

Evaluating a Hepatitis C Quality Gap: Missed Opportunities for HCV-Related Care

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Chronic hepatitis C is a blood-borne virus affecting approximately 4 million Americans. After exposure to the hepatitis C virus (HCV), about 20% of people spontaneously clear the virus within the first 6 months of exposure, and the remaining 80% develop chronic HCV.¹ Chronic HCV contributes significantly to the rising incidence of cirrhosis and hepatocellular carcinoma (HCC) in the United States.²⁻⁶ The cost of care increases with the severity of liver disease and chronic HCV-related cirrhosis is now the most common indication for liver transplantation in adults.^{7,8}

The diagnosis of chronic HCV is a 2-step process. Step 1 is initial HCV antibody (HCVab) testing (Figure 1). If the HCVab test is positive, Step 2 is an additional test to determine if viral RNA is present in the blood;^{9,10} it is required to establish or refute the diagnosis of chronic HCV. A positive HCVab test and a positive RNA test indicate the presence of chronic HCV, whereas a positive HCVab result and a negative RNA result indicate that the exposed person has either spontaneously cleared the virus or has achieved a sustained virologic response from treatment.

Individuals who have a positive HCVab but have never completed viral testing cannot be classified as chronic or not because there is no virologic evidence to establish the diagnosis. The chronic HCV status of these patients remains unknown until viral RNA testing is complete. These individuals represent an important care gap in the management of HCV because their undetermined status can lead to missed opportunities for appropriate HCV-related care, such as alcohol cessation counseling, screening for HCC for those at risk, and/or timely receipt of potentially curative therapies.¹¹

Several recent investigations have highlighted this issue and indicated that a significant proportion of their study populations fell into this care gap.¹²⁻¹⁵ Additionally, recent recommendations to broaden HCV testing beyond a risk-based model to include all patients in the birth cohort of

ABSTRACT

Objectives

Diagnosis of chronic hepatitis C virus (HCV) is a 2-step process involving hepatitis C antibody (HCVab) testing followed by viral ribonucleic acid (RNA) testing. The HCV status of those with a positive HCVab without viral testing cannot be determined. This study sought to describe the HCV-related care provided to patients in this care gap.

Study Design

Retrospective cohort study of active patients with a positive HCVab test who did not complete viral testing.

Methods

Electronic medical records (EMRs) were reviewed to determine if each subject's first positive HCVab result was acknowledged by a provider. For results acknowledged, we described provider actions in response to the result. When providers performed specific clinical actions within 1 year of the positive HCVab test, we captured the type of action taken. When the unsubstantiated diagnosis was documented in the EMR, we determined if the diagnosis was mentioned by subsequent providers.

Results

Positive HCVab results were not acknowledged in 31% of subjects. In 35%, providers added chronic HCV to the problem list in the EMR, resulting in a higher likelihood of subsequent providers mentioning the diagnosis in their EMR documentation. In 143 subjects whose providers recommended HCV-related clinical actions within 1 year of the positive result, 45% were educated about HCV and 42% had their liver enzymes monitored.

Conclusions

With more widespread testing anticipated and more effective treatments available, health systems should ensure the HCV diagnostic process results in the delivery of an accurate and timely HCV diagnosis, to reduce the risk of harm to patients.

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Take-Away Points

Given expanded hepatitis C virus (HCV) screening recommendations, management of positive screening results needs optimization to ensure that tested patients can benefit from recent treatment advances.

- For patients with a positive HCV antibody and no viral RNA testing, 31% of the antibody results were not acknowledged by any provider, including the ordering provider.
- HCV care was performed in the absence of viral testing, leading to unnecessary treatments or stigma in those without chronic HCV.
- An unsubstantiated diagnosis of chronic HCV in a patient's electronic medical record's problem list leads to a large percentage of providers referencing this diagnosis.

1945-1965 would translate to an additional 20 million people being candidates for HCV testing.¹⁶⁻¹⁸ Given this volume and the need to reduce HCV-related morbidity, it is important to gain a better understanding of why RNA testing is not completed and what the consequences of this care gap are to patients.

To determine this, we conducted a retrospective cohort study of all active patients at our institution who had at least 1 positive HCVab test but who did not complete viral RNA testing to address the following questions: 1) What actions were and were not taken by medical providers after a positive HCV antibody result?, and 2) What were the downstream effects of documentation of a HCV diagnosis in the absence of viral testing?

METHODS

Study Design and Participants

Our cohort included all active patients who had at least 1 positive HCVab result between January 1, 1991, and January 1, 2010, but no subsequent history of completing HCV viral RNA testing at the Louis Stokes Cleveland Veterans Affairs Medical Center (LSC-VAMC), its 13 associated community-based outpatient clinics, or any other Veterans Affairs (VA) facility. Active patients were defined as any patient with a medication refill or patient encounter (including test result/vital sign) within 730 days of the date of the data query. The start and end dates were selected because 1) the availability of EMRs became more widespread in the VA system around the beginning of 1991, and 2) in early 2010, our facility implemented the VA national directive calling for HCV Reflex Testing at all VA facilities. This directive was designed to prevent additional patients from failing to complete viral testing in a timely manner, and calls for an additional blood sample to be collected when the screening antibody test is drawn.¹⁹ If the antibody test is positive, the second blood sample is to be used for viral testing, circumventing the need for

another blood draw to complete this step. Thus, these dates were chosen to provide the highest likelihood of ascertaining the outcomes of interest while also capturing the majority of cases.

Our locally created Hepatitis C Population Management Application was used to identify subjects for this investigation. This application captures and stores data from the VA Region 3 Data Warehouse and has been previously validated through an iterative development process. A query of this application was conducted on May 20, 2011, and identified 419 subjects.

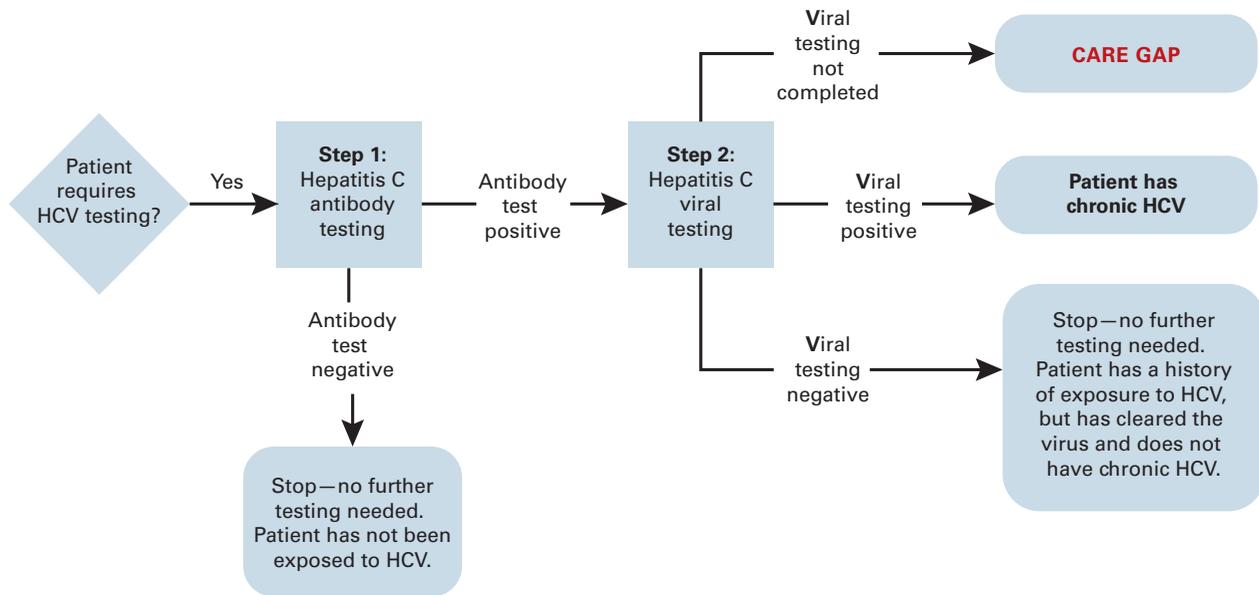
Medical records of all subjects were systematically reviewed by a single co-investigator over a 5-month period to evaluate the outcomes of interest. Weekly meetings between this co-investigator and the senior investigator were held to ensure consistency and accuracy in the adjudication of outcomes. This investigation was reviewed and approved by the Institutional Review Board at LSC-VAMC. Given the retrospective nature, obtaining informed consent was not required.

During 1999, our facility underwent transitions in medical record system configurations, resulting in uncertainties about completeness of transfer of progress notes prior to December 31, 1999. These uncertainties became apparent during our review of the 78 subjects (18.6%) who had HCVab testing prior to this date. Twenty-nine of the 78 subjects had only mental health encounter progress notes available for review while the remaining subjects had both mental health and medical provider progress notes for review. As a result, we could not determine with absolute certainty if all progress notes did transfer or if some patients had only mental healthcare during that time period. This uncertainty may limit our ability to evaluate outcomes determined by review of provider progress notes; however, since fewer than 10% of our total subjects were potentially affected and because other outcomes could still be evaluated, these patients were not excluded from the investigation.

Subject Demographics and Clinical Characteristics

We collected the following demographic information on all subjects: age at date of data query, gender, race, and presence of current or previous alcohol abuse (by *International Classification of Diseases, Ninth Revision, Clinical Modification* code 350.0x) in the EMR. We collected the number of subjects with a most recent serum albumin

■ **Figure 1.** The Hepatitis C Diagnostic Process



HCV indicates Hepatitis C.

value <3.5 g/dL, platelet count $<150 \times 10^3 /\mu\text{L}$, alanine aminotransferase (ALT) >45 U/L, and aspartate aminotransferase (AST) >36 U/L. The value immediately preceding the query date (May 20, 2011) was chosen to provide a snapshot of the current health of this cohort. We also calculated the total number of consecutive years that each subject had received healthcare from our VA facility. The time span between the first test result, vital sign, or patient encounter ever and the date of the data query was used to calculate this parameter. These variables were able to be collected for all subjects as its determination was not dependent on review of provider documentation in progress notes (Table 1).

Positive Hepatitis C Antibody Test Characteristics

For each subject, we identified the first positive HCVab test result, then conducted a detailed review of entries to the subject's EMR made after the date of this first positive HCVab test. For each subject's first positive HCVab test, we determined which healthcare service (eg, inpatient medicine, psychiatry service, etc) ordered the test. The number of subsequent HCVab tests per subject was also captured.

Provider Management of Positive HCVab Screening Results

To determine if the positive HCVab test was acknowledged by a healthcare provider, we reviewed all progress

notes after the date of the first positive HCVab test. We classified an HCVab test as "acknowledged" if, at any point in time after the date of the positive result, a provider did one of the following: 1) mentioned viral RNA testing in their progress note, although the testing was never completed, or 2) completed other types of management, which included "documentation actions" and/or "clinical actions."

"Documentation actions" were defined as provider documentation of chronic HCV in the subject's EMR, either by recording chronic HCV in a subsequent progress note, or by entering the diagnosis of "Chronic Hepatitis C" into the subject's problem list at any time after the positive HCVab result.

"Clinical actions" were defined as any mention of an HCV-related medical recommendation in any subsequent progress note after the positive HCVab test. To characterize the recommendations that occurred in response to the positive HCVab we captured HCV-related medical recommendations made within the 12 months after the positive HCVab test result. These included: 1) documentation of HCV education provided during a medical encounter, 2) documentation of provider request for HCV genotype testing, 3) recommendation for or administration of a Hepatitis A and/or B vaccine, 4) documentation of alcohol reduction counseling, 5) request for an alpha-fetoprotein test or imaging of the liver, 6) a referral to the HCV clinic, or 7) serial monitoring liver function tests (LFTs).

Table 1. Subject Demographics and Selected Clinical Characteristics

Subject Demographics	n = 419
Current age in years, mean (SD)	59.6 (8.4)
Male gender, n (%)	407 (97)
Race, n (%)	
Black	198 (47)
White	186 (44)
Native Hawaiian/Pacific Islander	4 (1)
Hispanic	1 (0.2)
Other	30 (7)
Prevalence of current or previous alcohol abuse, n (%)	163 (39)
Clinical Characteristics	
Most recent albumin <3.5 g/dL, n (%)	72 (17)
Most recent platelet count <150 103/μL, n (%)	54 (13)
Most recent ALT >45 U/L, n (%)	140 (33)
Most recent AST >36 U/L, n (%)	177 (42)
Number of years receiving care at LSCVAMC, mean (SD)	8.1 (3.0)

ALT indicates alanine aminotransferase; AST, aspartate aminotransferase, LSCVAMC, Louis Stokes Cleveland Veterans Affairs Medical Center.

Table 2. Positive Hepatitis C Antibody Test Result Characteristics

Number of positive HCVab tests in absence of viral RNA testing	n = 419
HCVab ordering service, n (%)	
Outpatient primary care	239 (57)
Mental health rehabilitation programs	133 (32)
Surgical service or medical subspecialty	26 (6)
Inpatient medical service	12 (3)
Psychiatry service	9 (2)
Subjects with 1 positive HCVab test result, n (%)	248 (59)
Subjects with 2 positive HCVab test results, n (%)	91 (22)
Subjects with ≥ 3 positive HCVab test results, n (%)	80 (19)
Median number of positive HCVab test results per subject, median (range)	1.8 (+/-1.52)
Subjects with positive HCVab test result acknowledged, n (%)	288 (69)

HCVab indicates hepatitis C antibody; RNA, ribonucleic acid.

Downstream Effects of Documentation of Chronic Hepatitis C

When a positive HCVab test result was acknowledged and the acknowledging provider performed documentation actions, we evaluated if any future medical providers referenced the unsubstantiated diagnosis of

chronic HCV through their own EMR documentation.

Statistical Analysis

Descriptive statistics were used to summarize subject demographics, clinical characteristics, positive HCVab test result characteristics, and clinical actions taken after positive HCVab test results. Chi-square tests of association were used to assess categorical variables.

RESULTS

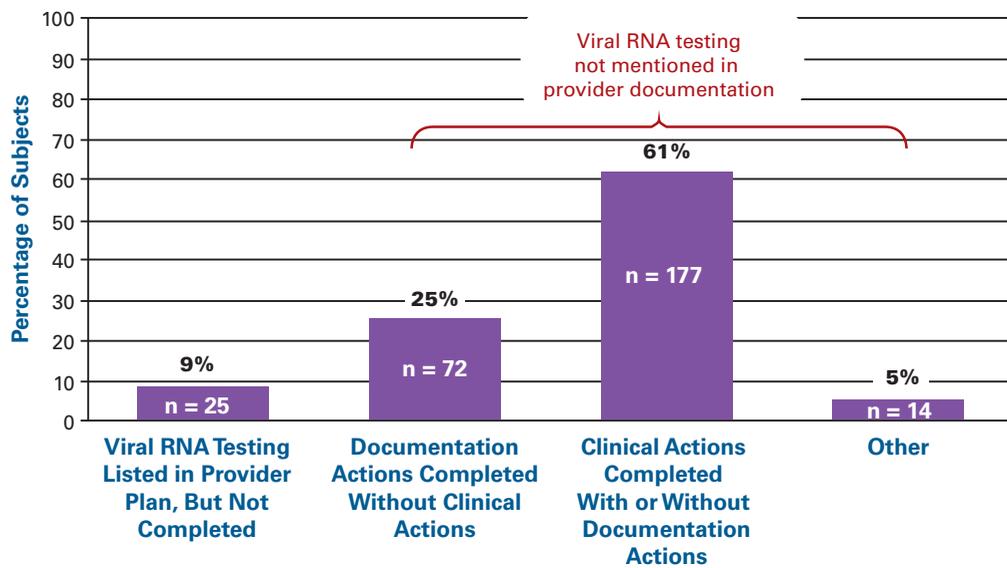
Demographics for the 419 subjects identified by the query are listed in Table 1. The mean age of subjects was 59.6 years at the date of the query and 97% (n = 407) of subjects were male. Almost 40% (n = 163) of subjects had either a current or past history of alcohol abuse. Subjects received care at our VA for a mean of 8.1 (SD ± 3.0) years.

Positive Hepatitis C Antibody Test Characteristics

Of the 419 subjects included in the data analysis, 57% (n = 239) of the first positive HCVab tests were ordered by providers located in VA outpatient primary care settings and 32% (n = 133) were ordered by providers in mental health rehabilitation programs (Table 2). Mental health rehabilitation programs included inpatient and outpatient substance abuse treatment, gambling rehabilitation, or domiciliary programs. Sixty-nine percent (n = 288) of subjects had their HCVab test acknowledged by a medical provider (Table 2) leaving 31% of subjects' results never acknowledged.

Forty-one percent of subjects (n = 171) had more than 1 positive HCVab test result in their medical record, and the number of positive tests ranged from 1 to 15 (Table 2). Subjects who had their first positive HCVab test ordered by a mental health provider were significantly more likely to have 3 or more positive antibody draws than those

■ **Figure 2.** Methods of Provider Knowledge of Positive HCVab Result (n = 288)



whose test was ordered by a non-mental health provider (40.6% vs 9.4%, $P < .001$).

Provider Management of Positive HCVab Screening Results

Of the 419 subjects evaluated, 31% (n = 131) of subjects had an initial positive HCVab test result that was never acknowledged by any medical provider. **Figure 2** illustrates the types of provider actions completed in the 69% of subjects (n = 288) for whom a medical provider acknowledged the positive HCVab test result. While in 9% (25 of 288) of these subjects, a provider mentioned the need for viral RNA testing, it was ultimately not completed. In 25% (72 of 288) of subjects, the provider performed only “documentation actions” by documenting an unsubstantiated diagnosis of chronic HCV in the progress note or adding it to the EMR problem list.

In 14 of the 288 subjects (5%), provider actions were difficult to adjudicate and could not be categorized as either documentation or clinical actions; they were placed into an “other” category (Figure 2). Subjects included in the “other” category were those in which it appeared the provider misinterpreted the positive HCVab result as a positive result for Hepatitis A or B.

In the absence of an established diagnosis of chronic HCV, in 61% (177 of 288) of subjects to whom the positive HCVab was acknowledged, a provider performed some type of chronic HCV-related medical recommendation with or without documenting chronic HCV in the subject’s medical record. For those (143 of 177) who

had any type of clinical recommendation performed within 12 months of the positive HCVab test result, we captured the type of recommendation that was made or performed. In subjects with clinical recommendations within 1 year, almost half (64 of 143) received education by the acknowledging provider regarding chronic HCV. Serial monitoring of LFTs was recommended to 42% of subjects (60 of 143). The need for hepatitis A or B vaccinations was mentioned in a progress note for 25% of these 143 subjects, with 18 subjects receiving at least 1 dose, and 5 completing the entire vaccination series. A referral was placed to the HCV clinic for 24% of subjects (35 of 143), and alcohol counseling was documented in the EMR for 22% (32 of 143) of subjects. No acknowledging providers ordered a HCV genotype test despite having the ability to do so.

Effects of Documentation of Chronic Hepatitis C

In the era of the EMR, we investigated the downstream effects of documenting chronic HCV in the problem list for subjects without an established chronic HCV diagnosis. In 35% of subjects (146 of 419), providers responded to a positive HCVab test result by entering chronic HCV into the patient problem list in the EMR. We found that in 86% of these subjects (126 of 146), future medical providers referenced this unsubstantiated diagnosis in their own EMR documentation. This was significant compared with subjects whose acknowledging provider did not add the chronic HCV diagnosis to the problem list ($P < .001$).

■ **Table 3.** Clinical Actions Occurring Within 1 Year of Positive HCVab Result (n = 143)

	n ^a (%)
Patient education on chronic hepatitis C documented in provider progress note	64 (45)
Provider mention of monitoring liver function tests	60 (42)
Recommendation for or administration of hepatitis A or B vaccine	37 (26)
Hepatitis C clinic referral made	35 (24)
Provider documentation of alcohol reduction counseling	32 (22)
Subjects receiving at least 1 dose of hepatitis A or B vaccine	18 (13)
Provider request for imaging exam of liver or alpha-fetoprotein test	7 (5)
Subjects completing hepatitis A or B vaccine series	5 (3)

^aSubjects often had more than 1 clinical action taken or recommended; therefore, the total n for the clinical actions in aggregate is greater than 143. HCVab indicates hepatitis C antibody.

DISCUSSION

With the increasing burden of chronic HCV-related morbidity, national attention is being directed toward systematic testing of those born between 1945 and 1965.^{16,17} Amidst this push for more widespread HCV testing, healthcare systems need to be aware of potential testing pitfalls to prevent patients from falling into the care gap described in this investigation. Our investigation has identified opportunities for improvement surrounding the process of establishing the diagnosis of chronic HCV, and we offer some potential healthcare system approaches to addressing these.

In our study, 31% of positive HCVab test results went unacknowledged by a medical provider, representing the largest missed opportunity for interventions such as risk-behavior modification and engagement in HCV care. The potential reasons for not acknowledging a positive HCVab test are multifactorial: a provider who orders the lab may forget to check the results, for instance, or in the setting of a teaching institution like ours, a trainee rotating through clinical settings who orders the test may not be the provider who sees the patient in follow-up when the results are available. While we were unable to determine exactly why these test results appeared to go unacknowledged, these data provide evidence of the realities of clinical practice and the ease by which actual care can deviate from ideal care.

In about two-thirds of subjects, despite the absence of viral RNA testing, providers documented the presence of chronic HCV or completed some type of clinical action that is only necessary if chronic HCV is present; this suggests confusion in the diagnostic criteria. For this subset of patients, a diagnosis of chronic HCV without confirmatory viral testing meant potentially unnecessary tests,

vaccinations, and clinical interventions, which always come with risks. It can be argued that these clinical actions were unnecessary, as some of these subjects likely did not have chronic HCV. (However, given the natural history of HCV, many—perhaps close to 80%—probably did, and for them, the interventions could be described as indicated.) Another risk that should not be discounted is the unnecessary stigma placed on patients who were given an unsubstantiated diagnosis.

Since the completion of this investigation, we have directed educational efforts to our providers in an attempt to correct misinformation and provide updated information on the HCV diagnostic process, the need for HCV clinic referral, and basic HCV management principles. Our investigation found that patients seen in mental health clinics were more likely to have multiple repeat HCV antibody tests completed after the initial positive test, suggesting confusion in the diagnostic process. As many of our mental health clinics promote screening, our first series of educational sessions was directed toward providers working within mental health settings. Going forward we will continue to include mental health providers in ongoing educational efforts, since they are an important connection for patients with and at risk for HCV who may not be currently engaged in HCV care.

In the 86% of cases in which an unsubstantiated diagnosis of chronic HCV was added to the EMR problem list, future medical providers referenced the diagnosis in their documentation. Once a diagnosis is entered into an EMR problem list, clinicians viewing the list in the future may perceive little need to validate the diagnosis and order the needed viral RNA testing, perpetuating this care gap. With increasing reliance on the EMR, the problem list is often shared across providers within healthcare

systems and the implications for such “false-positives” can lead to unnecessary stigma and/or medical interventions. While we believe our educational efforts will improve this problem locally, ultimately global efforts toward standardization of how problem lists are developed are needed.

This investigation has some limitations. As a single center study, our findings may be unique to our facility; however, these data are consistent with the findings of others.^{12,15,20} Given the retrospective nature of this investigation, it was difficult to draw conclusions about providers’ intentions, so these findings were subject to the interpretation of the research team. For example, in the absence of viral testing, the documentation of chronic HCV in the EMR after a positive HCVab result seems to suggest provider confusion about the diagnostic criteria for chronic HCV; however, we are unable to determine this with certainty. Also, because a small percentage of subjects may have been missing EMR progress notes, our data may potentially overestimate the number of subjects who did not have their test results acknowledged and underestimate the clinical actions that were recommended by providers.

Despite these limitations, our study demonstrates several important issues relevant to this HCV care gap. System improvements to close this quality gap will help maximize the effectiveness of more widespread screening, allowing patients to follow a more ideal care path. At our facility in 2008, we added the ability for patients to complete viral testing at our satellite clinic laboratories, which significantly increased the number of patients who were able to complete viral testing in a timely manner. After local implementation of reflex testing, we were able to demonstrate another significant increase in the completion of timely viral testing in those newly screened for HCV (unpublished observation). These local results are mirrored by national VA data. In 2011, 95% of veterans who were tested for HCV also completed viral testing, illustrating the effectiveness of the VA Reflex Testing directive.²¹ Expanding patient access to needed viral testing and the implementation of reflex testing are 2 successful approaches that can be leveraged at other non-VA facilities.

Considering the expanding pipeline of highly effective, better tolerated HCV treatments, efforts to identify and engage patients in HCV care are vital at this time. Health systems need to address failures surrounding the process of establishing the diagnosis of chronic HCV within their settings. Doing so is the first step toward taking advantage of the many opportunities that exist to

improve HCV care, thereby reducing the morbidity and mortality associated with this disease.

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