

Pharmacists' Opinions on the Implementation of HIV and HepC Point-of-Care-Testing in a U.S. Pharmacy Chain

Elizabeth So, PharmD, MBA¹; Monica Brands, RPh¹; Erin Suomala, PharmD¹; Bridget Ogden, PharmD¹; Jennifer Riss, PharmD¹; Alina Cernasev, PharmD, MSc, PhD Candidate²; Jon Schommer, PhD, MS, RPh²
¹SUPERVALU/Cub Pharmacies; ²College of Pharmacy University of Minnesota

Abstract

Background: The role of community pharmacists continues to expand with immunizations, medication therapy management, and point-of-care testing (POCT). Current guidelines recommend that Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) testing become integrated into routine care. Current guidelines recommend all people aged 13-64 be tested for HIV at least once in their lifetime, with those at higher risk for HIV tested at least annually.¹ Regarding HCV, current guidelines recommend a one-time HCV test in persons born from 1945 to 1965, as well as other individuals based on exposures, behaviors, and conditions or circumstances that increase HCV infection risk.² Currently available HIV and HCV treatment regimens are safe and highly effective. With HCV, successful treatment can halt disease progression to cirrhosis, end-stage liver disease, and hepatocellular carcinoma.³ POCT in community pharmacy offers an ideal location due to its accessibility, convenience, and lower cost to patients who might not otherwise be tested. However, HIV and HCV screenings are not routinely conducted by community pharmacists due to many barriers. Though many barriers to HIV and HCV POCT have been identified at the patient, provider, and institutional level, little is known about pharmacist-perceived barriers. It is worth noting that the barrier of state legislation limiting POCT in pharmacies has been resolved – currently 49 states have some form of statute that allows for delegation of prescriptive authority between a prescriber and community pharmacist.⁴ Though this removed barrier means increased availability of POCT, as the studies above have demonstrated, the mere availability of POCT is not enough for its implementation.

Objective: The main objective of this study is to identify pharmacist-perceived barriers and their level of confidence in performing community pharmacy-based POCT for HIV and HCV.

Methods: A cross-sectional survey was sent to all pharmacists working in a regional grocery store chain to evaluate their opinions and attitudes toward the implementation of POCT for HIV and HCV. The electronic survey questions consisted of Likert scale, select-all-that-apply, yes/no and no open-ended questions.

Results: The perceived barriers to implementation of HIV and HCV POCT in a community setting identified by pharmacists include staffing, time to conduct test, patient out-of-pocket cost, and discussion of positive results. Pharmacists' perceived level of confidence was greatest with providing basic education and incorporating HIV and HCV POCT into workflow; whereas discussion of a positive result was perceived as less confident.

Conclusions: While this survey determined pharmacist support for the implementation of HIV and HCV POCT, additional studies are needed before effective implementation of HIV and HCV POCT in a community pharmacy chain.

Keywords: Point-of-care-Testing (POCT), HIV, Hepatitis C, Barriers, Community pharmacy

Introduction

Current U.S. guidelines recommend that HIV and HCV testing become integrated into routine care, and that novel approaches, such as point-of-care-testing (POCT), are needed to make testing more accessible, especially in patients who have never been tested.⁵ According to the Centers for Disease Control and Prevention (CDC), there were 39,782 newly diagnosed patients with Human Immunodeficiency Virus (HIV) in the U.S., an overall decrease of 5% from 2011 to 2015.⁶ While this decline is likely from targeted HIV prevention efforts, this progress has been uneven, with annual infections and diagnoses increasing among a few groups. For example, from

2011 to 2015, HIV diagnoses increased 14% among Hispanic gay and bisexual men.⁶ Hepatitis C (HCV) is now recognized as the most common, chronic blood borne infection in the U.S.⁷ According to the CDC, there were 2,436 people newly diagnosed with HCV, an overall increase of 49% from 2011 to 2015.⁸ Risk factors for HIV include men who have sex with men (MSM), having sex with an HIV-positive partner, having more than one sex partner since last HIV test, using injectable drugs, sharing needles or works, exchanging sex for drugs or money, diagnosis of a sexually transmitted disease, hepatitis or tuberculosis, and having sex with someone whose sexual history is unknown.⁹ The CDC recommends HCV testing for all people in the U.S. born from 1945 to 1965, prior recipients of transfusions or organ transplants, and prior or current users of injectable drugs.¹⁰

Community pharmacies are an ideal testing location because of their accessibility, convenience, and less stigmatization than traditional testing sites.¹¹ With about 60,000 community

Corresponding author: Elizabeth So, PharmD, MBA
PGY-1 Pharmacy Resident, SUPERVALU/Cub Pharmacies
3620 Texas Ave S, St Louis Park, MN 55426
Phone: 952-933-3177; Fax: 952-933-4187
Email: elizabethso1070@gmail.com

pharmacies in the U.S, many open nights, weekends, and holidays, and 89% of Americans living within five miles of a community pharmacy, the community pharmacist has long been recognized as the most accessible healthcare provider.⁴ In addition, POCT takes about 20 minutes to complete in one visit, as compared to two weeks when sending tests to established laboratories.¹² However, many barriers have prevented implementation of POCT for HIV and HCV in a variety of settings. Though many barriers to HIV and HCV POCT have been identified at the patient, provider, and institutional level, little is known about pharmacist-perceived barriers. The main objective of this study is to identify pharmacist-perceived barriers and level of confidence in performing community pharmacy-based POCT for HIV and HCV.

Methods

Sample, Data Collection and Analysis

This cross-sectional, online survey was utilized because of its timesaving opportunity, convenience, cost-efficiency, reach, anonymity, objectivity, and quick results.¹³ The survey included 20 optional Likert scale, select-all-that-apply, and yes/no questions administered via SurveyMonkey®. These survey questions can be found in Appendix A. Surveys were emailed to all full-time, part-time, and relief pharmacists employed by a regional grocery store chain operating in the states of Illinois, Maryland, Minnesota, Missouri, North Carolina, and Virginia. Data collection occurred between December 2nd, 2017 and January 2nd, 2018, with a reminder to complete the survey emailed two weeks after the initial email. A descriptive analysis of statistics was performed using SurveyMonkey® in order to evaluate pharmacists' opinions and attitudes toward the 482 of POCT for HIV and HCV. The study was determined to be exempt by the University of Minnesota Institutional Review Board as non-human subject research.

Results

482 pharmacists were sent an invitation to participate in the survey, with 224 located in Minnesota, 111 in Virginia, 60 in Missouri, 53 in Maryland, 20 in Illinois, and 2 in North Carolina. 113 pharmacists accepted the invitation and completed the survey for a 23.4% response rate. The percentage of pharmacists who completed the survey by state was 40.9% (n=45) in Minnesota, 28.2% (n=31) in Virginia, 11.8% (n=13) in Missouri, 13.6% (n=15) in Maryland, 5.5% (n=6) in Illinois, and 0% in North Carolina.

The majority of pharmacists who already conduct POCT perform glucose screenings (71%), followed by hemoglobin A1C (26%) and lipid (23%) screenings (Figure 1). A total of 63% of pharmacists believe that HIV POCT is within their scope-of-practice, while 65% believe that HCV POCT is within their scope-of-practice (Figure 2).

The majority of pharmacists (63%) currently have patients who receive antiretroviral therapy. However, the majority of pharmacists (83%) do not currently have patients who receive medications for the treatment of HCV.

Pharmacists' opinion of the total amount of time needed to conduct a POCT for HIV was found to be 39% for 15 to 30 minutes and 35% of pharmacists for 30 to 60 minutes (Figure 3). For HCV POCT, pharmacists' opinion of the total amount of time needed was found to be 41% for 15 to 30 minutes and 34% for 30 to 60 minutes (Figure 4).

A specific scenario was posed before a series of questions were asked about pharmacists' level of confidence regarding certain situations (see Appendix A). Pharmacists had the highest levels of confidence when providing basic education to patients. A total of 35% of pharmacists were slightly confident and 32% were moderately confident regarding HIV education. For HCV education, 36% of pharmacists were slightly confident and 30% were moderately confident. The majority of pharmacists were slightly confident (28%) and moderately confident (27%) incorporating both HIV and HCV POCT into workflow. Pharmacists had the lowest levels of confidence when discussing results of a positive preliminary test with patients. A total of 22% of pharmacists were not confident or extremely unconfident and 17% were extremely unconfident regarding a positive HIV test. For a positive HCV test, 25% of pharmacists were not confident and 15% were extremely unconfident (Figure 5).

Eight perceived barriers were posed and asked if they were considered to be a barrier, maybe a barrier, or not a barrier. These barriers included: staffing, time to conduct test, out-of-pocket cost of test to patients, educating patients, training and certification, handling false positive results, physical assessment to aid in diagnosis, and administrative burden. The top three pharmacist-perceived barriers to HIV and HCV POCT were staffing, time to conduct test, and patient out-of-pocket cost. Less pharmacists perceived educating patients and training/certification as barriers (Figure 6).

Figure 1. Point-of-care testing conducted by community pharmacists

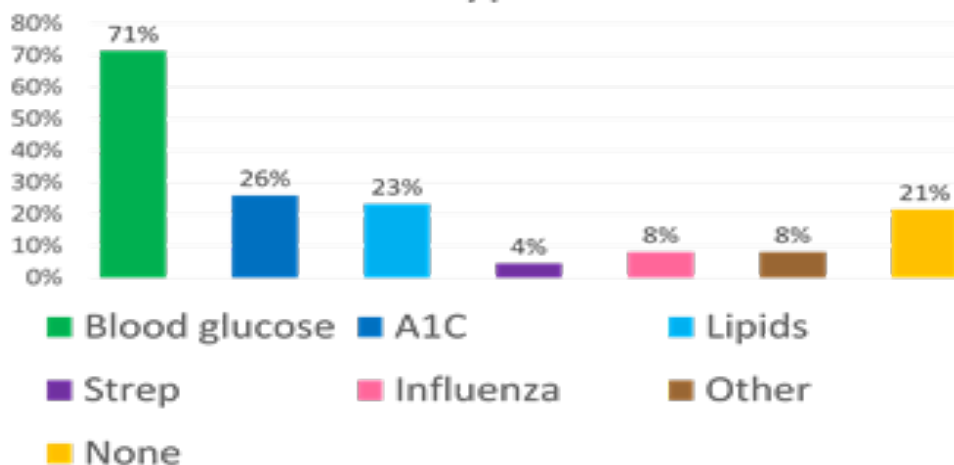


Figure 2. Pharmacists' opinion of whether or not HIV and HCV POCT is within their scope-of-practice

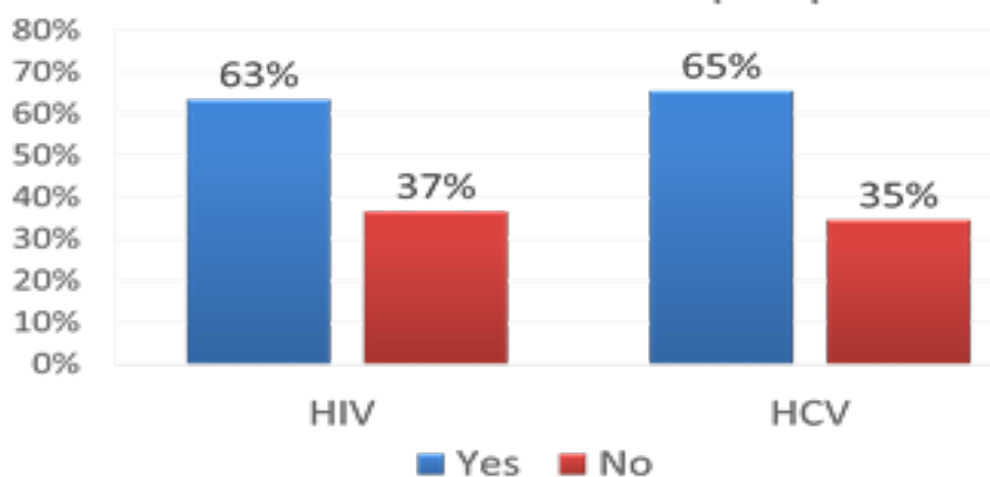


Figure 3. Amount of time needed to conduct an HIV POCT

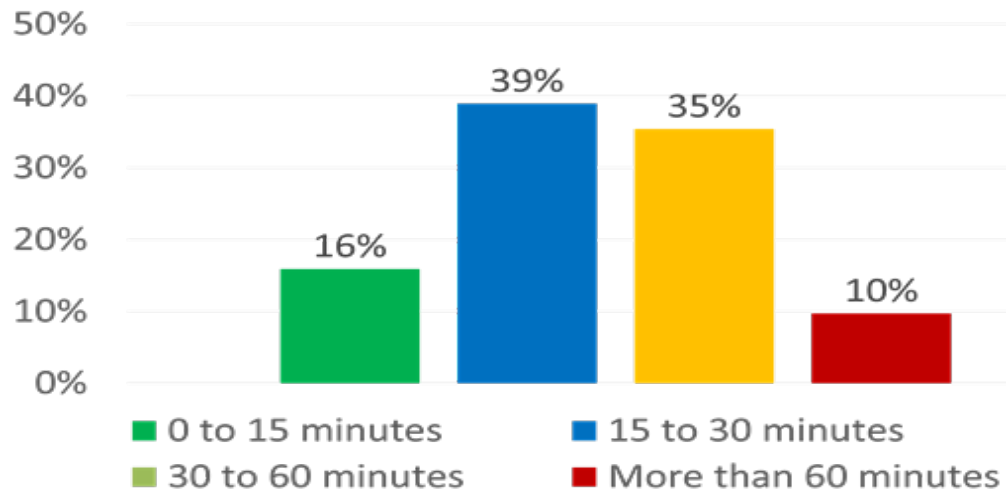


Figure 4. Amount of time needed to conduct an HCV POCT

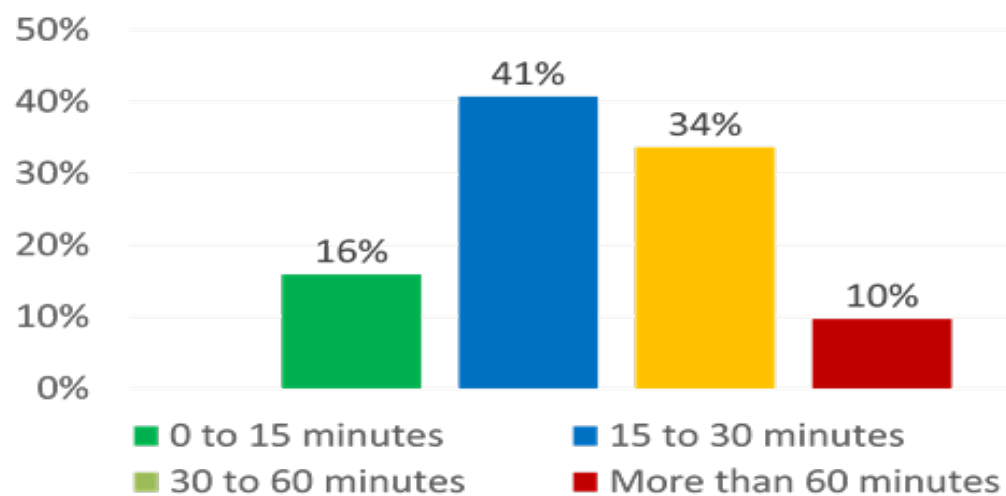


Figure 5. Level of confidence with HIV and HCV POCT

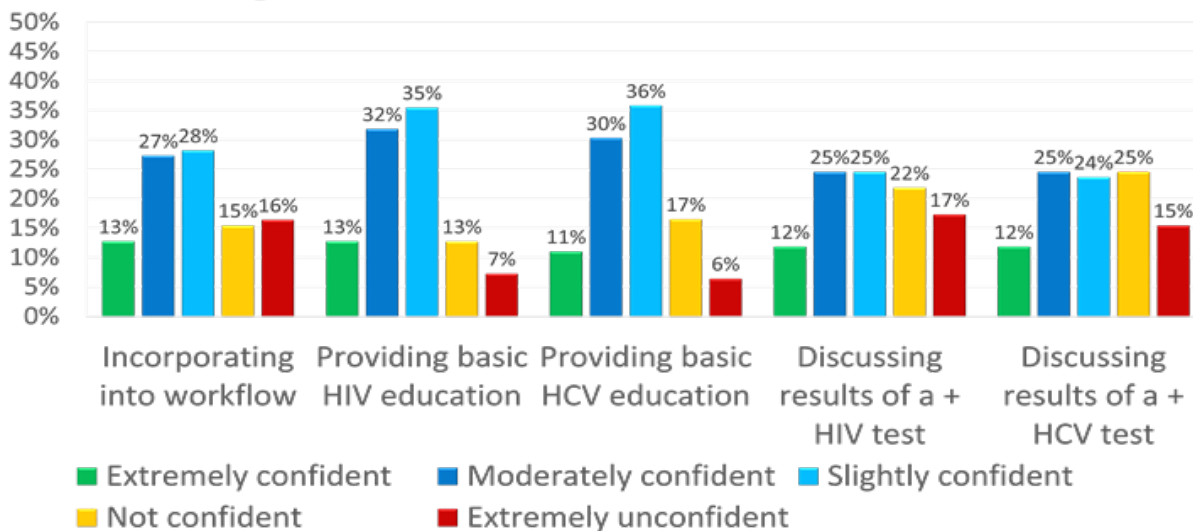
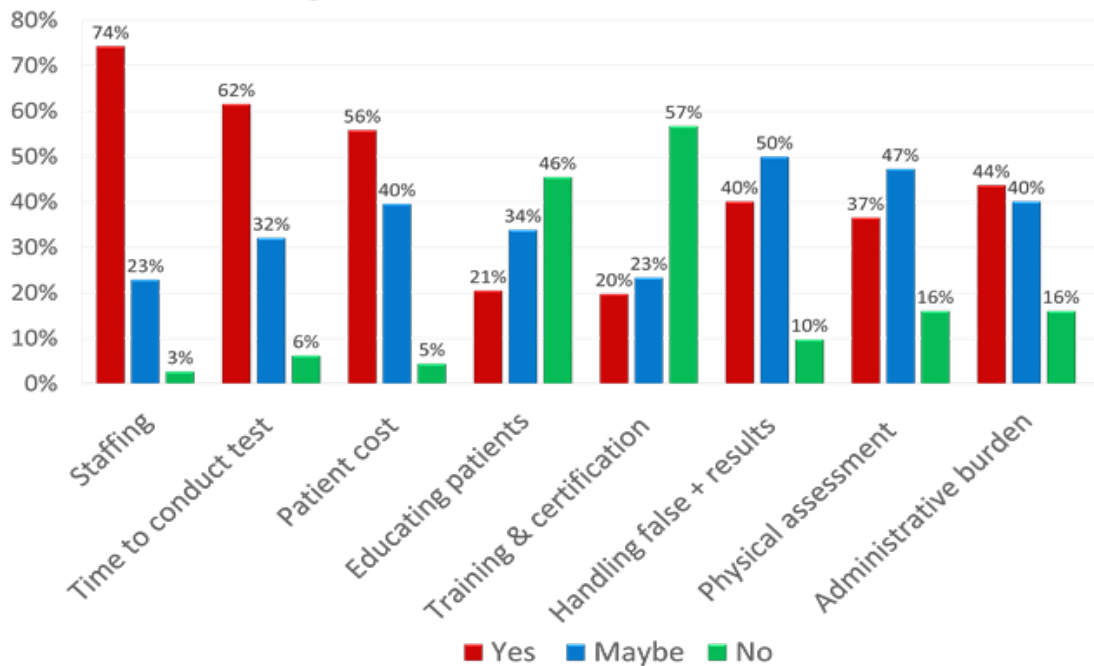


Figure 6. Perceived barriers to HIV and HCV POCT



Discussion

This pilot study provided key information about community pharmacists' readiness for POCT for HIV and HCV. The top three pharmacist-perceived barriers to HIV and HCV POCT were staffing, time to conduct test, and patient out-of-pocket cost. Less pharmacists perceived educating patients and training/certification as barriers. Pharmacists had more confidence providing basic HIV and HCV education to patients as compared to discussing the results of a positive HIV or HCV preliminary test.

Several studies have identified diverse barriers to POCT in a variety of settings, primarily regarding integration into workflow, accuracy of POCT, and pharmacist education and training. In one study, barriers to implementation of HIV POCT in populations around the world were identified in real-world settings between January 1996 to February 2014.¹⁴ A total of 132 studies were identified from a range of study types, primarily diagnostic evaluations and surveys, and evaluated by two independent reviewers. The authors concluded that the majority of barriers found were regarding integration of POCT and test device related concerns, such as accuracy. The authors discussed that ideal implementation of HIV POCT can be achieved with clear protocols, training on quality assurance and control, clear communication, and linkage plans to improve patient outcomes.

In another study, barriers to implementation of HCV POCT were identified in a U.S. community pharmacy study conducted in 2016.¹⁵ A total of 83 patients were tested during a 3-month pilot study. Of those tested, 80% denied previous HCV testing and 12 of 81 patients self-identified two or more HCV risk factors. Only 1.2% of patients were found to be HCV antibody-positive. Two primary barriers identified by pharmacists included recruiting patients for testing and balancing the time required to perform, interpret, and provide test results to the patient within the normal pharmacy workflow. In general, pharmacists were supportive of promoting HCV screening in pharmacies both before and after the pilot study. The authors concluded that trained and motivated community pharmacists have the ability to perform POCT for potentially high-risk patients not currently in care. However, this study did not identify any facilitators for the implementation of POCT.

On the contrary, the results of another study identified different barriers to implementation of HCV POCT in a U.S. community pharmacy chain between 2015 to 2016.¹⁶ A total of 1,298 patients aged at least 18 years old with at least one HCV risk factor were tested during a 6-month pilot study. Only 8% of patients were found to be HCV antibody-positive. One primary barrier identified by the authors was lack of follow-up – only 52% of patients who received a positive result responded during the 21- to 28-day follow-up period. Another barrier was cost of treatment. The authors concluded their study provided evidence in support of point-of-care HCV screening in retail pharmacies for at-risk individuals in the U.S.

One study discussed barriers to implementation of infectious disease POCT in U.S. community pharmacies between November 2012 and May 2013.¹⁷ Barriers identified deficits in pharmacist education and training, and variance/vagueness in state statutes governing the practice of pharmacy. Fewer than 20% of states address POCT in their statutes and regulations governing pharmacy in 2012. The authors concluded that these challenges are not insurmountable if pharmacists obtain proper training, understand their state regulations and statutes, and work with regulators and stakeholders to ensure that such services and follow-up care are provided.

Our pilot study confirmed findings from previous studies regarding barriers of integration of POCT into workflow and pharmacist education and training. Pai *et al.* found similar barriers such as integration into workflow and training. Dong *et al.* also found integration into workflow to be a primary barrier. Lastly, Arora *et al.* also identified handling positive results as a barrier.¹⁸

Our study did not assess the accuracy of HIV and HCV POCT as a barrier. This is because the accuracy of POCTs have been demonstrated to be greater than 99%. One barrier that our study evaluated that had not been assessed by previous studies included the use of physical assessment to aid in diagnosis. In addition, this study provided new information about facilitators from the scenario-based questions 8 to 12. Participants demonstrated that incorporation of POCT into workflow and providing basic education for both HIV and HCV were facilitators, as they had higher levels of confidence with these proposed activities.

There are several limitations of this pilot study. One limitation was the potential for response bias due to a low response rate. Some plausible reasons for a low response rate include the survey being optional and the timing of the survey over two major holidays. Another limitation is that pharmacists were not provided any background information, such as existing barriers about HIV or HCV POCT. This survey assumed that there are barriers, pharmacist-perceived or not, to HIV and POCT. In addition, not every pharmacist completed all questions of the survey. In a few cases, there was a tendency of completing the beginning, or more straightforward questions, and not answering the remainder of questions before submission. In addition, the survey was also conducted by the pharmacists' employer; thus, pharmacists may have felt pressured to answer that they were more confident in conducting HIV and HCV POCT. Lastly, a more robust analysis including pharmacist demographic information could not be completed.

After evaluation of the top three pharmacist-perceived barriers, another discussion can be had to overcome these barriers. Regarding staffing as a barrier, HIV and HCV POCT could be piloted in community pharmacies with more pharmacist overlap and during times of the year that don't include holidays and peak flu season. Regarding time to conduct

the test as a barrier, pharmacists need education that existing HIV and HCV POCTs only take about 15 minutes to conduct, similar to other POCTs. In addition, a pilot could initially be performed by pharmacists with more clinical responsibilities or those who are motivated to provide POCT. These pharmacists could set up one-on-one appointments with patients who are interested and have never been screened for HIV and HCV. Patient out-of-pocket cost is likely the most difficult barrier to overcome due to lack of insurance reimbursement of POCT. In one study evaluating the implementation of HIV POCT in a community pharmacy in 69 participants, most (78.3%) indicated they would be willing to pay \$16 to \$20 or less for the HIV test, and only 9% would pay \$30 or more.¹⁹ Unfortunately, cost is likely to remain an issue and barrier for many patient populations.

Conclusion

Understanding barriers perceived by pharmacists will assist with potential implementation of HIV and HCV POCT throughout a community pharmacy chain. While this study found pharmacist support for the implementation of HIV and HCV POCT, additional studies are needed before effective implementation of HIV and HCV POCT in community pharmacy.

Acknowledgements: Preliminary results were presented as a poster at the American Pharmacists Association conference in Nashville, TN in March of 2018.

Conflicts of Interest: We declare no conflicts of interest or financial interests that the authors or members of their immediate families have in any product or service discussed in the manuscript, including grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patents and royalties.

Treatment of Human Subjects: IRB determined project was non-HSR

References

1. HCV Testing and Linkage to Care. *American Association for the Study of Liver Diseases and Infectious Diseases Society of America*. Last updated May 24, 2018. Accessed December 12, 2018. <https://www.hcvguidelines.org/evaluate/testing-and-linkage>
2. Frequency of HIV Testing and Time from Infection to Diagnosis Improve. *CDC*. Last updated November 28, 2017. Accessed December 1, 2017. <https://www.cdc.gov/media/releases/2017/p1128-frequency-hiv-testing.html>
3. Smith BD, Morgan RL, Beckett GA, et al. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. *MMWR Morbid Mortal Wkly Rep*. 2012;61(RR-4):1e32.
4. Klepser DG, Klepser ME. Point-of-care testing in the pharmacy: how is the field evolving? *Expert Rev Mol Diagn*. 2018;18(1),5-6.
5. Branson BM, Handsfield HH, Lampe MA et al. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. *MMWR Morb Mortal Wkly Rep*. 2006;55(14):1-17.
6. HIV in the United States: At A Glance. *CDC*. Last updated November 29, 2017. Accessed October 7, 2017. <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>
7. Emerging Issues: Hepatitis C. *CDC*. Last updated June 4, 2015. Accessed October 7, 2017. <https://www.cdc.gov/std/tg2015/emerging.htm>
8. Surveillance for Viral Hepatitis – United States, 2015. *CDC*. Last updated June 19, 2017. Accessed October 7, 2017. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm>
9. HIV/AIDS Testing. *CDC*. Last updated March 16, 2018. Accessed June 3, 2018. <https://www.cdc.gov/hiv/basics/testing.html>
10. Testing Recommendations for Hepatitis C Virus Infection. *CDC*. Last updated October 15, 2015. Accessed December 1, 2017. <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>
11. Weidle PJ, Lecher S, Botts LW et al. HIV testing in community pharmacies and retail clinics: A model to expand access to screening for HIV infection. *J Am Pharm Assoc*. 2014;54:486-492.
12. Wick JY. Point-of-Care HIV Testing Promising in Pharmacies. *Pharmacy Times*. Published October 11, 2015. Accessed June 12, 2018. <https://www.pharmacytimes.com/resource-centers/hiv/point-of-care-hiv-testing-promising-in-pharmacies>
13. Dillman DA, Smyth JD, Christian LM. *Internet, Mail, and Mixed-Mode Surveys: The Tailored Design Method*. 3rd ed. Hoboken, NJ: John Wiley & Sons, Inc; 2009.
14. Pai NP, Wilkinson S, Deli-Houssein R, et al. Barriers to Implementation of Rapid and Point-of-Care Tests for Human Immunodeficiency Virus Infection: Findings From a Systematic Review (1996–2014). *Point Care*. 2015;14(3):81-87.
15. Dong BJ, Lopez M, Cocohoba J. Pharmacists performing hepatitis C antibody point-of-care screening in a community pharmacy: A pilot project. *J Am Pharm Assoc*. 2017;57:510-515.
16. Kugelmas M, Pedicone LD, Lio I, et al. Hepatitis C Point-of-Care Screening in Retail Pharmacies in the United States. *Gastroenterol Hepatol (N Y)*. 2017;13(2):98-104.
17. Gubbins PO, Klepser ME, Dering-Anderson AM, et al. Point-of-care testing for infectious diseases: Opportunities, barriers, and considerations in community pharmacy. *J Am Pharm Assoc*. 2014;54:163-171.
18. Arora DR, Maheshwari M, Arora B. Rapid Point-of-Care Testing for Detection of HIV and Clinical Monitoring. *ISRN AIDS*. 2013;2013:1-5.
19. Darin KM, Klepser ME, Klepser DE, et al. Pharmacist-provided rapid HIV testing in two community pharmacies. *J Am Pharm Assoc*. 2015;55:81-88.

Appendix A

Survey Questions

1. SUPERVALU offers Point-of-Care Testing (POCT) as part of their clinical services. Have you had the opportunity to conduct POCT at your pharmacy? If so, which POCT have you conducted? Please select all that apply.
 - Blood glucose
 - A1C
 - Cholesterol
 - Strep
 - Influenza
 - Other (type in response)
 - I have never conducted POCT
2. Do you currently have patients who receive antiretroviral therapy?
 - Yes
 - No
3. Do you currently have patients who receive medications for the treatment of Hepatitis C?
 - Yes
 - No
4. Do you think Point-of-Care Testing (POCT) for **HIV** is within a pharmacist's scope-of-practice?
 - Yes
 - No
5. Do you think Point-of-Care Testing (POCT) for **Hepatitis C** is within a pharmacist's scope-of-practice?
 - Yes
 - No
6. What would you consider a suitable amount of time to conduct POCT for **HIV**, including time for potential questions a patient may have?
 - 0 to 15 minutes
 - 15 to 30 minutes
 - 30 to 60 minutes
 - More than 60 minutes
7. What would you consider a suitable amount of time to conduct POCT for **Hepatitis C**, including time for potential questions a patient may have?
 - 0 to 15 minutes
 - 15 to 30 minutes
 - 30 to 60 minutes
 - More than 60 minutes

For questions 8 through 12, consider the following scenario: SUPERVALU is rolling out a new clinical service – POCT for HIV and Hepatitis C. You are a pharmacist working at a store that has been identified to have a high HIV and Hepatitis C population and will be required to undergo training and certification to both conduct POCT and provide education to these patients. Each POCT will be conducted via an oral swab and will take place during an appointment-based session. In addition, each POCT takes about 15 minutes for results.

Please indicate how confident you are...	Extremely confident	Moderately confident	Slightly confident	Not confident	Extremely unconfident
8. Incorporating POCT for HIV and Hepatitis C into workflow at your store?					
9. Providing basic HIV education to a patient?					
10. Providing basic Hepatitis C education to a patient?					
11. Discussing the results of a positive preliminary HIV test?					
12. Discussing the results of a positive preliminary Hepatitis C test?					

For each of the following items related to HIV and Hepatitis C POCT, indicate whether you would consider them to be barriers:

	Yes	Maybe	No
13. Staffing			
14. Time to conduct test			
15. Out-of-pocket cost of test to patient			
16. Educating patients			
17. Training and certification			
18. Handling false positive results			
19. Physical assessment to aid in diagnosis			
20. Administrative burden			