



Findings from a US-Based Multi-Site Pilot to Screen Hepatitis B Surface Antigen-Positive Patients for Hepatitis D

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HDV landscape in the US

Gilead's HDV pilot program

- HDV prevalence and risk factors remain under-studied in US population
- HDV screening guidelines are contradictory and unclear
- A better understanding of HDV prevalence, risk factors, and guidance for screening recommendations is needed

HDV screening & linkage to care (SLTC) pilot

A national, multi-site pilot across 8 health systems in the US

- An HDV SLTC pilot conducted by FOCUS/GA&P and Medical Affairs was launched in April 2022 to examine:
 - HDV prevalence
 - Laboratory practices
 - Potential approaches for SLTC
- Nine agencies invited to participate (8 agreed) based on criteria:
 - Conducting routine HBV SLTC with HBsAg seropositivity $\geq 1\%$ and minimum 4,000 HBV tests/year
 - Proven dissemination track record
 - Experience serving impacted patient populations

HDV SLTC pilot

A national, multi-site pilot across 8 health systems in the US

Asian Health Services (Oakland, CA)	Site type: CHC Lab process: Add-on testing
Cooperman Barnabas (Livingston, NJ)	Site type: ED, Inpatient Lab process: Reflex testing
Family Health Centers at NYU Langone (Brooklyn, NY)	Site type: CHC Lab process: Reflex testing
Hackensack Meridian Medical (HUMC & PMC) (Hackensack, NJ)	Site type: ED Lab process: Add-on testing
Newark Beth Israel Medical Center (Newark, NJ)	Site type: ED Lab process: Reflex testing
New-York Presbyterian Queens (Flushing, NY)	Site type: Hospital Lab process: Add-on testing
Norton Healthcare (Louisville, KY)	Site type: Hospital Lab process: Reflex testing
Sinai Chicago (Chicago, IL)	Site type: Hospital Lab process: Add-on testing

TABLE 1 | Characteristics of pilot sites, 2022.

Name	Location	Setting	Patient populations	Data collection period	Partner lab
Asian Health Services	Oakland, California	Urban	Asian, uninsured or publicly insured, immigrants, ~75% non-English speaking	1 August 2022 to 30 June 2023	Quest Diagnostics
Cooperman Barnabas Medical Center	Livingston, New Jersey	Urban and sub-urban	Black/African American, White, Hispanic/Latinx, Asian Pacific Islander, immigrants, mixed income	1 August 2022 to 31 August 2023	LabCorp
Family Health Centers at NYU Langone	Brooklyn, New York	Urban	Hispanic/Latinx, Black/African American, Asian Pacific Islander, immigrants, low-income, LGBTQ+	1 September 2022 to 30 April 2024	ARUP Laboratories
Hackensack Meridian Medical Center (HUMC and PMC)	Hackensack, New Jersey	Urban	Hispanic/Latinx, Black/African American, Asian Pacific Islander, immigrants, low-income	1 January 2022 to 31 March 2024	Quest Diagnostics
Newark Beth Israel Medical Center	Newark, New Jersey	Urban	Hispanic/Latinx, Black/African American, Asian Pacific Islander, immigrants, low-income, LGBTQ+	1 October 2022 to 30 September 2023	LabCorp
NewYork-Presbyterian Queens	Flushing, New York	Urban	Hispanic/Latinx, Asian, Black/African American, immigrants, low-income	Site unable to provide data	ARUP Laboratories
Norton Healthcare	Louisville, Kentucky	Urban	White, Black/African American, low-income, injection and non-injection drug use, foreign-born residents, LGBTQ+	1 November 2023 to 30 April 2024	ARUP Laboratories
Sinai Health System	Chicago, Illinois	Urban	Hispanic/Latinx, Black/African American, Asian, immigrants, low-income	15 April 2022 to 30 April 2024	Alverno Laboratories

Site and location	Manual Reflex Testing	Add-on Testing
Cooperman Barnabas Medical Center (Livingston, New Jersey)	HBV → HDV Ab → HDV RNA	
Family Health Centers at NYU Langone (Brooklyn, New York)	HBV → HDV Ab → HDV RNA	
Newark Beth Israel Medical Center (Newark, New Jersey)	HBV → HDV Ab → HDV RNA	
Norton Healthcare (Louisville, Kentucky)	HBV → HDV Ab → HDV RNA	
Asian Health Services (Oakland, California)		HBV → HDV Ab → HDV RNA
Hackensack Meridian Medical Center (HUMC&PMC) (Hackensack, New Jersey)		HBV → HDV Ab → HDV RNA
NewYork-Presbyterian Queens (Flushing, New York)		HBV → HDV Ab → HDV RNA
Sinai Health System (Chicago, Illinois)		HBV → HDV Ab → HDV RNA

FIGURE 1 | Laboratory processes of pilot sites, 2022. ■, initial sample; ●, second sample; HBV, hepatitis B surface antigen positive; HDV Ab, hepatitis delta virus antibody; HDV RNA, hepatitis delta virus ribonucleic acid.

TABLE 2 | Patient characteristics and testing outcomes.

	HBsAg tested	HBsAg-positive		HDV tested	HDV Ab-positive		HDV RNA-positive	
	<i>n</i> (%)	<i>n</i> (%)	Prevalence	<i>n</i> (%)	<i>n</i> (%)	Prevalence	<i>n</i> (%)	Prevalence
Race/Ethnicity								
Non-Hispanic White	23,197 (21.7)	118 (10.6)	0.51	39 (6.0)	1 (11.1)	0.85	1 (50.0)	0.85
Non-Hispanic Black	29,712 (27.8)	288 (25.9)	0.97	88 (13.6)	2 (22.2)	0.69	1 (50.0)	0.35
Non-Hispanic Asian	7496 (7.0)	393 (35.3)	5.24	359 (55.7)	5 (55.6)	1.27	0 (0.00)	0.00
Hispanic/Latino	31,386 (29.4)	107 (9.6)	0.34	30 (4.7)	1 (11.1)	0.93	0 (0.00)	0.00
Other/Unknown	14,902 (14.0)	206 (18.5)	1.38	128 (19.8)	0 (0.00)	0.00	0 (0.00)	0.00
Sex								
Male	40,863 (38.3)	570 (51.3)	1.39	348 (54.0)	5 (55.6)	0.88	2 (100.0)	0.35
Female	65,341 (61.2)	541 (48.7)	0.83	297 (46.0)	4 (44.4)	0.74	0 (0.00)	0.00
Other/Unknown	488 (0.5)	1 (0.1)	0.20	0 (0.0)	0 (0.00)	0.00	0 (0.00)	0.00
Age (mean)	47.2	50.1		51.6	44.0		40.0	
Total patients tested	106,693	1112 (1.04)	1.04	645 (58.0)	9 (1.40)	0.81	2 (22.22)	0.18

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- Collectively, the collaborative performed HBsAg testing in a total of 106,693 unique patients.

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- Overall HBsAg positivity was 1.04%.

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- While the majority of HBsAg testing was performed among females (61.2%), a slightly higher proportion of HBsAg+ results occurred among males (51.3%) compared to females (48.7%).

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- While the majority of HBsAg testing was performed among persons of Hispanic/Latino ethnicity (29.4%) and those identifying as non-Hispanic Black (27.8%), the largest portion of HBsAg+ results was observed among persons identifying as non-Hispanic Asian (35.3%).

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- Among HBsAg+ samples, 58.0% were tested for HDV Ab.

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- The HDV Ab positivity rate was 0.81% (n = 9).

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- HDV Ab+ results were observed across all racial/ethnic groups: non-Hispanic White and Hispanic/Latino (11.1%, n = 1, respectively); non-Hispanic Black (22.2%, n = 2); and non-Hispanic Asian (55.6%, n = 5).

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- HDV RNA positivity was 0.18%.

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- HDV RNA+ results (n = 2) were observed among non-Hispanic White and non-Hispanic Black (50%, n = 1, respectively).

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Total patients tested	106,693	1112 (1.04)	1.04	645 (58.0)	9 (1.40)	0.81	2 (22.22)	0.18

- A total of nine HDV Ab+ results were identified, with two of these also being RNA+.

HDV Ab+ and RNA+ (n=2)

Patient 1: Non-Hispanic White Male, Aged 49

Country of origin: Ukraine.

No coinfection with HCV or HIV

Tested for HBV during refugee screening

Viral load at the time of HDV diagnosis was 68,500

Patient 2: Non-Hispanic Black male, Aged 31

Country of origin: Eritrea

No coinfection with HCV or HIV

No history of substance use

Viral load at HDV diagnosis was > 5,800,000

HDV Ab+ and RNA- (n=5)

Patient 1: 52-year-old female from the Philippines; hx of deceased donor renal transplant and hx of chronic hepatitis B

Patient 2: 56-year-old female from Afghanistan; no coinfection with HCV or HIV; no history of substance use

Patient 3: 50-year-old male from China; reactive HCV Ab with undetectable HCV RNA; no coinfection with HIV; no hx of substance use

Patient 4: 53-year-old male from China; hx of prior cocaine use; labs showed patient had previously cleared HCV infection and was HIV-negative

Patient 5: 53-year-old Hispanic female; country of origin unknown; no coinfection with HCV or HIV; no hx of substance use

HDV Ab+ and RNA unknown (n=2)

Patient 1: non-Hispanic Black male, aged 68; past medical hx of HBV and intravenous drug use; had been on HBV treatment but had discontinued it and had not been tested for HDV RNA

Patient 2: 83-year-old female from China, could not have her RNA status determined as she was lost to follow-up

Take-aways from the pilot

Successes, challenges, and implications for future HDV sx

- Guidelines can be confusing / differ in their suggested approach
- Routine HBV Sx is paramount to successful HDV Sx
 - Provider awareness of HBV Sx guidelines varies
- Lab costs and lab processes – challenges varied across sites
 - Low rate of HDV testing among HBsAg+
 - Confusion around tests – which one to use
 - Sample availability
- Double reflex is recommended

**MORE THAN MEDICINE.
IT'S PERSONAL.**



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