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**COMMENTARY | HIV Testing**

## **Utilization of Rapid Diagnostic Testing in sub-Saharan Africa: Challenges and Effects on HIV Prevention**

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### **ABSTRACT**

The human immunodeficiency virus (HIV) remains a global threat to health. To prevent and control the disease caused by the virus, developed and developing countries continue to invest heavily in research and equipment so as to accurately detect the virus. The utilization of highly sensitive and effective rapid diagnostic tests (RDTs) have the potential to detect HIV in high-burden countries, especially those in sub-Saharan Africa (SSA). Yet, in SSA, challenges associated with HIV-RDT result inaccuracy, HIV misdiagnosis, poor tester capacity, and the improper storage of HIV-RDT kits have negatively impacted the benefits, and threaten to undermine HIV prevention. This paper focuses on the utilization of RDTs in HIV diagnosis in SSA, HIV-RDT challenges, and the effects of HIV-RDT challenges on HIV prevention. Subsequent to reviewing available literature, the authors found that although HIV-RDTs can negatively impact HIV-prevention efforts in SSA due to the likelihood of false positive HIV diagnoses, they generally provide quick results for people in resource poor settings, and do not require them to return to the testing sites to obtain their results. Obtaining accurate rapid HIV results means people who test positive can immediately seek care and take steps to prevent future transmission of the virus.

**Key words:** • HIV • Rapid HIV testing • HIV prevention • Sub-Saharan Africa

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### **Introduction**

In 2019, about 38 million people were living with the human immunodeficiency virus (HIV) globally. Of this population, 36.2 million were adults and 1.8 million were children (<15 years old).<sup>1</sup> Accounting for only 11% of the world's population, sub-Saharan Africa (SSA) continues to be the hardest hit region in the world, with an estimated 20.7 million people (54%) in East and Southern Africa, and 4.9 million (13%)

in West and Central Africa, living with the virus. While SSA was able to reduce HIV incidence by 14% between 2010 and 2015 in East and Southern Africa, and by 8% in West and Central Africa<sup>2</sup> due to a heightened focus on prevention, treatment, and care, challenges remain. SSA still accounts for two-thirds of the global HIV incidence.<sup>2</sup>

Access to HIV testing services is crucial to HIV prevention. Knowing one's HIV status is the

gateway to accessing life-saving treatment and care. Recognizing the critical role of HIV testing in HIV prevention, the Joint United Nations Program on HIV/AIDS (UNAIDS) launched the 90-90-90 targets in 2015, with the goal that by 2020, “90% of all people with HIV will know their status, 90% will be diagnosed and receive sustained antiretroviral therapy (ART), and 90 % of people receiving ART will achieve viral suppression.”<sup>3</sup> In 2017, UNAIDS indicated that the greatest barrier to achieving the 90-90-90 targets will be access to HIV testing in SSA, where more than two-thirds of people living with HIV reside.<sup>4</sup>

Prior to the introduction of rapid tests for HIV diagnosis, HIV tests were primarily done in advanced laboratories. The long wait times for the receipt of test results (1–2 weeks) contributed to low HIV testing uptake, the non-return of people for their results, and consequent missed opportunities for linkage of HIV positive persons to HIV treatment and care services.<sup>5,6</sup> To address this problem, the World Health Organization (WHO) recommended that tests that relied solely on laboratories be replaced with simpler methods like rapid diagnostic tests (RDTs),<sup>7</sup> as such tests provide same day results within an average of 10 minutes and can be performed by non-laboratory staff.<sup>8</sup> The utilization of RDTs have made the delivery of HIV testing services in SSA much easier and faster.<sup>9</sup> However, there are challenges with the quality, accuracy, and reliability of these tests. This paper focuses on the utilization of RDTs in HIV diagnosis in SSA, HIV- RDT challenges, and the effects of HIV RDT challenges on HIV prevention in SSA.

## HIV Rapid Diagnostic Tests Utilized in SSA

Due to technological advancements, a wide variety of HIV-RDTs such as agglutination, dipstick, flow-through membrane, and lateral flow membrane assays are used in SSA for HIV testing. The majority of these tests are in the form of strips or cartridge-incorporating reagents that do not require additional equipment, can be administered by appropriately trained health-care workers, and can be stored at room temperature.<sup>10</sup> There are currently three types of HIV-RDT tests: (1) nucleic acid amplification

tests that are used to detect HIV in blood; (2) antigen/antibody tests that are used to detect both HIV and antigens;<sup>11</sup> and (3) antibody-based tests that are used to detect HIV in the blood, urine, or oral fluid.<sup>12,13</sup> The first two types of RDTs are not routinely used because they are expensive, complex, require training, and must be performed in advanced laboratories. The third type on the other hand, is a point-of-care RDT that has a quick turnaround time, is cost effective, easy to use, and more frequently used in SSA.<sup>14,15</sup>

Globally, the WHO recommends an HIV testing system that comprises 2-3 RDTs (screening, confirmatory, tiebreaker) based on their clinical sensitivity and specificity (usually up to  $\geq 99\%$ ).<sup>14</sup> In Ghana, the First Response<sup>®</sup> HIV1/2, OraQuick<sup>®</sup> HIV1/2, and INNO-LIA<sup>®</sup> HIV I/II Score are the RDTs used for HIV screening, confirmatory, and tiebreaker tests respectively.<sup>16</sup> These tests are listed in the WHO prequalified RDTs for 2020.<sup>17</sup> In Uganda, Determine<sup>™</sup> HIV-1/2, HIV 1/2 Stat-Pak<sup>®</sup> Dipstick, and Uni-Gold<sup>™</sup> HIV<sup>18</sup> are the RDTs used and in South Africa, the GeneXpert cartridge-based platform is used to rapidly test for tuberculosis and HIV viral load.<sup>19</sup> The choice of HIV RDT testing systems in many SSA countries usually depends on the decision of country ministry of health officials and the availability of funding from foreign donors.

## HIV-RDT Challenges

HIV-RDT challenges associated with HIV prevention in SSA are due to several factors<sup>20</sup> such as the inaccuracy of test results, HIV misdiagnosis, tester capacity, and the storage of kits at inappropriate temperatures.

### *Inaccuracy of RDT Results*

A major issue with the utilization of RDTs in HIV diagnosis in SSA is their inaccuracy, poor sensitivity and specificity, and high rates of false HIV positive results. Sensitivity of RDTs is the probability of getting an HIV positive test result when the disease is truly present, and specificity is the probability of getting a negative test result when the disease is truly absent.<sup>21</sup> The score of these variables range from 0-100%. According to the WHO, HIV- RDTs should

have a sensitivity of at least 99% and a specificity of at least 98%.<sup>22</sup> The results of a study conducted by researchers on the utilization of Determine, a commonly used HIV-RDT in Cameroun, showed a sensitivity result of 100% and only a 91.5% specificity.<sup>23</sup> However, when the samples were retested, 129 of the 295 people who were initially diagnosed as HIV-positive, were actually HIV-negative.<sup>23</sup> A similar situation occurred in Uganda. In the Rakai district of Southwestern Uganda, an area with high HIV prevalence, three of the most commonly used HIV-RDTs (Determine™, STAT PAK®, and Uni-Gold™) revealed critical inaccuracies in results. About 45% of patients who received HIV positive results received them in error.<sup>23</sup>

### **HIV Misdiagnosis**

Results from HIV-RDTs can sometimes be difficult to interpret, especially when tests lines or bands are faint. In such cases, results are left to the subjective interpretation of testers, which most often leads to false positive HIV diagnosis. In a recent assessment of HIV-RDT administration in South Africa,<sup>24</sup> issues with subjective interpretation of results were identified.<sup>25</sup> This led to the misdiagnosis of some patients. In another incident that occurred between 2004 and 2005, *Médecins Sans Frontières* (MSF) staff offering HIV-RDTs in SSA, misdiagnosed 44 people in the Democratic Republic of Congo, Burundi, and Ethiopia with HIV.<sup>26</sup>

### **Tester Capacity**

Low staff capacity, coupled with high workload, and the lack of comprehensive quality management systems, have been found to contribute to HIV-RDT result errors.<sup>27</sup> While the number of people receiving HIV-RDTs in SSA has significantly increased in the past few years, the number of health personnel available to administer these tests has not increased proportionally. Of those available to offer the service, several have not been adequately trained on how to adhere to standard operating procedures and to maintain quality assurance such as tester competency, pre-test preparations, quality control, and record keeping.<sup>28</sup> Inadequate staff training in HIV-RDT methodology is costly. This is because it can negatively affect testing accuracy. The results of

a study conducted in South Africa showed that the sensitivity and specificity of HIV-RDTs performed by lay nurses and counsellors were 92.5 – 97.3% and 97.6 – 98.2% respectively, while those performed by trained laboratory technicians showed a 100% performance.<sup>28</sup> The researchers concluded that the inadequate training of lay nurses and counsellors may have contributed to the discrepancies and difficulties in the interpretation of RDT results.<sup>28</sup> Several other HIV-RDT studies conducted in SSA also identified lack of adequate tester testing capacity to be responsible for some of the false positive and negative HIV diagnosis.

### **Poor HIV RDT Kit Storage**

HIV-RDTs are to be stored at ambient temperatures specified by manufacturers (36° - 86° F or 2-30°C) and used before their expiration dates.<sup>28</sup> Yet, in some SSA countries, HIV-RDTs are stored in suboptimal conditions and those nearing expiration, are not discarded. This affects the quality and accuracy of test results. Researchers of a quality assurance study conducted to test the effects of higher than manufacturer-specified temperatures for three HIV-RDTs (OraQuick, Determine 1/2™ and Uni-Gold™) on 378 participants at Ndirande Health Centre in Blantyre, Malawi, found seven false HIV negative results among test kits that were stored at suboptimal temperatures.<sup>29</sup> Facente et al also found a significant decline in test specificity of OraQuick ADVANCE® tests that were used a month after expiration.<sup>30</sup>

## **HIV-RDT Challenge Effects on HIV Prevention and Recommendations**

### **Testing Credibility**

Poorly trained and inexperienced staff have the tendency to increase the likelihood of inaccurate interpretation of HIV-RDT results.<sup>23</sup> Inaccurate results can lead to low HIV testing uptake, negate the goal and credibility of HIV-RDTs, and create missed opportunities for linking HIV positive people to care and prevention services.<sup>23</sup> Inaccurate results can also cause the unintentional transmission of HIV to previously uninfected people.<sup>23</sup> As HIV-RDT testing technology is rapidly evolving and is frequently

utilized in SSA, appropriate health personnel need to be trained, certified, and provided with routine support and supervision to ensure that testing procedures are followed correctly, and results are accurately interpreted. They also need to be trained in quality assurance, so they can ensure that expired kits are not used. Doing this will increase public trust and confidence in the technology.

To increase their efficacy and accuracy, HIV-RDT kits need to be stored at prescribed temperatures, and those nearing expiration need to undergo quality control checks before they are used. When it comes to temperature, it can be monitored by placing thermometers in storage areas where the kits are stored. This will enable site supervisors to surveil storage temperature ranges and to preserve kit quality. Temperature control logs can be posted outside storage areas so readings can be checked and recorded daily. Investing in proper storage protocols and facilities will ensure that manufacturer recommended instructions are observed. This will minimize false HIV diagnosis and wastage.

### **Social, Emotional, and Economic Consequences**

The social and emotional consequences of a false HIV positive diagnosis can be severe and more difficult to handle than the physical effects of the infection. A false positive HIV result can put people at risk of physical and verbal abuse, abandonment, and ostracization by friends, family, and community members.<sup>33</sup> These outcomes are disproportionately higher among women, as they are more likely than men to access health care facilities and to be tested for HIV. In addition to psychological trauma, an HIV misdiagnosis can also lead to unnecessary ART initiation and stigma. Some researchers who conducted studies on the effects of false HIV positive diagnosis on people found that it led to divorce, the incurring of unnecessary expenses due to clinical visits, and physical harm in some communities in the Democratic Republic of Congo, Burundi, Ethiopia,<sup>26</sup> and Ghana.<sup>14</sup>

To address the socio-economic and emotional consequences associated with the inaccurate interpretation of HIV-RDT results, health workers need to work with a “second-reader” to validate test

results when they are unsure before pronouncing a diagnosis. Retesting also needs to be done as part of routine service prior to putting people on ART. This will help to save people falsely diagnosed from debt and financial ruin.

### **Conclusion and Global Health Implications**

HIV-RDTs have proven to be of great benefit in SSA. Although these tests have the tendency to negatively impact HIV-prevention efforts due to the likelihood of false HIV positive diagnosis, they generally provide quick results and do not require a return to testing sites for results. Providing accurate HIV-RDT results means people who test positive can immediately seek care and take steps to prevent future transmission of the virus. The challenges caused by the inaccurate interpretation of HIV-RDT results have serious social, economic, and emotional consequences and thus, need to be addressed. With the need to scale-up HIV testing, diagnosis and linkage to care and treatment in SSA, a parallel push to improve the quality of HIV testing services and accurate diagnosis is essential.

#### **Key Messages**

- ▶ The utilization of RDTs have made the delivery of HIV testing services in SSA much easier and faster.
- ▶ A major issue with the utilization of RDTs in HIV diagnosis in SSA is their inaccuracy, poor sensitivity and specificity, and high rates of false HIV positive results.
- ▶ Providing accurate HIV-RDT results means people who test positive can immediately seek care and take steps to prevent future transmission of the virus.

### **Compliance With Ethical Standards**

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