BACKGROUND

Hepatitis Delta Virus (HDV) infection leads to the most aggressive form of human viral hepatitis. It is estimated that 4-6% of the HBVinfected population is co-infected with HDV. In the US the rate of co-infection is believed to be 3-5%, however targeted testing may yield significantly higher rates of HDV positivity. For example, testing HBsAg (+) patients may yield positivity rates between 8-12% (Gish 2012 and Martins 2017).

Worldwide prevalence of HDV infection is between 15-20 million. Global migration in the last decade has shifted HDV-infected population into the western world. US prevalence of HDV infection is estimated to be between 110,000 (Martins 2017) and 135,000 (DelveInsight 2018). This may be an underestimate due to underdiagnosis in foreign-born individuals.

This epidemiological study sought to: (1) estimate the number of foreign-born individuals with HDV in the US and (2) identify areas of the US with high HDV prevalence and opportunities to improve screening and diagnosis based upon the composition of foreignborn individuals.

METHODS

Our analysis combined Symphony Health Solutions' (SHS) Integrated Universe's PatientSource[™] database, US Census Data of foreign-born populations from 109 countries and published HBV and HDV epidemiology studies (Kowdley 2012, Alfaiate 2015). SHS 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.

This analysis focuses predominately on those countries with a known HDV prevalence rate among people infected with HBV and whose foreign-born population is tracked by the US Census Bureau to the zip code level.

Limitations to this study include the capture rates from SHS database and the finite number of countries captured in the US census data. Both limitations are likely to underestimate the number of foreign-born people in the US with HDV.

CONCLUSIONS

- In the US, the number of newly diagnosed HDV patients has grown consistently (2008-2016)
- It is estimated there are at least 55,000 foreign-born individuals with HDV in the US.
- HDV is no longer limited to the East and West coasts of the US.
- HDV testing among chronic HBV patients and foreign-born individuals is recommended.
- Current US HDV prevalence of 110,000 individuals may be an underestimate.

Growing Hepatitis Delta Virus (HDV) Infection Prevalence in the US: Underdiagnosis in Foreign-born Individuals R Franco¹, J Glenn², R Gish^{2,3}, D Apelian¹

Eiger BioPharmaceuticals¹, Stanford University School of Medicine², Hepatitis B Foundation³

RESULTS



> 1.1 MILLION FOREIGN-BORN, **HBV-INFECTED PATIENTS IN THE US**

- 32 countries account for 80% of the foreign-born population in the US.
- Nearly 50% of those foreign-born people with HBV come from China, Vietnam and the Philippines.
- HDV prevalence rates are known for 31 countries whose foreign-born population is tracked by the US Census Bureau.

_argest HBV-Infected Population in the US					
Country	Foreign-Born Living in US 2009 (#)	HBV Prevalence (%)	HBV Population (#)		
China	1,987,625	12.3%	243,484		
Vietnam	1,149,355	12.5%	143,440		
Philippines	1,733,864	7.4%	127,612		
Dominican Republic	791,593	10.7%	84,542		
Western Africa	534,058	13.2%	70,335		
Mexico	11,478,234	0.5%	56,243		
India	1,665,055	3.2%	53,781		
Korea	1,012,911	5.3%	53,279		
Guatemala	790,508	3.7%	29,407		
Nigeria	207,031	13.3%	27,556		
Laos	195,988	13.6%	26,674		
Haiti	535,966	4.8%	25,780		
Jamaica	644,958	3.9%	25,411		
Cambodia	144,379	10.3%	14,828		
Ghana	109,091	13.4%	14,662		
Ethiopia	151,879	9.6%	14,565		
Romania	177,035	7.2%	12,729		
Thailand	205,280	6%	12,255		
Pakistan	282,507	4.2%	11,781		
Russia	405,731	2.89%	11,726		



> 50,000 HDV-INFECTED PATIENTS DIAGNOSED BETWEEN 2008-2016

- Based upon ICD-10 codes, there were 53,186 unique patients diagnosed with HDV in the US from 2008-2016. This includes all patients diagnosed with HDV regardless of their birth country.
- The diagnosis of HDV in the US is steadily increasing as HDV testing becomes readily accessible and potential treatments advance through development.

ICD-10	Description		
B17.0	Hepatitis delta without		Newly
	mention of active	10,000	
	hepatitis B disease or	9,000	
	hepatic coma	8,000	
B16.0	Viral hepatitis B with hepatic	7,000	
	coma, acute or unspecified,	6,000	
	with hepatitis delta	5,000	4,946
B16.1	Viral hepatitis B without mention of hepatic coma,	4,000	4,2
	acute or unspecified, with	3,000	
	hepatitis delta	2,000	
B18.0	Chronic viral hepatitis B	1,000	
	without mention of hepatic coma with hepatitis delta	_	2008 20

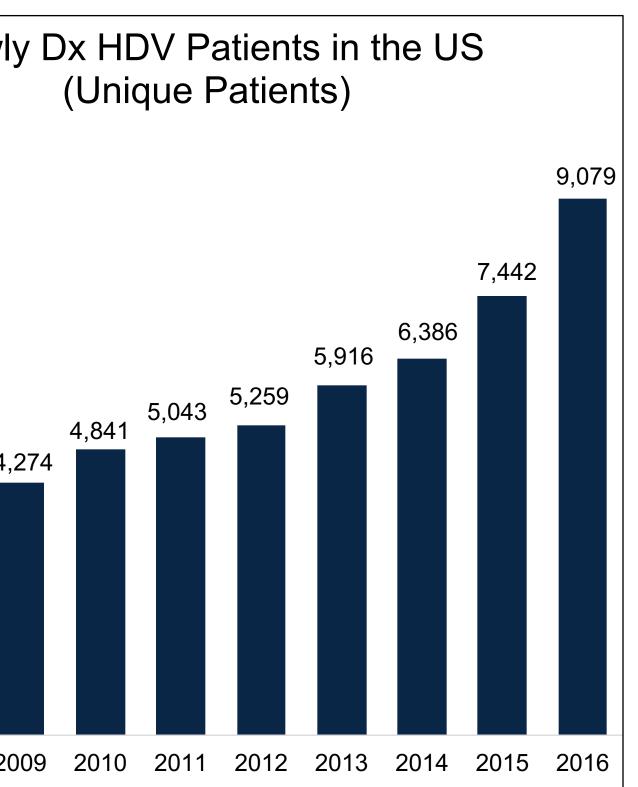
COUNTRIES WITH FOREIGN-BORN IN US WITH HIGHEST PREVALENCE OF HDV

• The US Census Bureau tracks the foreign-born population at the zip code level for most countries with a moderate to high (> 10%) HDV prevalence rate among those infected with HBV.

* There are a select number of countries with a high HDV prevalence rate are not tracked by the US Census Bureau (i.e. Mongolia, Central African Republic). This data is not included in this analysis.



Top 20 Countries with Largest HR\/_Infected Population in the LIS

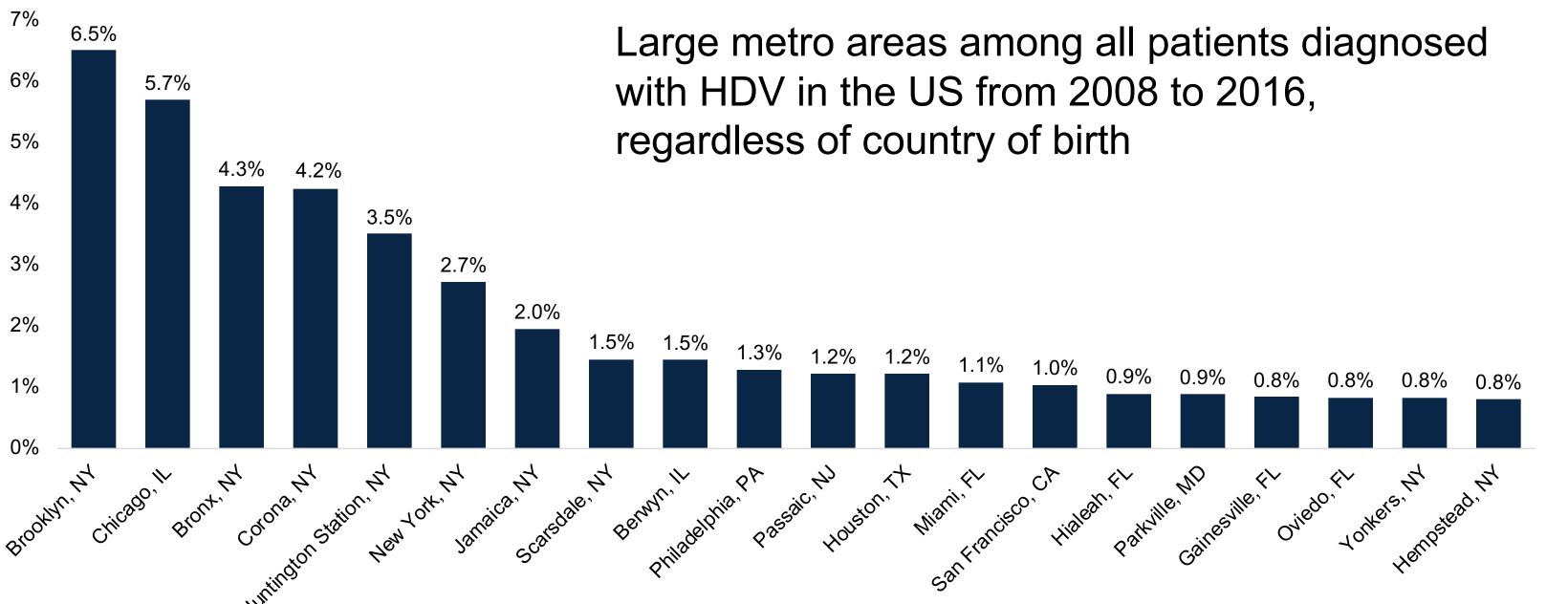


Country	HDV Prevalence in HBV-Infected Patients (%)		
Romania	48%		
Kenya	40%		
Bangladesh	40%		
Pakistan	40%		
Turkey	40%		
Albania	40%		
Brazil	40%		
Colombia	40%		
Venezuela	33%		
Somalia	10%		
Afghanistan	10%		
Saudi Arabia	10%		
Latvia	10%		

HDV AMONG FOREIGN-BORN PEOPLE WITH HBV

- There are at least 55,000 foreignborn people infected with HDV in the US.
- Foreign-born people infected with HDV represent approximately 40% of all HDV patients in the US.
- Approximately 50% of all foreignborn HDV patients come from either Romania, Pakistan, Albania, Vietnam or Colombia.

U.S. CITIES WITH HIGHEST PREVALENCE OF HDV





TOP US CITIES WHERE HDV IS MOST PREVALENT AND THE ESTIMATED NUMBER OF FOREIGN-BORN PEOPLE WITH HDV

- Top 20 US cities where HDV is most prevalent have been identified.
- It is estimated that 10,284 foreignborn people in the US reside in these top 20 cities where HDV is most prevalent.
- HDV prevalence rates in foreignborn in these cities range from 14-100%.



UNDERDIAGNOSIS OF HDV IN THE US

Grand Prairie

Westminste

US Cities Where HDV is Likely Underdiagnosed Based Solely on the Composition of Foreign-born Individuals					
City	Total # Diagnosed with HDV (2008-2016)	Estimated Number of Foreign-born Individuals with HDV	Estimated Number of Foreign-born Individuals with HDV, NOT Diagnosed		
1inneapolis, MN	165	665.7	-500.7		
awrenceville, GA	297	781.4	-484.4		
rand Prairie, TX	268	683.7	-415.7		
Vestminster, CA	148	498.9	-350.9		
Ashburn, VA	118	461.3	-343.3		
Malden, MA	445	775.9	-330.9		
Redmond, WA	222	540.8	-318.8		
Katy, TX	162	480.6	-318.6		
Pacoima, CA	82	392.9	-310.9		



HEPATITIS B

Country	Foreign-born in US (#)	HBV Prevalence (%)	HBV Population (#)	HDV Prevalence Among HBV (%)	HDV Population (#)
Romania	177,035	7.2%	12,729	47.6%	6,059
Pakistan	282,507	4.2%	11,781	40.0%	4,712
Albania	79,562	12.4%	9,858	40.0%	3,943
Vietname	1,149,355	12.5%	143,440	2.5%	3,586
Colombia	617,738	1.2%	7,413	40.0%	2,965
Bangladesh	139,773	4.8%	6,751	40.0%	2,700
Brazil	356,531	1.8%	6,346	40.0%	2,539
Turkey	110,212	5.3%	5,863	40.0%	2,345
Somalia	69,333	12.4%	8,597	25.0%	2,149
Kenya	80,657	5.7%	4,597	40.0%	1,839
Afghanistan	59,699	10.5%	6,245	25.0%	1,561
Egypt	136,159	4.6%	6,277	20.0%	1,255
Venezuela	159,655	1.9%	3,081	40.0%	1,233
Ethiopia	151,879	9.6%	14,465	7.5%	1,092
Moldova	43,970	9.6%	4,226	25.0%	1,056

City	# Diagnosed HDV 2008-2016	Estimated # of Foreign-born with HDV	% Foreign-born with HDV
Brooklyn, NY	4,195	1,346	32%
Chicago, IL	3,672	620	17%
Bronx, NY	2,767	582	21%
Corona, NY	2,736	1,251	46%
Huntington Station, NY	2,261	369	16%
New York, NY	1,755	435	25%
Jamaica, NY	1,261	791	63%
Scarsdale, NY	943	187	20%
Berwyn, IL	933	129	14%
Philadelphia, PA	833	472	57%
Passaic, NJ	790	698	88%
Houston, TX	786	840	107%
Miami, FL	700	946	135%
San Francisco, CA	674	223	33%
Hileah, FL	580	684	118%
Parkville, MD	571	200	35%
Gainesville, FL	543	52	10%
Yonkers, NY	539	114	21%
Oviedo, FL	539	150	28%
Hempstead, NY	523	195	37%
Total	27,601	10,284	

• Comparing the number of unique patients diagnosed by city and the estimated number of foreign-born HDV patients in that city, it is possible to identify cities where HDV may be underdiagnosed.