National Estimates for HCV Screening and Diagnosis Rates in the United States (2013-2016) Based on a Large Real-World Dataset

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INTRODUCTION

- Current estimates suggest that while the combination of risk-based and age-based (birth cohort) screening for Hepatitis C virus (HCV), as recommended by both the U.S. Center for Disease Control and the U.S. Preventative Services Task Force, has improved screening rates among baby boomers and higher risk patients, screening rates remain low.[1-3]
- Low screening rates are a primary barrier to linkage to effective and tolerable treatments for HCV, including direct acting antivirals, which have substantially improved outcomes among infected patients.[3-5]
- Nationally representative and system-specific screening estimates have been published; however, data on HCV screening and RNA confirmatory testing are limited, particularly on the state-level.[3,6-8]
- A better understanding of barriers to HCV screening and diagnosis is needed to achieve elimination of HCV.

OBJECTIVE

- Identify and describe gaps in national HCV screening and diagnosis in the United States by year (2013-2016), age group, and by state.

METHODS

- The study used a comprehensive dataset derived by combining clinical tests results and characteristics on 17,149,480 unique patients from 2 large national laboratory companies, as described in previous literature.[9]
- Active HCV infection was defined as having a positive HCV RNA test (RNA+) after a positive antibody (AB+) test. AB screening rates, AB+ rates, RNA follow-up testing rates, and RNA+ rates were assessed descriptively over the four years spanning 2013-2016.
- Given the evolving disease epidemiology with the influx of young newly infected people, the analysis was stratified by two age cohorts: baby boomers 48-71 years old and young adults 18-39 years old.
- The rate of AB screened, AB+, RNA tested, and RNA+ per 1000 residents was calculated for each state (using Census data) and presented for 2016 as the most recent year of data availability.

RESULTS

- The number of persons screened per year steadily increased without decline in the overall proportion of AB+ from 4,079,551 in 2013 (5.3% AB+) to 5,152,475 in 2016 (5.6% AB+) **(Figure 1)**.
- Similarly, the absolute number of persons who were AB+, RNA tested, and RNA positive also increased over time, among baby boomers and young adults **(Figure 2)**.
- Among the older cohort of baby boomers, AB+ rates declined (9.1-8.1%) between 2013-2016 whereas among younger adults AB+ rates increased (2.8-3.9%).
- Trends were similar by gender as well over 2013-2016:
  - Among baby boomers, AB+ rates decreased for males (12.2-11.0%) and females (6.4-5.7%)
  - Among baby boomers, AB+ rates increased males (4.1-5.6%) and females (2.2-3.0%).
- Among AB+ persons, the rate of confirmatory RNA testing increased every year from 45.0% in 2013 to 76.5% in 2016 **(Figure 1)**.
- The number of persons with detected active infection (RNA+ post AB+ test) increased from 28,139 in 2013 to 67,223 in 2016 for baby boomers and from 10,794 to 42,263 for young adults. 525,426 patients had HCV RNA+ test and no previous HCV AB test over 2013-2016.

RESULTS CONTINUED

Figure 1. Number of People Screened and Diagnosed from 2013 through 2016 in the United States

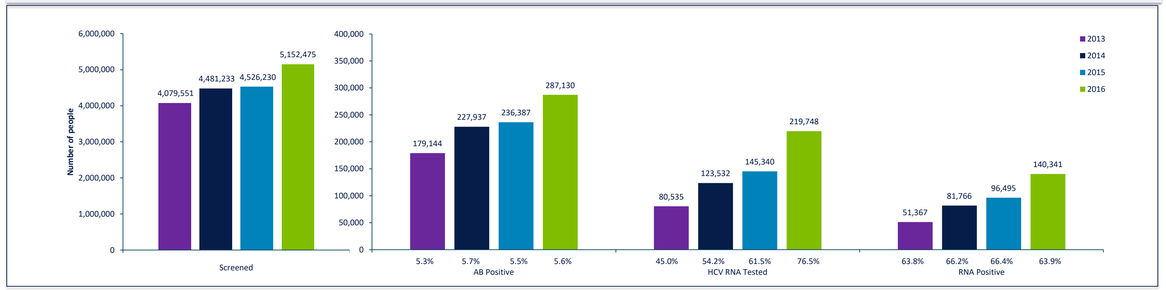
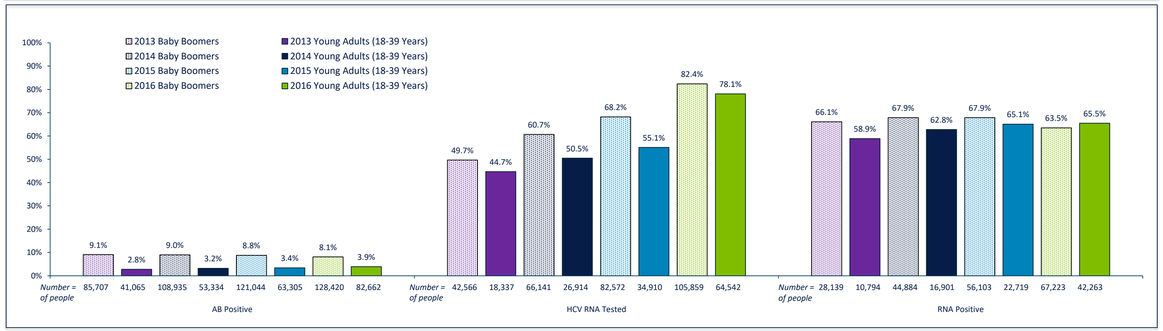


Figure 2. Percentage Antibody Positive, HCV RNA Tested, and RNA Positive 2013-2016 by Age Cohort



- For states that implemented new screening policies, the screening rate per 1000 residents increased for Massachusetts from 9.1 in 2013 to 17.1 in 2016, Colorado (from 10.9 to 12.3), California (from 12.7 to18.4), Connecticut (from 16.8 to 28.0), New York (from 20.1 to 23.9) **(Table 1)**.

Table 1. Screening Rates by States in 2016 per 1000 residents

State Name	Rate of AB Screened	Rate of AB Positive	Rate of HCV RNA Tested	Rate of RNA Positive
Alaska	13.0	0.78	0.65	0.43
Alabama	9.7	0.75	0.54	0.38
Arkansas	9.1	0.83	0.67	0.47
Arizona	6.3	0.34	0.23	0.16
California	18.4	1.10	1.02	0.65
Colorado	12.3	0.60	0.48	0.30
Connecticut	27.8	1.33	1.30	0.71
D.C.	35.8	1.71	1.37	0.99
Delaware	18.3	1.21	0.66	0.44
Florida	30.8	1.38	1.22	0.74
Georgia	16.1	0.59	0.47	0.28
Hawaii	0.2	0.01	0.00	0.00
Iowa	3.1	0.18	0.15	0.10
Idaho	3.7	0.18	0.13	0.09
Illinois	10.4	0.39	0.32	0.19
Indiana	4.2	0.33	0.23	0.16
Kansas	9.0	0.36	0.27	0.17
Kentucky	17.1	2.08	1.50	1.10
Louisiana	13.1	1.05	0.71	0.49
Maryland	26.9	1.32	1.08	0.69
Maine	4.8	0.21	0.18	0.11
Massachusetts	17.1	1.18	1.14	0.73
Michigan	5.1	0.34	0.30	0.20
Minnesota	3.2	0.11	0.09	0.05
Missouri	11.5	0.66	0.55	0.34
Mississippi	5.6	0.41	0.27	0.17
Montana	3.5	0.30	0.23	0.15

State Name	Rate of AB Screened	Rate of AB Positive	Rate of HCV RNA Tested	Rate of RNA Positive
North Carolina	9.7	0.58	0.38	0.27
North Dakota	0.8	0.04	0.03	0.02
Nebraska	2.2	0.13	0.11	0.08
Nevada	23.2	1.16	1.04	0.62
New Hampshire	9.3	0.57	0.44	0.28
New Jersey	21.9	0.84	0.64	0.39
New Mexico	7.6	0.64	0.52	0.35
New York	23.9	0.83	0.56	0.29
Ohio	7.2	1.08	0.77	0.58
Oklahoma	4.1	0.32	0.22	0.15
Oregon	6.2	0.46	0.39	0.25
Pennsylvania	17.0	0.93	0.72	0.46
Puerto Rico	0.2	0.01	0.00	0.00
Rhode Island	5.0	0.18	0.15	0.07
South Carolina	10.3	0.57	0.40	0.28
South Dakota	1.6	0.07	0.05	0.03
Tennessee	12.5	1.04	0.76	0.51
Texas	15.2	0.72	0.58	0.36
Utah	5.6	0.30	0.23	0.14
Virginia	13.6	0.46	0.31	0.19
Vermont	4.5	0.38	0.34	0.24
Washington	7.0	0.41	0.32	0.21
Wisconsin	1.9	0.10	0.07	0.05
West Virginia	13.1	1.76	1.22	0.89
Wyoming	3.5	0.16	0.11	0.06
States Mean	10.83	0.64	0.50	0.33
States Median	9.20	0.57	0.40	0.28

Rates were calculated using state-specific 2016 population from www.census.gov as denominator.

DISCUSSION

- The number of persons screened for HCV antibody have increased over the four year period with a corresponding increase in confirmatory HCV RNA testing, which may be due to the introduction of reflex RNA testing.
  - The net result is in an increase in the number of HCV RNA positive.
- Among those screened, the RNA+ hit rate increased on an annual basis with 1.2% for 2013, 1.8% for 2014, 2.1% for 2015, and 2.7% for 2016; this may be reflective of more targeted screening of at risk populations.
- This observation supports the need for further efforts to increase screening in order to reach the World Health Organization goal of eliminating HCV by 2030.
- Despite CDC recommendation for a universal one time screening for all baby boomers, screening rates of young adults have outpaced that of baby boomers year-over-year.

LIMITATIONS

- There is a chance that a patient may appear in both laboratory datasets.
- Patients identified as HCV AB positive in 2016 may not have had enough follow up time for HCV RNA test.
- Patients may have been HCV screened or tested prior to 2013.
- Patients of certain states were of small sample size resulting in wide confidence intervals for the estimate of proportion treated.
- State-specific screening rates are dependent on study data from the two merged laboratory datasets; other laboratory services not covered by the dataset may be more prevalent in any given state.

CONCLUSION

- This is the largest study assessing real-world HCV screening practices in the US from 2013 through 2016.
- While rates of HCV AB screening and confirmatory RNA testing are improving, results from this study confirm a rising HCV epidemic among young adults.
- Revisions to the current recommendations for HCV AB screening should be considered to improve detection of active HCV among younger persons for whom risk behaviors (such as injection drug use) may not be reported due to stigma.
- HCV reactivity rates among baby boomers suggest that baby boomers at risk for cirrhosis remain an important reservoir of undiagnosed HCV infection in the US.

DISCLOSURES

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  - Mark Sulkowski reports grants from AbbVie, Assembly Bioscience, Gilead, Proteus Digital Health, and the National Institutes of Health and personal fees from AbbVie, Gilead, and Merck.
  - Steve Marx, Shivaji Manthena, and John Strezewski are employees of AbbVie and may own AbbVie and/or Abbott stock.
  - Viktor Chirikov is an employee of Pharmerit International and has received funding from AbbVie to conduct this research.
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