Hepatitis C Virus Screening: A Review of the OraQuick Hepatitis C Virus Rapid Antibody Test

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Abstract

Objective: To provide a review on the use, percent positive agreement (PPA), percent negative agreement (PNA), and implementation of using the OraQuick HCV Rapid Antibody Test for hepatitis C virus (HCV) screening in community pharmacies in an effort to increase overall HCV screening in target populations. **Data Sources:** PubMed and Sagepub were searched for the following keywords: hepatitis C virus, rapid diagnostic tests, rapid assay, and rapid HCV assay. Dates searched were from January 2000 to October 2013. **Study Selection:** All studies including the use of the OraQuick HCV Rapid Antibody Test were included. **Data Synthesis:** Sensitivity and specificity of this device are compared with several standard laboratory tests for detecting HCV antibodies. In comparing these values with the clinical “standards,” PPA and PNA are more applicable terms to describe whether the OraQuick device is an effective tool for initial screening by pharmacists. The OraQuick HCV Rapid Antibody Test demonstrates high accuracy in providing accurate HCV infection status. **Conclusion:** The OraQuick HCV Rapid Antibody Test is a unique tool pharmacists can use in an effort to enhance the screening capabilities for HCV infection. Pharmacists often have the most contact with those patients at high risk for having contracted HCV in the past. With a relatively high PPA and high NPA, a high confidence in the accuracy of the device can be placed on initial test results. Patients should then be triaged to proper follow-up care depending on initial results.

Keywords

hepatitis C virus, biotechnology, antivirals, clinical pharmacy, clinical practice, pharmaceutical care, pharmacist/physician issues, viral infections

Introduction

The Centers for Disease Control (CDC) estimates that approximately 3.2 million persons living in the United States are infected with the hepatitis C virus (HCV), the most common chronic blood-borne infection in the country.¹ It was recently reported that deaths in the United States secondary to HCV now exceed those caused by HIV.² Unfortunately, many cases of HCV infection are not detected, and most patients remain asymptomatic until the late stages of disease. As a result, many health care professionals miss opportunities to screen their patients for HCV. Historically, patients at risk for HCV acquisition were injection drug users, chronic hemodialysis patients, health care workers with exposure risks, HIV-infected patients, and those who had received a blood transfusion or organ donation prior to 1992. Recently, the CDC released an update for the screening of HCV to include all persons born from 1945 through 1965, or the “Baby Boomer” generation.³ The justification for this recommendation was that even though this population represents only 27% of the US population, they account for 75% of the individuals chronically infected

with HCV. By screening this population for the virus, it is estimated that >800 000 individuals with previously undiagnosed HCV infection could be identified and 120 000 HCV-related deaths could be avoided. If no change in screening were to occur, it was estimated that 1.76 million individuals would develop cirrhosis, and 400 000 individuals in the United States would progress to hepatocellular carcinoma by mid-2030.⁴ Currently, HCV infection is the leading cause of liver transplantation in the United States.⁵ Although some people who acquire the initial infection will eradicate the virus without intervention, approximately 80% of individuals will develop chronic HCV infection, which can potentiate further health problems such as chronic liver disease (60% to 70%), cirrhosis (5% to 20%), liver cancer and need for liver transplant, and/or death (1%

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to 5%).^{5,6} In addition to offering earlier treatment to those who have been infected with HCV, expanded screening can also serve to protect those without evidence of infection. By raising awareness and encouraging prompt treatment of infected individuals, it is reasonable to believe that secondary transmission rates may be reduced.

With the publication of the new screening recommendations, a greater accountability has been placed on health care professionals to screen patients at risk for HCV. As approximately 84.2 million people fall into the Baby Boomer birth cohort, this recommendation places a tremendous burden on a network of primary health care providers that is already stretched thin. Recently, a new Clinical Laboratory Improvements Act (CLIA)–waived rapid antibody test for HCV was approved. The fact that this test has received a CLIA waiver signifies that it may be conducted in a nontraditional laboratory setting by an institution that possesses a CLIA waiver, such as pharmacists in a community or retail setting. Owing to their accessibility and existing rapport with patients, pharmacists are uniquely positioned to serve their patients by offering HCV screening. Unfortunately, many pharmacists are not aware of this potential role, nor do they possess sufficient knowledge about this test to use it appropriately.

Screening for HCV

Current standard practices for HCV infection screening and diagnosis employ an array of qualitative and quantitative laboratory tests. These tests can be broken down into those that detect anti-HCV IgG (immunoassays, rapid assays, and recombinant immunoblot assays) and those that measure actual HCV molecules (nucleic acid testing and core antigen assays).

Confirmatory Tests

Nucleic acid testing (NAT) measures the amount of HCV RNA present in serum. This methodology is considered to be the most reliable means of diagnosing HCV infection, but due to its high cost and amount of technical expertise required to perform the assay, it is used solely as a confirmatory test after initial screening for HCV infection.⁷ Polymerase chain reaction (PCR) is the basis for current NAT. This allows for the detection of small quantities of HCV RNA in specimens and results in a highly sensitive assay.

Immunoassays for HCV core antigen are also used as a confirmatory test for diagnosis of HCV infection. Luminescence-anti-HCV antigen antibodies are placed on a membrane that reacts with core antigens.⁷ These types of tests show relatively high sensitivity and specificity in the early period of infection, but it does have a higher detection threshold than NAT as the infection progresses.⁷

Recombinant immunoblot assays (RIBAs) are also used as follow-up tests for detecting anti-HCV IgG in serum. Synthetic and recombinant NS3, NS5, and core peptides are each impregnated onto a membrane in bands. Anti-HCV IgG becomes immobilized on these bands if present.^{7,8} Positive tests correlate to the presence of reactivity to 2 or more proteins, while reactivity to 1 peptide is indicative of an indeterminate response that may be due to recent infection or from cross-reacting antibodies.⁷ Like the immunoassays, a positive test result does not confirm ongoing infection, but only a history of HCV exposure. However, manufacturing of the sole FDA-approved RIBA is no longer available in the United States.³

Screening Tests

Several anti-HCV IgG immunoassays have been developed to detect the NS3 and NS4 regions of the HCV genome and core antigens.⁷ Immunoassays are capable of identifying anti-HCV IgG with >99% specificity; however, this does not confirm the presence of an active infection from previous exposure/infection.⁷ Regrettably, the clinical utility of these tests has been limited owing to observed low positive predictive values (PPV) in cohorts of patients with <10% prevalence of HCV infection.⁶ Along with low PPVs in certain populations, confidence in these tests has been hampered by reports of false positive and false negative results. As such, additional testing had been required regardless of the results obtained from immunoassay screening.^{2,3,6,7}

Anti-HCV IgG immunoassay and RIBA test results are typically reported as a ratio of the optical density of the sample being run to the optical density of the cutoff for the run. Accordingly, a signal-to-cutoff ratio (S/CO) of less than one would indicate a nonreactive test, whereas values greater than one signify various intensities of a reactive test. The S/CO of an assay can then be validated to predict positive supplemental test results. This helps account for assay variability and provide more reliable test results on which to base clinical decisions. Two approaches for S/CO interpretation have been developed: the screening assay (SA) approach and the CDC-based algorithm (Table 1).⁹ The SA method is recommended by manufacturers of the assays and simply states that positive tests correlate with S/COs of ≥ 1.0 .^{2,3,10,11} The CDC algorithm approach is more discriminating and recommends reactive samples with S/COs ≥ 1.0 but < 8.0 be tested with RIBA or NAT-PCR to confirm the presence of HCV.^{2,3,10,11} This algorithm was developed to minimize the number of false positive result interpretations stemming from overly generalized recommendations for S/CO ratios.⁷

CLIA-Waived Screening Tests

In November of 2011, OraSure Technologies (Bethlehem, CA) received a CLIA waiver for their previously

Table 1. Anti-HCV IgG Immunoassay and RIBA Interpretation Criteria.

Screening Assay Reference Method	CDC HCV Testing Algorithm
<ul style="list-style-type: none"> • Anti-HCV EIA <ul style="list-style-type: none"> ◦ Anti-HCV positive: S/CO ≥ 1.0 ◦ Anti-HCV negative: S/CO < 1.0 	<ul style="list-style-type: none"> • Anti-HCV negative: Screening anti-HCV nonreactive with S/CO < 1.0 • Anti-HCV positive: Screening anti-HCV reactive with S/CO ≥ 8.0: • Reactive samples with S/CO ≥ 1.0 but < 8.0 <ul style="list-style-type: none"> ◦ RIBA positive: Anti-HCV positive ◦ RIBA negative: Anti-HCV negative

Abbreviations: HCV, hepatitis C virus; RIBA, recombinant immunoblot assay; CDC, Centers for Disease Control and Prevention; S/CO, signal-to-cutoff ratio.

FDA-approved anti-HCV IgG rapid diagnostic test (RDT). Similar to other immunoassays, The OraQuick HCV Rapid Antibody Test uses a nitrocellulose membrane impregnated with synthetic and recombinant core proteins, NS3 and NS4 regions of the HCV genome along the test zone and goat anti-human IgG along the control zone.¹² Although previously mentioned screening tests did possess relatively high sensitivities and specificities, their use outside of a certified laboratory setting was hampered by long turnaround times and technical complexity. The OraQuick HCV Rapid Antibody Test was designed to be fast, simple to conduct, and relatively low cost while retaining appropriate sensitivity and specificity parameters.

The OraQuick HCV Rapid Antibody Test

Intended Use

The OraQuick HCV Rapid Antibody Test is a single-use, disposable immunoassay developed for the qualitative detection of antibodies to HCV from a whole blood specimen from individuals 15 years and older. Results of the test can be used to provide presumptive evidence of HCV infection in persons with evidence or risk factors for infection. The assay has not been approved for use in patient populations that do not exhibit signs or symptoms or possess risk factors for HCV infection.

Summary of the Test

HCV is a single-stranded RNA virus that results in progression to chronic infection in upwards of 80% of acutely infected individuals. Presence of antibodies to HCV in a patient indicates the individual has been exposed to HCV at some time and had mounted an immune response against the virus. Detection of anti-HCV does not unquestionably indicate that the individual has circulating HCV RNA; therefore, confirmatory testing is warranted. The OraQuick HCV Rapid Antibody Test is intended to detect antibodies to the core and NS3 and NS4 regions of the HCV genome. Synthetic peptides and recombinant antigens of these regions

are immobilized as a single test line on the assay strip. Antibodies from a patient sample that bind to these peptides and antigens react with colloidal gold labeled protein A that results in the generation of a visible line in the test zone.

Principles of the Test

The OraQuick HCV Rapid Antibody Test was developed to perform screening of blood samples via finger stick method or venipuncture. Each assay comes in a divided pouch. One side contains the test device, a lateral flow cassette attached to an absorbent pad, and an absorbent packet intended to protect the device from moisture. The other side of the packet contains 0.75 mL of buffered saline (developer solution). Additionally, reusable test stands and disposable 5 μ L specimen collection loops are included in the test kit.

To perform a test, blood is obtained from the patient using the collection loop and mixing it with the developer solution until the solution turns pink. The developer solution facilitates the transfer of the specimen into the test cassette and onto the assay strip by capillary action. Within 60 minutes of mixing blood and developer solution, the test device should be inserted into the solution with the flat pad touching the bottom of the vial and the result window facing forward. The vial and cassette should remain untouched for at least 20 minutes but no more than 40 minutes. The test may be read at any time during this 20- to 40-minute window. As the solution flows through the test cassette, antibodies from the sample bind to the protein A gold colorimetric reagent present in the test strip. When the labeled antibodies bind to antigens in the Control (C) or Test (T) regions on the test strip, a reaction occurs and a reddish-purple line becomes visible. A valid test, reactive or nonreactive, must display a line in the control (C) zone of the test window. This is caused by the reaction of IgG antibodies in the patient's blood with goat anti-Human IgG affixed to the assay strip in the control region. Reactive tests result following immobilization of anti-HCV antibodies in the patient's blood in the test (T) zone of the assay strip resulting in the appearance of a test line. The test should be read as reactive if a line is noted in the C zone and a line of any intensity is noted in the T zone. The intensity of the test

Table 2. Definitions for Performance Characteristics.

Sensitivity = (Number of true positive test results/(Number of true positives + Number of false negatives)) × 100	Specificity = (Number of true negative test results/(Number of true negatives + Number of false positives)) × 100
Percent Positive Agreement = (Number of reactive results/Total number of HCV-infected individuals by reference method) × 100	Percent Negative Agreement = (Number of nonreactive results/Total number of non-HCV-infected individuals by reference method) × 100

line is not directly proportional to the amount of HCV RNA present in the sample.

Quality Control

Prior to a new operator performing a test or before a new lot/shipment of assays are used, the manufacturer recommends that external positive and negative controls be run. These are antibody-containing solutions that must be purchased separately from the test kits. External controls are intended to validate the integrity of the technology by detecting affixed peptides and antigens in the appropriate regions of the assay strip. If the external controls do not produce the expected results, patient testing should not occur.

Qualification of New Users

Since a reactive test is indicated by the presence of a line of any intensity in the T zone, it must be assured that each new user be able to accurately detect lines of varying intensities. This is accomplished by using an OraQuick HCV Visual Panel that must be purchased separately. Each panel contains 3 test cassettes representing nonreactive, HCV limit of detection, and low reactive results. Failure of a user to be able to reliably detect results at the limit of the assay detection may result in failure to detect HCV in these specimens and lead to reporting false negative results.

Limitations of the Test

For test results to be considered valid, the test must be used in accordance with the manufacturer's instructions and with appropriate controls and user qualifications. If specimens are collected via venipuncture, collection in tubes containing anti-coagulants other than EDTA, lithium heparin, sodium heparin, or sodium citrate may yield inaccurate results. Clinical performance data have not been collected from individuals less than 15 years of age or from pregnant women. Last, it may take an individual months following infection with HCV to develop antibodies against the virus. Therefore, a nonreactive test does not preclude the possibility of a recent infection.

Performance Characteristics

Traditionally the performance characteristics of an assay are reported as sensitivity and specificity if an accepted

reference standard is available for comparison. For the detection of HCV, however, a single accepted reference methodology for confirmation of infection is not available. In such cases, the performance of an assay should be characterized by determination of percent positive agreement (PPA) and percent negative agreement (PNA; Table 2). For confirmation of HCV infection, there are 2 methods that may be used to compare the assay performance against, the SA and the CDC algorithm (Table 1). Since variability exists between these confirmatory strategies, use of PPA and PNA is appropriate for describing the performance of the OraQuick HCV Rapid Antibody Test. As a result, even though sensitivity and specificity were reported in individual studies, we will defer to using PPA and PNA in our discussions.

Several studies have evaluated the performance of the OraQuick HCV Rapid Antibody Test compared to results obtained from established laboratory tests. Cha et al¹³ measured the PPA of the OraQuick test in 137 oral and 114 serum specimens from patients with a previous diagnosis of HCV infection (Table 3). Results obtained following the testing of serum samples revealed 100% PPA of the OraQuick tests with confirmatory tests. However, results provided from testing of oral samples yielded a PPA of 97.8%. The investigators determined the PNA by testing 300 oral samples from healthy blood donors and 200 stored serum samples from HCV negative blood donors. The OraQuick test demonstrated 100% PNA with no reported false positive test results observed. Final determination of positive and negative HCV status was confirmed by testing the samples with the Architect EIA (Abott Laboratories, Abott Park, IL).

Lee and colleagues evaluated the performance of the OraQuick for HCV Rapid Antibody Test in asymptomatic patients with HCV infection risk factors and diagnosed HCV-positive patients.¹⁴ A total of 2206 patients were identified. A total of 757 patients were determined to be HCV positive and 1426 were HCV negative based on laboratory testing for HCV RNA (EIA, RIBA, or PCR). Twenty-three patients were unable to be classified as HCV negative or positive and were excluded from the PPA and PNA calculations. Although the protocol called for serum, plasma, whole blood from venipuncture and finger stick, and oral fluid specimens to be collected from each enrollee, not all specimens were obtained from each participant. With the exception of oral fluid, the PPA of the assay for each of the

Table 3. Performance of the OraQuick HCV Rapid Antibody Test.

Authors	Population/Specimens	Specimen (n)	S/CO Method	PPA 95% CI	PNA 95% CI
Cha et al	137 HCV-positive Subjects	Oral (137)	Not explained	97.8% (93.2-99.4)	100% (98.4-100)
	300 Random subjects	Oral (300)			
	200 Negative subjects	Serum (200)			
	200 Positive samples	Serum (200)			
Lee et al	2206 subjects symptomatic or asymptomatic with 1 risk factor	Serum (2180)	Not explained	99.9% (99.3-100)	99.9% (99.6-100)
		Plasma (2178)		99.9% (99.3-100)	99.9% (99.5-100)
		Finger stick (2176)		99.7% (99.9-100)	99.9% (99.6-100)
		Venous blood (2178)		99.7% (99.9-100)	99.9% (99.5-100)
		Oral (2176)		98.1% (96.9-99)	99.6% (99.2-99.9)
Lee et al	122 HCV seropositive and 450 subjects of unknown or low risk	Venous blood ^a	Not explained	100% (97.0-100)	100% (99.2-100)
		Finger stick ^a		100% (97.0-100)	100% (99.2-100)
		Plasma ^a		100% (97.0-100)	99.8% (98.8-100)
		Serum ^a		100% (97.0-100)	99.8% (98.8-100)
		Oral ^a		99.2% (95.5-100)	100% (99.2-100)
Smith et al	285 Samples New York	Oral (285)	SA	94.4% (90.4-96.8)	95.8% (88.5-98.6)
		Oral (285)	CDC	94.7% (90.8-97.0)	92.1% (83.8-96.3)
	265 Samples Seattle	Oral (265)	SA	90.8% (85.4-93.7)	98.6% (92.4-99.8)
		Oral (264)	CDC	92.2% (87.5-95.2)	97.2% (90.9-99.3)
	266 Samples Seattle	Serum (266)	SA	95.9% (91.6-97.6)	100% (94.9-100)
		Serum (265)	CDC	97.4% (94.1-98.9)	98.6% (92.9-99.8)
Smith et al	1083 stored specimens from injection drug users from the CIDUS II study	Serum (1083)	SA	97.8% (96.2-98.7)	99.6% (98.7-99.9)
		Serum (1081)	CDC	99.3% (98.1-99.7)	99.5% (98.4-99.8)

Abbreviations: HCV, hepatitis C virus; S/CO, signal-to-cutoff ratio; PPA, percent positive agreement; PNA, percent negative agreement; CI, confidence interval; SA, screening assay; CDC, Centers for Disease Control and Prevention.

^an unavailable for each specimen.

specimens was at least 99.7%. The PPA found with oral fluid was reported at 98.1%. Similarly, 99.9% PNA was reported for each specimen except oral fluid for which a PNA of 99.6% was calculated (Table 3). One significant finding from this study was the observation that PPA derived for the assay with serum, plasma, venous blood and finger stick specimens were equal to a commonly used laboratory serum EIA test. These results illustrate the high positive predictive value of the rapid HCV test in a group of patients at risk for HCV infection.

In another study, results of the OraQuick HCV Rapid Antibody Test were compared to RIBA.¹⁵ One hundred and twenty-two previously diagnosed HCV positive patients and 450 low-risk and/or unknown HCV status patients consented to serum, plasma, venous blood, finger stick, and oral specimen collection. Of the 122 HCV-positive patients, the OraQuick HCV Rapid Antibody Test correctly identified 121 of the patients as positive for anti-HCV antibodies. Of particular interest, the single misidentified negative report was obtained using oral fluid for the test. This correlated to 99.2% PPA for the oral specimen group, while the other 4 specimen types each had 100% PPA (Table 3). PNA

was calculated by comparing the OraSure device results to HCV-ELISA laboratory test results from the 450 low-risk or unknown HCV status patients. Accordingly, 448 subjects produced negative results from both the OraQuick test and the HCV-ELISA. The OraQuick assay yielded one false negative after confirmatory HCV-ELISA found the sample to be positive for HCV RNA. Another patient was found to be positive by the OraQuick device only in the serum and plasma specimen, but RIBA and PCR determined the patient was indeed negative for HCV RNA. The PNA was calculated to be 99.8% with plasma and serum samples and 100% with oral fluid and whole blood samples (Table 3).

In 2011, 2 studies were conducted in response to a Federal Register notice of opportunity for collaboration on the evaluation of candidate rapid anti-HCV assays. The first study employed 3 anti-HCV rapid assays, one of which was the OraQuick assay, at 4 National HIV Behavioral Surveillance System (NHBS) sites.¹⁰ Of the 4 sites that participated in the study, 2 sites (New York, NY, and Seattle, WA) were assigned to use the OraQuick HCV Rapid Antibody Test. Participants consented to blood draws for testing with standard anti-HCV laboratory assay (Abott

AxSYM anti-HCV micro-particle immunoassay) and with the OraQuick HCV rapid assay. The performance of the rapid diagnostic test was assessed based on the FDA-approved anti-HCV screening assay (SA) reference method and the CDC recommended HCV testing algorithm (Table 1). At the New York site, only oral specimens were obtained, whereas in Seattle oral and whole blood specimens were collected. Based on the SA method for comparison, OraQuick had a PPA and PNA of 94.4% and 95.8%, respectively, for the oral samples taken in New York (Table 3). Using the CDC method for comparison, a similar PPA was noted, 94.7%; however, a slightly lower PNA of 92.1% was determined. At the Seattle site, oral samples produced PPAs of 90.8% and 92.2% for the SA and CDC approaches, respectively. PNAs using oral fluid were reported to be 98.6% by the SA method and 97.2% by the CDC algorithm. Blood samples obtained from Seattle were determined to have a PPA of 95.9% by the SA approach and 97.4% by the CDC approach. PNA was similar at 100% and 98.6% by SA and CDC approaches (Table 3). Regardless of the method used for comparison, the OraQuick rapid test provides better PPA and PNA when whole blood specimens are used to perform the assay.

Rather than testing blood samples drawn from patients during the study period, the second evaluative study screened banked blood specimens obtained from injection drug users.¹¹ The samples used were originally collected from 1997-1999 for use in the Collaborative Injection Drug User Study (CIDUS) II. A total of 1100 specimens from this project were reanalyzed for HCV and the SA and CDC approaches were employed to evaluate the PPA and PNA of the OraQuick device. When using the SA method PPA was reported as 97.8% and PNA as 99.6%, whereas when the CDC algorithm was used PPA increased to 99.3% and PNA remained similar at 99.5% (Table 3). These values were consistent with those reported above.

The manufacturer presents the results of an analysis of 1660 finger stick whole blood specimens in the package insert.¹² Of these specimens, 78.7% were collected from asymptomatic individuals at risk for HCV infection and 21.3% from subjects with signs and symptoms of HCV infection. This population consisted predominately of Caucasians (53.1%) and African Americans (40.6%). Rapid test results were confirmed by EIA, with supplemental RIBA and PCR assays as required. The S/CO interpretative method was not described. In the entire population of 1660 individuals, the PPA and PNA were reported as 97.9% and 98.5%, respectively.¹² These values did not differ among ethnic groups, age, or concurrent disease states.

Limit of Detection

According to the package insert,¹² the lower limit of detection (defined as the EIA S/CO which provided reactive results 95% of the time) with the OraQuick HCV Rapid

Antibody Test was calculated to be 0.75 for venous whole blood and 0.89 for finger stick whole blood.¹² These findings suggest that the rapid assay may provide a reactive test result when the comparator EIA is equivocal.

CLIA Waiver Study

In support of the CLIA waiver application, the performance of the OraQuick HCV Rapid Antibody Test was compared among intended users and trained laboratory personnel.¹² PPA and PNA were similar among users. Of specific interest, tests at the lower limit of detection were read correctly 97.8% and 96.6% of the time by intended users and trained laboratorians.

Role of the OraQuick HCV Rapid Antibody Test in Pharmacy Practice

It is widely noted that there is a shortage of primary health practitioners in the United States. As a result, access to the health care system by nonacutely ill individuals is becoming more restrictive. In contrast, pharmacists continue to enjoy unparalleled access to patients at all health acuity levels. This has placed pharmacists in an enviable position to interact with patients and function in an expanded primary health care role. With respect to HCV infection, despite the recommendation that all baby boomers be screened for HCV, rates of screening among this population continue to be poor. This appears to be both a function of access and time limitations with traditional primary health care providers. The approval of the CLIA-waived OraQuick HCV Rapid Antibody Test put a powerful tool into the hands of pharmacists. However, before pharmacists attempt to use tests such as this they must develop policies and procedures for conducting tests and establish protocols for patient referral.¹⁶ Appropriate partners for referral may include a clinical specialist in infectious disease, gastroenterology or hepatology. In some states, collaborative practice agreements can be developed that would allow a pharmacist, under the delegated power of a physician, to write a laboratory order for the follow-up testing, which could provide quicker follow-up times for definitive diagnosis. These steps are critical in establishing a HCV screening program. Last, although CLIA-waived tests are intended to be used by nontrained individuals, pharmacists should be encouraged to seek training on the use of RDTs, physical assessment, and liability.

Summary

Screening patients for HCV infection may not yet be common practice for most pharmacists; however, the availability of the tests like the OraQuick HCV Rapid Antibody Test may change this. As the scope of pharmacy practice evolves, pharmacists will offer more testing services using CLIA-waived

RDTs. By providing screening for HCV infection, pharmacists can be frontline providers capable of decreasing the transmission and improving the course of this debilitating infection. The OraQuick HCV Rapid Antibody Test provides an accurate means to screen patients and allows pharmacists to collaborate with providers to furnish patients with appropriate follow-up care. In partnering with various health care providers to screen for HCV infection, pharmacists can actively participate in the potential identification of upwards of 800 000 individuals with yet undiagnosed HCV infection.² Based on the information discovered during this review there are limitations to the use of RDTs such as the OraQuick HCV Rapid Antibody Test. Restrictive use of this tool with only finger stick blood specimens may decrease potential false negatives and positives. In addition to limiting sample specimens, ensuring pharmacists are properly trained in identifying correct patient populations and proper testing procedure will enhance the efficacy of this currently underutilized tool. Training in these areas should be a primary focus of pharmacists interested in developing a screening program at their respective sites of practice.

Declaration of Conflicting Interests

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