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## We Can Do More Than Just Sell the Test: Pharmacist Perspectives About Over-the-Counter Rapid HIV Tests

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#### Abstract

Pharmacist attitudes about the over-the-counter (OTC) sale of HIV rapid tests in pharmacies were explored through interviews conducted among 17 licensed community pharmacists in a Midwestern, moderate HIV incidence state between May and September 2012. Participants recognized that OTC rapid HIV tests would increase the number of people aware of their HIV status. Concerns included linkage to care and results consultation for those who test HIV-positive. Point of sale was identified as an opportunity for consultation about the test and to establish a relationship for future discussion about results and linkage to care. Pharmacists could provide initial test consultation or information, and consultation about the test results in order to provide post diagnosis support and facilitate linkage to care.

#### Resumen

Las actitudes de los farmacéuticos sobre el over-the-counter (OTC) venta de las pruebas rápidas del VIH en farmacias se exploró a través de entrevistas entre los 17 farmacéuticos comunitarios con licencia en un estado del Midwestern en Estados Unidos, moderado incidencia del VIH entre Mayo y Septiembre de 2012. Los participantes reconocieron que OTC pruebas rápidas de VIH aumentaría el número de personas que conocen su estado serológico. Las preocupaciones incluyen la vinculación con cuidado y consulta los resultados para los que el resultado es VIH-positivo. Point of sale de venta fue identificado como una oportunidad de consulta sobre la prueba y establecer una relación para un discussion futuro sobre los resultados y la vinculación a la atención. Los farmacéuticos podría ofrecer consulta inicial de prueba o información y consulta sobre los resultados de la prueba con el fin de ofrecer apoyo después de diagnóstico y facilitar la vinculación a la atención.

#### Introduction

HIV disease has become a manageable health condition in the United States. Appropriate treatment can reduce viral load such that it not only improves the health of patients, but also decreases the sexual risk of HIV for their partners [1]. Yet even with this encouraging news, we know that 20 % of the people living with HIV do not know it [2], and 40 % of those who learn their HIV status, do so very late in the disease process [3]. This past summer, the Food and Drug Administration approved a rapid HIV test for over-the-counter (OTC) sale and home use [4]. The test is now available for sale in pharmacies across the country and on the Internet.

The availability of the OTC rapid HIV test is an indicator of the evolution of HIV diagnostic testing toward greater decentralization–away from provider and laboratory dependence and into the hands of people everywhere. This shift increases the opportunity for people to learn about their HIV status, and to monitor it on a regular basis as part of ongoing sexual health. The community pharmacy sale of this test facilitates access to an HIV test, and potentially, to results consultation with linkage to primary care. This last point should be emphasized given current challenges in our system of linkage to care following an HIV diagnosis. Only 77 % of people who test positive are actually linked to medical care [5], and of those, only 66 % are retained in care. This essentially means that only 24 % of people living with HIV in the United States have the virus under control [6]. Thus, while we widen access to HIV testing, we must also identify opportunities for linkage to HIV treatment.

The community pharmacy setting emerges as an excellent public health opportunity as we consider the availability of OTC rapid HIV tests; particularly given the evolution of pharmacy practice over the last twenty years [7-9]. Community pharmacies now provide a range of public health services such as immunizations [10-12], health counseling for various diseases and conditions [8, 13-16], medication therapy management consultation [17-19], and testing for a number of chronic conditions [20, 21].

HIV testing in U.S. pharmacy settings has emerged recently in public health research, primarily for large urban areas. Studies have explored perceptions about the value of pharmacy based HIV prevention and testing among injection drug users [22], pharmacist attitudes about HIV consultation and testing in pharmacies participating in syringe exchange programs,(21) and attitudes of acceptability, feasibility and readiness for community pharmacy based HIV testing in a Midwestern state [23]. These studies explore the provision of testing by pharmacists or the hosting of community based organizations to provide HIV testing in pharmacy settings. What remains unknown is pharmacist attitudes about the OTC availability of HIV rapid tests, and pharmacist opinions about opportunities for public health support. What roles might pharmacists play in OTC sales of the HIV test kit? What are the public health opportunities for pharmacist interaction in and around that exchange? What is meant by 'public health opportunities' in this context?

This study explores community pharmacist attitudes and perceptions about OTC sale of HIV rapid tests by pharmacies, and identifies their opinions about public health opportunities created by this innovation in HIV test availability.

## Methods

Exploratory interviews were conducted among a convenience sample of licensed community pharmacists in Indiana, a Midwestern state with moderate HIV incidence. Interview questions were part of a larger study to explore pharmacist perceptions of pharmacy based HIV testing.(23) Participants were recruited through referral from two area pharmacy schools, two pharmacy associations, through professional networks of interested pharmacists, and through snowball sampling among pharmacists considering interview participation. Participants were asked to complete a brief survey to classify participants by demographics and pharmacy setting characteristics. Interviews were conducted in person or by telephone, and lasted an average of 30 min. Interviews were conducted between May and September 2012, during which the FDA approved the over the counter sale of the rapid HIV test kit.(4) Interviews were recorded and transcribed for a priori and open coding. Three investigators independently coded transcripts to assure interrater reliability. The study was approved by the Indiana University and Butler University Institutional Review Boards.

## Results

Seventeen Indiana licensed community pharmacists participated in the study. Participants were primarily from the greater Indianapolis area. One pharmacist served the Gary area and four pharmacists served rural areas or small towns. The race/ethnicity of the sample was White, non-Hispanic. The interview sample had a gender balance of 9 men and 8 women. The mean age was 37.9 years (SD9.7); 64.7 % (11) held a PharmD degree, while the remainder were baccalaureate-level registered pharmacists; and all but one participant received their training from a pharmacy school in Indiana. Just under half (43.8 %) reported that they currently served people living with HIV. Two pharmacists had experience with HIV testing within their pharmacies. In these cases, a local community based organization would come into the pharmacy and provide rapid HIV testing for interested clientele. A majority of participants were not aware of the pending or recent approval (depending upon interview date) of the over the counter sale of the rapid HIV test kit.

## **Comfort Level With Pharmacy Based Testing Generally**

Pharmacist participants had a lot of experience with the provision of and consultation about various tests in the pharmacy setting. Examples of such tests included blood glucose monitoring, cholesterol testing, home drug testing, pregnancy tests, tests for yeast infections, fecal occult blood testing, bioidentical hormone testing, various other whole blood tests including A1C. Generally pharmacists reported engaging people at the point of sale if tests were to be conducted at home. For tests conducted inside the pharmacy, participants reported having a high comfort level with providing consultation related to behavioral risk reduction, and with medications

management related to a test outcome. Some pharmacists indicated that when requested to do so, they have helped customers take an over-the-counter test in the pharmacy for conditions other than HIV.

We do bioidentical hormone replacement and we have a kit that the patient takes home. And they can either test saliva or blood spot, and then they submit that to the lab. Then we get the results, and then we meet with the patient. What kinds of hormones they are testing for, what does the test look like, can I administer it myself, and how to do the test? These are the most common questions.

## More Than Just Selling the Test

All pharmacists indicated that rapid HIV testing would likely result in more people learning their HIV status. However, many pharmacists felt that the OTC sale of an HIV test was not sufficient, because the purchaser would not necessarily engage with the pharmacist. Participants often had strong feelings about engaging with the person buying the test so that they could serve as a resource for the person testing. It was recognized that with the OTC model, the person buying the test may not be the same person as the one who takes the test.

It's so important that they would understand how to do it properly and even maybe some resource. I mean, what do they do if they get a positive test? I mean, they're home, they get a positive test, now what? I guess I would hope to be more of a resource for them with some information.

For these pharmacists, the issue was getting people linked into primary care. These pharmacists were not comfortable with "just selling it (the test) and having them leave" the pharmacy. The test was important as was the opportunity to provide consultation about the results. The majority of pharmacists were concerned for the person who tested positive.

I think that a lot of pharmacists would agree that more access is good, and consultation from a healthcare professional is superior to just testing on your own and dealing with those results alone in your house without anybody to tell you, 'okay, there are things you can do; this is not the end of your life; there are things we can do....to help you.'

Participants felt that results consultation was important, but equally so was linkage to HIV treatment from a long-term health standpoint. For pharmacists, this was a point of conflict about the OTC HIV test. While it was recognized that over the counter access to rapid HIV testing would likely result in more people testing, this kind of anonymous and potentially isolated testing presented other issues. Participants reflected on their role with OTC tests and felt that those who tested positive would have important needs that could not be met when testing alone.

They can pick that up off the shelf and bring it to the pharmacy counter and ring it up and not have anything said at all about it; and that might be a way to get more people to do the test. But

then we're kind of losing that network of people. You don't get them in the system by just having that be the transaction. So I think there's a trade-off. Do you want to test more people or do you want to make sure the people that you test that are positive get into the correct system to get treatment?

# **Consultation Opportunities**

All pharmacist participants discussed the importance of consultation about the test at point of sale, and they saw this as the job of the pharmacist. The comfort around and desire for consultation about the test appeared to be based on participant experience selling other types of tests in their pharmacies. According to participants, discussion was a pharmacist's goal; and it usually happened at the point of sale.

Even when someone purchases any of our diagnostic tests, there's some sort of discussion with them. I mean, we don't hardly ever let them get out of the door (without consultation).

For some pharmacists, consultation meant discussions about test procedure and questions about the test validity. For other pharmacists, consultation meant engagement at point of sale to establish the relationship around testing, so as to set up the possibility that the person might come back after their test to consult with the pharmacist if desired.

I guess the biggest thing is, I don't care if they do it at home or they prefer we do it here. I don't care one way or another, but I would be very adamant that they know that we're open for discussion pending results.

The point of sale was the moment of opportunity to express pharmacist openness for test consultation or questions. One participant suggested a system that would provide information even when the pharmacy is closed or if someone wished to initially avoid interaction at point of sale.

Somebody that might just buy over the counter, they might be a little bit more embarrassed to ask or might come in when I'm closed and not have the opportunity to ask; but they could always come back too. I mean we could put up a sign and say 'if you have any questions, please feel free to stop by the pharmacist.'

Participant desire for consultation about the HIV test was closely linked to the decision to place the test close to the pharmacist: behind the pharmacy counter or in front of it. While some participants recognized they may not have control of test placement—"they (pharmacy chain) will likely require that it is out on the floor"—participants felt that test placement might increase the opportunity for consultation about the test. One participant used the analogy of selling Plan B (levonorgestrel, or the 'morning after' pill) in thinking of kit location. I probably would like it to be sold just behind the counter, kind of like the plan B, just for the fact that it gives the pharmacists kind of an opportunity to open up to that person and ask, "Hey would you like any other advice on how to use the test?" or to answer questions on HIV.

For participants, there were obvious tradeoffs for placement on the floor and behind the counter:

I guess for the sake of the patient, it is kind of nice. I would probably do both scenarios because that way if it's on the floor, they can come up, grab it and walk and take care of it without having to interact and feel awkward or uncomfortable. Maybe if it was kept behind the pharmacy, for some people that might deter them from wanting to purchase it. But the other big thing too, if it's held behind the counter, is that once they purchase the test at that point, you're able to say, "well if you have questions or concerns once you get your results, we're here for you to talk to;" and be able to offer more than they thought they would get just purchasing the test.

## Discussion

Pharmacist participants overwhelmingly identified a public health need related to the OTC sale of rapid HIV test kits: test consultation and linkage to care. The opportunity raised by participants was pharmacist consultation at point of sale and as needed. This emerging image of pharmacist-as-health consultant reflects an observed pharmacy practice shift during the past decade from the isolated druggist to health care team member, immunizer, medications consultant and, in some cases, tester.

Participant opinions about the pharmacist role suggests that there are likely two potential services that could be offered at or around point of sale for OTC HIV rapid tests: (1) initial test consultation or information to establish trust for future consultation, and (2) consultation about the test results in order to provide post diagnosis support and facilitate linkage to care. Participants expressed an important need to reduce isolation around an HIV test, while at the same time recognizing that such isolation, or perhaps anonymity, may be the element that brings a person to seek an OTC HIV test. Linkage to care was a major priority for participants, and all discussed care linkage using terms such as 'resources' or 'referrals' or 'someone to help you.' Participant comfort with conversation about linkage to care appeared to be based on assumptions about the ease of care access. Comments implied that information and referral were necessary and sufficient for HIV primary care access. No participant mentioned barriers to care.

Study findings are likely limited by the sample selection, as it is probable that only pharmacists receptive to HIV issues agreed to participate. Future studies should investigate pharmacist opinion and attitudes about OTC sale of rapid HIV test kits among a representative and larger sample of pharmacists in a state such as Indiana as well as in states with other geographic, socio demographic and epidemiologic characteristics.

With the excitement to solve the intractable issue of HIV testing access, it is likely that in such haste, an important opportunity was missed to leverage the surrounding system to assure health

access. This is critical because the OTC HIV rapid test is already on the market, and there are no extant evaluations as to the adequacy of package insert materials for linkage to consultation and (if HIV-positive) treatment. The current model of OTC sale of the rapid HIV test provides test purchasers with testing package insert material containing related website and call center contacts for information.

Study findings reinforced the importance and intensity of an HIV test. Expanded opportunities for HIV testing should be surrounded by public health systems of support to assure not only increased access to testing but also increased access to HIV treatment. Creative thinking about pharmacists and their unique proximity to OTC HIV rapid tests should be considered further. Exploration should include strategies to reinforce system sustainability, such as reimbursement to pharmacists who offer test consultation. This kind of systems thinking is paramount if we are going to increase the number of people who know their status and also increase the number of people in HIV treatment.

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