

Rapid Oral Fluid Testing for HIV in Veterans With Mental Health Diagnoses and Residing in Community-Assisted Living Facilities

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Veterans with a history of mental health and substance abuse diagnoses, residing in assisted living facilities, are more likely to have an undiagnosed HIV infection related to high-risk behaviors. We determined (a) the cross-sectional prevalence of HIV infection among 65 veterans of unknown HIV serostatus with mental health diagnoses who resided in 11 community-assisted living facilities, and (b) whether patients who had not consented to standard physician-initiated blood testing in the previous 5 years would consent to rapid oral fluid HIV testing by nurses familiar to the subjects. We found an HIV prevalence of 3.1% in the subjects who agreed to be tested (n = 64, 98%). High test acceptance, especially in a group with little HIV screening experience, and the identified high prevalence of disease, suggest that this diagnostic method is effective. Patients' familiarity with the nurses who conducted the testing most likely supported the success of the procedure.

(Journal of the Association of Nurses in AIDS Care, 22, 81-89) Published by Elsevier Inc. on behalf of Association of Nurses in AIDS Care

Key words: Assisted living, HIV, mental health diagnosis, rapid HIV testing, veterans

The rapid oral fluid HIV test (OraSure, 2007) has the potential to mitigate some of the obstacles to standard blood-based HIV testing and can provide other

potential benefits as well. Research has shown that nurse-initiated rapid testing might be more acceptable to patients than standard testing (more than twice the acceptance rate) and it results in increased patient receipt of results (a greater than 5-fold increase; Anaya et al., 2008). Some rapid tests for HIV infection use oral secretions rather than blood, thereby avoiding the problems associated with people who are afraid of needles and eliminating the risk of needlestick injuries. Accidental HIV transmission through saliva is extremely unlikely, especially in this setting. Results can be provided within 20 minutes, facilitating patient acquisition of results and counseling, and the test is easy to perform and

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read. It is based on colorimetric antibody detection presented in a format similar to the widely available over-the-counter pregnancy tests. Such testing can be offered routinely in a variety of clinical settings and outreach efforts to identify persons with HIV infection (Centers for Disease Control and Prevention [CDC], 2007; Keenan, Keenan, & Branson, 2005; O'Connell et al., 2003). Although positive tests must be confirmed by Western blots using blood samples, the new oral fluid rapid HIV test provides quicker results, thereby eliminating the need for people to return to the facility to obtain test results. Therefore, a strategy based on rapid oral fluid HIV testing has many useful features.

In total, 25% of U.S. veterans returning from the wars in Afghanistan and Iraq have been diagnosed with a mental health disorder (Seal, Bertenthal, Miner, Sen, & Marmar, 2007) and 26% of the veterans who were treated at Veterans Affairs Medical Centers (VAMCs; approximately six million of the total 24 million) have been specifically treated for mental illness (Zeiss, 2010). Patients with mental illness pose a challenge for HIV testing, especially when substance abuse is also present. Health care providers sometimes fear a patient's reactions to discussions related to either sexual practices (Coverdale & Aruffo, 1992) or to positive HIV tests (Walkup, Satriano, Barry, Sadler, & Cournos, 2002); some providers fear that discussions related to sexuality and HIV may worsen mental health symptoms. Health care providers also fail to appreciate the HIV risk factors among those with mental illness, as they underestimate the sexual activity of this group of people (Walkup et al., 2002). Moreover, the time required to obtain accurate patient histories may be higher for those with mental illness, thereby straining the already limited time available for psychiatric and other medical care. Researchers in a Veterans Affairs (VA) health study discovered that those with serious mental health diagnoses had a 2-fold increase in HIV risk as compared with those without these diagnoses (Himelhoch et al., 2007). Although those with mental illness are at an increased risk for HIV (Blank, Mandell, Aiken, & Hadley, 2002; Carey, Weinhardt, & Carey, 1995; Essock et al., 2003; Goldberg, 2004; McKinnon & Rosner, 2000; Rosenberg et al., 2001), they are less likely to receive post-test counseling (Desai, Rosenheck, & Desai, 2007). The reasons for

this disparity are still not fully clear, but patients with mental illness may remain untreated until the HIV disease reaches an advanced and life-threatening stage.

Drug-dependence (alcohol or illicit drugs) has been reported to be present in 3.3% of veterans (Substance Abuse and Mental Health Services Administration, 2003) and has been linked to the acquisition of HIV either directly (intravenous drug use with needle sharing) or indirectly in association with risky sexual practices and usage of intravenous drugs (DeHovitz et al., 1994; Edlin et al., 1994; Petry, 1999). Although the exact prevalence is unknown, a reasonable proportion of people with mental illness residing in assisted living facilities (ALF) have been reported to be dependent on drugs and may be at an increased risk for undiagnosed HIV infection.

According to a report by the CDC, an estimated 1.1 million Americans were living with HIV infection in 2006, but one fifth, or 232,700, of them were unaware of it (CDC, 2007). This problem contributes to the continued spread of the disease, with 54% to 70% of the 56,300 transmissions in the United States occurring each year from undiagnosed individuals (Hall et al., 2008). Among those who are tested in the U.S. population at large, 30% do not return for their test results (which are typically available 2 or more weeks after the test is performed; CDC, 2007). Approximately 8,000 of those people who do not return for the results test positive for HIV and remain unaware of their serology results. This puts HIV-infected individuals at a risk for HIV progression and for developing potentially fatal opportunistic infections such as *Pneumocystis jiroveci* pneumonia. It also puts their sexual partners and those exposed to their blood through needle sharing at a risk for viral transmission. Previous investigators have shown that awareness of one's HIV status leads individuals to engage in unsafe sexual practices less frequently, thus, most likely reducing the spread of HIV (Marks, Crepaz, Senterfitt, & Janssen, 2005; Weinhardt, Carey, Johnson, & Bickham, 1999). In addition, antiretroviral treatment lowers viral loads in most cases, as demonstrated by many hundreds of clinical trials (reviewed in Bartlett et al., 2006) with concomitant decreases in the potential for

transmission (Becquet et al., 2009; Graham et al., 2007; Vernazza et al., 2000). Moreover, naturally lower steady-state viral loads predispose to lower rates of HIV transmission from untreated HIV-infected individuals (Ragni, Faruki, & Kingsley, 1998), and most likely from treated individuals as well. Therefore, higher rates of unsafe sexual practices and drug use combined with higher viral loads cause undiagnosed, and therefore untreated, HIV-infected individuals to spread the infection more readily.

In general, people give a variety of reasons for not returning for their test results, with the frequency of each response depending on the population demographics. The most commonly given reasons include the following: fear of a positive result (and the associated fear of death), lack of transportation, belief that they were at a lower risk for HIV and therefore the result would be negative, and fear that HIV status would be disclosed to someone else (e.g., relatives, sexual partners, employers, insurance companies) (Carey, Carey, & Kalichman, 1997; Desai et al., 2007; Senn & Carey, 2009; Valdiserri et al., 1993), although the latter is a greater deterrent to testing than to receipt of results.

In VAMCs, HIV risk assessment screening and testing are mainly performed by primary care providers and their staff during clinic visits. HIV testing requires drawing of a blood sample, counseling, and, at the time of this study, consent. Despite the Veterans Health Affairs' efforts to conduct HIV testing during primary care visits among the vulnerable population of veterans with chronic mental illnesses, such as schizophrenia, schizoaffective disorder, bipolar disorder, depression, and post-traumatic stress disorder, testing was often not performed (Rosenberg et al., 2004). There are many challenges to standard venous blood HIV testing in busy health care settings in which patients may not be acquainted with the health care providers. The exact reasons as to why HIV testing is not performed more often on this population include some of the issues mentioned previously (i.e., health care provider biases about patient attitudes/responses and patient risk, as well as time constraints). In addition, some patients dislike blood withdrawal or leave before blood is collected because of delays in the phlebotomy laboratory (our unpublished observations).

Methods

Our initial outreach program was initiated because of two patients residing in ALF whose HIV serology results were unknown, and who were admitted to hospitals outside the facility and died of opportunistic infections associated with AIDS within a short time. We hypothesized that people with chronic mental illness who reside in ALF would most likely have a higher prevalence of HIV and we discovered that many had not been tested in the usual health care setting despite showing signs of increased risk such as hepatitis B and C seropositivity. As part of a VA-sponsored initiative, funding was obtained to test our subjects and maintain records. We performed a cross-sectional study of HIV prevalence in veterans with mental health diagnoses, many of whom had substance abuse disorders, and who were residing in community ALF. In addition, this was a pilot intervention to determine acceptability of rapid oral fluid HIV testing performed by nurses known to the subjects. The CDC has recommended HIV testing for any population with a prevalence rate of greater than 0.1% based on a cost-effectiveness analysis (Branson et al., 2006; Paltiel et al., 2005; Sanders et al., 2005). We reasoned that if HIV prevalence was found to be higher than this CDC threshold of 0.1%, and acceptance was high compared with standard physician-initiated testing, then this approach could be expanded to similar patient groups within and outside the VA system, and could prompt more detailed testing of this approach with randomized interventions.

Patient Sample and Data Collection

The HIV/AIDS program coordinator and community residential care case manager nurse interacted on a daily basis with veterans who were diagnosed with substance abuse disorders and chronic mental illness. The community residential care case manager nurse also worked with 20 community group residences within the Philadelphia catchment area, and visited them regularly, meeting between 15 and 20 patients per week. Given the familiarity and trust established between these two nurses and our patient population, the community residential care case manager nurse

and the HIV/AIDS program coordinator decided that they would be the people to have direct contact with the patients in the community. During the period between October 2006 and September 2007, the community care nurse identified 65 veterans under care in association with the VA, who lived in 11 community ALF, who had mental illness diagnoses (defined as schizophrenia, schizoaffective disorder, bipolar disorder, depression, and post-traumatic stress disorder in their computerized medical records), and who had not been tested for HIV in the previous year despite being seen in primary care clinics. None were known to be infected with HIV. These veterans were approached to participate in the testing intervention. None of the subjects had been declared incompetent, and study nurses deemed all subjects as being capable of understanding the consent process well enough to participate. All except one consented to oral testing. Participants were provided with HIV prevention information and they obtained their test results during the nurse's visit to the facility. Counseling of all subjects occurred within 1 week of testing but was not conducted immediately, so as to avoid psychologically overwhelming the study participants. Those testing positive were referred to the VA HIV clinic where blood was drawn for confirmatory Western blotting, and further follow-up care was scheduled.

Demographic data were collected prospectively as part of the clinical intervention funded by the VA. The data were de-identified for research analysis. The VA Institutional Review Board approved all research procedures.

Rapid Oral HIV Testing Procedure

This study used oral swab testing with the Ora-Quick ADVANCE Rapid HIV-1/2 Antibody Test kit manufactured by OraSure Technologies, Inc. (Bethlehem, PA). This test has a specificity and sensitivity of 99.8% and 99.3%, respectively (CDC, 2004), has been approved by the Food and Drug Administration, and carries a Clinical Laboratory Improvement Amendments waiver (meaning that the tests can be performed without the need for any frequent official quality assessments). Subjects were given the choice of doing the swabbing by themselves or having it performed by one of our two nurses. The nurses who performed the

tests were trained by the microbiology clinical laboratory and had quarterly quality control assessments. As per the recommendations of the manufacturer (OraSure, 2007), the tester placed the absorbent pad end above the individual's teeth along the outer gum and swabbed once around both the upper and lower gums. The device was then inserted into a vial of developing solution for 20 minutes, after which it indicated whether HIV-1/HIV-2 antibodies were present by way of an appearance of a bar. Positive tests, similar to standard blood enzyme-linked immunosorbent assays, were confirmed by Western blot, even though patients were informed immediately of reactive and presumptively positive test results.

Data Analysis

After the commencement of the intervention, it was decided to examine the prevalence of HIV in veterans with mental health diagnoses and the acceptability of the oral testing among our patients. This design was adequate for the task of a pilot analysis that could be extended to a randomized intervention trial in the future, if the data were promising enough. We calculated percentages for demographic data. The prevalence of HIV infection (positive tests/number tested) was calculated for all subjects and for those who had not been tested for HIV in the previous 5 years. We also calculated a rate of acceptance for the HIV testing protocol (number consenting to testing/number approached).

Results

General demographic data on the 65 subjects involved in this study are presented in Table 1. All subjects were diagnosed with mental illness, and substance abuse was also present in 39% of the subjects. Serologic evidence of exposure to hepatitis B (hepatitis B core antibody positive and/or hepatitis B surface antigen positive) and/or hepatitis C (positive serology) was present in 34% of the tested individuals. As is typical for our veteran population, 94% were men, 60% were African American, and the average age was 61 years. The vast majority (95%) had been seen at least once in clinic, and 52% had been hospitalized at the Philadelphia VAMC between

Table 1. Patient Data

	<i>n</i> (%)
Diagnoses	
Mental health diagnosis	65 (100%)
Mental health and substance abuse diagnoses	25 (39%)
Mental health diagnoses	
Paranoid schizophrenia	27 (42%)
Schizophrenia not otherwise specified	12 (18%)
Depressive disorder	5 (8%)
Bipolar disorder	3 (5%)
Schizoaffective disorder	3 (5%)
Post-traumatic stress disorders	2 (3%)
Psychotic disorder not otherwise specified	1 (2%)
Prevalence of hepatitis exposure	
Hepatitis B only (by positive core antibody and/or surface antigen testing)	3 (5%)
Hepatitis C only (by positive antibody testing)	10 (15%)
Hepatitis B and C	9 (14%)
Gender	
Male	61 (94%)
Female	4 (6%)
Race/Ethnicity	
Black/African American	39 (60%)
White	25 (39%)
Pacific Islander	1 (2%)
Average age in years (range)	61.2 (44-86)
Marital status	
Married	1 (2%)
Never married	37 (57%)
Divorced	11 (17%)
Separated	8 (12%)
Widowed	6 (9%)
Unknown	1 (2%)
Hospitalized in previous 5 years	
Yes	34 (52%)
No	31 (48%)
Enrolled in VA clinic with at least one visit in previous 5 years	
Yes	62 (95%)
No	3 (5%)
Tested for HIV in previous 5 years	11 (17%)

October 2002 and September 2007. Despite these contacts with the medical system, only 17% of the subjects had been tested for HIV in the reviewed 5-year period.

Of the 65 participants, 64 (98%) consented to HIV testing (Table 2). Most participants (95%) preferred to have the nurse collect the oral fluid with the

swab rather than perform self-collection. The program discovered two subjects who were HIV-infected but had not been previously tested (3.1% prevalence, Table 2); if only those who were not tested for HIV in the previous 5 years were considered, the prevalence rate would rise slightly to 3.8%.

Discussion

In 2006, two veterans who resided in community ALF, and who had mental illness, admitted to non-VA hospitals and died of AIDS-associated infections. These events prompted testing of outreach to this population, who we believed would be at a high risk for HIV infection, using a newly available oral fluid testing method. The main goals of our study were to estimate the magnitude of the problem (i.e., the prevalence of undiagnosed HIV in those with mental illness residing in community ALF) and to determine whether oral fluid testing could improve the rates of HIV testing in this population.

In this study, we have demonstrated that an outreach program for veterans with mental health and substance abuse diagnoses residing in ALF can be effective. Given the challenges normally associated with this group of individuals—to convince them to attend a clinic, to obtain their consent for HIV testing, to have physicians order testing despite their busy schedules, and to have patients follow-up to receive their test results and counseling—the high acceptance for testing (98%) that we obtained was remarkable. The intervention was especially successful given the low rate of testing in the entire 5 years before our study (17%). It is quite likely that the subjects' familiarity with the nurses greatly increased acceptance of testing as compared with testing in the clinical setting in which patients may see various health care providers at different visits. Supporting this notion, a stronger "therapeutic alliance" has been found to correlate with increased testing (Desai et al., 2007). Despite the fear that patients would react poorly to discussions related to sexual practices (Coverdale & Aruffo, 1992) and HIV diagnosis (Walkup et al., 2002), or fears that such discussions might worsen mental symptoms, our experience found that patients were forthright and calm while discussing these issues. There may also have been a difference in acceptance because of the

Table 2. Testing Results

	<i>n</i> (%)
Participation	
Agreed to participate	65 (100%)
Consented to HIV testing	64 (98%)
Refused HIV testing	1 (2%)
Swabbed	
Nurse	61 (95%)
Self	3 (5%)
Test results	
Received results	64 (100%)
Positive (all confirmed with Western blot)	2 (3.1%)
Negative	62 (96.9%)
HIV prevalence (all tested)	2/64 (3.1%)
HIV prevalence (no testing in previous 5 years)	2/53 (3.8%)

testing being offered by a nurse rather than a physician, as nurse-initiated testing increases acceptance rates as compared with standard physician-initiated testing (Anaya et al., 2008). However, the contributions of the initiator as opposed to other factors, such as time constraints for different types of health care providers, were not separately assessed.

Our approach allowed for immediate counseling of HIV-infected individuals with the potential benefit of early health intervention and reduced transmission, without the high rate of no-shows for test results. The strengths of this program included testing by a nurse known to the residents, HIV testing offered by oral fluid sampling in a rapid format, and facilitated follow-up with the HIV/AIDS program coordinator. In addition to the safety benefits (because lack of usage of needles removes the risk for needlestick exposure), there may be better acceptance by individuals who do not like needlesticks or are otherwise afraid of a blood test. With immediate results, HIV-infected individuals can begin to receive treatment sooner and can take immediate steps to prevent transmission of the virus. Unlike standard enzyme-linked immunosorbent assay tests (Ortho-Clinical Diagnostics, 2008), the rapid test does not require refrigeration of blood samples, thereby streamlining the workflow and increasing the mobility of the program. Additionally, the test does not require any specialized equipment such as microplate readers, centrifuges, and refrigerated reagents, thereby allowing for this method to be extended to more remote rural areas and developing countries.

The prevalence rate (3.1%) determined in our study was >30-fold higher than the CDC's 0.1% prevalence estimate for undiagnosed HIV in the United States (CDC, 2008). If the prevalence rate among other individuals with mental illness residing in ALF matches our findings, then this population should be tested. There were over 48,000 U.S. veterans residing in community ALF in 2007 (Kinosian, Stallard, & Wieland, 2007), and on the basis of prevalence of mental illness in the general veteran population (Zeiss, 2010), this translates to approximately 12,000 veterans with mental illness residing in assisted living.

The CDC recommends that any population with an HIV prevalence of greater than 0.1% should be tested for HIV on the basis of a cost-effectiveness analysis (Branson et al., 2006; Paltiel et al., 2005; Sanders et al., 2005). The 3.1% prevalence rate in our study participants was far greater than the threshold value, and therefore it should be cost-effective to test for HIV in our study population, and others like it.

Study strengths include a sample large enough to show acceptance rates for testing and an estimate of prevalence in this veteran patient population. Although we were able to show clearly that this model was highly effective at achieving higher acceptance rates for testing, the number of positive tests did not allow for more complex statistical analyses of risk factors for HIV positivity in our study population. A much larger group would be needed for those types of analyses. In addition, because only two nurses performed the testing, generalizability will remain to be seen in various populations and settings, although data have been promising even for minimally trained individuals, prompting an application for over-the-counter Food and Drug Administration approval (OraSure, 2007).

Conclusion

In summary, we found a high HIV infection prevalence in a population with mental health diagnoses residing in assisted living. The rapid oral fluid HIV test was quick and easy to perform, and had a very high acceptance rate when delivered by nurses known to the individuals undergoing the test. This pilot project may prove to be a fruitful model to scale up

for use in other vulnerable, high-risk populations. In fact, we have now expanded use of oral fluid rapid testing by nurses known to the patient for other vulnerable populations including the mentally ill, drug users, and the homeless, in a clinical setting at the Philadelphia VAMC. The advantages of rapid oral fluid testing are widely applicable to any group of patients, but this method is especially useful in those with lower rates of testing by standard methods.

Clinical Considerations

- The high prevalence of undiagnosed HIV suggests that veterans with mental illness should be tested for HIV on a regular basis.
- Rapid HIV testing of oral fluid is fast and it increases the opportunity to provide patients with test results and counseling.
- Patient trust is a critical component for accomplishing HIV testing and counseling to reduce unsafe practices. Testing by a nurse who is already known to the patient increases trust.
- Regular HIV prevention methods need to be explained to veterans with mental illness to lower unsafe sexual and drug use practices.

Disclosures

Funding for the HIV tests and prevention materials was provided by a seed grant from the VHA Public Health Strategic Health Care Group and Office of Nursing Service.

The authors report no real or perceived vested interests that relate to the article (including relationships with pharmaceutical companies, biomedical device manufacturers, grantors, or other entities whose products or services are related to topics covered in this manuscript) that could be construed as a conflict of interest. The research was not funded by or influenced by the test manufacturer. The contents of this paper do not represent the views of

the Department of Veterans Affairs or of the U.S. Government.

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