

## Introduction

Chronic infection with hepatitis C virus (HCV) represents an escalating public health concern worldwide and within the United States (US). The disease burden of HCV is increasing, driven in large part by a high prevalence among those born between 1945 and 1965 (the “baby boomer generation”). Like other individuals with chronic HCV, many HCV-positive baby boomers (up to 75%) are unaware of their infection.<sup>1</sup> Predictive modeling studies suggest that, in the absence of intervention, cirrhosis from HCV will peak at 1.0 million in 2020, and hepatic decompensation and liver cancer prevalence is anticipated to increase for another 10 to 13 years. Hepatitis C can be cured, which significantly decreases the likelihood that someone will die of liver-related complications. In order to reap the benefits of treatment, patients must first be identified.<sup>2</sup>

Although risk-based screening guidelines have been in place for many years, the CDC, USPST, and others have recently published recommendations for one-time testing for HCV infection among all baby boomers, regardless of the presence of other risk factors.<sup>3-5</sup> Numerous potential barriers to timely identification in this setting have been proposed. Thus, we developed a quality improvement initiative to evaluate contemporary screening patterns among patients in the guideline-targeted birth cohort and elucidate the barriers that must be overcome to facilitate adherence to new recommendations and ensure timely care and optimal outcomes for patients with chronic HCV.

## Methods

### Physician HCV Knowledge, Clinical Confidence, and Contemporary Barriers

Clinician knowledge, clinical confidence, and self-reported HCV screening practices were evaluated by electronic surveys distributed to 118 physicians (MDs and DOs) within the Duke University Primary Care Research Consortium (PCRC) between May 29, 2013 and July 29, 2013. Survey respondents received a nominal stipend for their time. Additionally, to evaluate knowledge and practice barriers that cannot be assessed in a multiple-choice format, we conducted a series of semi-structured interviews with 6 staff members (4 physicians, 1 nurse or nurse practitioner (NP), and 1 administrative staff member) at each of the 5 PCRC clinics participating in this initiative (total 20 physicians, 5 nurses/NPs, 5 staff members). Interview participants received a stipend for their time.

### Evaluation of Clinical Practice Patterns

To evaluate HCV testing practices, we conducted a retrospective electronic health record review of 9,046 patients born between January 1, 1945 and December 31, 1965 (i.e. baby boomers) without a prior diagnosis of HCV who were cared for within 5 Duke University Health System-affiliated primary care clinics in North Carolina between March 1, 2013 and May 31, 2013. In addition, we reviewed HCV testing patterns among patients with HIV through evaluation of the electronic health records of 96 patients to evaluate changes in a population which was not the focus of the study. To evaluate linkage to care practices for those patients with positive anti-HCV antibody results, the EHRs were further reviewed for documentation of either referral to an HCV specialist (hepatologist or infectious disease physician) or a negative HCV RNA test. This evaluation process was repeated monthly following the first educational intervention and continued for a total of 6 months; data were reviewed for patient visits between November 2013 and April 2014. Over the course of the entire initiative, 24,822 records from baby boomer patients were reviewed, as well as 282 records from patients with HIV infection.

## Methods – Cont’d

### Interventions

Performance feedback related to HCV testing and linkage to care was shared with clinicians within the 5 PCRC clinics following abstraction of the baseline data and with each monthly review of the electronic health records. Data sharing reports included comparative data allowing clinics to evaluate their performance in comparison to their peers as well as suggestions for improving current practice from clinical leadership. Additionally, this initiative included a series of educational interventions, namely one CE/CME-certified publication and six brief (one-to-two) page publications. All data reports and educational publications were shared with participating clinicians through a local designee.

The protocol for this initiative was reviewed and approved by the Duke University School of Medicine Institutional Review Board.

## Results

### Survey data

Of the 118 physicians within the PCRC who received the electronic survey, 41 responded (RR = 34.7%). Responses to the survey indicated high baseline knowledge of the prevalence and morbidity associated with HCV infection but low levels of understanding of the potential for cure with therapies available at the time of the survey. The majority of respondents reported that they were aware of CDC guidelines for birth cohort screening. (Figure 1a) Clinicians reported very high confidence in their ability to counsel patients about the need for screening and discuss new screening recommendations with patients; fewer than one-quarter (22%) of clinicians reported that they were extremely likely to test a patient born between 1945 and 1965 for HCV in the absence of symptoms (data not shown). Barriers to linkage of HCV antibody positive patients to specialty care include a high percentage of physicians reporting that 1) the majority of their HCV antibody positive patients do not return for follow-up testing and 2) the impact of liver enzyme assays, symptoms, and perceptions of patients’ treatment plans and physician willingness to refer. (Figure 1b)

### Qualitative Interviews

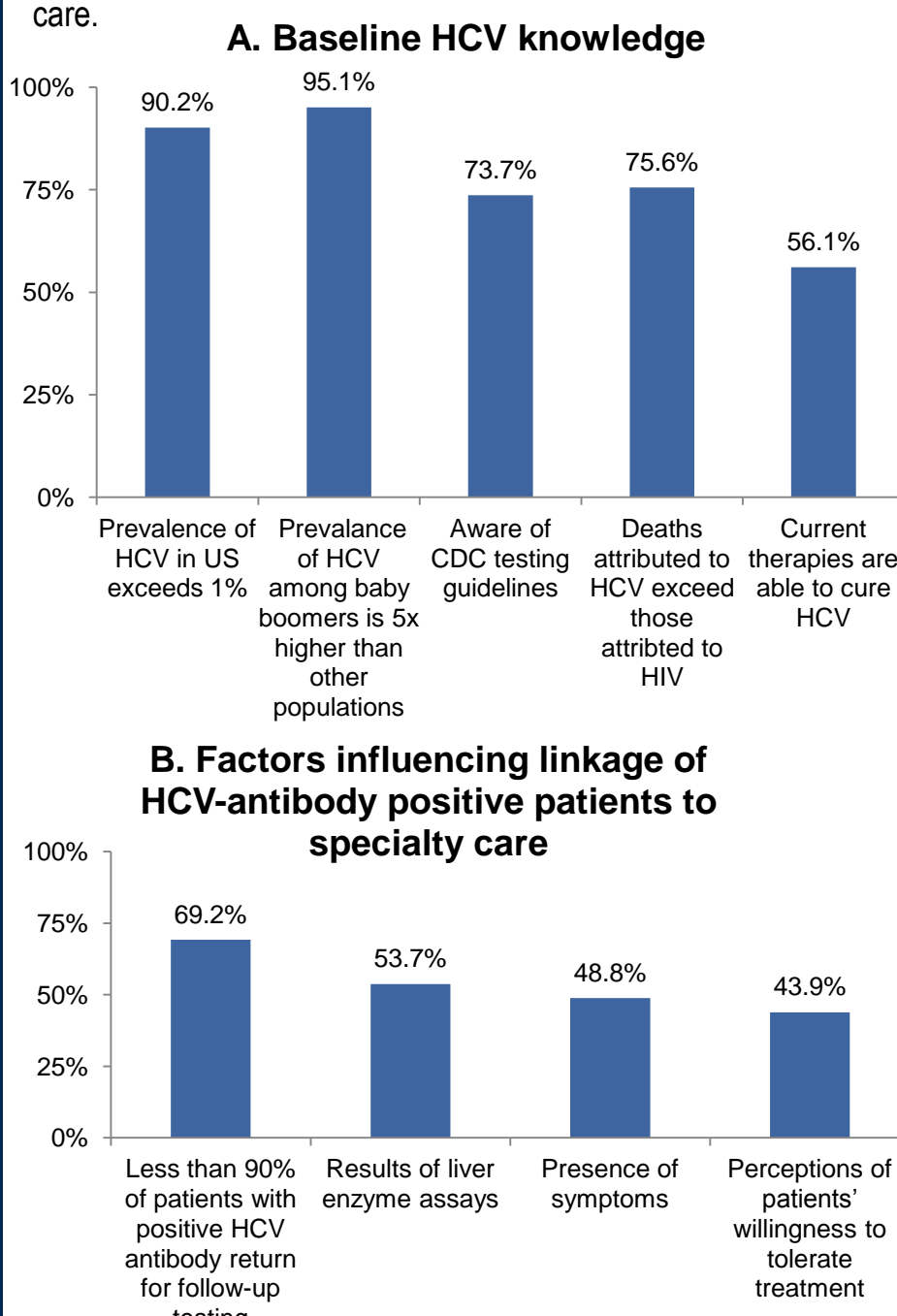
During the semi-structured interviews, 15 clinicians answered questions about HCV cure rates and five clinicians remarked that they were too unsure to comment. Those who answered this question expressed variable beliefs about cure rates for HCV with available therapies ranging from 20% to 80%. Two clinicians made specific references to improved cure rates with more recently available drugs.

Twelve of the 20 interviewed physicians commented on their implementation of birth-cohort-based recommendations for HCV testing. Ten physicians responded that they implement the new recommendations “at least some of the time,” one physician indicated a lack of agreement with the recommendations without commenting on the implementation of them, and one physician identified a complete lack of integration of the guideline recommendations in clinical practice. Four physicians directly commented on the need for a reminder prompt within the electronic medical record. Fifteen interviewees (10 physicians and 5 nurses) commented on the success of follow-up testing, 7 indicated that follow-up testing is a struggle within their clinic, and 8 indicated that this is not an area of concern.

During the interviews, 16 physicians commented on referring newly identified patients to specialty care. Of those responding, all 16 indicated that they refer all patients newly diagnosed with HCV infection; 3 indicated that they evaluate patients’ readiness for treatment but refer even those who seem unlikely to accept it. One physician mentioned needing more information about ideal practices prior to referring, including the use of a viral load evaluation (HCV RNA) and platelet count. When asked to identify their biggest challenge related to HCV identification and/or management, among the 25 interviewed healthcare professionals (20 MDs/DOs, 5 NPs/RNs), 12 identified a lack of knowledge as the greatest barrier to identification, 9 identified time as the biggest barrier, and 2 commented on a need to better understand why to test.

## Results – Cont’d.

Figure 1. Factors influencing suboptimal HCV testing and linkage to care within 5 Duke PCRC clinics. A. Baseline knowledge of HCV prevalence, clinical practice guidelines, and current therapies. B. Barriers to linkage of HCV antibody-positive patients to specialty care.



### HCV Testing Rates

Between March 1, 2013 and May 31, 2013, among all 5 participating clinics, 9,046 patients met criteria for HCV testing based on birth year and had no other risk factors, 96 patients were identified as HIV positive based on ICD-9 codes and therefore at risk for HCV.

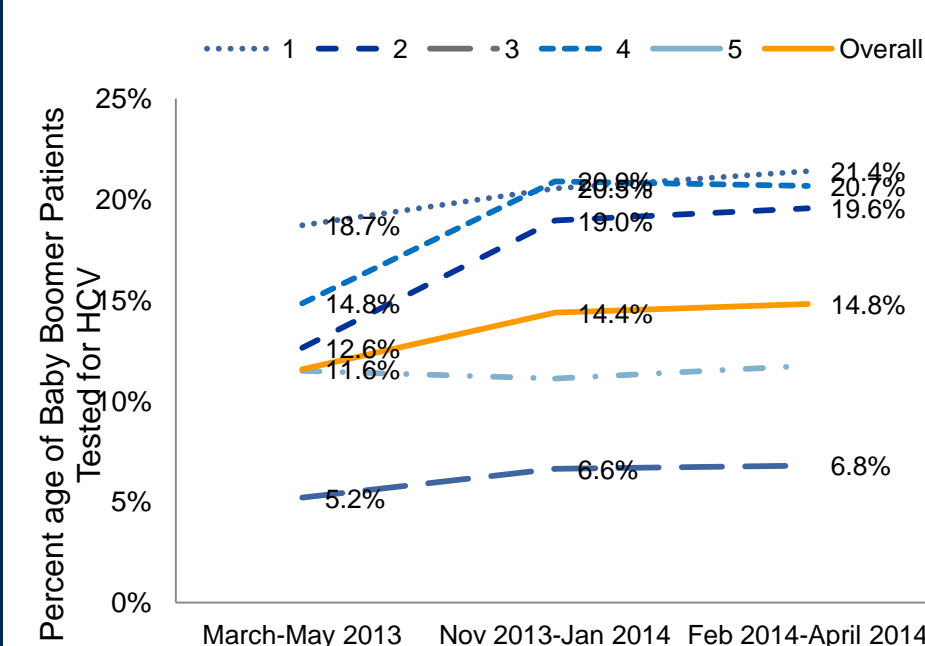
Among the 9,046 baby boomer patients, 1,047 (11.6%) had documentation of an HCV antibody test. In the population of patients with HIV, 75 (78.1%) had record of HCV antibody testing. Across the 5 clinics, variability in testing within both patient groups was evident; birth cohort testing rates varied between 5.2% and 18.7% and testing within HIV-positive patients varied between 58.3% and 87.5%.

Over the course of the intervention, HCV testing in baby boomer patients rose to 14.4% in the first three months (November 2013- January 2014) of the intervention period to 14.8% in the final three months (February 2014-April 2014) of the intervention period. (Figure 2a) HCV testing among patients with HIV fell to 75.0% in the first three months (November 2013-January 2014) and rose to 79.8% in the final three months (February 2014-April 2014). (Data not shown)

### Linkage to Care

Between March 1, 2013 and May 31, 2013 a total of 26 patients were identified as HCV antibody positive within the 5 participating Duke PCRC clinics. Of those patients, 15 (57.7%) were either documented to have an undetectable HCV viral load (HCV RNA) or were appropriately referred to specialty care. Variability in appropriate linkage to care was observed among the 5 participating clinics (0.0% to 80.0%). During the intervention period, linkage to care rates rose above the baseline rate in 5 of the 6 months. (Data not shown)

Figure 2. HCV testing rates among baby boomer patients in 5 Duke PCRC clinics before and during an HCV QI intervention



## Discussion

In our study, physicians largely reported knowledge of newer recommendations for HCV testing and the rationale for birth cohort-based screening, were able to identify an increased prevalence of HCV infection among baby boomers, and understood the high mortality rates associated with HCV infection. This knowledge, however, is in direct contrast with clinical practice as illustrated through our retrospective electronic medical record data extraction, which showed suboptimal application of birth cohort-based screening. Within our study group, barriers to guideline adherence are multifactorial, including systems-based challenges, patient factors, and clinician challenges. Clinicians reported that optimal and timely linkage of identified cases to specialty care is hindered by many of these same barriers.

This initiative provided participating clinicians with continuous performance feedback related to testing baby boomer patients for HCV and linkage of antibody-positive patients to specialty care. These improvement efforts were supported by multiple educational offerings which provided clinicians with an in-depth look at the evidence for HCV testing among the baby boomer populations, a resource outlining the process of HCV testing within the primary care clinic, best practices for provision of primary care services to patients with HCV, and a series of brief, focused publications to highlight and reinforce key educational concepts. The combination of continuous data sharing and education helped clinicians improve HCV testing rates within the targeted population.

Our study has a number of limitations, including those related to searching an electronic medical records database. Additionally, since participation was voluntary, the data may only represent the views of clinicians who are more aware of their need for improvement initiatives and have a strong desire to participate. Finally, our study cohort represents clinics that are all part of a single academic healthcare system and may not be representative of all primary care settings.

Recent studies powerfully illustrate that improving screening processes among the baby boomer generation has great potential to identify infected persons who are not aware of their disease, decrease premature mortality, and positively influence healthcare utilization.<sup>1,6-8</sup> Our data suggest that important improvements in testing and linkage to care are possible through focused quality improvement efforts. We believe that the process of continuous data sharing was a key component of the success of this initiative.

Identification alone is not sufficient to decrease HCV-associated morbidity and mortality. Effective linkage to care is critical to provide patients the opportunity for cure of the HCV infection. Well tolerated and highly effective therapies are now available and offer patients greater than 90% chance of cure of their HCV infection.<sup>9,10</sup> The quiet nature of HCV infection necessitates this emphasis on screening in order to identify patients at earlier stages of disease before the complications of cirrhosis develop. These tremendous advances in therapy will not be able to truly impact the HCV outcomes at the population level until we can better identify patients with HCV infection and get them on the path to treatment.

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