

Hepatitis C Antibody Screening in a Retail Pharmacy Setting: Local Testing and Linkage to Care via an HCV Management Specialist

Kugelmas, Marcelo^{1, 2}; Pedicone, Lisa³; Lio, Idania³; Simon, Susan⁴; Pietrandoni, Glen⁵

¹South Denver Gastroenterology P.C., Englewood, CO. ²Chronic Liver Disease Foundation, Clark, NJ. ³Cantara Clinical Solutions, Morristown, NJ. ⁴Hepatitis C Association, Scotch Plains, NJ. ⁵Walgreen Co., Deerfield, IL.

Background

- 3.5 million (range 2.5-4.7 million) individuals are estimated to be infected with hepatitis C (Edlin et al., 2015).
- Up until 2012, screening guidelines recommended HCV antibody screening of individuals who had identifiable risk factors (e.g., history of injection drug use, hemodialysis).
- Epidemiology data noted that an estimated 75-80% of persons with chronic hepatitis C were born between 1945 and 1965.
- In 2012, the Centers for Disease Control and Prevention (CDC) and the US Preventive Services Task Force (USPSTF) recommended that all individuals born between 1945 and 1965 receive a one time screening for hepatitis C.

Rationale

- All individuals recommended for HCV testing should first be tested for HCV antibody (anti-HCV) (CDC, 2013).
- FDA-approved tests include
 - Lab-based assays (requires test ordered by healthcare provider)
 - Point-of-care assay (OraQuick HCV Rapid Antibody Test, OraSure Technologies)
- Point-of-care testing can increase the number of individuals diagnosed; however, linkage to care is a major challenge and is essential to improve patient outcomes.

Primary Objective

- Identify the prevalence of hepatitis C using birth cohort and high risk factors screening at a retail pharmacy and to link hepatitis C (HCV) antibody positive individuals with a pathway to care.

Methods

Consortium of Partners: Maximizing Pathway to Care



Locations of Participating Cities



Patient Population

- Males and females within the birth cohort (born between 1945–1965, inclusive), or if outside the birth cohort window, at least 18 years of age with CDC defined high risk factors for chronic hepatitis C.
- Willingness to give written informed consent*.
- Willingness to provide an email address and a telephone number for communication of test result.
- Ability to read and understand English.

* Protocol and informed consent were approved by central IRB.

Site Location

- Walgreens stores located within lower income areas of major metropolitan cities.
- Each participating store had a private room for testing.
- Each market had 5 stores and testing was performed at each store 1x/week (1 phlebotomist assigned per market).
- Individuals were recruited by direct advertising at each store.

Study Entry Assessment

- Interested individual provided with informed consent and CDC defined risk factors literature or pamphlet.
- If individual interested and qualified, phlebotomist (Maxim staff who was trained on the protocol and administering informed consent) obtained informed consent.
- Individual completed screening form.
- Phlebotomist provided the individual with an instruction sheet to wait for an email from CLDF or a call from the HCV Management Specialist (help4hep.org).

Antibody Testing Procedure

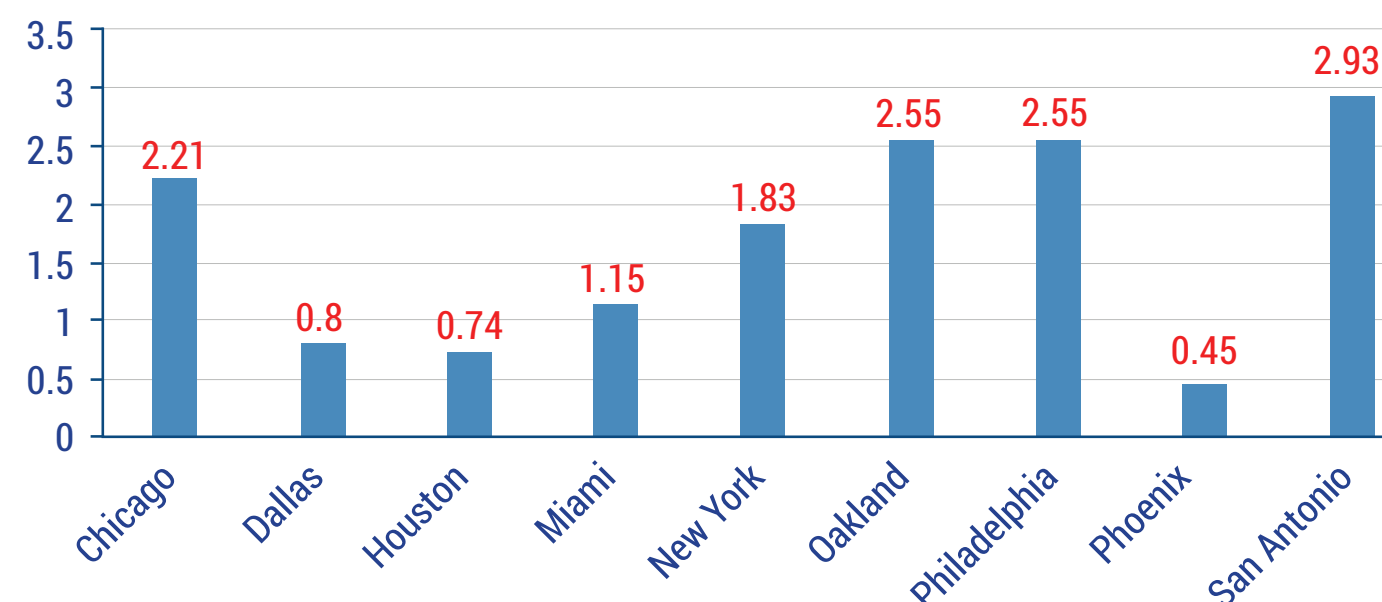
- Each participating Walgreens was provided with
 - OraQuick HCV Rapid Antibody Test kits
 - Positive and negative controls
 - Ancillary supplies (lancets, gloves, BandAids, etc)
- Prior to testing, each phlebotomist received personal training on administration of antibody test and interpretation of the results.
- Phlebotomist entered individual's information, including OraQuick result, into electronic database (Part 11 compliant) on the same day of testing.

Results

Individuals Screened Per City

Screening Location	First Site Opened	Last Site Closed	# Days Open (Excluding Weekends/Holidays)	# Individuals Screened
Chicago, IL	20 OCT 15	5 FEB 16	75	166
Dallas, TX	15 OCT 15	11 DEC 15	41	33
Houston, TX	22 SEP 15	22 JAN 16	85	63
Miami, FL	1 OCT 15	5 FEB 16	88	101
New York, NY	16 SEP 15	5 FEB 16	100	183
Oakland, CA	28 SEP 15	5 FEB 16	91	232
Philadelphia, PA	15 SEP 15	5 FEB 16	100	255
Phoenix, AZ	22 SEP 15	11 DEC 15	58	26
San Antonio, TX	13 OCT 15	5 FEB 16	81	237
Total				1296

Number of Individuals Screened/Day Per City



Communication of OraQuick Antibody Results

NEGATIVE

- Within 3 business days, individual received email with test result and participation was considered complete.
- If email was undeliverable or not provided, individual was contacted by telephone by the HCV Management Specialist.

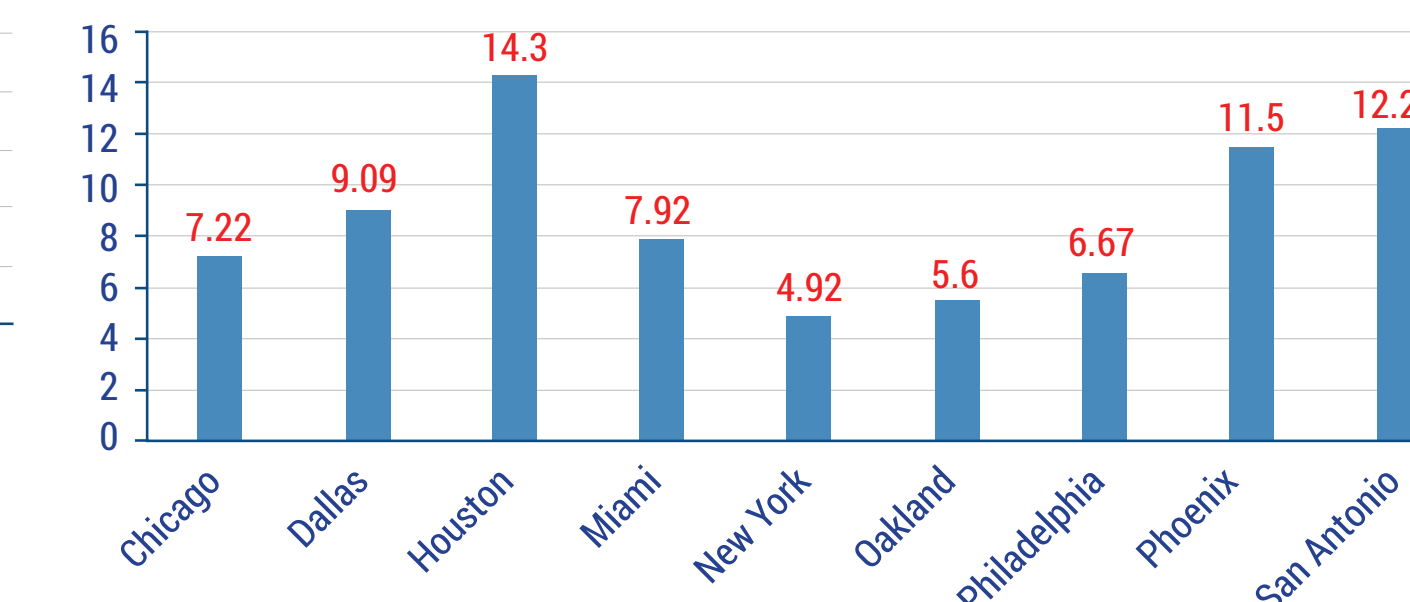
POSITIVE

- Within 3 business days, individual was contacted by HCV Management Specialist via telephone.
- HCV Management Specialist provided
 - Positive test result
 - Explanation of the test result
 - Information for a pathway to care for follow up testing and education
- HCV Management Specialist followed up with individual 21-28 days after initial contact.
- At least 3 attempts were made to contact each individual.

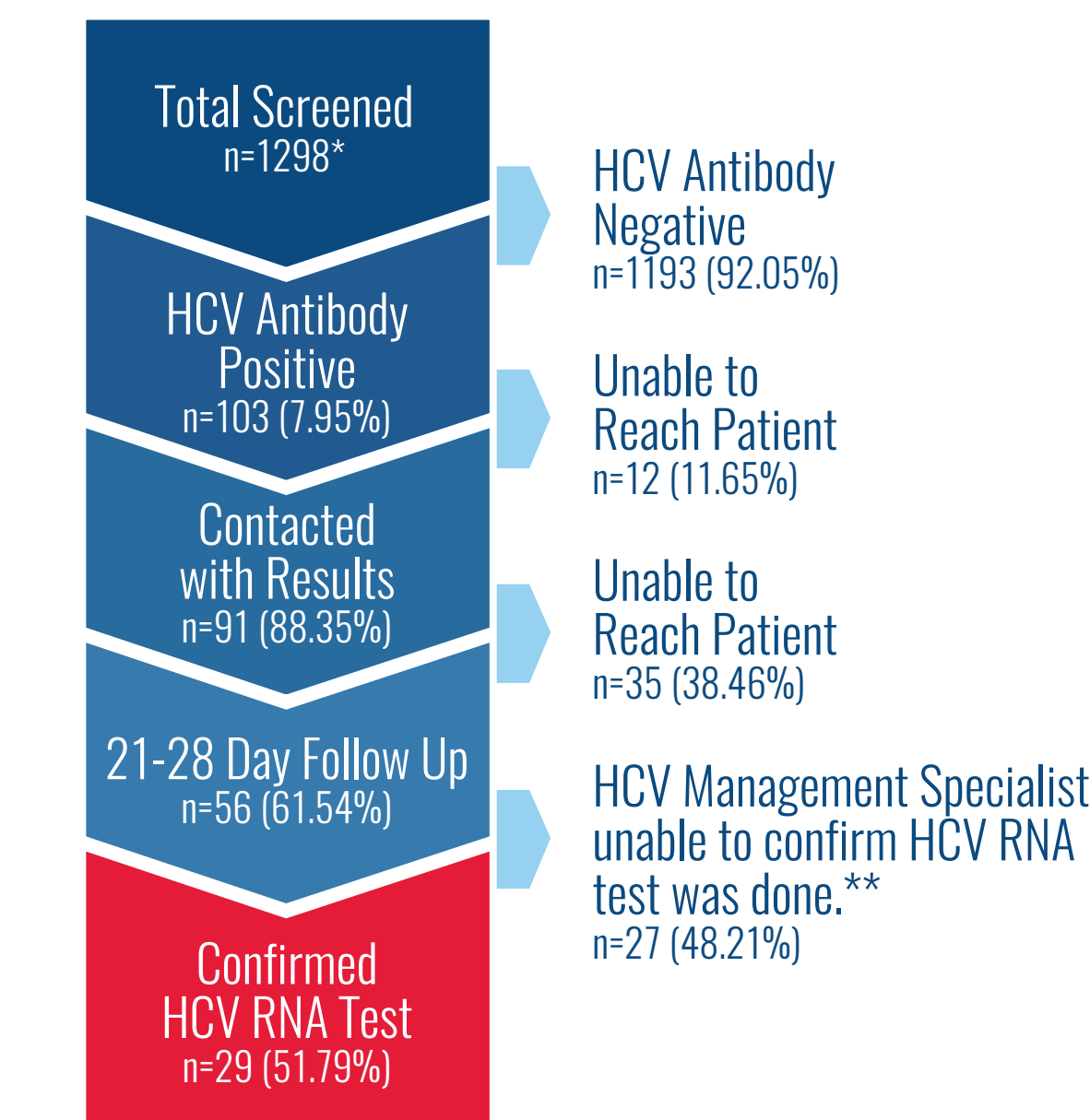
Individuals Testing HCV Antibody Positive/City

Screening Location	# Individuals Screened	# Individuals Antibody Positive
Chicago, IL	166	12
Dallas, TX	33	3
Houston, TX	63	9
Miami, FL	101	8
New York, NY	183	9
Oakland, CA	232	13
Philadelphia, PA	255	17
Phoenix, AZ	26	3
San Antonio, TX	237	29
Total	1296	103

Percentage of Screened Individuals Testing Antibody Positive/City



Testing and Pathway to Care



**2 individuals signed informed consent, were tested and subsequently withdrew consent. **Individual unreachable after 3 attempts, did not want to get confirmatory test or was planning on having HCV RNA done but had not done so yet.

Summary

- 7.95% of individuals tested in retail pharmacies located in lower income neighborhoods tested HCV antibody positive.
- Of those testing positive, 88.35% received their test results from the HCV Management Specialist.
- Of those who received their positive test results, 61.54% had a follow up call with the HCV Management Specialist.
- Overall, the HCV Management Specialist was able to confirm 28% (29/103) of HCV antibody positive patients had confirmatory HCV RNA testing.

Conclusions

- Screening of HCV exposure in high risk individuals using point of care technology is effective.
- Screening of HCV exposure in high risk individuals at a retail pharmacy setting is effective.
- Targeted screening identifies individuals with high likelihood of having been exposed to the Hepatitis C virus.
- The HCV Management Specialist was able to link 51.79% of contacted individuals to confirmatory testing.
- Other barriers to link individuals to care need further exploration and creative solutions.

Disclosures

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