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Prevalence of Hepatitis Delta Virus Infection in the United States

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Phone/Audio Option

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Questions?



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PREVALENCE OF HEPATITIS DELTA VIRUS INFECTION IN THE UNITED STATES

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Disclosures

- Eiger Biopharmaceuticals
 - Employee
 - Shareholder

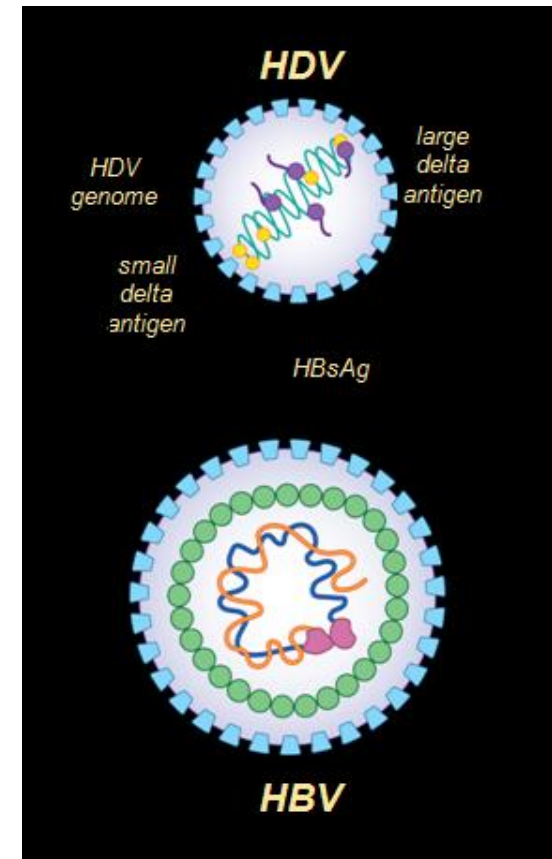
Outline

- Chronic Hepatitis Delta (HDV) background
 - HDV infection
 - Global prevalence
 - US data
- US Prevalence study
 - Methods
 - Results
 - Limitations
 - Conclusions

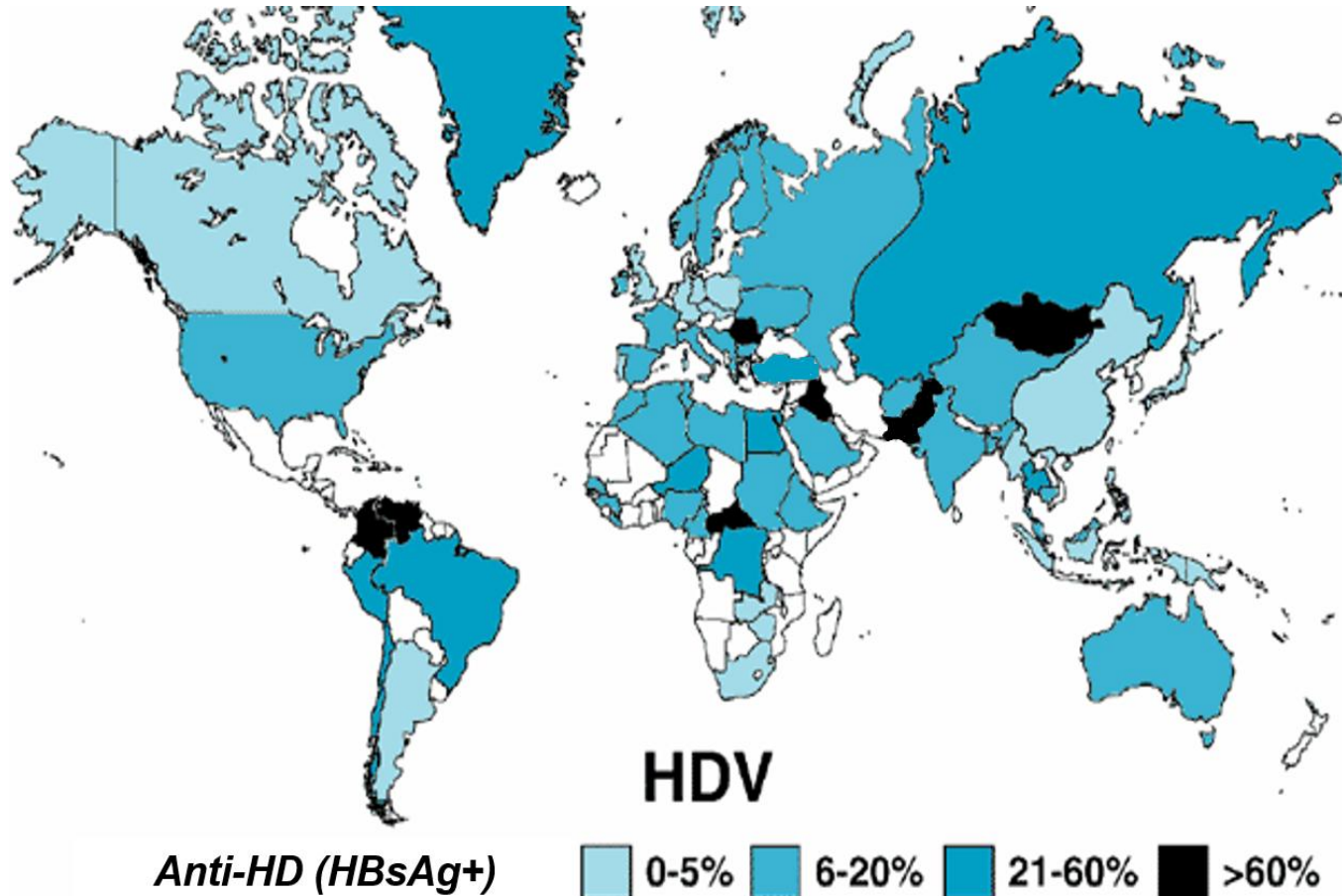
Hepatitis Delta Virus

The Most Severe Form of Chronic Viral Hepatitis

- HDV leads to the most severe form of viral hepatitis
 - More rapid progression to liver cirrhosis
 - 5-7x more likely to develop cirrhosis and vs HBV
- HDV is always associated with HBV Infection
 - Defective virus that needs HBsAg for propagation
- No FDA approved Rx for HDV
 - PEG IFN α demonstrates modest benefit
- HDV worldwide prevalence is 15 - 20 million
 - Approximately 4-6% of HBV population is infected with HDV
 - Orphan disease in US and EU



HDV Global Prevalence: 15-20 Million 4-6% of HBV-Infected Population Infected with HDV



Migration and Viral Hepatitis

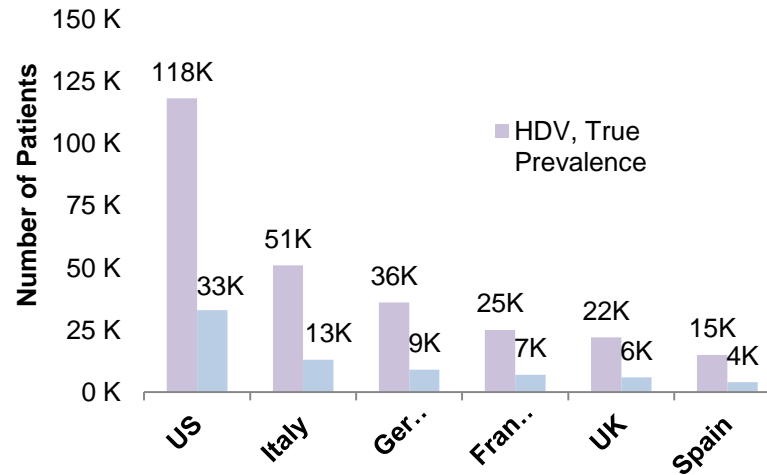
Globalization of Disease



Estimates of HDV Prevalence in the US and EU-5

Ranges Vary From 15K-118K

Prevalence of HDV by Geography



	US	Italy	Germany	France	UK	Spain
Estimated HBV Prevalence	2 M	600 K	328 K	496 K	256 K	212 K
Estimated Dx HBV Prevalence	553 K	148 K	81 K	132 K	67 K	52 K
Percent of HBV Co-infected with HDV	5.9%	8.5%	11%	5%	8.6%	7.1%
Estimate for Total HDV Patient Pool	118 K	51 K	36 K	25 K	22 K	15 K
Estimate for Dx HDV Patients	33 K	13 K	9 K	7 K	6 K	4 K

HBV in Foreign-Born Persons in the US

- Estimates of the prevalence of HBV in the United States differ significantly
- Systematic review of HBsAg seroprevalence rates in 102 countries
 - 256 seroprevalence surveys in emigrants from 52 countries (including 689,078 persons)
 - 1,797 surveys in the general populations of 98 countries (including 17,861,035 persons)
- Data combined using meta-analytic methods to determine country-specific HBV prevalence rates
- Rates calculated using the number of FB living in the United States in 2009 by country of birth
- 1.32 million (95% confidence interval: 1.04-1.61) FB in the United States with HBV
 - 58% migrated from Asia, 11% migrated from Africa, and 7% migrated from Central America

HDV in the US Veterans Administration

- Retrospective study of all veterans positive for HBsAg from Oct 1999 to Dec 2013
- 25,603 patients with positive HBsAg
 - 2175 (8.5%) were tested for HDV; 73 (3.4%) tested positive
- HDV testing associated with being tested for HBV, HIV, and HCV
- Predictors of (+)ve HDV results
 - Substance abuse and cirrhosis
 - Abnormal ALT with suppressed HBV DNA (OR 3.2, 95%CI 1.4–7.5)
- Incidence rates of HCC 2.9 fold higher in HDV (+)ve ($p = 0.002$)
- HDV independently associated with HCC (OR 2.1, 95%CI 1.1–3.9)

HDV in Northern California

- Retrospective chart review of all HBV patients at CPMC
- 1191 HBV patients
 - 499 had been tested for HDV
 - 42 (8%) coinfecting; half of these were also hepatitis C virus-infected
 - Cirrhosis in 73% of HBV/HDV, 80% of HBV/HDV/HCV, 22% of HBV
 - 29 patients (69%) Caucasian non-Hispanic
 - 10 (24%) Asians and Pacific Islanders

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Results from an ICD-10 Review

Methods

- Analysis of International Classification of Diseases (ICD) 9 and 10 codes for patients with HDV/HBV coinfection data from two longitudinal patient databases
- Initial analysis using Truven MarketScan®
 - Database contains medical claims info for over 170 million de-identified US patients
- 2nd, more detailed analysis used SHS Integrated Universe's PatientSource™
 - Comprehensive longitudinal patient database with over 4 billion prescription, medical, and hospital claims linked to anonymous patient identifiers, practitioners and payers
 - Claims' information for over 274 million patients, accounting for over 73% of all prescriptions, over 58% of all electronically processed medical claims and 25% of all hospital claims
 - The entire dataset is linked to each de-identified patient, with 75% of patients with a linked prescription and diagnosis claim
- To avoid counting a single patient multiple times only unique patient counts are included

ICD-9 and ICD-10 Codes for HBV and HDV

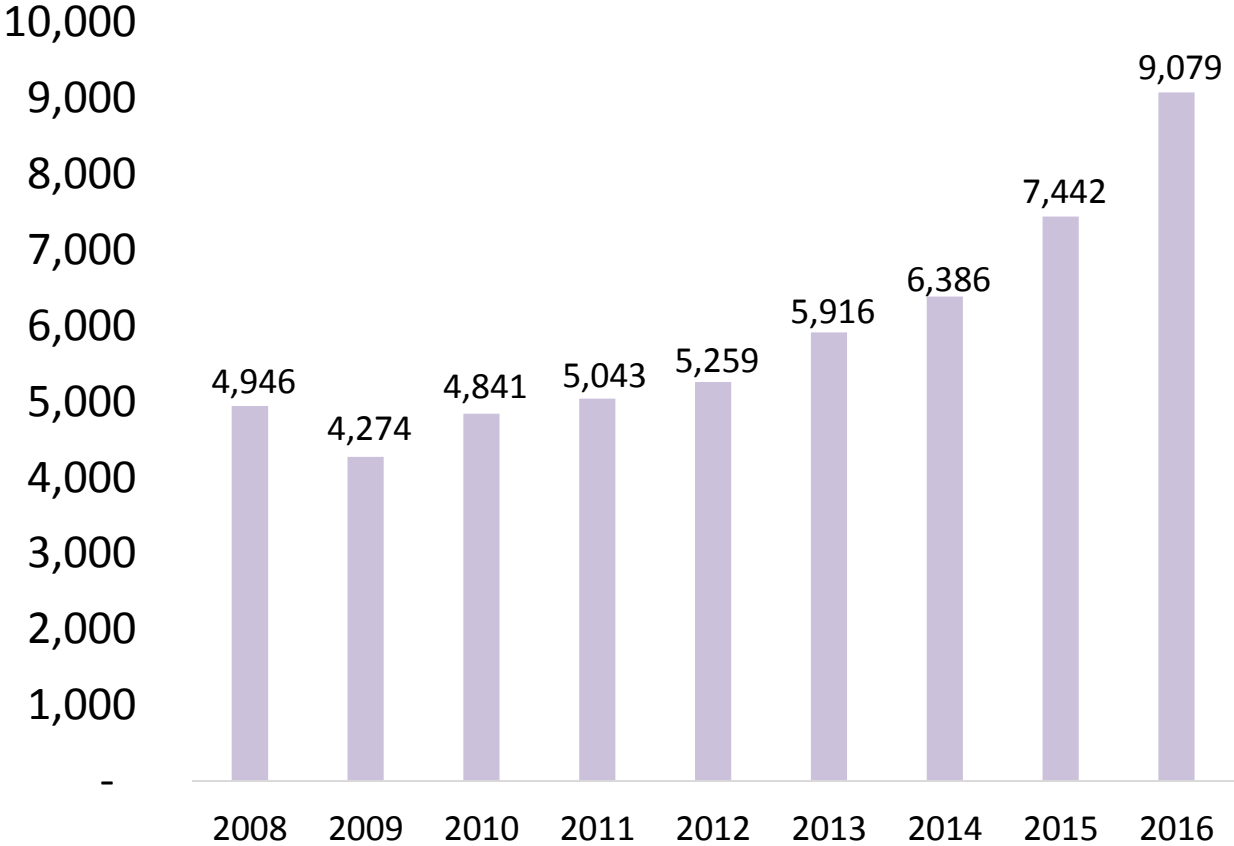
HBV

ICD-10	ICD-9	Description
B18.0	70.33	Chronic viral Hepatitis B without mention of hepatic coma with hepatitis delta
B18.1	70.32	Chronic viral Hepatitis B without delta-agent
B19.10	70.30	Viral Hepatitis B without mention of hepatic coma, acute or unspecified, without mention of hepatitis delta
B16.9	70.30	Viral Hepatitis B without mention of hepatic coma, acute or unspecified, without mention of hepatitis delta
B16.2	70.30	Viral Hepatitis B with hepatic coma, acute or unspecified, without mention fo hepatitis delta

HDV

ICD-10	ICD-9	Description
B17.0	70.52	Hepatitis delta without mention of active hepatitis B disease or hepatic coma
B16.0	70.21	Viral hepatitis B with hepatic coma, acute or unspecified, with hepatitis delta
B16.1	70.31	Viral hepatitis B without mention of hepatic coma, acute or unspecified, with hepatitis delta
B18.0	70.33	Chronic viral hepatitis B without mention fo hepatic coma with hepatitis delta

Growing Number of Newly Diagnosed HDV Patients* in the US

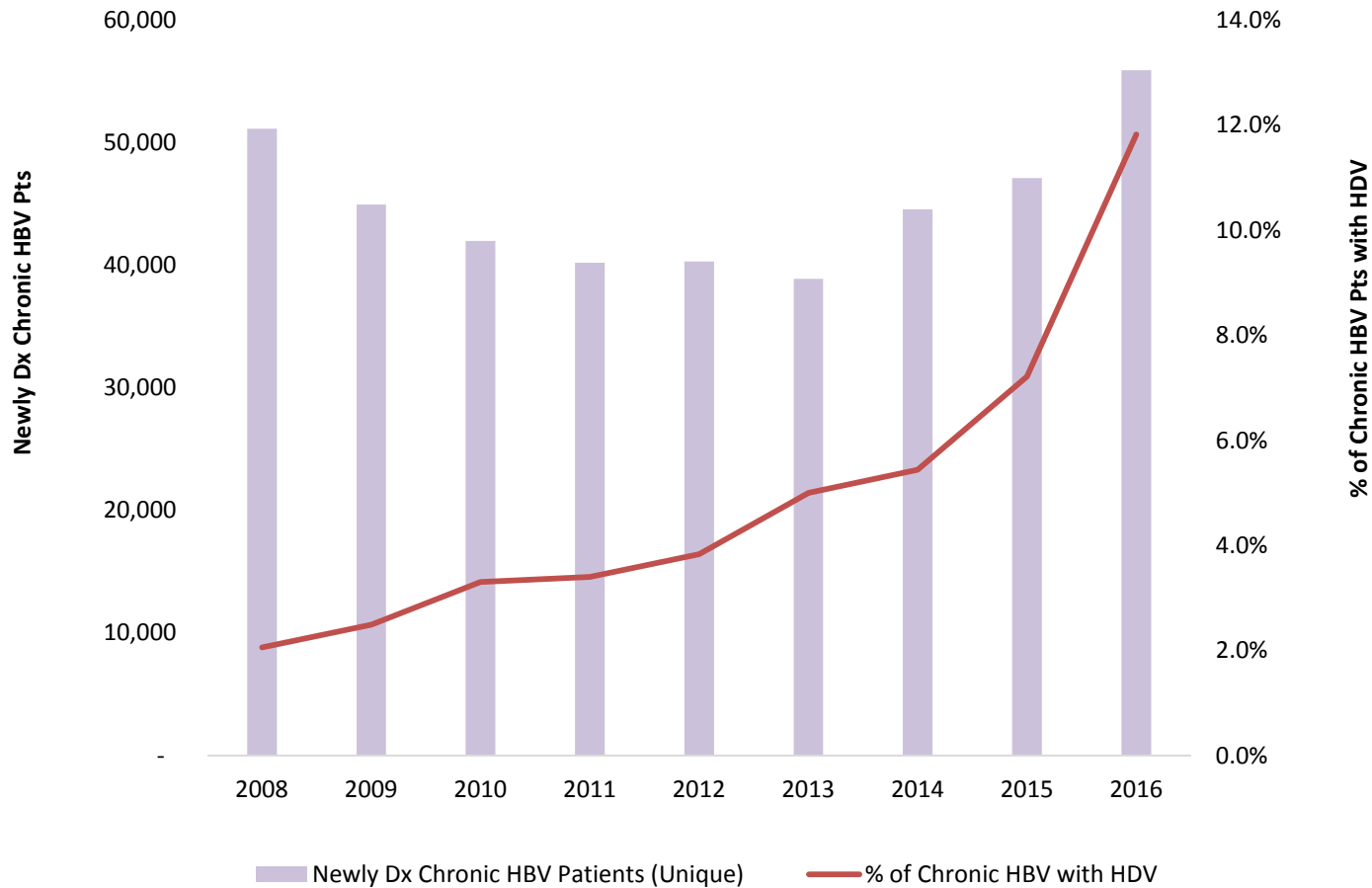


* Unique Patients

Martins, E and Glenn, J. Prevalence of Hepatitis Delta Virus (HDV) Infection in the United States: Results from an ICD-10 Review. Poster Sa1486 DDW May 2017.



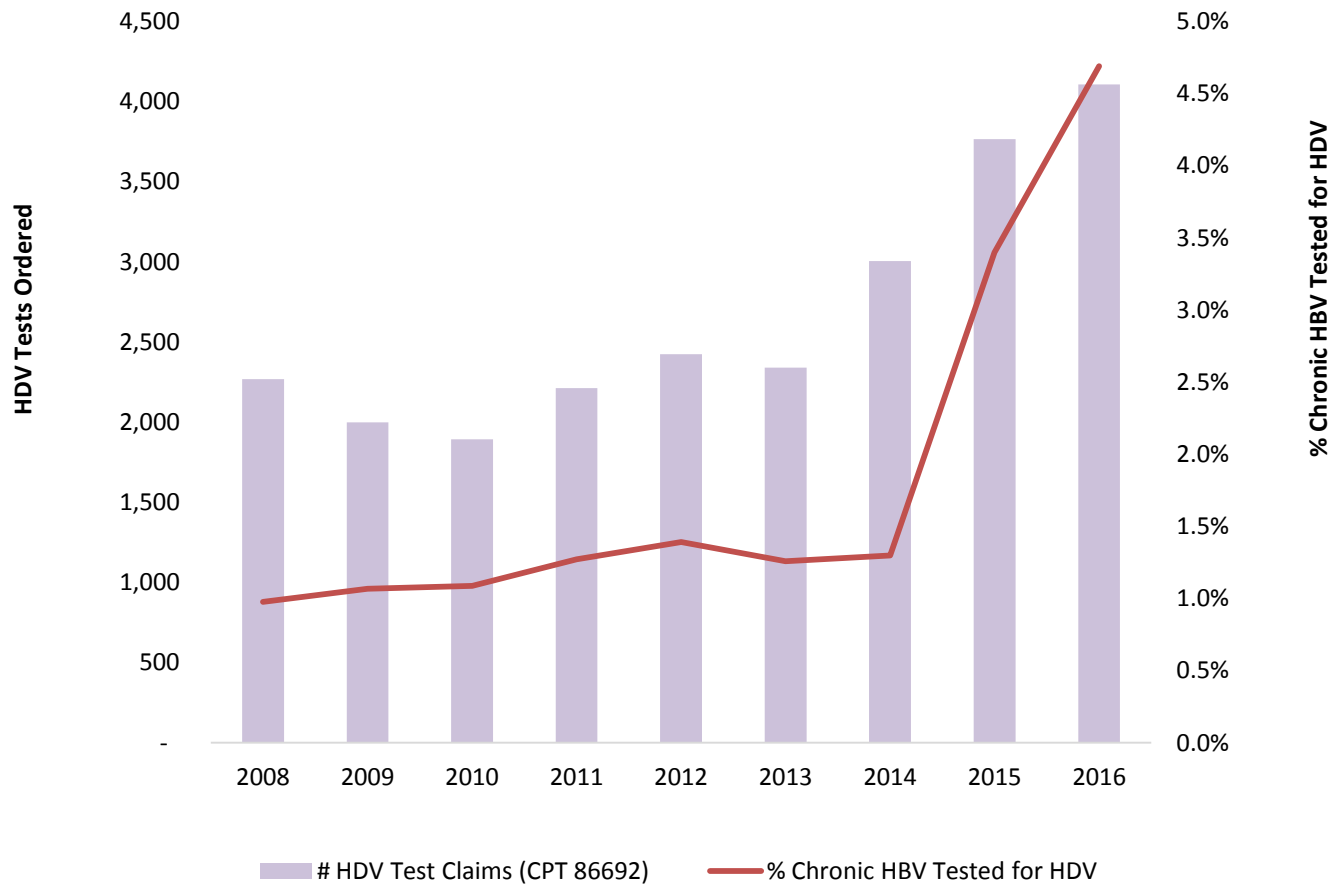
Newly-Diagnosed Chronic HBV Patients and % with HDV Incidence Appears Higher Than Previous Estimates



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% Chronic HBV Patients Tested for HDV

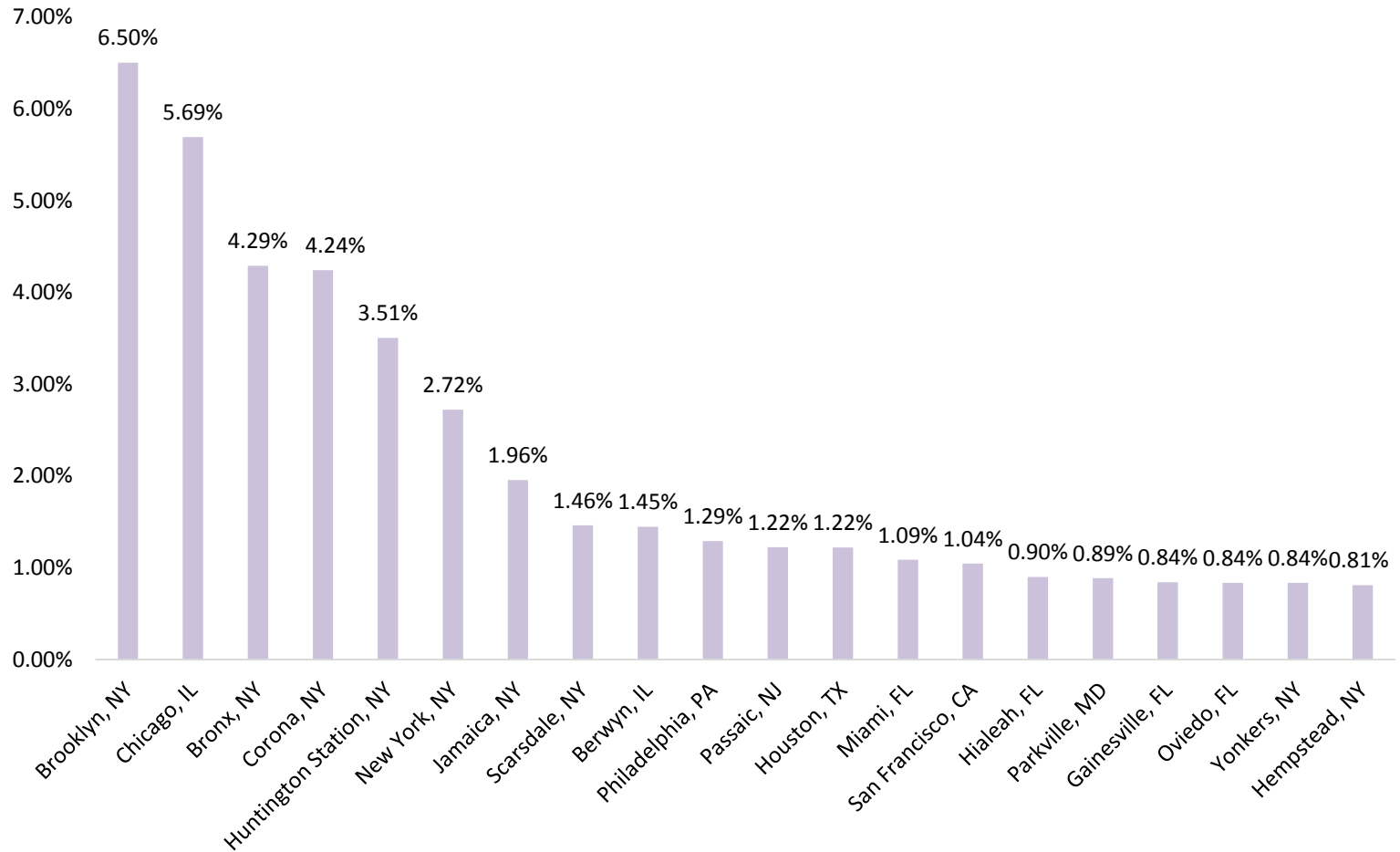
Low Testing Rate May be Concealing True Prevalence



HDV Geographic Footprint is Growing

- 25% (15,631) of all HDV patients in the US reside in 5 three-digit zip codes (Brooklyn, NY, Chicago, IL, Bronx, NY, Corona, NY and Huntington Station, NY)
- The HDV population resident in the top 20 three digit codes comprise 43% (27,601) of **all** HDV patients in the US

Top 20 US Geographies for HDV Patients



HDV Geographic Footprint is Growing

Consistently high areas of HDV patient concentration

Brooklyn, NY	Bronx, NY	Corona, NY
Scarsdale, NY	Passaic, NJ	Jamaica, NY
San Francisco, CA	Yonkers, NY	Pittsburgh, CA
Huntington St, NY	Philadelphia, PA	
New York, NY	La Puente, CA	

Based on inclusion in top 20 HDV patient geographies ≥ 4 times from 2008 to 2013

Specific areas that have recently become high concentration include:

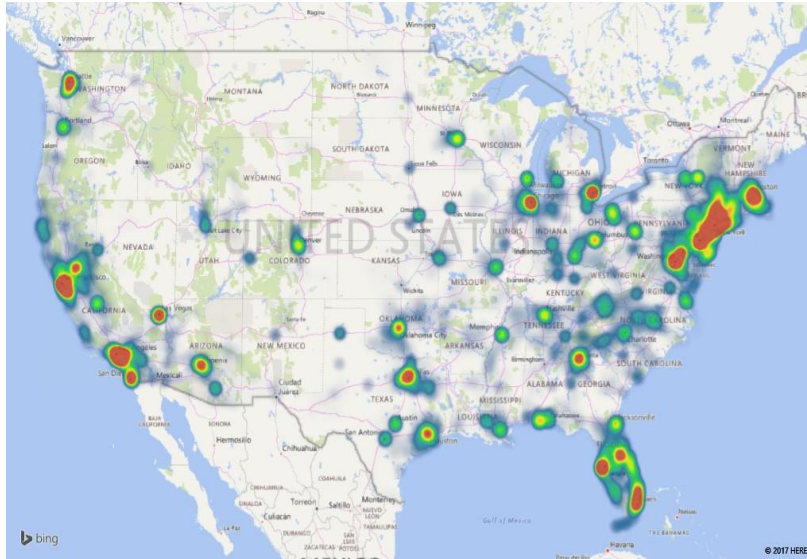
Chicago, IL	Berwyn, IL	Oviedo, FL
Miami, FL	Parkville, MD	Gainesville, FL
Lombard, IL	Orlando, FL	Staten Island, NY
Waukegan, IL	Hempstead, NY	Hialeah, FL

Based on inclusion in top 20 HDV geographies ≥ 2 times from 2013-2016. Cannot be included on top 20 list >3 times between 2008 and 2012

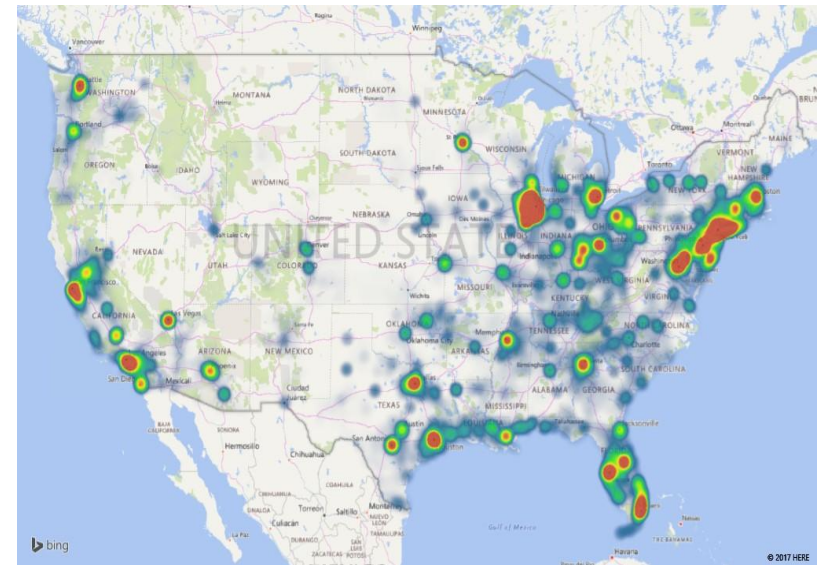
Comparison of HDV Patient Footprint 2008 vs 2016

Top 20 Geographies for Each Year

2008



2016



1. Brooklyn, NY	6. Bronx, NY	11. La Puente, CA	16. Chicago, IL
2. New York, NY	7. Philadelphia, PA	12. St. Petersburg, FL	17. Franklin, MA
3. Yonkers, NY	8. Jamaica, NY	13. Staten Island, NY	18. Las Vegas, NV
4. Corona, NY	9. San Francisco, CA	14. Pittsburg, CA	19. Newburgh, NY
5. Scarsdale, NY	10. Passaic, NJ	15. Detroit, MI	20. Huntington ST, NY

1. Chicago, IL	6. New York, NY	11. Huntington ST, NY	16. Cicero, IL
2. Berwyn, IL	7. Bronx, NY	12. Philadelphia, PA	17. Parkville, MD
3. Brooklyn, NY	8. Jamaica, NY	13. Houston, TX	18. Miami, FL
4. Corona, NY	9. Lombard, NY	14. Passaic, NJ	19. Hialeah, FL
5. Waukegan, IL	10. Aurora, IL	15. Staten Island, NY	20. Las Vegas, NV

Limitations of Our Study

- Databases mostly capture insured patients
- Ethnicity of identified patients is not captured in this study
- Given the high prevalence of HBV in foreign-born, it is conceivable that many HBV-infected patients are not captured in our data
- Antibody test may not correlate with HDV RNA by PCR
- Data may be skewed by disproportionate impact of tertiary centers
- Total anti-HDV test does not differentiate between ongoing and past infection

Conclusions

- More than 11.8% of patients with chronic HBV may be coinfecting with HDV
- Only 4.7% of chronic HBV patients are tested for HDV coinfection
- Even a small increase in HDV testing among chronic HBV patients has yielded significant increases in the numbers of detected HDV/HBV coinfection cases in the US
- Given the propensity for HDV to cluster geographically, it is important for clinicians to be aware of the growing footprint associated with the HDV patient population and the potential for undiagnosed HDV cases
- These data support the need for increased HDV testing among chronic HBV patients. HDV testing is readily available through commercial laboratories in the US

Thank you!

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Please submit questions for Dr. Martins
in the chat box!

Q & A

Thank you for attending!

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New FAQ page!
Includes detailed
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