# Poster: Sa1486

# PREVALENCE OF HEPATITIS DELTA VIRUS (HDV) INFECTION IN THE UNITED STATES: RESULTS FROM AN ICD-10 REVIEW Eduardo B Martins<sup>1</sup> MD, DPhil and Jeffrey S Glenn<sup>2</sup> MD, PhD 1. Eiger BioPharmaceuticals, Palo Alto, CA, 2. Stanford University, Palo Alto, CA

# BACKGROUND

Hepatitis Delta virus (HDV) infection leads to is the most aggressive form of human viral hepatitis. It only occurs as coinfection with chronic hepatitis B virus (HBV), and is associated with rapid progression of fibrosis, early development of cirrhosis, liver decompensation and hepatocellular carcinoma. Globally, it is estimated that 15-20 million people have HDV/HBV coinfection and it has been approximated that 4.3% to 5.7% of chronic HBV patients will also have HDV. A single center study in Northern California reported a prevalence rate of HDV/HBV coinfection of 8% (Gish 2013). A lower prevalence – 3.4% - was identified in the US Veterans Affairs system (Kushner 2015), although testing for HDV was incomplete. Recent data from the CDC estimates the prevalence of all HBV in the US at ≈730,000 people (95% CI 550,000 – 940,000) (Wasley 2010). The true rate of HDV/HBV coinfection in the US is likely underestimated due to low levels of HDV testing.

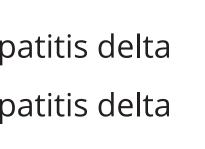
# METHODS

- We analyzed International Classification of Diseases (ICD) 9 and 10 codes for patients with HDV/HBV coinfection data from two longitudinal patient databases; Truven MarketScan® and Symphony Health Solutions' (SHS) Integrated Universe's PatientSource™
- The initial analysis was performed using Truven MarketScan<sup>®</sup>, a database containing medical claims information for over 170 million de-identified patients in the US
- The second, more detailed analysis used SHS Integrated Universe's PatientSource™. SHS Integrated Universe's PatientSource is a comprehensive longitudinal patient database with over 4 billion prescription, medical, and hospital claims linked to anonymous patient identifiers, practitioners and payers. The patient database includes 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 in this analysis

In October 2015 the tenth version of ICD codes was launched. To evaluate data from 2008 to 2016 all ICD-9 codes used were correlated with their closest ICD-10 code match. The following ICD codes were used for this analysis (Table 1):

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 hepa
B16.9	70.30	Viral Hepatitis B without mention of hepatic coma, acute or unspecified, without mention of hepa
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
	70.33	Chronic viral hepatitis B without mention fo hepatic coma with hepatitis delta
B18.0	70.55	en one vital nepatitis D without mention to nepatie conta with nepatitis delta

## Table 1: ICD-9 and ICD-10 Codes for HBV and HDV Evaluated



Consistently Growing Number of Newly Diagnosed HDV Patients in the US (Figure 1)

RESULTS

- Prior to 2013 the annual number of patients diagnosed with HDV had been flat at ≈5,000/year
- 9,079 patients were newly diagnosed with HDV in 2016, a 22% increase over 2015
- 53,186 patients were newly diagnosed with HDV between 2008-2016
- Between 2012 and 2016 the number of patients diagnosed with HDV has steadily increased along with year-over-year (YoY) growth rate
- YoY growth 2015 vs 2014 and 2016 vs 2015 was 17% and 22% respectively

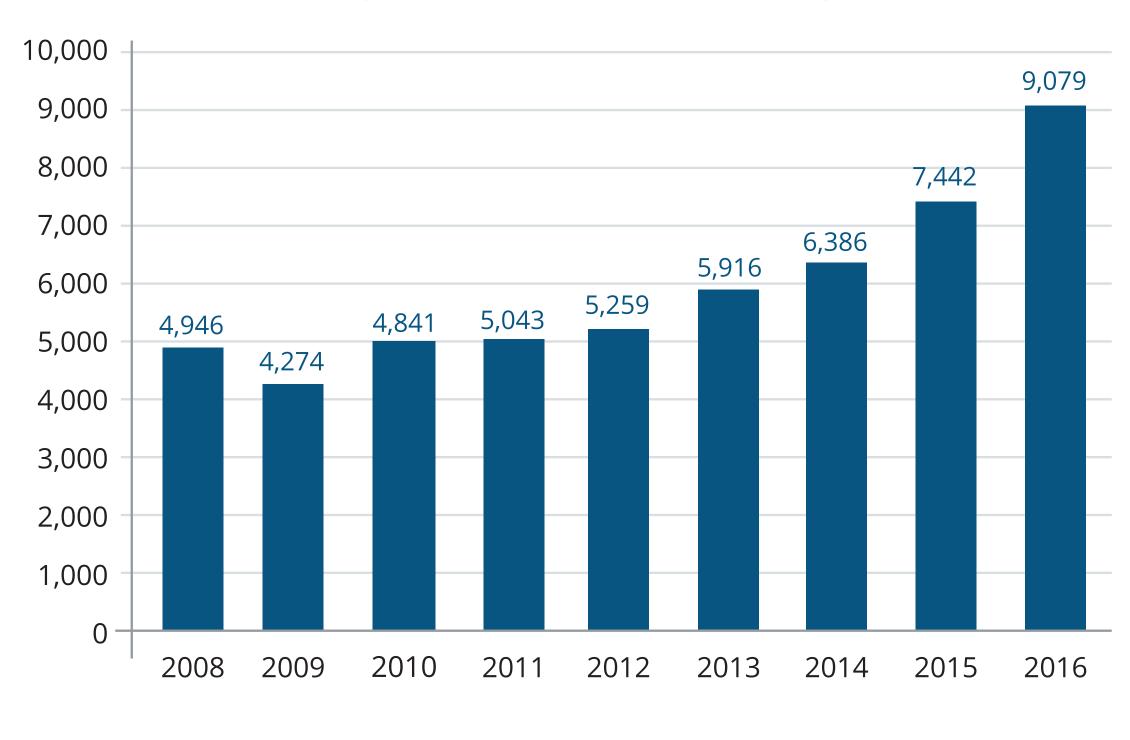
### The Incidence of HDV Coinfection Among Chronic HBV Patients in the US Appears Markedly Higher than Previous Estimates (Figure 2)

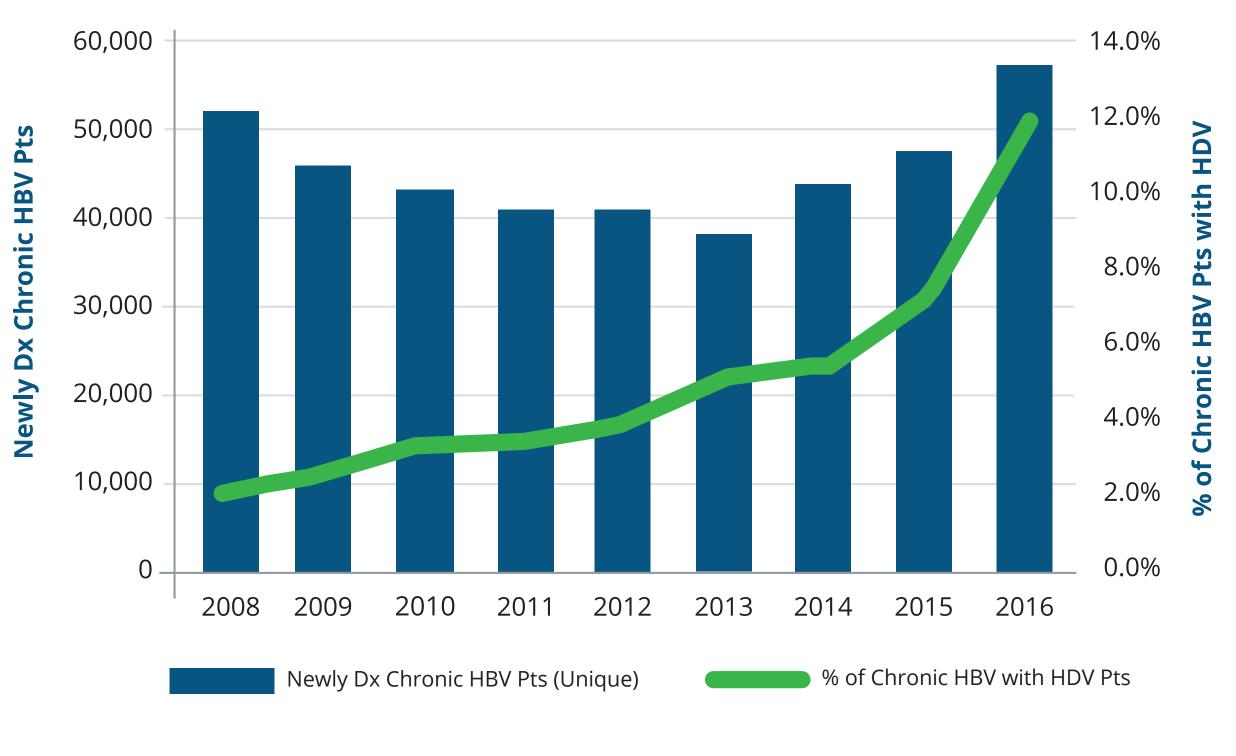
- The rate of HDV diagnosis among patients with chronic HBV has more than doubled since 2013
- In 2016 ≈56,000 unique patients were newly diagnosed with chronic HBV
- Among those with chronic HBV, 6,613 (11.8%) patients were diagnosed as having chronic viral HBV with hepatitis delta (ICD-10 code 18.0). The original analysis using the Truven MarketScan database revealed the same rate of HDV diagnosis among patients with chronic HBV
- Applying the rate of HDV/HBV coinfection found in this research (11.8%) to the high end of CDC's HBV estimate suggests that there may be  $\approx 110,000$  HDV/ HBV coinfected patients in the US

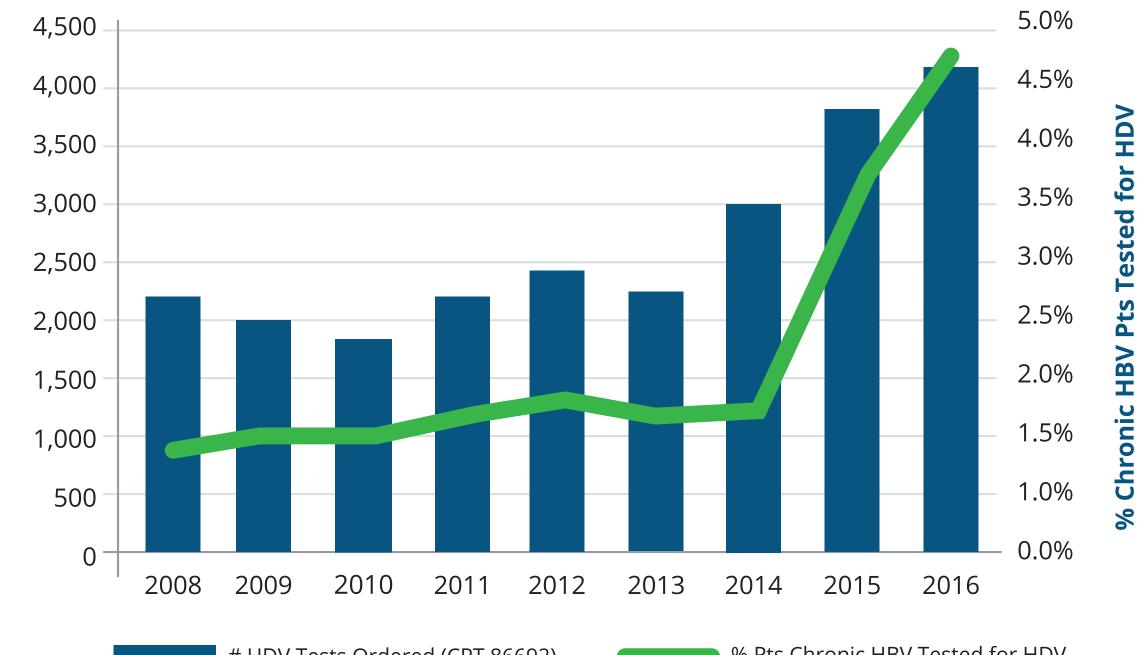
## Low Rate of HDV Testing May Be Concealing True Rate of HDV/HBV Coinfection in the US (Figure 3)

- Just over 4,000 HDV antibody tests (CPT 86692) were ordered in 2016
- Although the number of HDV tests being ordered is increasing, the percentage of chronic HBV patients being tested for HDV remains very low
- In 2016 there was a 30% increase in HDV testing versus 2012
- Only  $\approx$ 2,600 (4.7%) HDV tests were for patients newly diagnosed with chronic HBV
- In 2016 ≈35,000 physicians diagnosed a new HBV patient while only 2,541 diagnosed a new HDV patient

### Figure 1: Annual # of Newly Diagnosed HDV Patients in the US (Unique Patients)







igure 2: # of Newly Diagnosed Chronic HBV Pts and % Diagnosed with HDV Coinfection

# HDV Geographic Footprint is Growing (Figures 4-5)

- 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 (Figure 4)
- The geographic footprint (based on three digit zip code) of patients diagnosed with HDV has grown amply from 2008 to 2016 (Figure 5)
- Consistently high areas of HDV patient concentration include:

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

Based on inclusion in top 20 HDV patient geographies  $\geq$ 4 times from 2008

Illinois and Florida are emerging as areas with a high concentration of HDV patients. Specific areas that have recently become high concentration include:

	<b>_</b>	
Chicago, IL	Berwyn, IL	Oviedo
Miami, FL	Parkville, MD	Gaines
Lombard, IL	Orlando, FL	Staten
Waukegan, IL	Hempstead, NY	Hialea

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

Figure 3: # of HDV Tests Ordered and % of Chronic HBV Patients Tested for HDV Coinfection

# CONCLUSIONS

This real-world US-specific assessment of medical claims suggests that:

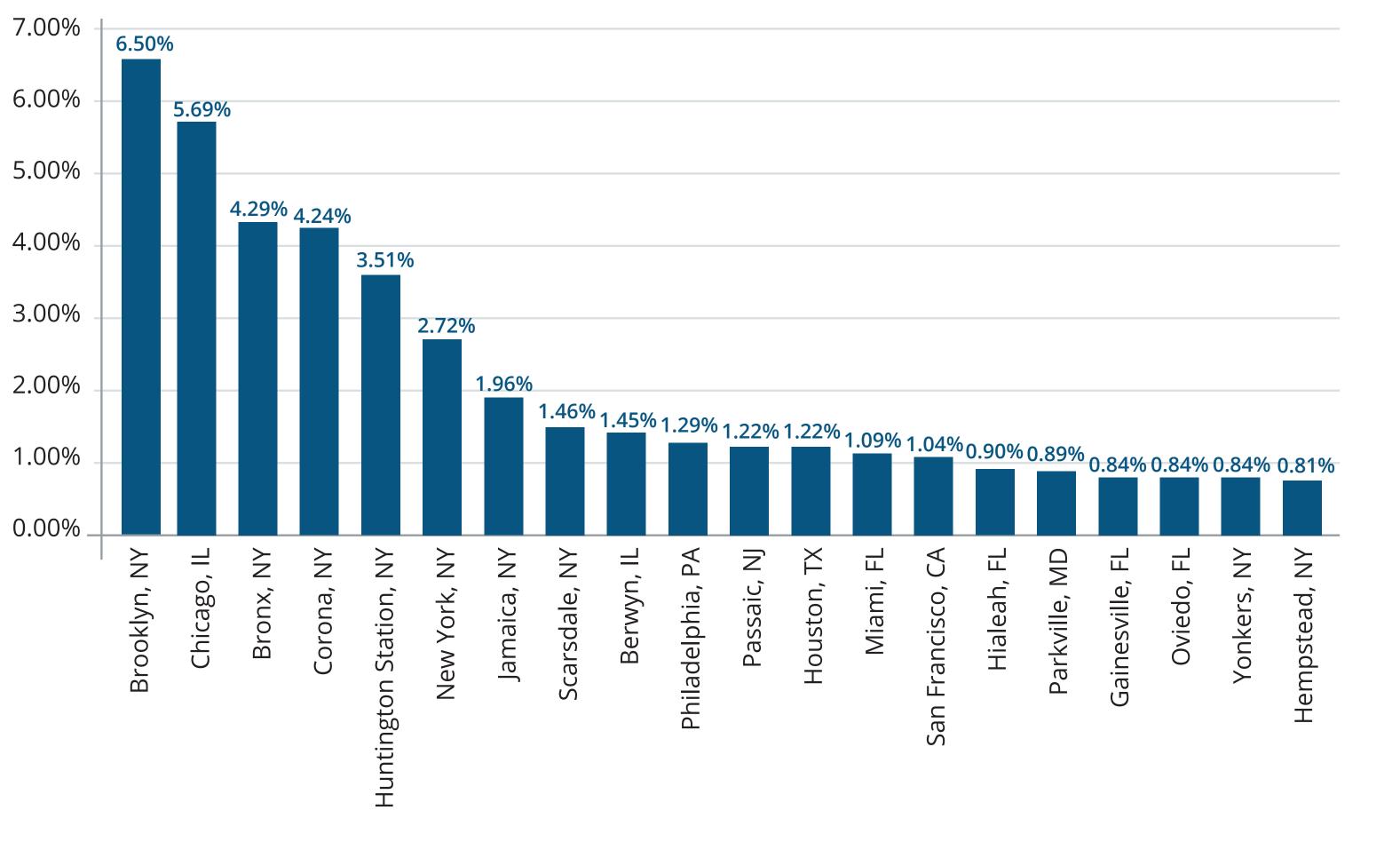
- More than 11.8% of patients with chronic HBV may be coinfected with HDV
- Only 4.7% of chronic HBV patients are tested for HDV coinfection
- Even a small increase in HDV testing among chronic HBV patients has yielded significant increases in the numbers of detected HDV/HBV coinfection cases in the 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

ests Ordered (CPT 86692)

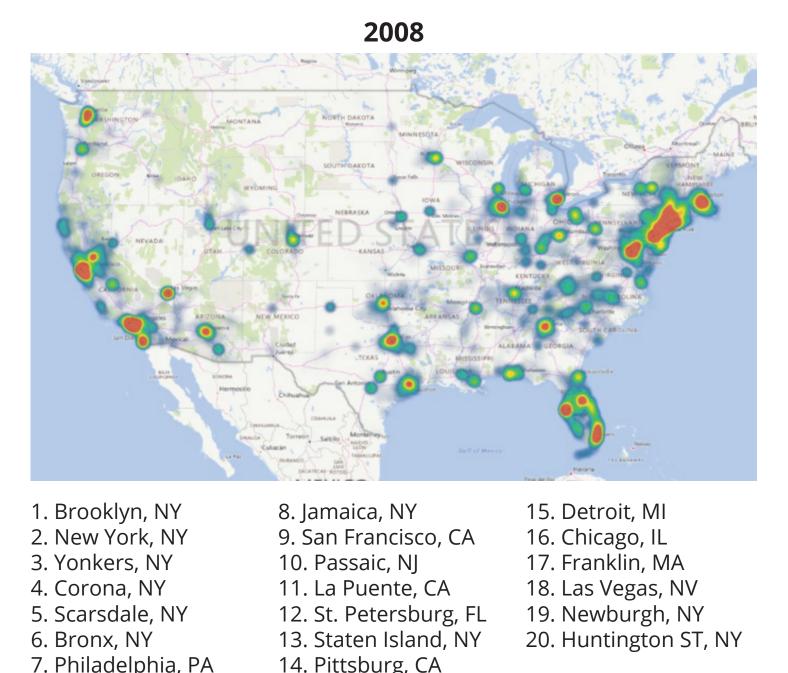
% Pts Chronic HBV Tested for HDV

NY

## Figure 4: Top 20 US Geographies for HDV Patients



## Figure 5: Comparison of HDV Patient Footprint 2008 vs 2016 and Top 20 Geographies for for Each Year



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# DISCLOSURES

Eduardo B Martins MD, DPhil: Employee, shareholder Eiger Biopharmaceuticals

## Jeffrey S Glenn MD, PhD:

Founder, Board of Directors, shareholder Eiger Biopharmaceuticals

