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Saliva Testing as a Practical Tool for Rapid HIV Screening

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1. Introduction

Whilst the annual number of new HIV infections is steadily declining, levels of new infections overall are high and the number of people living with HIV has increased worldwide. An estimated 73,000 people in the UK are living with HIV, of which it is estimated that 24,000 are undiagnosed or unaware of their HIV status (Health Protection Agency, 2007). The prevalence of undiagnosed HIV infection would therefore seem a key driver for increased and routine HIV testing, both to lessen the potential for unwitting transmission of HIV and to support early detection and timely access to medical care in those infected. It has been shown that late diagnosis of HIV infection, resulting in delayed patient management, is associated with poorer survival (Losina et al., 2009). In the UK, the National Strategy for Sexual Health and HIV (Department of Health, 2001) aims to reduce the prevalence of undiagnosed HIV by increasing screening.

This is a rapidly advancing field and whilst it is beyond the scope of this chapter to encapsulate all the current evidence in this field, a brief overview is presented of saliva testing as a diagnostic tool, the benefits and the caveats. The contexts in which saliva testing for HIV are currently conducted is considered both in the UK and internationally. The evidence for the sensitivity and specificity of this method will be considered. Attitudes of recipients towards rapid HIV screening, in particular saliva testing, are considered together with attitudes towards the contexts in which testing is undertaken.

2. Diagnosis of HIV/AIDs

HIV screening is undertaken for a number of purposes, the UNAIDS/WHO summarise these as i) testing for screening blood, ii) testing for epidemiological surveillance and iii) testing for diagnosing infected individuals (UNAIDS, 1997). A variety of specific tests might be used to these ends. The British HIV Association (BHIVA) states that, "a potentially important mechanism for limiting the HIV epidemic is the widespread use of HIV testing in

a variety of clinical settings,” but provides no specific guidance on how the testing should be done (BHVA, 2005). The selection of the most appropriate test, and testing protocol, should not only be informed by test sensitivity and specificity, but also by a number of economic and logistic factors (Branson, 2003). The following sections outline some key information relating to procedures for HIV testing, categories of HIV testing, and HIV testing guidelines, and consider technical and process issues relating to HIV testing.

2.1 Testing for HIV

HIV testing has evolved from initial concerns, in the mid/early 1980s, for screening the supply of donated blood, to now reflect a broader range of concerns which include clinical diagnosis and strategic public health intervention (Branson, 2000a, 2000b). UNAIDS/WHO have identified four distinct categories of HIV testing: Diagnostic testing, Voluntary counselling and testing (VCT), Routinised testing in specific setting, and Mandatory testing. Diagnostic HIV testing is testing undertaken where signs and symptoms related to an HIV infection are observed in any individual. Testing is carried out to ensure timely clinical diagnosis, and to ensure the provision of adequate clinical support and services. People with certain diseases, such as tuberculosis and any other sexually transmitted disease, are also tested for HIV infection on a regular basis to this end.

Voluntary counselling and testing, also referred to as ‘client focused testing’, categorises those programmes of HIV testing which are designed to promote HIV awareness and to broaden access to HIV testing. Such testing is carried out in the absence of individual symptoms and is combined with group and individual counselling around HIV issues to raise awareness and educate in relevant health, and health behaviour, areas. This kind of testing programme is often undertaken with those who are perceived to be at high-risk of exposure to the HIV virus, or those who are concerned that they have been recently exposed to HIV. Testing is provided in local health and community settings, and pre and post-test counselling is offered to all those being testing. Pre-test counselling is often delivered in group settings, with post-test and follow-up counselling delivered on a one-to-one basis. UNAIDS/WHO identify VCT as the most effective approach to testing for achieving behaviour change to prevent HIV transmission in public settings.

Routine HIV testing of those accessing clinical or medical services is often carried out in those settings where high risk client groups are prevalent. Such testing is carried out with the purpose of early (asymptomatic) identification, with associated benefits for reduced risk of unwitting transmission of the virus. Carried out in community health centres, specialist clinics or hospitals settings such testing includes that undertaken in sexual health clinics with people who are undergoing diagnostic testing for other sexually transmitted diseases. It also incorporates the testing of intravenous drug users in primary and secondary care settings. Routine testing of this kind often utilises rapid HIV tests, which are described in more detail in section 3.

Mandatory HIV testing may be carried out for all donors prior to procedures involving transfusion of blood, bodily fluids or any organ transplant. In some countries, HIV testing is compulsorily carried out at the time of immigration, pregnancy and during routine medical check-ups of military personnel.

The individual, and health service cost, benefits associated with early detection and early medical intervention in cases of HIV infection offer a strong argument for routine testing, even amongst those populations where the incidence of HIV is low (Paltiel, 2006). Whilst

evidence for screening programmes reducing the transmission of HIV is unclear (Paltiel, 2006), a range of studies indicate that those who are aware of their HIV status amend their behaviour so as to limit the risk of HIV transmission to others (Marks et al., 2005; Crepaz et al., 2006; Chou et al., 2005).

In the United States (U.S.) in 2006, in an effort to improve the identification of HIV-positive individuals, the Center for Diseases Control and Prevention (CDC) released their current HIV testing guidelines. These recommended routine testing for those age 13 to 64 years regardless of risk factors, unless testing is specifically declined by the individual (opt-out testing) (Branson et al., 2006). In the U.S. the following criteria apply: opt-out HIV screening is recommended for patients in all healthcare settings, with people at high risk for HIV infection screened for HIV at least annually. Here, separate written consent for HIV testing is not required; general consent for medical care should be considered sufficient to encompass consent for HIV testing. Finally, prevention counselling should not be required with HIV diagnostic testing or as part of HIV screening programmes in healthcare settings (Branson et al., 2006). Although one-third of people with HIV infection in the UK remain undiagnosed, current UK guidelines recommend opt-out testing only for pregnant women and people attending genitourinary clinics (Hamill et al., 2007).

2.2 HIV tests

HIV testing involves the detection of antibodies produced by the body in an unsuccessful attempt to fight HIV infection, such antibodies being more easily detected than the virus itself. Testing can be carried out on whole blood, plasma, serum, urine, dried blood spots and saliva samples, but might only be carried out after a 3-8 week period following infection (Schopper & Vercauteren, 1996). During this 3-8 week window the HIV antigen is rarely identified - bar in exceptional circumstances at the peak of high circulation of virus particles (Carne, 1988; Chin, et al., 2007).

Initial developments in HIV screening centred upon the need to ensure that donated blood remained free of the HIV virus. A *testing paradigm* thus emerged to protect the supply of donated blood, a paradigm marked by "tests with high sensitivity, suitable for batch processing of high volumes of specimens in centralised laboratories with specialised equipment." (Branson, 2000a). The enzyme-linked immunosorbent assay (ELISA) was indicative of this; a screening test for blood, efficient in large-scale hospital settings and reliant upon specialist laboratory equipment. The ELISA is the most appropriate, and most commonly used, screening test for samples greater than 100 per day; the ELISA is most appropriate for population level surveillance of HIV infection (UNAIDS, 1997). Performed by trained medical staff the ELISA test is reliable, but incurs substantial costs and might only offer results a few days after testing. Whilst this cost and delay are less important in screening donated blood, for other forms of testing they might act as a barrier.

During the late 1980s and early 1990s the benefits of *voluntary counselling and testing* were increasingly recognised and other testing algorithms were developed to meet this end (Branson, 2000a). Concerns about false positives from the ELISA test led the U.S. Public Health Service recommending secondary testing with the Western Blot (WB) to ensure accuracy. Although once again, the significant time delay associated with this combination of tests, of up to 2 weeks before test results are returned to patients, was a significant barrier. Also ELISA both in isolation and in combination with the WB test has limited suitability for remote or smaller clinical settings where resources are limited and access to adequate

facilities is restricted (McCarthy et al., 1993; Owens et al., 1996). With particular concern for testing in the developing world, and to reflect a growing number of simple and rapid assays, the UN/WHO offers an informative typology of testing combinations (UNAIDS, 1997; Branson, 2000a, 2003).

For blood screening, population surveillance (of high risk groups) and diagnosis of individuals from high risk populations (who are displaying signs/symptoms of HIV infection) a single screening assay is adequate; and, a reactive test should be considered sufficient for a HIV positive diagnosis. For population surveillance (low and mid-risk groups), asymptomatic individual diagnosis (high risk group) and symptomatic diagnosis (low and mid-risk social group) a second screening assay should follow an initial reactive test; if both initial and second assays are reactive then the specimen is considered positive. For asymptomatic diagnosis (low and mid-risk social group) a third screening assay should be carried out following initial and second reactive tests; the specimen is considered positive if the third test is also reactive.

2.3 Technical and process issues

Above all, HIV testing should be carried in accordance with ethical principles designed to protect human rights. Testing should be carried out in a confidential manner and the person being tested should be fully informed about the nature and procedures of the test. Tests should be undertaken with caution since clinicians may be both civilly and criminally liable if they take a blood sample for HIV testing without disclosing to the patient (i) the nature of the test, (ii) the possible consequences of a positive result, and (iii) without obtaining informed consent (Sherrad & Gatt, 1987).

Further, where a positive HIV test manifests, appropriate psychological counselling should be provided to the diagnosed individual (WHO, 2004). Other technical and process issues include consideration of the cost-effectiveness of testing, of the quality of tests and testing procedures, and of the potential for home testing and the associated benefits and caveats.

Cost-effectiveness

Evidence from the U.S. suggests that routine, voluntary HIV testing is not only of crucial public health importance but is also economically justified (Walensky et al., 2007). The cost of HIV testing kits is variable, although this expenditure accounts for a substantial portion of the budget in national AIDS programmes. Selecting the most appropriate and cost-effective products for each particular setting therefore includes careful consideration of a range of factors including cost of test kit, storage, equipment maintenance and training of personnel.

Quality of testing procedures

Ensuring that quality is maintained and standard operating procedures are followed is critical to the generation of reliable results. The majority of HIV diagnostic products perform very well when used according to specific instructions. However, there is a risk that kits may be produced that do not meet exacting standards for quality, or make fraudulent claims for endorsement by WHO or the U.S. Food and Drug Administration (Kurtzweil, 1999). This remains an ongoing challenge.

Home testing

Home testing has positive implications for offering an alternative to people who might otherwise not seek testing in traditional health care facilities. For example, in some countries, a high uptake has been achieved by delivering both HIV counselling and testing

at home, in the highest uptake in rural areas, in young people and groups with low educational attainment; this has resulted in substantial reductions in existing inequalities in accessing such services (Mutale et al., 2010). However, there are serious caveats associated with home testing which must be considered and balanced against any perceived benefits. Firstly, there is a potential that such kits may be fraudulent (e.g. Kurtzweil, 1999) or less accurate than those administered by trained staff. Secondly, there may be a risk of abuse if individuals are forced to take tests against their will. Finally, there is a need for immediate confirmation of results and also access to counselling for those with a positive test result. In the UK little HIV testing is currently performed outside GUM and antenatal settings (Tweed et al., 2010).

3. Rapid testing and saliva testing

The introduction of rapid and 'point of care' testing in HIV was primarily to increase identification of HIV infected individuals, to enable inexpensive and convenient methods of testing amongst rural, outreach and at-risk populations, and to improve consumer experience of the testing procedure (Holt, 2009). Such rapid tests use finger-stick capillary whole blood (FSB) or oral fluid (OF), thus avoiding the need for venous blood sampling and centrifugation (Pavie et al., 2010). Specific benefits associated with rapid testing include immediate communication of test results (in standard tests between 25% and 33% of those tested do not return to receive their results), and advantages in immediate medical staff awareness of HIV status so as to limit the potential for HIV transmission during medical procedures (Kane, 1999; Branson, 2000a).

Rapid tests modified to use oral fluid samples obviate the need for either venepuncture or finger prick blood analysis (Hamill et al., 2007). Oral fluid HIV tests offer additional advantages due to their non-invasive nature, can be performed anywhere, do not require specialist phlebotomy training or equipment, and reduce biohazardous risk (Delaney et al., 2006). Rapid, reliable and affordable tests, requiring no equipment and minimal training, are now also available for HIV infection in developing countries (Peeling & Mabey, 2010).

3.1 Nature of rapid testing and saliva testing

In recent decades, a number of rapid test assays have been developed that enable HIV antibody status to be determined quickly, efficiently and less invasively than traditional forms of testing. Most rapid tests can be conveniently carried out 'on site' by someone with basic training and for this reason these are often referred to as 'point-of-care testing' (Kendrick et al., 2005). These tests are designed to detect antibodies in several different body fluids including whole blood from finger-prick blood, plasma, urine, or saliva. Rapid tests are simple to perform, can be conducted in rural settings without laboratory equipment, and remove the need to process and store specimens and transport them from the field (Pascoe et al., 2009).

Rapid tests rely on samples of blood taken from fingertip or saliva sample obtained by rubbing an absorbent pad across the lower and upper gums in the mouth. Obtained blood or saliva sample is then transferred into a plastic device already containing a developer solution, followed by the insertion of an assay test strip into the device. After a brief waiting period of approximately 15-20 minutes the appearance of two lines on the test strip is interpreted as a positive test result, indicating the presence of HIV-1 antibodies; however, a single line indicates a negative test result, and no visible lines imply an invalid test.

The speed with which test results can be produced make rapid HIV tests very popular and extremely useful particularly in public outreach settings (Spielberg et al., 2005). In such settings there may be limited access to a HIV test centre and furthermore, there may be a reluctance to be assessed for HIV infection amongst certain groups (e.g. sex-workers, drug-injectors). Moreover, it is not uncommon that individuals who have agreed to take a HIV test, do not return for their conventional laboratory blood test results and thus remain unaware of their HIV virus carrier status, presenting a danger to society as potential HIV transmitters (Galvan et al., 2004). Use of rapid saliva tests also have the potential to prevent HIV infections occurring in health workers due to handling of blood during standard ELISA, WB or rapid blood tests.

The unique features manifested by all rapid tests are their non-invasive testing procedure and the immediacy of producing results. Another advanced characteristic of rapid tests is the level of anonymity offered since the saliva, blood or urine specimen can be collected at home, sent to the laboratory for testing and results declared via the telephone, without a need to visit the clinic in person.

3.2 Diagnostic accuracy of HIV rapid tests

All diagnostic tests have limitations and sometimes their use may produce erroneous or questionable results. The accuracy of tests is often described in terms of 'sensitivity' (the percentage of results that will be positive when HIV is not present) and 'specificity' (the percentage of results that will be negative when HIV is not present). False positives occur when the test incorrectly indicates that HIV is present in a non-infected person. Conversely, false negatives occur when the test incorrectly indicates that HIV is absent in an infected person.

In a review of the risks and benefits of HIV screening, the U.S. Preventive Services Task Force concluded in 2005 that, "...the use of repeatedly reactive enzyme immunoassay followed by confirmatory Western blot or immunofluorescent assay remains the standard method for diagnosing HIV-1 infection. A large study of HIV testing in 725 U.S. laboratories reported a sensitivity of 99.7% and a specificity of 98.5% for enzyme immunoassay, and studies in U.S. blood donors reported specificities of 99.8% and greater than 99.99%. With confirmatory Western blot, the chance of a false-positive identification in a low-prevalence setting is about 1 in 250,000 (95% CI, 1 in 173,000 to 1 in 379,000)" (Chou et al., 2005).

The specificity rate outlined above for enzyme immunoassay screening tests indicates that, in every 1,000 positive HIV test results, there will be around 15 false positive results. However, confirming the test result (e.g. repeating the test, if this option is available) may reduce the likelihood of a false positive to just 1 result in every 250,000 tests. The sensitivity rating outlined above indicates that, in every 1,000 negative HIV test results, there will be 3 false negative results. Nevertheless, the high negative predictive value of these tests is extremely high, meaning that a negative test result will be correct more than 9,997 times in 10,000 (99.97% of the time). Due to the high negative predictive value of HIV screening tests, the CDC recommends that a negative test results be considered conclusive evidence that an individual does not have HIV.

Non-specific reactions, hypergammaglobulinemia, or the presence of antibodies directed to other infectious agents that may be antigenically similar to HIV can produce false positive results. Auto-immune diseases, such as systemic lupus erythematosus, have also rarely caused false positive results. Most false negative results are due to the window period; other factors, such as post-exposure prophylaxis, can rarely produce false negatives (Hare et al., 2004).

Rapid tests have been used for more than two decades to test serum and plasma, particularly in developing countries and for emergency diagnosis. They are simple to use and have high specificity, however, false positives do occur and they have been criticised in previous years for lacking in sensitivity relative to reference enzyme immunoassays (EIA/ELISA), particularly during primary HIV infection and infection by variant strains (Makuwa et al., 2002). There is, however, research evidence to indicate that rapid HIV tests produce results of comparable sensitivity and specificity to the ELISA test (Franco-Paredes et al., 2006; Greenwald et al., 2006; Branson, 2000a). Laboratory testing of 1266 specimens at rural peripheral laboratories of varied combinations of seven rapid HIV tests even showed a specificity of 100% (Stetler et al., 1997). Empirical studies have shown promising findings in a range of settings and populations including HIV positive individuals (DeBattista et al., 2007), HIV negative individuals (Makasso, 2005), sexual health clinic attenders (DeBattista et al., 2007), pregnant adult women in Namibia (Hamers et al., 2008), acute care (Lee et al., 2011) and adults presenting for voluntary testing elsewhere in the developing world (Pascoe et al., 2009).

Furthermore, whilst some early work has suggested that salivary testing should be recommended only for epidemiological studies (Mortimer & Parry, 1992), more recent studies have continued to demonstrate that rapid oral fluid tests show a high standard of sensitivity and specificity (e.g. DeBattista et al., 2007; Hamers et al., 2008; Delaney et al., 2006). Independent performance data for 4 FDA approved rapid HIV tests (Franco-Paredes et al., 2006) and a wider range of rapid tests (Branson, 2000a) highlight product testing with both sensitivity and specificity outcomes of 100% (Oraquick and Retrocell HIV-1/2) (Branson, 2000a). Data from 2006 showed that in testing, sensitivity and specificity exceeded 99% in 4 FDA approved tests (with the exception of Reveal G2 Plasma test where specificity is 98.6%) (Franco-Paredes et al., 2006). Comparisons between rapid HIV tests are inconsistent. It has been suggested that there may be differences in diagnostic accuracy, with tests being less sensitive on oral fluid than on finger-stick whole blood and less sensitive on finger-stick whole blood than on serum (Pavie et al., 2010). More recently, in a direct comparison of the performance of all 6 tests currently approved by the FDA for use in the U.S. (using whole blood, oral fluid, serum, and plasma specimens), it has been shown that *all* rapid tests have statistically equivalent performance characteristics, based on overlapping confidence intervals for sensitivity and specificity, compared with conventional ELISA (Delaney et al., 2011).

It should be noted that although rapid tests using saliva have been shown to have high sensitivity and specificity parameters (Delaney et al., 2011), these are essentially brief screening tests and it has long been recognised that in cases where the first screening test utilised saliva, the diagnosis should be reconfirmed through a rapid test that involves blood testing (Andersson et al., 1997). In fact, it is now generally accepted that a second confirmatory test which detects the presence of a specific type of antibody to HIV 1/2 *must* follow (Franco-Paredes, et al., 2006). WHO recommends that for diagnostic purposes, two assays be used with a third test for discrepant results (Strategy II and III); the first test must have the highest sensitivity and the second test a similar or higher specificity (UNAIDS/WHO, 2004). Accuracy may be altered in pregnancy, and to improve diagnostic accuracy and to reduce false-positive results it may be necessary to use two rapid tests during labour and delivery (Pai et al., 2007). Some further limitations have been identified with oral fluid assays (e.g. unlikely to detect those in early stages of HIV infection or with reduced viral load) these limitations also apply to other rapid assays (Pascoe et al., 2009).

A large number of studies have been published to date on various aspects of test performance specifically for oral mucosal transudate (OMT) and saliva tests. A number of brief narrative reviews published between 1994-2006 have focused predominantly on the description of oral rapid test technologies, although this early work has not evaluated diagnostic accuracy. Two more recent systematic reviews on diagnostic accuracy have been conducted (Wesolowski, 2006; Pai, 2007). These include a review undertaken by the CDC as part of a post-marketing surveillance of one rapid test (Wesolowski, 2006) and a systematic review focused exclusively on performance of all rapid tests in pregnant women (Pai, 2007). A recent meta-analysis has evaluated OMT, saliva based rapid and point of care tests in at-risk populations worldwide from 1986-2011 (Balram & Pai, 2010). This data provided evidence of good overall performance of oral fluid-based HIV tests in global settings. The authors recommended these oral rapid tests as first line screening alternatives to blood-based rapid test and suggest their enhanced use in global expanded HIV testing initiatives (Balram & Pai, 2010). Furthermore, rapid testing is deemed to be suitable for use in community-based clinical research settings, to assess eligibility both for trial participation and for the provision of on-site voluntary counselling and testing services (Everett et al., 2009).

3.3 Acceptability of HIV rapid tests

Non-invasive rapid HIV tests have been consistently shown to be a preferred method of testing amongst varied population groups in both youth (Peralta et al., 2001; Pugatch et al., 2001) and adults, including men who have sex with men (MSM) (Sy et al., 1998; Chen et al., 2010) and injecting drug users (Colfax et al., 2002; Greensides et al., 2003; Spielberg et al., 2000). Recent research has also considered the acceptability of testing amongst healthcare professionals.

Youth populations

Although universal testing of adolescents is currently recommended in the U.S., previous studies have demonstrated that only 41% to 61% of adolescents offered a non-rapid HIV test agree to testing (Mehta et al., 2007; Goodman et al., 1994). Furthermore, only between one and two-thirds of adolescents who are tested return to receive their results and post-test counselling (Goodman et al., 1994; Ilegbodu et al., 1994; Lazebnik et al., 2001; Tsu et al., 2002). A recent study by Mullins et al. (2010) showed that 70% of adolescents preferred rapid to traditional HIV testing, and that rapid testers were more likely to receive their results within the follow-up period. This study suggested that for adolescents non-invasive testing may have a greater impact on their choice of a rapid method than the availability of same day test results. A high preference for rapid oral tests in comparison to invasive blood tests has also been demonstrated elsewhere (Pugatch et al., 2001; Peralta et al., 2001). Studies of rapid testing in specific settings have shown that paediatric emergency departments have been highly rated by adolescents aged 14-21 years, as a preferred location for rapid HIV testing. This supports the need for increased development of prevention and testing programs in this setting (Haines et al., 2011). It has been acknowledged that rapid testing should be followed by HIV prevention opportunities and rapid linkage to care (Peralta et al., 2001).

Adult populations

A high level of acceptance for rapid testing and a preference for rapid oral tests in comparison to invasive blood tests has been demonstrated in adult 'at risk' populations

including MSM, high-risk heterosexual populations and injecting drug users (Speilberg et al., 2000; Greensides et al., 2003; Colfax et al., 2002; Sy et al., 1998, Chen et al., 2010).

Research has shown that the majority of adults tested (95%) preferred results to be disclosed by telephone, again highlighting the importance of privacy issues in testing procedures (Speilberg et al., 2000). Positive implications of, rapid testing also include potential for, and increased monitoring and awareness of HIV related risk-behaviour (Speilberg et al., 2000). In MSM, injecting drug users and high risk heterosexuals attending a sexual health clinic (Greensides et al., 2003; Colfax et al., 2002), concerns have been raised about rapid testing in relation to associated costs, privacy issues, accuracy and reliability of results, access to post-test counselling and information, lack of access to testing, and lack of knowledge about testing centres and procedures (Greensides et al., 2003). It has been suggested that concerns regarding the accuracy of the rapid test might limit test acceptance and should be addressed during pre-test information procedures (Merchant et al., 2009).

Nevertheless, despite these concerns, a strong preference has been identified for non-invasive quick testing procedures, in particular, rapid oral testing methods (Chen et al., 2010). Although rapid testing procedures appear to be preferred in these populations, a large proportion of these individuals (almost half) remain unaware of the availability of home collection kits for HIV testing in areas where these are accessible (Greensides et al., 2003; Colfax et al., 2002). Many individuals 'at risk' have reported that they would test more frequently if testing was available for clinic or home use (Chen et al., 2010). In certain populations, such as MSM, those who prefer rapid testing may be significantly more likely to have some formal education, to have discussed testing with a sexual partner, to be aware of rapid testing, and to have had a previous test (Cohall et al., 2010).

Research has investigated the potential for offering rapid testing in commercial and community venues, although a significant number of barriers have been raised. Again, concerns have been raised about the lack of confidentiality and privacy for testing in social venues, and about the potential lack of post-test support for those who test positive (Prost et al., 2007).

Healthcare populations

Studies of HIV testing have mainly considered *patient* preferences, although recent work has investigated the attitudes of *healthcare* staff towards testing (Arbelaez et al., 2009; Sahoni et al., 2010). For example, it has been shown that hospital staff satisfaction and overall attitudes towards HIV testing program in an emergency department is high, and that healthcare staff attitudes do not represent a barrier to program implementation (Sahoni et al., 2010). Rapid advances in technology have also led to widening of training opportunities for rapid testing across geographically remote healthcare facilities (Knapp et al., 2011). Further, research is emerging which considers the role of various healthcare professionals rapid diagnostic testing for HIV in various regions of the world (e.g. oral health care workers; Patton et al., 2011). Whilst conducting rapid screening in the dental clinic setting has been identified as a viable option (Dietz et al., 2008; Patton et al., 2011), oral healthcare professionals have expressed a lack of confidence that graduating dentists have the skills and willingness to conduct HIV counselling and testing in dental practice; in fact lack of training in prevention counselling has been identified as a primary barrier (Patton et al., 2002). Additional challenges to rapid testing have been identified in a range of medical settings including insufficient staffing, inadequate privacy or space, associated administration, time limitations and competing priorities.

4. Conclusions

This is a rapidly advancing field and as such this chapter presents an overview of the key issues with selected evidence. In conclusion, it seems that rapid screening tests and/or alternative biological samples (such as oral fluid) are now thought to be effective in HIV prevention strategies by reaching a larger population through improved accessibility and general consent in approaches to screening, immediate referral of HIV positives for medical treatment and partner notification. Oral fluid testing has been implemented in a range of settings. The test appears to perform well in field settings, and can be considered a good alternative to blood samples, suitable for use in epidemiologic surveys aiming to estimate HIV prevalence in general populations and in high risk groups. There are several limitations in that oral fluid assays may be unlikely to detect those in early stages of HIV infection or with reduced viral load, and have shown altered accuracy in pregnancy; however, such limitations also apply to other rapid assays.

Research has suggested that in adults the most important factors in HIV testing are test accuracy, time to results and privacy of results. Studies have also suggested that patients express a preference for oral testing over venepuncture sampling since it is rapid and less invasive, although preferences may vary in different settings. Less invasive methods are preferred also in youth. Indeed, offering less invasive rapid testing to at-risk youth may assist clinicians in increasing the proportion of teens who agree to undergo testing and receive their test result. In general rapid testing is better accepted by patients in both developed and resource-limited settings. Point of care tests specifically assist in making testing accessible in areas with limited laboratory facilities. These tests have the potential for reducing the number of people who do not return to clinics to learn of their test result, and thus reduce the proportion of infected individuals who remain unaware of their diagnosis.

Overall, the majority of studies have demonstrated high sensitivity and specificity of oral fluid-based rapid HIV test in comparison with routinely utilized methods. With recent research showing comparable accuracy for a range of currently approved tests and specimen types, it may be characteristics such as convenience, time to result, shelf life, and cost that will be likely determining factors for selection of a rapid screening test for a specific application (Delaney et al., 2011). This suggests that rapid tests with well documented performance characteristics should be made available in public health and clinical settings.

Specifically, it seems that saliva specimens can be easily collected under difficult field conditions with minimal training and provide a valuable alternative to testing blood for HIV-seroprevalence studies. Salivary testing for HIV may therefore be a convenient and potentially accurate epidemiological tool, although should be used with caution since single test systems may be less appropriate to diagnose HIV infection in an individual without follow-up testing. There is a drive for continual improvement of test performance, such that it has been suggested that all initial positive findings should be repeated by second test method with a second confirmatory specimen found positive prior to informing the patient. This may serve to mitigate the emotional distress and unnecessary treatments associated with false positive HIV testing.

5. References

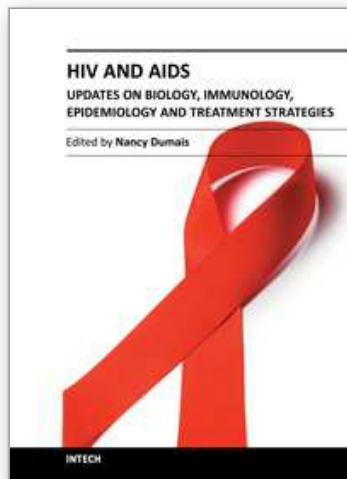
- Andersson, S., da Silva, Z., Norrgren, H., Dias, F. & Biberfeld, G. (1997). Field evaluation of alternative testing strategies for diagnosis and differentiation of HIV-1 and HIV-2 infections in an HIV-1 and HIV-2-prevalent area, *AIDS*, 11 (15), 1815-1822.

- Arbelaez, C., Wright, E., Losina, E. & et al. (2009). Emergency provider attitudes and barriers to universal HIV testing in the emergency department. *J Emerg Med.* Oct 13 [Epub ahead of print].
- Balram, B. & Pai, N. (2011). Salivary and oral fluid based HIV antibody assays for rapid diagnosis of HIV infection. The 9th Annual Cochrane Canada Symposium, Early Exposure to Cochrane: accessible, credible & practical, 16-17 Feb 2011, Vancouver, BC.
- Branson, B. (2000a). Rapid Tests for HIV Anti-body, *AIDS Reviews*, 2, 76-83.
- Branson, B. (2000b). Assessing Diagnostic Technologies Marketed to Less Industrialised Countries, *Journal of International Physicians in AIDS Care*, Feb 2000, 28-30.
- Branson, B. (2003). Point of Care Rapid Tests for HIV Antibodies, *Journal of Laboratory Medicine*, 27 (7/8), 288-295.
- Branson, B., Handsfield, H., Lampe, M. & et al. (2006). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep*, 55(RR-14), 1-17.
- British HIV Association (2005). *Guidelines for the treatment of HIV-infected adults with antiretroviral therapy*. www.bhiva.org/cms1191541.asp.
- Carne, C. (1988). *Testing and screening for HIV infection*. Health Education Authority: London.
- Chen Y., Bilardi, J., Lee, D., Cummings, R., Bush, M. & Fairley, C. (2010). Australian men who have sex with men prefer rapid oral HIV testing over conventional blood testing for HIV. *Int J STD AIDS* 21(6):428-30.
- Chin, B., Lee, S., Kim, G., Kee, M., Suh, S., & Kim, S. (2007). Early Identification of Seronegative Human Immunodeficiency Virus Type 1 Infection with Severe Presentation. *Journal of Clinical Microbiology*, 45, 1659-1662.
- Chou, R., Huffman, L., Fu, R., Smits, A. & Korthuis, P. (2005). Screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force, *Annals of Internal Medicine*, 143, 55-73.
- Cohall, A., Dini, S., Nye, A., Dye, B., Neu, N. & Hyden, C. (2010). HIV testing preferences among young men of color who have sex with men. *Am J Public Health*. 100(10), 961-6. Epub 2010 Jan 14.
- Colfax, G., Lehman, J., Bindman, A., Vittinghoff, E., Vranizan, K., & Fleming, P., et al. (2002). What happened to home HIV test collection kits? Intent to use kits, actual use, and barriers to use among persons at risk for HIV infection. *AIDS Care* 2 (14), 675-82.
- Crepaz, N., Lyles, C., Wolitski, R., Passin, W., Rama, S., Herbst, J. & et al. (2006). Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials [Editorial], *AIDS*, 20 (1), 143-157.
- Debattista, J., Bryson, G., Roudenko, N., Dwyer, J., Kelly, M., Hogan, P., & Patten, J. (2007). Pilot of non-invasive (oral fluid) testing for HIV within a clinical setting. *Sexual Health*, 4 (2), 105-109.
- Delaney, K., Branson, B., Uniyal, A., Kerndt, P., Keenan, P., Jafa, K., Gardner, A., Jamieson, D. & Bulterys, M. (2006). Performance of Oral Fluid HIV- 1/2 test: experience from four CDC studies, *AIDS*, 20, 1655-1660.
- Department of Health (2001). *National Strategy for Sexual Health and HIV*, DoH, London.
- Dietz, C., Ablah, E., Reznik, D. & Robbins, D. (2008). Patients' attitudes about rapid oral HIV screening in an urban, free dental clinic. *AIDS Patient Care STDS* 22(3):205-12.
- Everett, D., Baisley, K., Chagalucha, J., Vallely, A., Watson-Jones, D., Cook, C., Knight, L., Ross, D., Mugeye, K., McCormack, S., Lacey, C., Jentsch, U. & Hayes, R. (2009). Suitability of simple human immunodeficiency virus rapid tests in clinical trials in community-based clinic settings. *J Clin Microbiol* 47 (4), 1058-62. Epub 2009 Feb 25.

- Franco-Paredes, C., Tellez, I., & del-Rio, C. (2006). Rapid HIV testing: A review of the literature and implications for the clinician. *Current HIV/AIDS Reports*, 3, 159-165.
- Galvan, F., Brooks, R. & Leibowitz, A. (2004), Rapid HIV Testing: Issues in Implementation, *Aids Patient Care and STDS*, 18 (1), 15-18.
- Goodman, E., Tipton, A., Hecht, L. & et al. (1994). Perseverance pays off: health care providers' impact on HIV testing decisions by adolescent females. *Pediatrics* 94 (6 Pt 1), 878-82.
- Greensides, D., Berkelman, R., Lansky, A., & Sullivan, P. (2003). Alternative HIV Testing Methods Among Populations at High Risk for HIV Infection. *Public Health Reports*, 118, 531-539.
- Greenwald, J., Burstein, G., Pincus, J. & Branson, B. (2006). A Review of Rapid HIV Antibody Tests, *Current Infectious Disease Reports*, 8, 125-131.
- Haines, C., Uwazuoke, K., Zussman, B., Parrino, T., Laguerre, R. & Foster, J. (2011). Pediatric emergency department-based rapid HIV testing: adolescent attitudes and preferences. *Pediatr Emerg Care* 27 (1), 13-16.
- Hamers, R., de Beer, I., Kaura, H., van Vugt, M., Caparos, L., & Rinke, de Wit T. (2008). Diagnostic accuracy of 2 oral fluid-based tests for HIV surveillance in Namibia. *Journal of Acquired Immune Deficiency Syndromes*, 48(1):116-8.
- Hamill, M., Burgoine, M., Farrell, F., Hamelaar, J., Patel, G., Welchew, D. & Jaffe HW (2007). Time to move towards opt-out testing for HIV in the UK. *BMJ*, 334: 1352-4.
- Hare, C., Pappalardo, B., Busch, M., Phelps, B., Alexander, S., Ramstead, C., Levy, J. & Hecht, F. (2004). Negative HIV antibody test results among individuals treated with antiretroviral therapy (ART) during acute/early infection. The XV International AIDS conference. pp. abstract No MoPeB3107.
- Health Protection Agency (2007). Testing Times. HIV and other Sexually Transmitted Infections in the United Kingdom. London: Health Protection Agency, Centre for Infections. November 2007.
- Holt, M. (2009). *Rapid HIV testing: A literature review*. Australian Federation of AIDS Organisation Inc.
- Ilegbodu, A., Frank, M., Poindexter, A., & et al. (1994). Characteristics of teens tested for HIV in a metropolitan area. *J Adolesc Health* 15 (6), 479-84.
- Kane, B. (1999). Rapid testing for HIV: Why so fast. *Annals of Internal Medicine*, 133 (6), 481-483.
- Kendrick, S., Kroc, K., Withum, D., Rydman, R., Branson, B. & Weinstein, R. (2005). Outcomes of Offering Rapid Point-of-Care HIV Testing in A Sexually Transmitted Disease Clinic, *J Acquir Immune Defic Syndr*, 38 (2), 142-146.
- Knapp, H., Chan, K., Anaya, H., Goetz, M. (2011). Interactive Internet-Based Clinical Education: An Efficient and Cost-Savings Approach to Point-of-Care Test Training. *Telemed J E Health*. Apr 14. [Epub ahead of print]
- Kurtzweil, P. (1999). Internet sales of bogus HIV test kits result in first-of-kind wire fraud conviction. *FDA Consum*, 33 (4), 34-5.
- Lazebnik, R., Hermida, T., Szubski, R. & et al. (2001). The proportion and characteristics of adolescents who return for anonymous HIV test results. *Sex Transm Dis* 28 (7), 401-4.
- Lee, B.E., Plitt, S., Fenton, J., Preiksaitis, J.K., Singh, A.E. Rapid HIV tests in acute care settings in an area of low HIV prevalence in Canada. *J Virol Methods* 172 (1-2), 66-71. Epub 2010 Dec 28.
- Losina, E., Schackman, B., Sadownik, S., Gebo, K., Walensky, R. & et al. (2009). Racial and Sex Disparities in Life Expectancy Losses among HIV-Infected Persons in the

- United States: Impact of Risk Behavior, Late Initiation, and Early Discontinuation of Antiretroviral Therapy. *Clin Infect Dis* 49, 1570-1578.
- McCarthy, B., Wong, J., Munoz, A., & Sonnenberg, F. (1993). Who should be screened for HIV infection? A cost-effectiveness analysis. *Archives of Internal Medicine*, 153, 1107-1116.
- Makuwa, M., Souquie`re ,S., Niangui, M., Rouquet, P., Apetrei, C. & et al. (2002). Reliability of rapid diagnostic tests for HIV variant infection. *J Virol Methods*, 103, 183-190.
- Marks, G., Crepaz, N., Senterfitt, J. & Janssen, R. (2005). Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs, *Journal of Acquired Immune Deficiency Syndrome*, 39, 446-453.
- Mehta, S., Hall, J., Lyss, S. & et al. (2007). Adult and pediatric emergency department sexually transmitted disease and HIV screening: programmatic overview and outcomes. *Acad Emerg Med*, 14 (3), 250-8.
- Merchant, R., Clark, M., Seage, G. 3rd, Mayer, K., Degruittola, V. & Becker, B. (2009). Emergency department patient perceptions and preferences on opt-in rapid HIV screening program components. *AIDS Care*, 21 (4), 490-500.
- Mortimer, P., Parry, J. (1992). Letter to the Editor: Salivary testing for HIV infection. *BMJ*, 305, 1093.
- Mullins, T., Braverman, P., Dorn, L, Kollar, L., & Kahn, J. (2010). Adolescent Preferences for Human Immunodeficiency Virus Testing Methods and Impact of Rapid Tests on Receipt of Results. *Journal of Adolescent Health*, 46, 162-168.
- Mutale, W., Michelo, C., Jürgensen, M.& Fylkesnes, K. (2010). Home-based voluntary HIV counselling and testing found highly acceptable and to reduce inequalities. *BMC Public Health*, 10, 347.
- Owens, D., Nease, R. & Harris, R. (1996). Cost-effectiveness of HIV screening in acute care settings. *Archives of Internal Medicine*, 156, 394-404.
- Paltiel, D., Walensky, R., Schackman, B., Seage, G., Mercincavage, L., Weinstein, M., & Freedberg, K. (2006). Expanded HIB Screening in the United States: Effects on Clinical Outcomes, HIV Transmission and Costs, *Annals of Internal Medicine*, 145 (11), 797-806.
- Pai, N., Tulskey, J., Cohan, D., Colford, J. & Reingold, A. (2007). Rapid point-of-care HIV testing in pregnant women: a systematic review and meta-analysis. *Trop Med Int Health*, 12 (2), 162-73.
- Pascoe, S., Langhaug, L., Mudzori, J., Burke, E., Hayes, R. & Cowan, F. (2009). Field Evaluation of Diagnostic Accuracy of an Oral Fluid Rapid Test for HIV, Tested at Point-of-Service Sites in Rural Zimbabwe, *Aids, Patient Care and STDs.*, 23 (7), 571-6.
- Patton, L., Ranganathan, K., Naidoo, S., Bhayat, A., Balasundaram, S., Adeyemi, O., Taiwo, O., Speicher, D. & Chandra, L. (2011). Oral Lesions, HIV Phenotypes, and Management of HIV-Related Disease: Workshop 4A. *Adv Dent Res*, 23 (1), 112-116.
- Patton, L., Santos, V., McKaig, R., Shugars, D. & Strauss, R. (2002). Education in HIV risk screening, counseling, testing, and referral: survey of U.S. dental schools. *J Dent Educ*, 66 (10), 1169-77.
- Pavie, J., Rachline, A., Loze, B., Niedbalski, L., Delaugerre, C., Laforgerie, E., Plantier, J., Rozenbaum, W., Chevret, S., Molina, J. & Simon, F. (2010). Sensitivity of Five Rapid HIV Tests on Oral Fluid or Finger-Stick Whole Blood: A Real-Time Comparison in a Healthcare Setting. *PLoS ONE* , 5(7): e11581. doi:10.1371/journal.pone.0011581
- Peeling, R. & Mabey, D. (2010). Point-of-care tests for diagnosing infections in the developing world. *Clin Microbiol Infect*, 6 (8), 1062-1069.

- Peralta, L., Constantine, N., Griffin D., Martin, L., & Ghalib, K. (2001). Evaluation of youth preferences for rapid and innovative human immunodeficiency virus antibody tests. *Archives of Pediatric and Adolescent Medicine*, 155 (7), 761-762.
- Pugatch, D., Levesque, B., Lally, M., Reinert, S., Filippone, W., Combs, C., Flanigan, T. & Brown, L. (2001). HIV testing among young adults and older adolescents in the setting of acute substance abuse treatment. *Journal of Acquired Immune Deficiency Syndrome*, 27, 135-42.
- Prost, A., Chopin, M., McOwan, A., Elam, G., Dodds, J., Macdonald, N. & Imrie, J. (2007). "There is such a thing as asking for trouble": taking rapid HIV testing to gay venues is fraught with challenges. *Sex Transm Infect*, 83, 185-188.
- Sohoni, A., Gordon, D., Vahidnia, F. & White, D. (2010). Emergency Department Staff Satisfaction With Rapid Human Immunodeficiency Virus Testing. *Academic Emergency Medicine* 17, 561-565.
- Schopper, D., & Vercauteren, G. (1996). Testing for HIV at home: what are the issues? *AIDS*, 10, 1455-1465.
- Sherrard, M. & Gatt, I. (1987). Human immunodeficiency virus (HIV) antibody testing. Guidance from an opinion provided for the British Medical Association. *Br Med J (Clin Res Ed)*. 295 (6603), 911-912.
- Smith, P., Buzi, R. & Weinman, M. (2005). HIV testing and counseling among adolescents attending family planning clinics. *AIDS Care*, 17 (4), 451-456.
- Spielberg, F., Critchlow, C., Vittinghoff, E., Coletti, A.S., Sheppard, H., Mayer, K., Metzger, D., Judson, F., Buchbinder S., Chesney, M., & Gross, M. (2000). Home collection for frequent HIV testing: acceptability of oral fluids, dried blood spots and telephone results. HIV Early Detection Study Group. *AIDS*, 14 (12), 1819-1828.
- Spielberg, F., Branson, B., & Goldbaum, G., et al. (2005). Choosing HIV counseling and testing strategies for outreach settings: a randomized trial. *Journal of Acquired Immune Deficiency Syndrome*, 38, 348-355.
- Stetler, H., Granade, T., Nunez, C., Meza, R., Terrell, S., Amador, L. & George, R. (1997). Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras, *AIDS*, 11, 369-375.
- Sy, F., Rhodes, S., Choi, S., Drociuk, D., Laurent, A., Naccash, R., & Kettinger, L. (1998). The acceptability of oral fluid testing for HIV antibodies. A pilot study in gay bars in a predominantly rural state. *Sexually Transmitted Diseases*, 25 (4), 211-215.
- Tsu, R., Burm, M., Gilhooly, J. & et al (2002). Telephone vs. face-to-face notification of HIV results in high-risk youth. *J Adolesc Health* 30 (3), 154-60.
- Tweed, E., Hale, A., Hurrelle, M., Smith, R., Delpech, V., Ruf, M., Klapper, P., Ramsay, M. & Brant, L. (2010) Monitoring HIV testing in diverse healthcare settings: results from a sentinel surveillance pilot study. *Sex Transm Infect* 86 (5), 360-4. Epub 2010 Apr 28.
- UNAIDS (1997). HIV Testing Methods - UNAIDS technical update, UNAIDS, Geneva.
- UNAIDS/WHO (2004). HIV Assays: Operational Characteristics (Phase 1) Simple/Rapid tests (Report 14) 2004.
- Walensky, R., Freedberg, K., Weinstein, M. & Paltiel, A. (2007). Cost-effectiveness of HIV testing and treatment in the United States. *Clin Infect Dis*, 45 (Suppl 4), S248-54.
- Wesolowski, L., MacKellar, D., Facente, S., Dowling, T., Ethridge, S., Zhu, J., Sullivan, P. & Post-marketing Surveillance Team (2006). Post-marketing surveillance of OraQuick whole blood and oral fluid rapid HIV testing. *AIDS*, 20 (12), 1661-1666.



HIV and AIDS - Updates on Biology, Immunology, Epidemiology and Treatment Strategies

Edited by Dr. Nancy Dumais

ISBN 978-953-307-665-2

Hard cover, 694 pages

Publisher InTech

Published online 26, October, 2011

Published in print edition October, 2011

The continuing AIDS pandemic reminds us that despite the unrelenting quest for knowledge since the early 1980s, we have much to learn about HIV and AIDS. This terrible syndrome represents one of the greatest challenges for science and medicine. The purpose of this book is to aid clinicians, provide a source of inspiration for researchers, and serve as a guide for graduate students in their continued search for a cure of HIV. The first part of this book, “From the laboratory to the clinic,” and the second part, “From the clinic to the patients,” represent the unique but intertwined mission of this work: to provide basic and clinical knowledge on HIV/AIDS.

How to reference

In order to correctly reference this scholarly work, feel free to copy and paste the following:

H. Blake, P. Leighton and S. Sharma (2011). Saliva Testing as a Practical Tool for Rapid HIV Screening, HIV and AIDS - Updates on Biology, Immunology, Epidemiology and Treatment Strategies, Dr. Nancy Dumais (Ed.), ISBN: 978-953-307-665-2, InTech, Available from: <http://www.intechopen.com/books/hiv-and-aids-updates-on-biology-immunology-epidemiology-and-treatment-strategies/saliva-testing-as-a-practical-tool-for-rapid-hiv-screening>

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