

UNRECOGNIZED CHRONIC HEPATITIS C VIRUS INFECTION AMONG BABY BOOMERS IN THE EMERGENCY DEPARTMENT

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Abbreviations: HCV = hepatitis C virus, ED = emergency department, EHR = electronic health record

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ABSTRACT

The Centers for Disease Control and Prevention and United States Preventive Services Task Force have highlighted public screening as an essential strategy for increasing hepatitis C virus (HCV) detection in persons born between 1945 and 1965 (“baby boomers”). As prior HCV screening efforts have not targeted Emergency Department (ED) baby boomer patients, we describe early experience with integrated opt-out HCV antibody screening of medically stable “baby boomers” presenting to an urban academic ED. We performed HCV antibody testing 24 hours per day and confirmed positive test results using PCR. The primary outcome was prevalence of unrecognized HCV infection. Among 2,325 unique HCV-unaware baby boomers, 289 (12.7%) opted-out of HCV screening. We performed HCV-antibody tests on 1,529 individuals, of which 170 (11.1%) were reactive. Among antibody reactive cases, follow-up PCR was performed on 150 (88.2%), of which 102 (68.0%) were confirmed RNA-positive. HCV antibody reactivity was more likely in males compared to females (14.7% vs. 7.4%, $p < 0.001$), African Americans compared to whites (13.3% vs. 8.8%, $p = 0.010$), and underinsured/ uninsured patients compared to insured patients (16.8%/ 16.9% vs. 5.0%, $p = 0.001$). Linkage-to-care service activities were recorded for 100 of the 102 confirmed cases. Overall, 54 (54%) RNA-positive individuals were successfully contacted by phone within five call back attempts. We confirmed initial follow-up appointments for 38 (70.4%) RNA-positive individuals successfully contacted, and 21 (55.3%) individuals with confirmed appointments attended their initial visit with a liver specialist; three (7.9%) are awaiting an upcoming scheduled appointment.

Conclusion: We observed high prevalence of unrecognized chronic HCV infection in this

series of baby boomers presenting to the ED highlighting the ED as an important venue for high-impact HCV screening and linkage to care.

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INTRODUCTION

Chronic hepatitis C virus (HCV) infection is an urgent public health challenge in the United States (US), affecting an estimated 5.2 million individuals.(1) Sequelae of untreated chronic HCV infection such as cirrhosis and hepatocellular carcinoma are common (2-30%), and rates of these complications are expected to rise.(2, 3) A recent surge in the number of highly effective direct acting agents has transformed the care of HCV infection, highlighting the urgency of identifying persons with this condition.(4, 5)

Due to the expansion of illicit drug use and contaminated transfusions that occurred in the 1970s and 1980s, HCV infection is particularly prevalent in the “baby boomer” population (those born between 1945 and 1965). Prior studies estimate that 3.3% of baby boomers are HCV-antibody positive, and this birth cohort accounts for up to 75% of all US HCV infections.(6) However, 43-85% of baby boomers are unaware of their HCV infection status.(7-9) For these reasons, the Centers for Disease Control and Prevention (CDC) and the United States Preventive Services Task Force (USPSTF) have highlighted public screening as an essential strategy for increasing HCV detection in this cohort.(6)

The Emergency Department (ED) offers a unique setting to test this recently endorsed HCV screening strategy. The National Health and Nutrition Examination Survey (NHANES) suggests that HCV-infected individuals are more likely to use the ED for care than any other healthcare venue.(10) Populations that are frequent users of ED care (minorities, Medicaid recipients, and uninsured/underinsured individuals) are also known to be disproportionately affected by HCV infection.(11) While prior studies estimate high rates of

HCV antibody prevalence (4-18%) in the general ED population, there have been no systematic efforts to screen ED baby boomer patients for HCV.(12-14)

We describe our early experience with an integrated, opt-out HCV screening and linkage to care program of baby boomers in an urban academic ED.

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METHODS

Study Design

We performed a cross-sectional study involving patients born between 1945 and 1965 presenting to the ED of University of Alabama at Birmingham (UAB) Hospital, Birmingham, Alabama, from September through November 2013. The Institutional Review Board of the University of Alabama at Birmingham approved the study.

Setting

UAB Hospital is an urban academic 1,000-bed tertiary care center serving the greater Alabama region. The UAB Hospital Emergency Department is a Level I trauma center and provides care for approximately 65,000 visits per year, including approximately 12,500 unique baby boomers. A high proportion of individuals served by UAB represent racial and ethnic minorities and the uninsured, not dissimilar from many US urban academic EDs. Seventeen percent (17%) of the UED's unique "baby boomer" population is uninsured, 24% receive Medicare benefits, 11% have Medicaid, and 3% are considered indigent. The ED laboratory staff is accredited by the College of American Pathologists (CAP), American Society for Clinical Pathology (ASCP) and the Clinical Laboratory Improvement Amendments (CLIA), with a monthly volume of 38,000 tests. Since 2011, the UED has conducted approximately 20,000 routine opt-out HIV screening tests annually with a seroprevalence of 0.5%.

Population

We offered opt-out screening to consecutive patients born between the years of 1945 and 1965 presenting to the ED for care, including prisoners and non-English speaking individuals. Patients excluded from HCV testing included (1) medically unstable cases, (2) those unable to complete the verbal HCV pre-screening questionnaire, (3) individuals that reported a known history of HCV-negative or HCV-positive status, and (4) individuals that left the ED prior to screening.

Opt-out HCV Screening

On September 3, 2013, the ED commenced opt-out HCV screening of baby boomer patients presenting to the ED for care. Opt-out HCV testing was conducted in consecutive patients utilizing a hybrid staffing model encompassing existing ED personnel with additional certified medical laboratory technician support. We conducted HCV screening as part of standard clinical care, and therefore the Institutional Review Board did not require informed consent.

ED nurses were trained to perform HCV screening by using a questionnaire embedded within the primary assessment section of the ED electronic health record system (EHR). Questions included: (1) "have you been tested for hepatitis C", and (2) if yes, "what was the result of the test?" For patients who had never been tested or who were unaware of their prior test results, the nurse delivered a statement informing the patient that one-time, free and confidential HCV-antibody testing would be performed unless the patient wished to

decline. For patients who did not decline, the EHR generated an automated order for the HCV-antibody test. HCV screening occurred 24 hours per day. No pre-test counseling was performed. Non-English speaking individuals were offered the HCV questionnaire through assistance of translation services.

ED laboratory personnel performed the HCV-antibody test using the Abbott ARCHITECT i1000 anti-HCV chemiluminescent assay, reporting results through the ED EHR system. The Abbott ARCHITECT instrument is random access with non-bracketed controls, which allows “on demand” HCV-antibody assay performance without the need for batching of samples. The mean elapsed time for HCV antibody assay results during the study period was 82 minutes; in comparison, the mean turnaround times for a complete blood count and urinalysis were 96 and 138 minutes respectively.

ED physicians informed individuals of HCV-antibody results. For HCV-positive cases, laboratory staff provided an informational packet for delivery by the physician to the patient. HCV “positive packets” contained information on HCV antibody testing, chronic HCV infection, and detailed instructions on the linkage to care process. The packet also included a brief counseling guide for physicians, as well as a form for collection of contact information from HCV-positive individuals. Risk reduction counseling including avoidance of alcohol and needle sharing. The information packet provided contact information for linkage to care specialists.

For instances of HCV-reactivity, the ED staff collected additional blood for PCR confirmation of HCV viremia and quantification of viral load. The hospital laboratory performed HCV viral load quantification without genotyping utilizing Roche Ampliprep for extraction and Roche TaqMan 48 for real time PCR. Mean processing time for HCV viral load quantification results during the study period was 2.1 days.

Linkage to HCV care

Our HCV screening program is supported by a dedicated linkage coordinator with Master's-level training in public health along with support from a part-time assistant. Both received HCV and linkage related training from experienced emergency medicine physicians, infectious disease specialists, medical social workers, and HIV linkage coordinators. Our linkage-to-care program is based on the successes and lessons learned from our HIV linkage model, which consistently links 80-85% of HIV+ cases to treatment and counseling services. After the ED visit, the linkage-to-care coordinator attempted to establish contact with all HCV antibody positive individuals by phone to deliver HCV confirmatory PCR test results, obtain further risk information, and assist with linkage to follow-up medical care with both a primary care physician and an HCV treatment center. For individuals who eloped from the ED prior to result counseling or who did not have an adequate PCR specimen obtained in the ED, the linkage coordinator established phone contact to provide counseling and coordination of PCR specimen collection. Individuals not successfully contacted within five callback attempts were mailed a letter informing them of their abnormal lab results and contact information to the linkage to care coordinator. The

coordinator scheduled HCV treatment center visits as a “next available” appointment. HCV treatment centers included the UAB Liver Center (hepatology) and UAB 1917 Liver Clinic (infectious diseases).

During follow-up phone interviews, the linkage coordinator collected additional clinical, social, and demographic details including prior HCV and HIV test dates and results, vaccination history, prior blood transfusions, past and current alcohol and injection drug use, transportation methods, current living arrangements, and employment status. Linkage-to-care data are recorded in a database and routinely updated by the linkage coordinator to track results of follow-up call attempts, pending or confirmed referrals, and overall linkage status.

Data Management and Statistical Analysis

The hospital EHR system (Cerner Millennium, Cerner, Inc. Kansas City, MO) stored all HCV screening questions and clinical results. Linkage to care and tracking data were collected and managed using REDCap electronic data capture tools hosted at the University of Alabama at Birmingham.⁽¹⁵⁾ REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for data downloads to common statistical packages; and 4) procedures for importing data from external sources.

We analyzed the data using descriptive statistics and logistic regression. We determined the numbers of screened and opt-out patients. We determined the proportion of screened patients with newly detected HCV infection, stratifying by sex, race and medical insurance status, assessing differences using Pearson Chi-square tests of association. We also determined the proportion of cases with HCV viremia confirmed by PCR.

Linkage-to-care outcomes included 1) call back success, 2) ability to schedule an HCV follow-up appointment, and 3) arrival at clinic for follow-up appointment. We stratified the linkage to care success by medical insurance status. We conducted all analyses using Stata v.12.2 (Stata Corporation, College Station TX).

RESULTS

From September 3 to November 19, 2013, there were 4,117 unique ED visits by individuals born between 1945 and 1965. Among 3,170 (77.0%) eligible for pre-screening, 2,323 were unaware of their HCV-status. Reasons for non-eligibility included self-reported known positive or negative HCV status and inability to complete the questionnaire. (Figure 1) Among the 2,323 patients eligible for HCV screening, 289 (12.7%) opted-out and 48 were not offered HCV testing. Of the 1,988 receiving automated HCV testing orders, 1,529 ultimately received HCV screening. A total of 459 (11%) eligible individuals did not have a test performed because they either left the ED before blood collection or did not have blood work performed as part of their ED diagnostics.

Among 1,529 tests, 170 were seropositive for HCV (11.1%; 95% CI 9.6-12.8). The rate of positive test results remained relatively constant over the eleven-week period. (Figure 2) Compared with privately insured patients, HCV-positive test rates were higher among individuals with public insurance or Medicaid (16.8% vs. 5.0%; OR 3.81, 95% CI 2.19-6.64) and the uninsured (16.9% vs. 5.0%; OR 3.83, 95% CI 2.22-6.61). Compared with females, males also had a higher HCV-positive test rates (14.7% vs. 7.4%; OR 2.17, 95% CI 1.55-3.05). African Americans were more likely than whites to be HCV-antibody positive (13.3% vs. 8.8%; OR 1.59, 95% CI 1.14-2.21).

Among the 170 HCV-antibody positive results, confirmatory PCR RNA testing results were available for 150 (88.2%). HCV viremia was confirmed in 102 of 150 (68.0%; 95% CI 59.9-

75.4). HCV viremia was more common in males than females (78.5% vs. 49.1%; OR 3.79, 95% CI 1.82-7.88). Confirmatory viremia rates did not vary by race or insurance status.

Call back attempts were recorded for 100 of the 102 RNA-positive cases. (Figure 3) Overall, 54 (54%) RNA-positive individuals were successfully contacted by phone within five call back attempts. Among those successfully contacted, 38 (70.4%) received a confirmed an appointment with a liver specialist. Among those with a confirmed appointment, 21 (55.3%) attended their initial appointment and three (7.9%) are awaiting an upcoming scheduled appointment.

Call back success was greater for persons with private insurance or Medicare compared to persons with Medicaid, public insurance, or uninsured (67.6% vs. 46.0%, $p=0.04$).

Obtaining a scheduled liver appointment was not significantly different for individuals with private insurance or Medicare compared to individuals with Medicaid, public insurance, and the uninsured (76.0% vs. 65.5%, $p=0.40$). Reasons for not scheduling a liver appointment for six RNA-positive individuals with private or Medicare insurance that were successfully contacted by phone include: one deceased, one patient request to schedule at another health system, three awaiting establishment of a primary-care physician or referral, and one lost to follow-up after initial contact. Reasons for not scheduling a liver appointment for 10 RNA-positive individuals that were uninsured or with Medicaid or publicly-funded insurance and successfully contacted by phone include: two cases of active chemotherapy treatment, four lacking coverage and a primary care provider, one with

coverage and lacking a primary care provider, and three lost to follow-up after initial phone contact.

Attending the initial visit with a liver specialist was not significantly different for private insurance or Medicare compared to persons with Medicaid, public insurance or uninsured (63.2% vs. 47.4%, $p=0.41$).

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DISCUSSION

Based upon eleven weeks of screening, our preliminary results identified unrecognized HCV antibody reactivity in one out of nine baby boomers presenting to the ED. This observed HCV-antibody seroprevalence is nearly four times greater than previous estimates for US baby boomers (3.3%).(6, 16) While the National Health and Nutrition Examination Survey (NHANES) suggests that approximately 2 million baby boomers in the US have HCV antibody reactivity, those estimates do not include high-risk groups that often present to the ED such as the homeless, nursing home residents or chronic hemodialysis patients.(16)These results substantiate recent HCV screening recommendations and highlight the ED as an important and feasible target for focused HCV screening.

Our effort is one of the first to broadly and systematically screen ED baby boomer patients for HCV and provide linkage to HCV care. Prior US ED studies have revealed HCV-antibody prevalence rates between 4% and 18%.(13, 14) Brillman et al. reported an HCV-antibody seroprevalence rate of 17% among a convenience sample of 220 ED patients older than 17 years in an urban ED, with 67% of the identified HCV-infected individuals unaware of their status.(12) Similar low HCV awareness and high seroprevalence rates are demonstrated in our study. Our large scale, targeted testing of the baby boomer birth cohort has further revealed racial and healthcare coverage disparities among the newly HCV diagnosed populations in the ED.

Our program offers other key observations to guide ED HCV screening and referral. HCV-antibody prevalence was higher among the publicly insured and uninsured individuals. These populations face significant barriers to accessing primary care, let alone specialty care. Denniston et al. observed that uninsured individuals have significantly lower self-awareness rates for HCV infection.(7) Stepanova et al. similarly reported that HCV-infected individuals were less likely to be insured than uninfected individuals, and were more likely to utilize the ED than any other healthcare arena.(10) HCV screening and care linkage programs must overcome these barriers to optimize outcomes.

While HCV detection is important, linkage-to-definitive care is also an essential component of an HCV screening program. We identified numerous challenges to successful HCV care linkage. Phone contact after the ED visit proved to be the greatest barrier, especially for the uninsured and underinsured. Although beyond the scope of this report, common challenges encountered to accessing expert liver care included the lack of access to a referring primary care physician, lack of healthcare coverage or financial support, and the prioritized treatment of other chronic medical co-morbidities, specifically cancer. Our experience verifies that organized care linkage is an essential element of an ED HCV screening program and may prove a more formidable barrier than the initial screening process.

ED HCV screening has many inherent challenges, including the costs of screening, the competing priorities of ED care, and the development of a linkage to care infrastructure. Our program has been successful due to the integration of ED clinical, laboratory, and

information technology resources. An important question is whether this design can be generalized to other EDs, without specialized funding, personnel or equipment. Our program was informed by prior experience with large-scale HIV screening in the ED, and leveraging existing screening infrastructure might provide options for HCV screening implementation in other EDs. The Centers for Medicare and Medicaid Services (CMS) recently proposed reimbursement for HCV screening limited to primary care settings and specifically excluding EDs.(17) This current decision limits the ability to perform ED-based screening without specialized funding. US EDs have previously overcome many similar challenges with successful implementation of non-targeted HIV screening and linkage models.(18)

We recognize that the overall success of this screening program should be measured on long-term HCV treatment outcomes. Due to the early nature of our report, we are not able to comment on treatment success rates. Future directions of study include improving linkage to care outcomes, treatment, and health outcomes for this cohort.

LIMITATIONS

While results only reflect an eleven-week period, HCV seropositive test rates have remained stable without significant temporal fluctuations. We expect current prevalence patterns will persist with on-going HCV screening targeting baby boomer ED patients. As we tested patients in a single, urban-based academic ED in the Southeastern US, expanding ED-based HCV screening efforts to multi-site scale is warranted. We utilized self-reported awareness of HCV infection/non-infection, which may be affected by recall bias, health literacy, and privacy concerns. We strived to overcome these limitations by: conducting interviews in private, training ED providers to address key counseling topics thoroughly and empathetically following HCV antibody-positive results, and using program support materials (i.e., pre-screening questionnaire and patient education materials) written at early elementary school reading levels. This study was limited to medically stable baby boomer ED patients capable of completing our pre-screening questionnaire; baby boomer ED patients with high medical acuity and individuals that left our ED (either discharged or eloped) before completion of screening procedures were excluded. In addition, a small number of patients declined or opted-out of HCV screening services; results on these individuals could have amplified the observed seroprevalence rates.

Linkage outcomes are only available for RNA-positive cases that were successfully contacted by Linkage Specialists following initial antibody screening and confirmatory testing procedures. While it is possible that some RNA-positive cases that were lost to

follow-up sought HCV treatment referral outside of our linkage network, we cannot accurately measure or report these speculations.

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CONCLUSION

In this series of baby boomers presenting to the ED, we observed a high prevalence of unrecognized chronic HCV infection. These results highlight the ED as an important venue for HCV screening and linkage to care.

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FIGURES AND TABLES (Uploaded Separately)

Table 1

Characteristics of Emergency Department baby boomers patients screened for hepatitis C virus.

* Age at screening ranged from 47-69.

** Includes behavioral health, uncoded grants, workers compensation, estates, risk management, special billing, group resources, and miscellaneous insurance.

P-values from Pearson Chi-square tests of association for HCV reactivity vs. non-reactivity.

HCV = Hepatitis C Virus.

Figure 1

Overview of Emergency Department baby boomer hepatitis C virus screening.

Figure 2

Weekly incidence of hepatitis C virus seroprevalence among screened Emergency Department baby boomers, September 3 – November 17, 2013. Black line represents weekly prevalence and bars represents the number unique individuals screened weekly

Figure 3

Linkage to care success rate for Emergency Department baby boomers with confirmed HCV chronic viremia.

* Two of 102 total RNA+ individuals identified did not have contact attempts recorded.

† Up to 5 callback attempts performed by the linkage to care coordinator for all RNA+ individuals before determining callback failure.

‡ An appointment was scheduled for a visit with a liver specialist once a primary care provider was established and charity care applications approved for eligible and uninsured individuals.

P-values from Pearson Chi-square tests of association for insurance status categories.

^a p=0.04

^b p=0.40

^c p=0.41 (patients with future appointments scheduled were excluded)

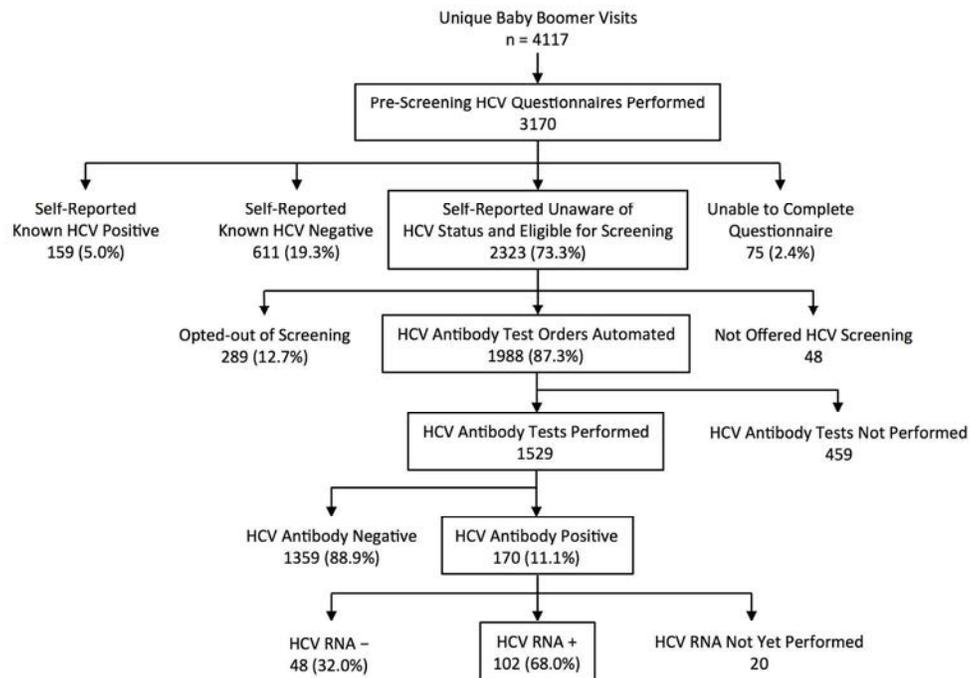
^d Reasons for not having a liver appointment scheduled detailed in results section

HCV = Hepatitis C Virus, Appt. = appointment

Table 1

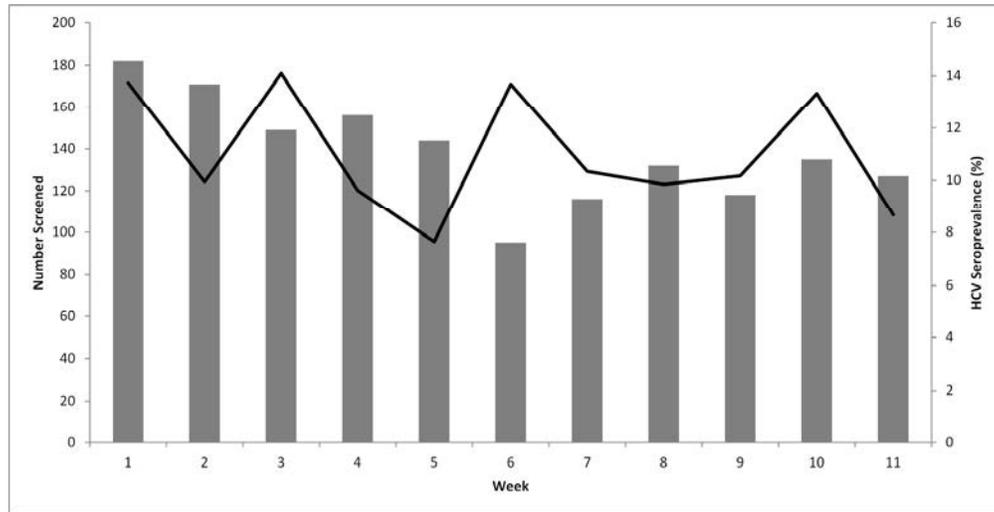
Characteristics of Emergency Department baby boomers patients screened for hepatitis C virus. *Age at screening ranged from 47-69. **Includes behavioral health, uncoded grants, workers compensation, estates, risk management, special billing, group resources, and miscellaneous insurance. P-values from Pearson Chi-square tests of association for HCV reactivity vs. non-reactivity. HCV = Hepatitis C Virus.

	Number Screened	HCV Reactivity N (row %)	p-value
	Total = 1,529	Total = 170 (11.1)	
Age (years)*			0.001
<50	240	19 (7.9)	
51-55	441	58 (13.2)	
56-60	392	59 (15.1)	
>60	456	34 (7.5)	
Sex			<0.001
Female	774	57 (7.4)	
Male	753	111 (14.7)	
Missing	2	2 (100.0)	
Race			0.012
White	717	63 (8.8)	
Black	784	104 (13.3)	
Other	24	1 (4.2)	
Missing	4	2 (50.0)	
Insurance			<0.001
Private	378	19 (5.0)	
Medicare	485	39 (8.0)	
Public/Medicaid	286	48 (16.8)	
Uninsured	326	55 (16.9)	
Other**	45	6 (13.3)	
Missing	9	3 (33.3)	



Overview of Emergency Department baby boomer hepatitis C virus screening.
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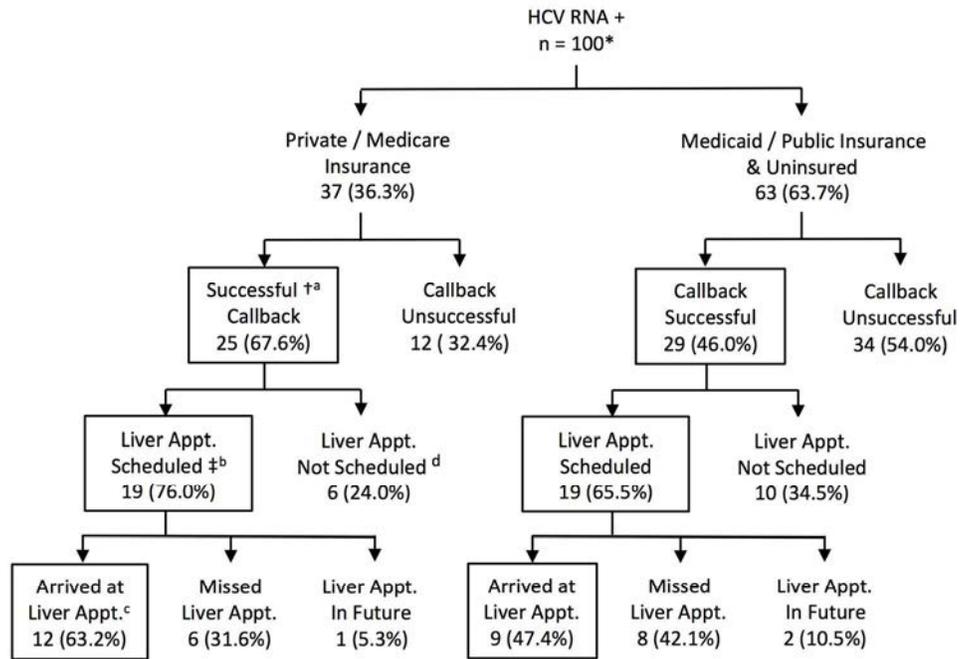
Accept



Weekly incidence of hepatitis C virus seroprevalence among screened Emergency Department baby boomers, September 3 – November 17, 2013.

Black line represents weekly prevalence and bars represents the number unique individuals screened weekly.
226x116mm (300 x 300 DPI)

Accepted



Linkage to care success rate for Emergency Department baby boomers with confirmed HCV chronic viremia.

* Two of 102 total RNA+ individuals identified did not have contact attempts recorded.

† Up to 5 callback attempts performed by the linkage to care coordinator for all RNA+ individuals before determining callback failure.

‡ An appointment was scheduled for a visit with a liver specialist once a primary care provider was established and charity care applications approved for eligible and uninsured individuals.

P-values from Pearson Chi-square tests of association for insurance status categories.

a p=0.04

b p=0.40

c p=0.41 (patients with future appointments scheduled were excluded)

d Reasons for not having a liver appointment scheduled detailed in results section

HCV = Hepatitis C Virus, Appt. = appointment

160x114mm (300 x 300 DPI)

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