insured Patients in the US

Robert J Wong[1,2], Robert G Gish[3], Ira M Jacobson[4], Joseph K Lim[5], Chong Hoon Kim[6], Marvin Rock[6]

[1]VA Palo Alto Healthcare System, Palo Alto, CA, USA; [2]Stanford University School of Medicine, Stanford, CA, USA; [3]Hepatitis B Foundation, Doylestown, PA, USA; [4]NYU Grossman School of Medicine, New York, NY, USA; [5]Yale University School of Medicine, New Haven, CT, USA; [6]HEOR – Global Value & Access, Gilead Sciences, Inc., Foster City, CA, USA

Objective

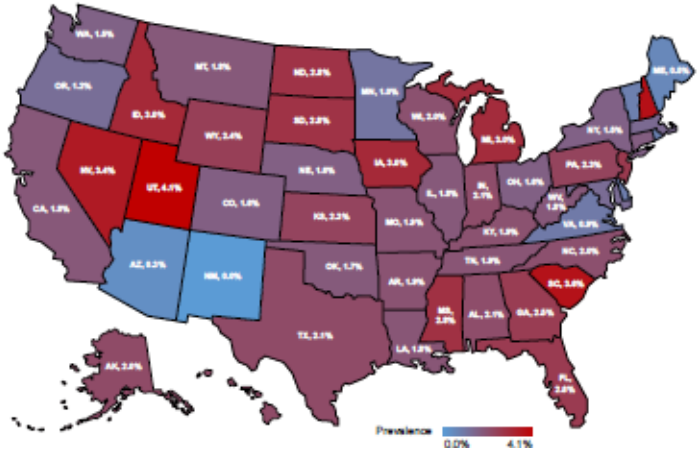
- To evaluate national and regional prevalence and incidence of HDV infection among commercially insured adults in the US

Methods

- In this retrospective study, adult patients with ≥1 HDV or HBV diagnosis *(ICD-9/10-CM)* were assessed from Jan 1, 2014, to Dec 31, 2021 (study period), using the IQVIA PharMetrics Plus database covering approximately 210 million US patients from primarily commercial payers
- The study population included commercially insured adults with ≥1 inpatient claim or ≥2 outpatient claims ≥30 days apart with an *ICD-9/10-CM* diagnosis code for HBV or HDV between Jan 1, 2015, and Dec 31, 2020 (identification period)
- Index date was defined as the first claim of HBV or HDV diagnosis between Jan 1, 2015, and Dec 31, 2020
- Patients in the HBV monoinfection cohort had no HDV diagnosis during the study period
- Yearly and state-level prevalence of HDV infection were determined among all adults with HBV
- Incidence was calculated among adults with no HDV infection diagnoses prior to the index date
- Annual prevalence was calculated based on the lifetime prevalence approach — Adults diagnosed on or before the year of assessment were included

- Among the 74,937 commercially insured adults with HBV infection, 1,422 had concurrent HDV infection identified, translating to a prevalence of 1.9%
- HDV prevalence among all commercially insured adults was 18.7 per million from 2015 to 2020
- HDV prevalence among patients with HBV ranged from 1.3% to 1.9% from 2015 to 2020
- Newly diagnosed HDV infections among HBV patients accounted for 1,312 cases, with an overall incidence of 1.8%
- Yearly HDV incidence among HBV patients ranged from 0.2% to 0.6% from 2015 to 2020

Figure 3. State-by-State Prevalence of HDV Among People With HBV From 2015 to 2020



Key Findings

- **Among 74,937 commercially insured adults with HBV infection between 2015 and 2020, 1,422 had concurrent HDV infection identified, translating into a prevalence of 1.9% and incidence of 1.8% in the US**
- **Yearly lifetime HDV prevalence among patients with HBV ranged from 1.3% to 1.9%, while yearly HDV incidence among patients with HBV ranged from 0.2% to 0.6%**
- **Regionally, prevalence and incidence of HDV infection were highest in Utah**

Conclusions

These findings underscore the need for earlier identification, diagnosis, and treatment of HDV infection among patients with HBV in the US

AASLD: The Liver Meeting; November 10–14, 2023; Boston, MA, USA

Laboratory-Confirmed Hepatitis Delta Virus Prevalence and Patient Characteristics Among Patients in the US

Robert J Wong[1,2], Robert G Gish[3], Ira M Jacobson[4], Joseph K Lim[5], Marvin Rock[6], Gary Leung[7], Chong Kim[6]

[1]Stanford University School of Medicine, Stanford, CA, USA; [2]VA Palo Alto Healthcare System, Palo Alto, CA, USA; [3]Hepatitis B Foundation, Doylestown, PA, USA; [4]New York University Grossman School of Medicine, New York, NY, USA; [5]Yale School of Medicine, New Haven, CT, USA; [6]HEOR — Global Value & Access, Gilead Sciences, Inc., Foster City, CA, USA; [7]RWE — Epidemiology, Gilead Sciences, Inc., Foster City, CA, USA

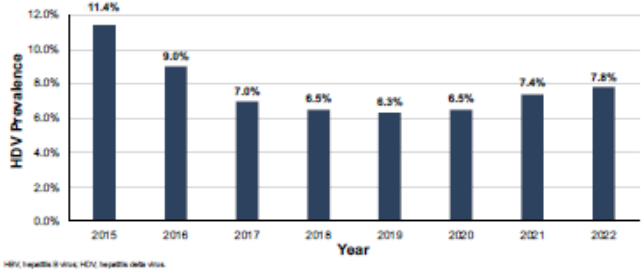
Objective

- To evaluate the prevalence and incidence of laboratory-confirmed HDV infection among adults with HBV in the US

Methods

- Adults (≥18 years old) diagnosed with HBV infection (*ICD-9/10-CM*) or who had an HDV RNA test completed between Jan 1, 2015, and Dec 31, 2022, from the HealthVerity Database linked with Quest laboratory data were included
- Yearly and state-level prevalence of lab-confirmed HDV infection was determined by RNA testing among adults with HBV
- Incidence was defined as the rate of new cases of a specific disease developed during a particular time period[5]
  - — Incidence of HDV was calculated among patients who had a negative HDV RNA or HDV antibody (Ab) result prior to a positive HDV RNA result
- Prevalence was defined as the total number of people with a disease within a specific period of time[5]
  - — Annual prevalence of HDV was calculated based on the lifetime prevalence approach; adults who were HDV RNA+ on or before the year of assessment were included
- HDV RNA and HDV Ab test rates among patients with HBV were reported
- Baseline (12 months pre-index) characteristics of laboratory-confirmed patients with HDV or with HBV only with at least 12 months pre- and post-index continuous enrollment were described

Figure 3. Yearly Prevalence of Lab-Confirmed HDV Among People With HBV From 2015–2022



HBV, hepatitis B virus; HDV, hepatitis delta virus.

- Among 1,217 patients with lab-confirmed HBV infection between 2015–2022, 95 were HDV RNA+, corresponding to an overall prevalence of 7.8%
- HDV prevalence among patients with HBV ranged from a high of 11.4% in 2015 to 6.3% in 2019, and steadily increased thereafter to 7.8% in 2022

Key Findings

- **Prevalence and incidence of lab-confirmed HDV among US adults infected with HBV was 7.8% and 5.7%, respectively, from 2015 to 2022**
- **Overall, among patients with HBV infection from 2015 to 2022:**
  - — **11.4% were tested for HDV Antibody or HDV RNA**
  - — **Of the patients who were HDV Ab+, 38.0% were tested for HDV RNA, and 38.7% of those HDV RNA-tested patients were HDV RNA+**

Conclusions

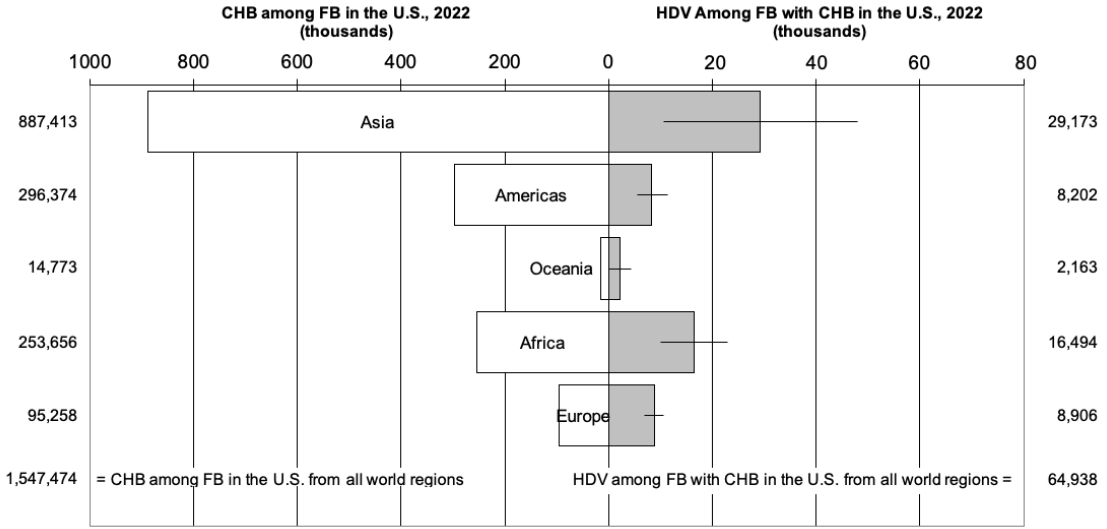
The overall low rates of HDV testing among adults with HBV emphasize the need for increased efforts in screening, diagnosis, linkage to care, and timely treatment of HDV infection

These data support the utility of reflex testing for HDV RNA following an HDV Ab+ result

AASLD: The Liver Meeting; November 10–14, 2023; Boston, MA, USA

HDV Prevalence in 2022 – ~75,000

- In 2022, the weighted average HDV prevalence among FB persons in the U.S. was
  - ***4.20% (64,938 [95% CI 33,055–97,392] persons***)
- When combined with updated estimates of U.S.-born persons with HDV, we estimate 75,005 (95% CI: 42,187–108,393) persons with HDV in the U.S.
- Based on updated meta-analyses and incorporation of most recent 2022 US Census data



Under Review

Association between hepatitis delta virus with liver morbidity and mortality: A systematic literature review and meta-analysis

Figure 1: PRISMA Flow Diagram of Screened and Included Studies

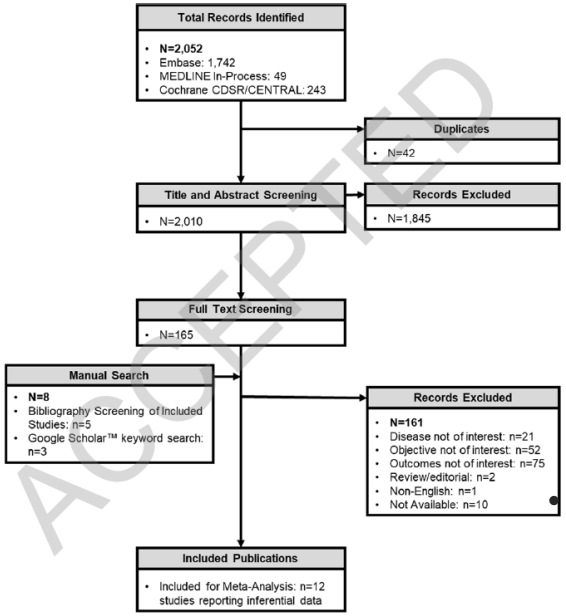
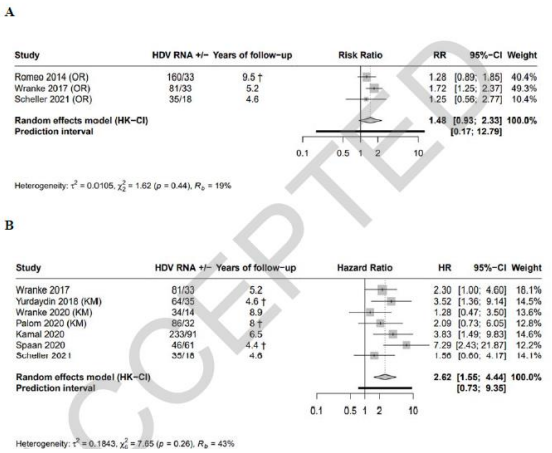


Figure 2: Association of HDV RNA Status with Any Liver-Related Event: Risk (A) and Hazard (B) Ratios



When compared to HDV RNA- patients, HDV RNA+ was associated with a significantly higher risk of progressing to

- compensated cirrhosis (RR 1.74 [1.24, 2.45]), decompensated cirrhosis (HR 3.82 [1.60, 9.10]),
- hepatocellular carcinoma (HR 2.97 [1.87, 4.70]), liver transplantation (HR 7.07 [1.61, 30.99]),
- liver-related mortality (HR 3.78 [2.18, 6.56]).

Figure 5: Association of HDV RNA Status with HCC: Risk (A) and Hazard (B) Ratios

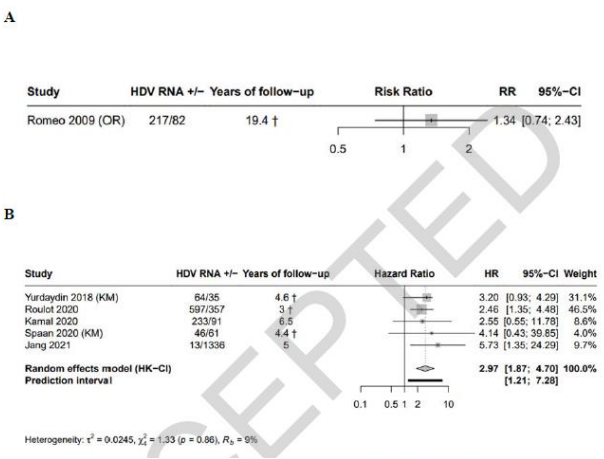
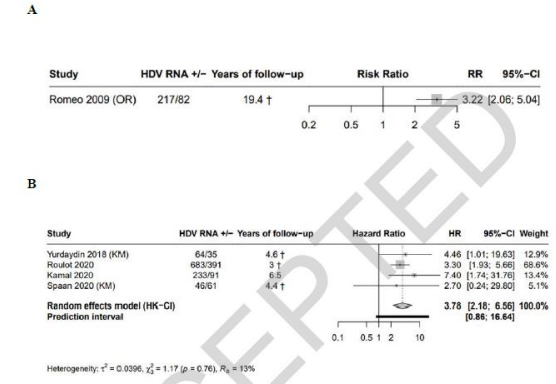


Figure 7. Association of HDV RNA Status with Mortality: Risk (A) and Hazard (B) Ratios



Gish, Wong, et al. Hepatology 2023

Increased Baseline Comorbidity Burden Among Commercially Insured Patients With Hepatitis Delta Virus Infection vs Hepatitis B Virus Monoinfection in the United States

Robert G Gish[1], Robert J Wong[2,3], Chong Kim[4], Gary Leung[5], Ira M Jacobson[6], Joseph K Lim[7], Ankita Kaushik[4]

[1]Hepatitis B Foundation, Doylestown, PA, USA; [2]Stanford University School of Medicine, Stanford, CA, USA; [3]VA Palo Alto Healthcare System, Palo Alto, CA, USA; [4]HEOR – Global Value & Access, Gilead Sciences, Inc., Foster City, CA, USA; [5]RWE – Epidemiology, Gilead Sciences, Inc., Foster City, CA, USA; [6]NYU Grossman School of Medicine, New York, NY, USA; [7]Yale University School of Medicine, New Haven, CT, USA

Objective

— Compare baseline (BL) characteristics between adults with HBV with concurrent HDV infection and those with HBV monoinfection among commercially insured US patients

Methods

— In this retrospective study, adult patients with ≥1 HDV or HBV diagnosis (*ICD-9/10-CM*) were identified from 1 Jan 2013 to 31 Dec 2021 (study period) using the IQVIA PharMetrics Plus database covering approximately 210 million US patients from primarily commercial payers

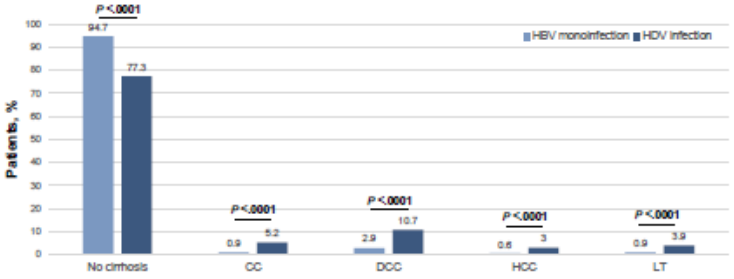
— The study population included commercially insured adults with ≥1 inpatient claim or ≥2 outpatient claims ≥30 days apart with an *ICD-9/10-CM* diagnosis code for HBV between 1 Jan 2014 and 31 Dec 2020 (identification period)

— The HBV index date was the first claim for HBV during the identification period, and patients were required to have ≥12 months of continuous enrollment before and after the HBV index date

— Patients in the HBV monoinfection cohort had no HDV diagnosis during the study period

— Patients with HDV had ≥1 inpatient or ≥2 outpatient claims ≥30 days apart with an *ICD-9/10-CM* diagnosis code for HDV during the identification period (earliest date of diagnosis considered index date), ≥1 claim of HBV diagnosis during BL, and no claims with HDV diagnosis during BL (12-month period prior to index date)

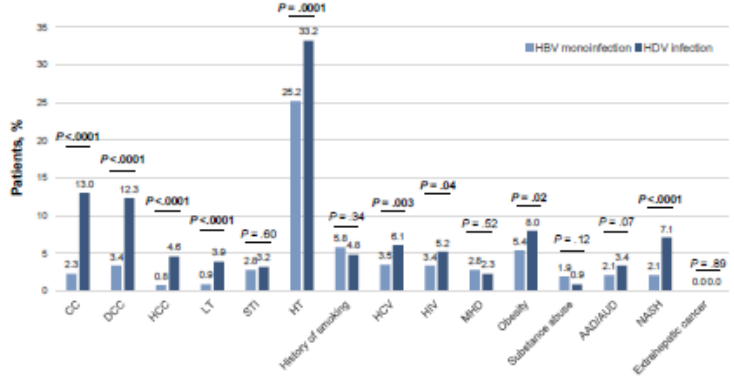
Figure 3. Greatest liver disease severity at baseline



CC, compensated cirrhosis; DCC, decompensated cirrhosis; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HDV, hepatitis delta virus; LT, liver transplant.

— Patients with HDV infection had significantly higher liver disease severity at BL compared with patients with HBV monoinfection (all comparisons $P < .0001$)

Figure 4. Baseline comorbidities



Key Findings

— Among a nationally representative cohort of commercially insured US patients, **those with HDV had a greater burden of comorbidities compared with patients who had HBV monoinfection**

— Additionally, **a greater proportion of patients with HDV had advanced liver disease** and complications at BL compared with patients who had HBV monoinfection

Conclusions

This study underscores the importance of early identification and linkage to treatment of patients with HDV to mitigate disease progression and improve patient outcomes

EASL Congress 2023, 21–24 June, Vienna, Austria

Healthcare Resource Use and Costs Associated With Hepatitis Delta Virus Infection Compared With Hepatitis B Virus Monoinfection Among Commercially Insured Patients in the US

Robert J Wong[1,2], Robert G Gish[3], Chong Kim[4], Gary Leung[5], Ira M Jacobson[6], Joseph K Lim[7], Ankita Kaushik[4]

[1]Stanford University School of Medicine, Stanford, CA, USA; [2]VA Palo Alto Healthcare System, Palo Alto, CA, USA; [3]Hepatitis B Foundation, Doylestown, PA, USA; [4]HEOR – Global Value & Access, Gilead Sciences, Inc., Foster City, CA, USA; [5]RWE – Epidemiology, Gilead Sciences, Inc., Foster City, CA, USA; [6]NYU Grossman School of Medicine, New York, NY, USA; [7]Yale University School of Medicine, New Haven, CT, USA

Objective

— To compare baseline characteristics, all-cause HCRU, and costs among commercially insured adults in the US with HBV monoinfection and HDV infection

Methods

— In this retrospective cohort study, adult patients with ≥1 HBV or HDV diagnosis (*ICD-9/10-CM*) were identified from 1 Jan 2013 to 31 Dec 2021 (study period) using the IQVIA PharMetrics Plus database, which includes fully adjudicated pharmacy, hospital, and medical claims from approximately 210 million patients

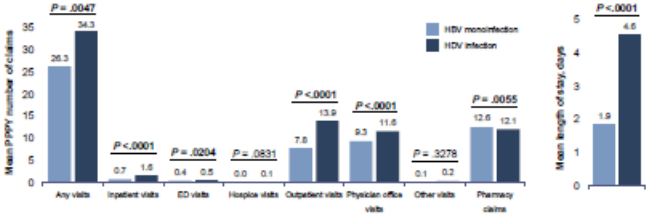
— The study population included commercially insured adults with ≥1 inpatient claim or ≥2 outpatient claims ≥30 days apart with an *ICD-9/10-CM* diagnosis code for HBV between 1 Jan 2014 and 31 Dec 2020 (identification period)

— The HBV index date was the first claim for HBV during the identification period, and patients were required to have ≥12 months of continuous enrollment before and after the HBV index date

— Patients in the HBV monoinfection cohort had no HDV diagnosis during the study period

— The HDV index date was the first claim for HDV during the identification period, and patients in the HDV infection cohort had ≥1 inpatient claim or ≥2 outpatient claims ≥30 days apart with an HDV index on or after the HBV index date and ≥12 months of continuous enrollment before and after HDV index

Figure 3. HCRU among patients with HBV monoinfection and HDV infection



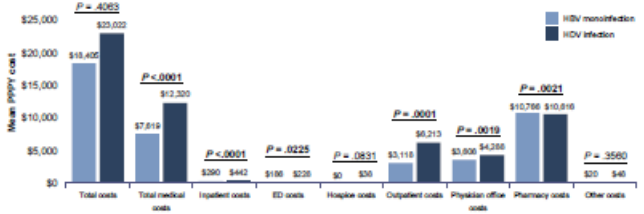
Outpatient visits include ambulatory care and outpatient hospital on-campus visits. ED, emergency department; HBV, hepatitis B virus; HCRU, healthcare resource use; HDV, hepatitis delta virus; PPPY, per patient per year.

— During the post-HDV index period, the mean PPPY numbers of total, inpatient, ED, outpatient, and physician office visits were greater among patients with HDV infection than among those with HBV monoinfection, and the mean PPPY number of pharmacy claims was lower

— Patients with HDV infection had a significantly longer mean PPPY length of stay for inpatient visits compared with patients with HBV monoinfection

— The largest absolute difference in HCRU was from ambulatory care and outpatient hospital on-campus visits, for which patients with HDV infection had approximately 6 more visits

Figure 4. Costs among patients with HBV monoinfection and HDV infection



Key Findings

— Among a large US commercial healthcare claims database, **all-cause HCRU and costs were higher for patients with HDV infection** compared with patients with HBV monoinfection

— **The largest increases in HCRU and costs observed** for patients with HDV infection vs patients with HBV monoinfection **were associated with ambulatory care and outpatient visits**, which contributed to 6 more annual visits and $3,094 more in annual costs

Conclusions

These findings highlight the need for timely and effective implementation of screening and linkage to care, which may reduce the patient morbidities and economic burdens associated with advanced HDV-induced chronic liver disease

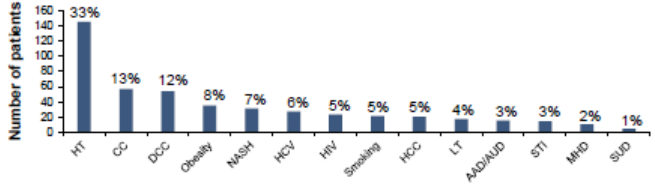
EASL Congress 2023, 21–24 June, Vienna, Austria

Significantly Higher Clinical and Economic Burden Following Diagnosis of Hepatitis Delta Virus Infection Among Commercially Insured Adults With Chronic Hepatitis B in the United States

Robert J Wong[1,2], Robert G Gish[3], Chong Kim[4], Gary Leung[5], Ira M Jacobson[6], Joseph K Lim[7], Ankita Kaushik[4]

[1]Stanford University School of Medicine, Stanford, CA, USA; [2]VA Palo Alto Healthcare System, Palo Alto, CA, USA; [3]Hepatitis B Foundation, Doylestown, PA, USA; [4]HEOR – Global Value & Access, Gilead Sciences, Inc., Foster City, CA, USA; [5]RWE – Epidemiology, Gilead Sciences, Inc., Foster City, CA, USA; [6]NYU Grossman School of Medicine, New York, NY, USA; [7]Yale University School of Medicine, New Haven, CT, USA

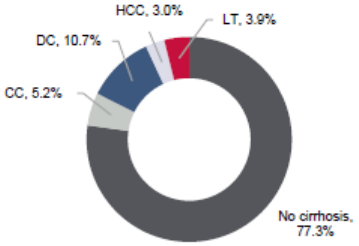
Figure 3. Baseline comorbidities among 440 patients with HDV infection



AAD, alcohol abuse or dependence; AUD, alcohol use disorder; CC, compensated cirrhosis; DCC, decompensated cirrhosis; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; HDV, hepatitis delta virus; HT, hypertension; LT, liver transplant; MHD, mental health disorder; NASH, nonalcoholic steatohepatitis; STI, sexually transmitted infection; SUD, substance use disorder.

Figure 4. Greatest liver disease severity at baseline among patients with HDV infection

- Approximately 23% of patients had liver complications at the time of HDV diagnosis



Liver disease severity increases from CC to DCC to HCC to LT. CC, compensated cirrhosis; DCC, decompensated cirrhosis; HCC, hepatocellular carcinoma; HDV, hepatitis delta virus; LT, liver transplant.

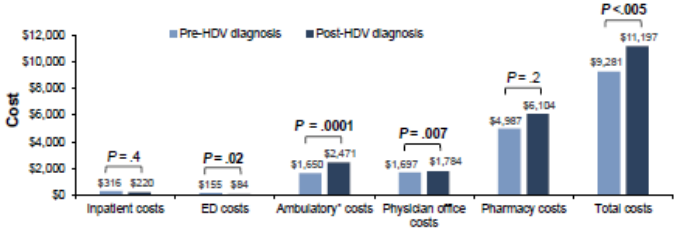
Table 2. HCRU comparison 12-month pre- vs 12-month post-HDV diagnosis

HCRU components, mean (SD)	12-month pre-HDV Dx	12-month post-HDV Dx	*P*-value
All-cause utilization	24.1 (24.7)	29.8 (31.4)	**<.0001**
Inpatient visits	0.9 (4.2)	0.9 (5.2)	.73
Emergency visits	0.4 (1.3)	0.3 (1.2)	**.002**
Ambulatory care and outpatient hospital on-campus visits	5.5 (10.8)	8.6 (21.0)	**<.0001**
Physician office visits	9.2 (9.5)	10.8 (10.5)	**<.0001**
Other visits*	0.1 (0.6)	0.1 (0.7)	.28
Pharmacy claims	11.6 (15.5)	13.5 (18.1)	**.0003**
Inpatient LOS days			
All patients	2.6 (11.2)	3.6 (26.8)	.22
At least 1 visit	15.2 (23.1)	22.1 (63.4)	.71

*Other visits include any visits that are not classified in the main categories. All values are presented as mean (SD).
Dx, diagnosis; HCRU, healthcare resource use; HDV, hepatitis delta virus; LOS, length of stay.

- A 23.7% increase in all-cause HCRU was observed from pre- to post-HDV diagnosis (*P* <.0001)
- The largest difference in HCRU (pre- vs post-HDV diagnosis) was from "ambulatory care and outpatient hospital on-campus visits," for which a 56.4% increase in HCRU was observed (*P* <.0001)

Figure 5. Mean PPPY all-cause total costs comparison pre- vs post-HDV diagnosis



*Ambulatory care and outpatient hospital on-campus visits.
ED, emergency department; HDV, hepatitis delta virus; PPPY, per patient per year.

- A 20.6% increase in all-cause total healthcare costs was observed from pre- to post-HDV diagnosis (*P* <.005)
- The largest difference in all-cause healthcare costs (pre- vs post-HDV diagnosis) was from "ambulatory care and outpatient hospital on-campus visits," for which a 49.8% increase in HCRU was observed (*P* = .0001)

Key Findings

- Over 20% of commercially insured patients in the US with HDV **had already developed cirrhosis or liver-related complications** at the time of diagnosis
- **Approximately 6 more visits and claims amounting to $1,916 were observed** in the 12 months after HDV diagnosis

Conclusions

The significant increase in HCRU and costs post HDV diagnosis underscores the need for more effective strategies for screening, diagnosis, linkage to care, and treatment of patients with HDV infection, to decrease the burden of disease for patients and the healthcare system

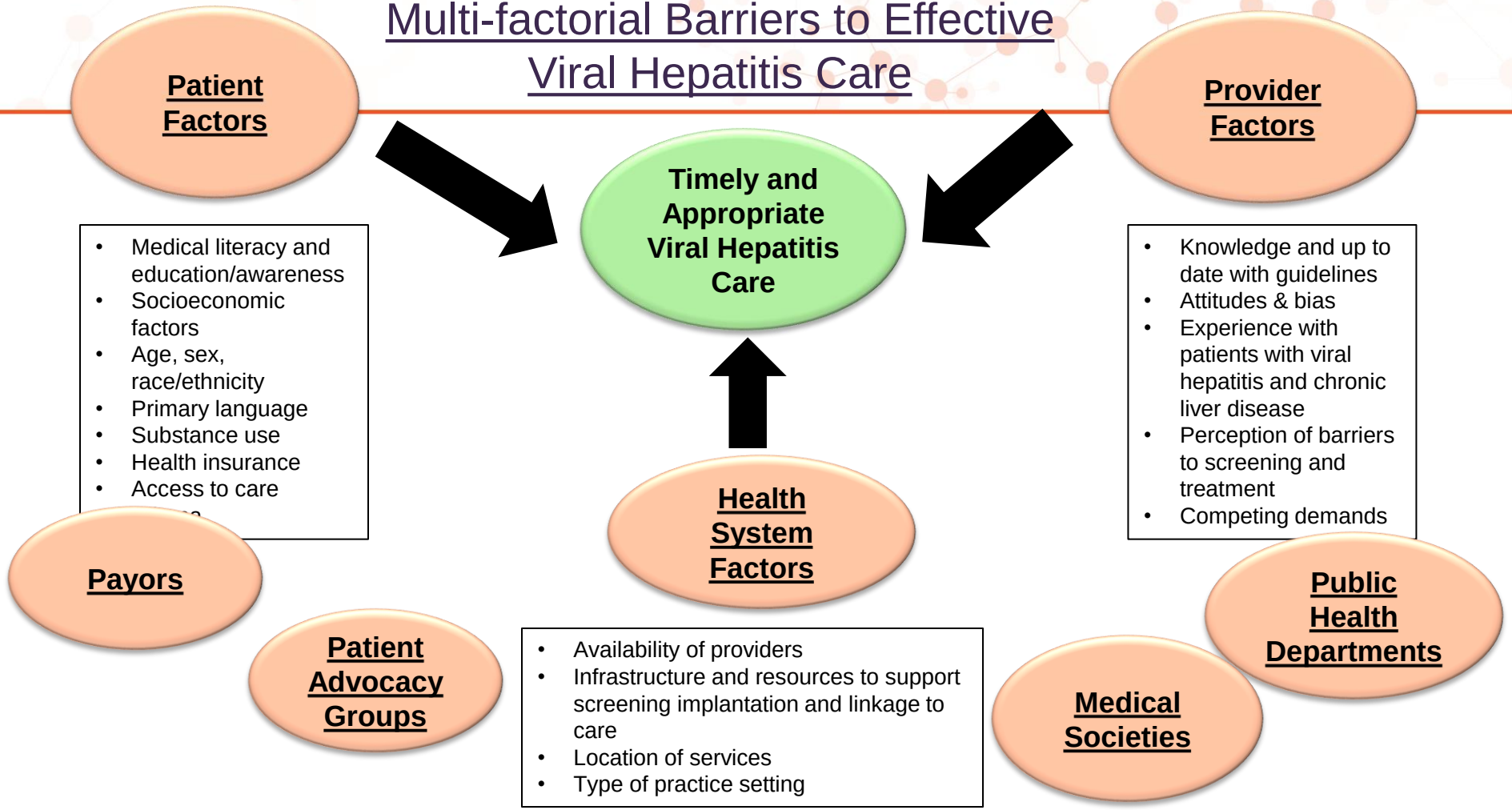
EASL Congress 2023, 21–24 June, Vienna, Austria

HDV testing recommendations

	AASLD	APASL	EASL
Who to Test	• Persons born in regions with reported high HDV endemicity • Persons who have ever injected drugs • Men who have sex with men • Individuals infected with HIV or HCV • Persons with multiple sexual partners or any history of sexually transmitted disease • Individuals with elevated ALT or AST with low or undetectable HBV DNA	• HDV testing should be considered in all patients with chronic HBV	• HDV testing should be considered in all patients with chronic HBV
What HDV Tests to Use	• Anti-HDV total antibody, followed by HDV RNA if positive	• No specific guidance on HDV testing methods	• No specific guidance on HDV testing methods

Terrault, et al. Hepatology 2018;67:1560-1599; Sarin, et al. Hepatol Int 2016;10:1-98; EASL. J Hepatol 2017;67:370-398.

Multi-factorial Barriers to Effective Viral Hepatitis Care



Take Home Points

- HBV and HDV are associated with significant morbidity and mortality
- Major gaps persist in the chronic HBV and HDV cascade of care
- Significant clinical and economic burden of HDV
- Effective screening for early linkage to care for both HBV and HDV is critical to reduce liver related complications and mortality

- Questions?

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