Effectiveness Of Hepatitis C Virus Screening Laws in the United States: Evidence From Paid Claims Data From 2010 To 2016

THU-113

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BACKGROUND

- With the availability of curative therapies, the World Health Organization [WHO] has set the goal of having 90% of the world's population screened for chronic hepatitis C virus (HCV) infection by 2030 to attain elimination.[1]
- The Centers for Disease Control (and Prevention (CDC) estimate the prevalence of HCV in the United States (US) to be 1.3% (1.2%–2.4%), which translates into an estimated 2.7–3.9 million chronically infected individuals.[2]
- In 1998, CDC recommended a risk-based screening strategy for HCV[3] to identify all exposed patients. However, studies have estimated that screening based on behavioral risk factors has missed between 49%–75% of total HCV infections.[4]
- In 2012, CDC recommended a one-time screening of all baby boomers,[3,5] but current estimates suggest that only 10–50 % of HCV-infected patients in the US are diagnosed.[6]
- Starting from 2014,[5] states have implemented policies which require all primary care and nurse practitioners to offer HCV screening for baby boomers (i.e. California [CA], Colorado [CO], Connecticut [CN], Massachusetts [MA], and New York [NY]) (Table 1).
- An initial analysis of this policy change in NY revealed a 51% increase in HCV screening tests performed one year after the law was enacted.[7]
- However, the number of undiagnosed patients remains a concern in order to meet HCV elimination goals especially in states that did not adopt screening policies, raising questions on the need and effectiveness of HCV screening programs for the general population.

OBJECTIVES

- Assess the effectiveness of screening laws in CA, CO, CN, MA and NY for increasing HCV antibody (AB) screening.
- Project the progress and timeline of all US states to achieve the WHO screening target for HCV elimination.

METHODS

Data source and inclusion criteria:

- Claims data for 2010–2016 from Optum Clinformatics® Data Mart, a de-identified claims database from the US. Novel DAAs became available in 2014.
- Patients were required to be at least 20 years at index date and have at least 6 months of continuous enrollment pre-index.

Screened cohort

- HCV screening was identified by paid claims for Current Procedural Terminology (CPT) codes 86803, 86804, or G0742.
- The date of first HCV screening was defined as the index date.
- Screened patients having a diagnosis of HCV during the pre-index period were excluded from the analysis.

Unscreened cohort

- A cohort of unscreened patients was created using a randomly selected pool of patients without an HCV AB test.
- A random date was selected as the index date for these patients.

METHODS (Continued)

Analytical method:

- Logistic regression models were used to estimate the likelihood of being screened, controlling for patient demographic and clinical characteristics (Table 2).
  - Three time periods [2010; 2011–13 and 2014–16] were used to measure the effect on screening of the availability of interferon (INF)-free treatments post 2014.
  - Variables identifying states with screening policies were entered as interaction terms with the 2014–2016 time period to test if new screening policies enhanced screening rates, beyond the availability of newer INF-free treatments.
- Further, the proportion of the population screened in each state was extrapolated to 2050 using each state's average screening rates during 2014–16 and applied to an assumed baseline diagnosis rate of 50%.

Table 1: Summary of HCV Screening Laws by State

State	Year	Screening Law
New York	2013	Requires the offering of hepatitis C screening for anyone born between 1945 and 1965 receiving services as an in-patient, outpatient, or emergency room hospital setting. Allows for exceptions in emergency situations or if the person has already been tested and/or cannot give consent.
	2014	Allows nurse practitioners and physicians to issue non-patient specific order to administer hepatitis C tests.
Massachusetts	2014	Requires primary care providers to offer hepatitis C screenings to people born between 1945–1965.
Connecticut	2014	Requires primary care providers to offer hepatitis C screenings to people born between 1945–1965.
Colorado	2014	Recommends that health care providers offer hepatitis C screenings to people born between 1945–1965.
California	2014	Allows for up to four public health demonstration projects for innovative, evidence-based approaches to provide outreach, HIV and hepatitis C screenings, and linkage to, and retention in, quality health care for the most vulnerable and underserved individuals with a high risk for HIV infection.

RESULTS – Descriptive Statistics

- A total of 1,056,583 patients received HCV AB screening and 1,243,581 randomly selected unscreened patients met the pre-defined selection criteria.
- In the subsample of 254,450 screened patients with a liver fibrosis measure, 97% were non-cirrhotic with fibrosis stage F0–F2 (Table 2).
- The demographic characteristics of screened and unscreened were similar with some notable exceptions.
- Screened patients were more likely to be female, consumed more health care per month prior to their screening date, and had a higher risk of comorbidities related to HCV such as cardiovascular disease, type 2 diabetes mellitus, nephritis, chronic kidney disease, fatigue and depression; hepatic comorbidities like cirrhosis and hepatic compensation; and coinfections like HIV and HBV.

RESULTS – Descriptive Statistics (Continued)

Table 2: Patient Characteristics at Baseline

	Not screened	Screened						
	Total	Total	NY	MA	CT	CO	CA	Other states
Sample Size [N]	1,243,581	1,056,583	91,636	11,438	11,965	34,751	67,784	839,009
Age [mean]	46.5	46.3	47.2	52.1	54.3	41.6	43.4	46.4
Baby boomer population[a]	35.5%	34.7%	26.74%	34.41%	37.92%	29.90%	29.07%	36.24%
Gender: Female[b]	51.3%	61.9%	56.64%	55.13%	56.70%	66.29%	57.06%	62.84%
Race								
Asian	3.7%	6.6%	14.88%	8.30%	5.51%	3.42%	19.64%	5.19%
Black	7.3%	11.5%	10.57%	4.99%	8.28%	3.48%	2.99%	13.62%
Hispanic	9.5%	11.5%	13.21%	13.37%	12.91%	11.50%	17.15%	11.65%
White	58.8%	59.7%	54.67%	68.05%	67.44%	76.31%	53.42%	64.52%
Unknown	4.6%	5.0%	6.68%	5.29%	5.86%	5.28%	6.80%	5.02%
Missing	16.1%	5.8%						
Medical cost prior 6 mos.	$4,674.87	$6,173.49	$5,563.60	$6,258.13	$8,023.55	$4,434.55	$4,395.13	$6,418.80
Pharmacy cost prior 6 mos.	$938.19	$2,768.99	$2,773.29	$2,479.23	$3,979.14	$2,254.96	$1,894.76	$2,847.14
Visits per month	2.74	2.01	2.49	2.17	2.65	1.46	1.71	1.98
FIB-4 Data for Sub-Sample with Laboratory Data								
FIB 4 Sample Size		254,450						
Mean FIB - 4 score		1.13	1.18	1.37	1.45	1.02	1.08	1.12
F0–F1	-	80.5%	75.51%	69.59%	68.06%	85.43%	83.30%	80.79%
F2	-	16.6%	21.61%	25.11%	25.79%	12.41%	14.02%	16.25%
F3–F4	-	2.9%	2.88%	5.30%	6.16%	2.15%	2.67%	2.96%
	Total	Total	NY	MA	CT	CO	CA	Other States
Sample Size [N]	1,243,581	1,056,583	91,636	11,438	11,965	34,751	67,784	839,009
Comorbidities	46.5	46.3	47.2	52.1	54.3	41.6	43.4	46.4
Cardiovascular disease	4.0%	6.9%	8.21%	8.76%	10.70%	3.71%	3.40%	7.15%
Type 2 diabetes mellitus	5.5%	12.9%	16.50%	17.04%	19.79%	5.53%	7.87%	13.12%
Nephritis, nephrotic syndrome, nephrosis	1.0%	3.2%	2.31%	4.24%	4.74%	2.03%	1.54%	3.46%
Chronic kidney disease	0.7%	2.9%	2.29%	3.39%	3.76%	1.71%	1.27%	3.16%
Inflammatory bowel disease	0.8%	1.3%	1.50%	1.27%	1.79%	1.06%	1.05%	1.34%
Fatigue	1.2%	3.6%	3.75%	2.40%	3.83%	2.38%	2.35%	3.79%
Fibromyalgia	2.3%	4.7%	3.81%	3.72%	4.74%	3.97%	3.79%	4.90%
Depression	3.9%	6.6%	5.63%	8.83%	7.99%	6.77%	4.27%	6.89%
Gastroesophageal reflux disease	5.1%	8.4%	7.64%	9.44%	10.09%	5.73%	4.76%	8.86%
Mixed cryoglobulinemia	0.0%	0.0%	0.05%	0.09%	0.09%	0.01%	0.03%	0.02%
Cirrhosis	0.3%	1.2%	0.93%	1.70%	1.76%	0.71%	0.66%	1.25%
Hepatic compensation	0.4%	1.5%	1.23%	2.22%	2.26%	0.97%	0.89%	1.62%
Obesity	3.6%	6.8%	5.97%	8.52%	7.77%	4.45%	5.13%	7.14%
Coronary arterial disease	1.2%	2.2%	2.24%	2.75%	3.03%	0.94%	0.77%	2.33%
Cardiac arrest	0.1%	0.1%	0.04%	0.05%	0.09%	0.03%	0.03%	0.08%
HIV	0.3%	5.5%	9.89%	3.56%	3.27%	4.50%	4.74%	5.19%
HBV	0.1%	0.7%	1.51%	0.52%	0.57%	0.21%	1.00%	0.55%

[a]Rest of the proportion represents non-baby-boomer population; [b]Rest of the proportion represents male population; The 5 states represent the only states that passed HCV screening laws in the US after 2013.

RESULTS – Logistic Regression

- The availability of INF-free treatments post 2014 was associated with increased odds of receiving screening relative to 2010 (odds ratio [OR]: 1.193; p < 0.0001) (Table 3).
- Residing in states that passed screening law post 2014 further increased the odds of getting screened (OR: 1.064; p < 0.0001)
- Other factors that increased the odds of HCV screening were female gender, Medicare enrollment and presence of comorbidities like chronic kidney disease, mixed cryoglobulinemia, type 2 diabetes mellitus and coinfection with HIV or HBV.
- Compared to states that did not pass screening laws, MA (OR: 1.26; p < 0.0001) and CT (OR: 1.19; p < 0.0001) had significantly higher odds of HCV screening but policies in NY, CA and CO had no significant effect.

RESULTS – Logistic Regression (Continued)

Table 3: Factors Driving HCV Antibody Screening

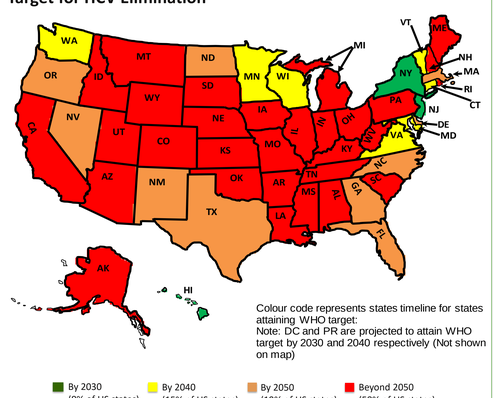
Effect	Odds ratio
Comorbidities	
Cardiovascular disease	0.912*
Type 2 diabetes mellitus	1.283*
Insulin resistance	0.778*
Nephritis, nephrotic syndrome, nephrosis	2.522*
Chronic kidney disease	3.194*
Mixed Cryoglobulinemia	2.604*
Cirrhosis	1.16**
Hepatic compensation	2.791*
HIV	8.364*
HBV	4.486*
Gender (Ref: Male)	
Female	1.806*
Time (Ref: 2010)	
2011–2013	1.012**
≥2014	1.193*
Interaction between ≥2014 and states with law change	1.064*
Race (Ref: White)	
Asian	1.364*
Black	1.248*
Hispanic	1.025*
Unknown	1.128*

*Represents statistical significance at alpha = 0.001; **Represents statistical significance at alpha = 0.05; N = 1,056,583

RESULTS – Antibody Screening Projections

- Figure 1 assesses the progress and timeline for US states to meet the WHO screening target for HCV elimination.
- Only 8% of states in the US are on track to reach the WHO target by 2030: NY (only state on track that passed HCV screening laws), Hawaii, New Jersey and Washington DC.
- Seven states (15% of total) are on track to reach WHO goals by 2040 (including CT which passed screening laws).
- 10 other states (19% of total) were projected to attain 90% diagnosis by 2050, and 29 states (58% of total) were not projected to attain this HCV screening target by 2050.

Figure 1. Timeline for US States to Achieve the WHO Screening Target for HCV Elimination



DISCUSSION

- At the currently observed HCV screening rates, 92% of states in the US are not on target to meet WHO screening goals for HCV elimination.
- These findings are consistent with a recent study suggesting that US the will not meet the WHO goals for HCV elimination by 2030 unless comprehensive policies for screening, diagnosis, linkage to care and treatment are put in place.[8]
- HCV screening based on well-documented risk factors might improve system performance

LIMITATIONS

- The inclusion criteria rely heavily on accurate identification of CPT and ICD-9 codes, which have well known limitations.
- It is possible that not every AB lab was captured and therefore there may have been patients whose first documented positive AB test was prior to 2010. We attempted to minimize this possibility by excluding patients who had a hepatitis C ICD-9 or detectable viral load documented prior to their first positive AB test.
- To assess progress towards the WHO screening goal, a baseline diagnosis rate of 50% was assumed across all states and future diagnosis was linearly extrapolated. Actual diagnosis rates may vary considerably by state and may not evolve linearly.
- This study used only data from a single large commercial payer, and thus the results may not be generalizable to other health systems or populations.

CONCLUSIONS

- The availability of curative therapies has increased the likelihood of HCV screening.
- New HCV screening laws were associated with increased HCV antibody testing.
- However, comprehensive efforts are required to attain WHO screening goals for HCV elimination, since more than 90% of states in the US are not on track to reach them by 2030.

DISCLOSURES AND CONFLICTS OF INTEREST

- Design and study conduct for the study was approved by AbbVie, Inc. AbbVie Inc. participated in the interpretation of data, and review and approval of the abstract. All authors contributed to the development of the publication and maintained control over the final content.
- Darshan Mehta: Financially supported for graduate research work by Abbvie Inc. as a part of fellowship agreement between AbbVie Inc. and University of Southern California (USC).
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- Steven Marx and Yuri Sanchez Gonzalez are employees of AbbVie Inc. and may own stocks and/or options of the company.
- Sammy Saab: Consultant to and serves on speaker bureau for AbbVie, BMS, Gilead, Janssen, Merck

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