

Low-cost tools for diagnosing and monitoring HIV infection in low-resource settings

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Abstract Low-cost technologies to diagnose and monitor human immunodeficiency virus (HIV) infection in developing countries are a major subject of current research and health care in the developing world. With the great need to increase access to affordable HIV monitoring services in rural areas of developing countries, much work has been focus on the development of point-of-care technologies that are affordable, robust, easy to use, portable and of sufficient quantitative accuracy to enable clinical decision-making. For diagnosis of HIV infection, some low-cost tests, such as lateral flow tests and enzyme-linked immunosorbent assays, are already in place and well established. However, portable quantitative tests for rapid HIV monitoring at the point of care have only recently been introduced to the market. In this review, we discuss low-cost tests for HIV diagnosis and monitoring in low-resource settings, including promising technologies for use at the point of care, that are available or close to market.

Abstracts in **عربي**, **中文**, **Français**, **Русский** and **Español** at the end of each article.

Introduction

New technologies and drugs for early diagnosis, continuous monitoring and treatment of human immunodeficiency virus (HIV) infection have improved the prognosis of infection and the quality of life among individuals living with HIV. In 2009, five years after the availability of antiretroviral therapy (ART) was expanded in sub-Saharan Africa, drug treatments alone reduced mortality due to HIV infection and acquired immunodeficiency syndrome by 20%.¹ However, in the same year only one third of the 15 million people in low- and middle-income countries who were in need of ART received it. In these areas, a lack of resources, be they infrastructural, financial or human, hampers access to care for the resident populace. This results in delayed treatment, poor patient follow-up and poor adherence to ART, all of which contribute to the high rate of transmission and mortality.² Therefore, substantial efforts have been taken to build low-cost and reliable point-of-care (POC) HIV diagnostic and monitoring solutions that effectively make early diagnosis and treatments available to even the most resource-constrained communities.

Current gold standards

Several gold standard technologies with high sensitivity and specificity are used worldwide to efficiently diagnose and monitor HIV infection. Enzyme-linked immunosorbent assays (ELISAs) and simple/rapid tests are performed to diagnose HIV infection on the basis of HIV antibody detection. Flow cytometry is used to monitor CD4+ T-cell count and thereby determine when to initiate ART. The more expensive nucleic acid tests, such as polymerase chain reaction (PCR) assays, are used to detect virologic failure by monitoring the HIV load. PCR of dried blood spots is also the most effective technology for early diagnosis of HIV infection in infants (also known as “early infant diagnosis”), since assays based on antibody detection are unsuitable because maternal anti-HIV antibodies can persist in infant blood for up to 18 months after birth. PCR using dried blood spots is also useful for diagnosing HIV infection when cold-chain

transport of liquid plasma samples is too costly or logistically complicated.^{3,4}

These technologies are useful in a broad spectrum of resource-limited settings but they have disadvantages. With the exception of rapid tests, the technologies are costly, take hours to perform and require highly skilled technicians and dedicated laboratory spaces. As a result, many developing countries are unable to meet the demand for HIV infection diagnosis and monitoring. Zambia, for instance, has one of the highest incidences of HIV infection in the world but only dedicates three PCR machines to the diagnosis of infection in infants. Furthermore, although clinical symptoms and CD4+ T-cell count have been used in resource-limited settings to determine when to initiate therapy and when virologic failure has occurred, there is growing support to consider the results of viral load monitoring before making therapeutic decisions. The high cost of nucleic acid tests, coupled with logistical challenges involved with cold-chain transport, will probably force many clinics to refer patients to larger clinics for further testing, which could make patient follow-up difficult and delay initiation of treatment.

On the basis of these considerations, it is not surprising that in some locations little or no overlap exists between the set of HIV-associated health-care technologies that meet a specific need and the set of technologies that are practical and affordable. Therefore, a more ideal suite of technologies for use at the point of care is called for, especially in resource-limited settings.

Ideal point-of-care tests

The ASSURED (affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end users) criteria, outlined by the World Health Organization (WHO), provide a good framework for evaluating POC devices for resource-limited environments. Tools that satisfy the ASSURED criteria primarily aim to provide same-day diagnosis and facilitate immediate decision-making.⁵ Quick receipt of results increases the number of people who know their HIV status, assists in delivering timely ART (especially to women

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in labour) and minimizes the number of patients lost to long-term follow-up.^{6,7} In addition, devices whose use requires minimal training and that have a high throughput can widen the pool of end users and alleviate congestion at HIV testing centres.⁸ Finally, such a device should be operable in resource-limited environs, which include those with unreliable electricity, non-sterile conditions and a lack of trained personnel to perform the duties typically reserved for nurses and health workers. Further examples of target specifications, listed in Table 1, will vary on the basis of the needs and setting in which the device will be used. For example, a device that detects a lower viral load may be less useful than a device that provides semiquantitative but clinically useful viral load ranges (e.g. levels denoting a low, medium and high risk of virologic failure). Hence, consultation with clinicians, health workers and other end users can result in well defined performance specifications that complement the ASSURED criteria and suit the specific needs of health professionals and patients.

Here, we provide an overview of low-cost and POC devices for the diagnosis and monitoring of HIV infection (Table 2). These include well established standard devices, those in the pipeline and those currently being researched. We focus only on low-cost devices that are free of the limitations associated with the use of gold standard laboratory tests in resource-limited areas. For a broader review of diagnostic and monitoring tests, we refer the reader to a recent summary of the nucleic acid tests in use and a review of commercially available ELISAs and nucleic acid tests.^{10,14}

Low-cost tests for low-resource settings

HIV screening

A plethora of simple/rapid commercial tests are used in low-resource settings for HIV screening.¹⁰ The most ready-to-use types of rapid tests are lateral flow tests, which do not require reagents. In general, rapid tests are cheap (less than 1 United States dollar [US\$] per capita), portable and easy to use, require few or no reagents or equipment and provide results within 30 minutes. Each test rapidly detects antibodies against

Table 1. ASSURED characteristics (WHO) and examples of target specifications for the evaluation of point-of-care devices

Characteristic	Target specification
Affordable	Less than US\$ 500 per machine, less than US\$ 10 per test
Sensitivity, specificity	Lower limit of detection: 500 HIV RNA copies per mL, 350 CD4+ T-cells per μ L
User-friendly	1–2 days of training, easy to use
Rapid and robust	< 30 minutes for diagnosis, < 1.5 hours for HIV load monitoring, minimal consumables (i.e. pipettes), shelf life > 1 year at room temperature, high throughput
Equipment-free	Compact, battery powered, on-site data analysis, easy disposal, easy sample handling, no cold chain
Deliverable	Portable, hand-held

ASSURED, affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end users; HIV, human immunodeficiency virus; RNA, ribonucleic acid; US\$, United States dollars; WHO, World Health Organization.

HIV type 1 (HIV-1) and/or HIV type 2 (HIV-2) from a small volume of plasma, serum, whole blood, saliva or urine, with high specificity and sensitivity.¹⁰ The use of these tests has substantially increased the volume of HIV tests performed and the number of patients who learnt their results before being lost to follow-up.¹⁵ Also, since speedy testing is critical in prescribing intrapartum prophylactic therapy and antiretroviral drugs to prevent mother-to-child transmission, rapid HIV testing has had a positive effect on programmes to prevent HIV infection.^{6,16}

Fear of stigmatization from testing positive for HIV can deter at-risk individuals from seeking consultation¹⁷ and can make people reluctant to disclose their HIV status. The use of saliva and urine specimens for rapid testing offers a discrete alternative to blood-based tests in settings where stigma, lack of education, cultural practices and privacy concerns undermine HIV prevention.¹⁸ In addition, the non-invasiveness of specimen collection eliminates the anxiety associated with blood collection and leads to higher rates of voluntary HIV testing.^{19,20} The OraQuick Rapid HIV-1/2 Antibody Test (Orasure Technologies, Inc., Bethlehem, United States of America) is a lateral flow rapid test for saliva specimens that performs as well as blood-based tests, even at low concentrations of HIV antigens in saliva.^{10,21} The Aware HIV-1/2 U (CALYPTE, Portland, USA), with 97.2% sensitivity and 100% specificity, is a rapid alternative to urine tests that rely on ELISAs and Western blots.²²

The use of rapid HIV tests is expanding to include combination tests that detect both anti-HIV antibody and p24 antigen, as well as tests for early infant diagnosis (discussed below) and for HIV-1 and HIV-2 subtype differentiation.²³ Detection of both antibody and antigen during the acute phase of infection is particularly beneficial to prevention efforts because the rate of HIV transmission is 26 times higher during this phase and can account for up to 50% of new HIV infections.²³ The fourth-generation Determine HIV-1/2 Ag/Ab Combo (Alere, Waltham, USA) is an immunochromatographic rapid test that detects antigen and antibody separately. In two independent studies, the Determine HIV-1/2 Ag/Ab Combo showed sensitivities of 50% and 86% for antigen detection.^{24,25} Although ELISA has higher sensitivity, the Determine HIV-1/2 Ag/Ab Combo test is still able to detect early HIV infection. Larger studies are needed to confirm whether the Determine HIV-1/2 Ag/Ab Combo test is a suitable alternative to ELISA in low-resource locations.

The results of rapid tests for HIV detection are often confirmed by performing a secondary and/or tertiary test. These testing algorithms improve the positive predictive value of rapid tests in populations with a low prevalence of HIV infection, in which false-positive results are more common. The Centers for Disease Control and Prevention and WHO recommend the use of POC rapid testing strategies in accordance with the objective of the test (surveillance, blood screening or diagnosis), the sensitivity and specificity of the test, the local

Table 2. Characteristics of low-cost tests for diagnosing and monitoring human immunodeficiency virus (HIV) infection

Test purpose, type	Commercial test(s)	Portable	Detection method	Cost (US\$)	Time to result	Advantage(s)	Limitation(s)
HIV diagnosis							
ELISA	Many available ⁹	No	Quantifies HIV DNA or RNA in serum	< 2	~3–5 hours	High throughput, sensitive	Requires dedicated laboratory equipment and confirmatory diagnosis, not for early infant diagnosis
Simple/rapid test	Many available ¹⁰	Yes	Qualitatively detects HIV antibodies in whole blood, serum or saliva	< 2	~30 minutes	Appropriate for screening large and rural populations, immediate result	For screening only (not quantitative), not high throughput for larger-scale screening
p24 test	Perkin-Elmer p24 Ultrakit ¹¹	No	Quantifies p24 core protein of HIV	5–10	~4 hours	Sensitive for paediatric diagnosis of HIV infection, cheaper than PCR	Requires dedicated laboratory space, additional buffer reagents and further validation
ART initiation, virologic failure							
POC CD4+ T-cell count	Pima Test; Point-Care NOW; Partec CyFlow miniPOC; Daktari CD4+ ¹²	Yes	Quantifies CD4+ T-cells	~6 per test	20 minutes (Pima), 8 minutes (Point)	Portable, sensitive, faster than flow cytometry	Requires further validation, tests CD4+ T-cell count only (Pima Test), not high throughput
POC PCR	Liat HIV Quant Assay (in pipeline) ¹²	Yes	Quantifies HIV DNA in blood	25 000 per instrument	88 minutes per sample	Portable	To be determined
Reverse transcriptase test	Cavidi EXAVir Load Version 3 ¹³	No	Quantifies reverse transcriptase levels	~20	90 minutes	Cheaper than virus load testing, tests for multiple HIV subtypes	High rate of false-positive results, long testing time, not POC

ART, antiretroviral therapy; DNA, deoxyribonucleic acid; ELISA, enzyme-linked immunosorbent assay; PCR, polymerase chain reaction; POC, point-of-care; RNA, ribonucleic acid; US\$, United States dollars.

prevalence of HIV infection and the resources available for testing.^{26,27}

HIV load monitoring

Reverse transcriptase, an enzyme present during viral replication, correlates linearly with HIV load and CD4+ T-cell count.²⁸ As such, commercial assays for measuring this protein are cheap alternatives for virus load monitoring in low-resource settings. These tests are not performed at the point of care, but they yield results in a few hours and cost 80% less than nucleic acid tests.²⁹

Several reports support the use of the EXAVir Load Version 3 nucleic acid test for HIV load monitoring in the developing world.^{14,29–31} In this test, a gel-separation step isolates virions from plasma components. The virions are then lysed and the lysates undergo a modified ELISA to measure the activity of reverse transcriptase. Virus load measurements with EXAVir versions 2 and 3 had excellent concordance with

gold standard HIV RNA assays.^{13,31,32} In one study, in which patients receiving ART were monitored for 48 weeks with EXAVir and HIV RNA assays (Roche and Bayer), EXAVir displayed a specificity of 95% for HIV RNA detection in samples with RNA levels > 400 copies/mL.³² Viral load estimates based on reverse transcriptase tests are not directly comparable to those obtained through PCR because they have been found to under-quantify the HIV load.^{31,32} However, in places where PCR is unavailable, results of reverse transcriptase tests can be a cheaper viral load monitoring method. Further advantages of reverse transcriptase tests include their ability to detect multiple subtypes of HIV and their possible use in monitoring HIV load in paediatric patients.²⁹

Levels of the HIV core protein p24 also correlate with HIV load and CD4+ T-cell count,²⁸ and thus early generation p24 immunoassays offered low-cost options for measuring HIV load. p24

immunoassays are no longer considered for this activity, however, because of their low sensitivity, the high variability of the results between assays and the difficulty in standardizing the correlation between p24 and virus load in persons receiving ART.^{14,33,34}

Early infant diagnosis

Since early intervention greatly reduces infant mortality due to HIV infection (by 75% in one study), HIV tests with high sensitivity would be enormously helpful to the thousands of infants at risk in countries where the distribution of PCR machines is limited.³⁵ Current p24 immunoassays have better sensitivity over past-generation p24 tests because of the inclusion of a heat-denaturation step for separating p24-antibody complexes that commonly interfere with assay sensitivity. Many studies support the use of the Perkin Ultra p24 immunoassay for early diagnosis in infants aged 10 days to 12 months.^{30,36,37} p24 immunoassay

of dried blood spot samples had 94.4% sensitivity and 100% specificity in another study. These findings are promising because dried blood spot analysis is common for infant diagnosis in rural areas.³⁷ Compared with standard or reverse transcription PCR, p24 immunoassays are cheaper (up to US\$ 10 in Africa) and less demanding of resources, which makes them a worthwhile option in clinics with limited access to more expensive tests.¹¹ However, p24 immunoassays are not widely used owing to a lack of validation data. Also, because p24 immunoassays require specialized equipment and skilled staff, p24 rapid tests are preferred for early infant diagnosis in resource-limited locations.

Development of p24 rapid tests has focused mainly on improving sensitivity.^{38,39} In 2010, Parpia et al. tested a microfluidic p24 test on 25- μ L plasma samples from 389 South African infants.⁴⁰ Their design included a heat-shock component to break the antigen-antibody complexes. They achieved 95% sensitivity, 99% specificity and a detection limit of 42 500 RNA copies/mL. The current prototype now returns results in 20 minutes. This work, part of the Northwestern Global Health Foundation, has clinical trials planned for 2012.¹²

Portable tests

Portable tests for HIV monitoring comprise CD4+ T-cell count assays and HIV quantification assays. Currently, only a handful of truly portable CD4+ T-cell counters are available commercially: PointCare NOW, the CyFlow miniPOC (Partec), Pima Test (Alere) and Daktari CD4+ (Daktari Diagnostics). All are fully automated, can be powered by batteries or electricity, use $\leq 25 \mu$ L of blood and provide same-day results. Additional POC CD4+ T-cell tests in development include a multiplex infectious disease test (MBio Diagnostics) and a semiquantitative, electricity-free CD4+ T-cell blood test (Zyomyx).¹²

Both the PointCare NOW and CyFlow miniPOC measure absolute CD4+ T-cell counts and the percentage of T-cells expressing CD4+ and do not require cold chain for reagent storage. The CyFlow miniPOC has a substantially high throughput, with the capability of processing 250 tests per day. No independent diagnostic data for either test were available at the time of writing.

The Pima Test and Daktari CD4+ are cartridge-based tests in which a blood sample is inserted into a disposable cartridge containing the necessary reagents per test. Daktari CD4+ is still undergoing performance evaluation but the Pima Test, introduced in late 2010, has yielded results comparable to those of other ART monitoring devices.^{8,41-43} While the majority of Pima Test measurements underestimate CD4+ T-cell counts, one study demonstrated 96.3% sensitivity for concentrations below a cut-off of 250 cells/ μ L.⁴² A recent study also found that Pima Test capillary blood samples yielded less precise results than venous blood samples.⁴³ This highlights the need to address sources of error that can decrease a POC test's accuracy.

No portable PCR tests for HIV quantification are currently on the market but several are in the pipeline. According to PATH, a low-cost version of a fully automated rapid PCR device is in development for resource-limited settings.¹² This test, known as the Liat HIV Quant Assay (IQuum Inc., Marlborough, USA), uses whole blood in a single container for PCR amplification and analysis in 88 minutes.⁴⁴ The SAMBA HIV-1 test is a dipstick-based nucleic-acid assay for HIV detection and amplification. After collection of viral RNA, isothermal amplification of RNA is automated by a machine. The current prototype tests one sample in < 2 hours but future prototypes are expected to test 5–10 samples simultaneously. In one study, SAMBA results agreed with reverse transcription PCR results for 69 clinical samples with different viral subtypes or viral loads (78 to 9.5×10^6 copies/mL).⁴⁵ Additional advantages of this test include: (i) its lower cost because, unlike PCR, it requires no thermocyclers; (ii) its multiplexing capability, which permits detection of HIV subtypes; and (iii) same-day diagnosis. An additional SAMBA test for qualitative early infant diagnosis is also in the works. Other companies developing POC viral load tests include Alere and Micronics. Several other POC PCR platforms in development might also be easily adapted for HIV-associated health care.¹²

Additional considerations

With the increased emergence of POC tests on the market, validation studies are useful to shed light on those ASSURED criteria that are not being satis-

fied by the tests. First, these studies have commonly shown that interpretation of a given test's results requires further analysis. For example, to determine when to initiate ART in children aged less than 5 years, the CD4+ T-cell fraction (%) is a better criterion for clinical decision-making than the CD4+ T-cell count, which is highly variable in this age group.⁴⁶ Therefore, an assay such as the Pima Test would be insufficient in settings where HIV-infected children 5 years of age or younger are in care, owing to the need for flow cytometry or age/clinical-stage tables to estimate the CD4+ T-cell fraction in these individuals.⁸ In other cases, linking data capture/analysis to POC testing may require equipment (e.g. power supplies, printers, optical equipment and data processors) and maintenance beyond that required by the POC test alone. Often, there are trade-offs between high-throughput devices (e.g. CyFlow miniPOC), portability (e.g. Pima Test) and time to result, and such tradeoffs may help determine which platform is most suitable for a particular locality.

Second, POC tests may have lower throughput, even if they yield faster results. The non-portable Partec CyFlow is capable of testing up to 400 samples per day, whereas the Pima Test is limited to 20–25 samples in an 8-hour workday. Third, some tests may require additional skill and consumable goods to ensure accurate, safe and sterile sample collection. Although lancets are appropriate for collecting the blood samples evaluated by POC tests, the Pima Test evaluation study showed that the volume of blood collected by a single fingerprick was in some cases insufficient for analysis.^{8,41} The discomfort from subsequent fingerpricks and the risk of sharps-related injury could be minimized by using microtainers for collecting large volumes (approximately 500 μ L) of blood. Fourth, overall a POC test may cost as much as current standard laboratory tests once the costs of maintenance, disposable goods, sample preparation, sample shipment and results analysis are factored in. Each Pima Test costs approximately US\$ 10 without counting additional costs, whereas a single nucleic acid test has an overall cost of approximately US\$ 7–8.⁴³ Early infant diagnosis test kits alone may cost up to 55% of the overall price of test-related materials.³⁵

Current research on POC tests

A substantial amount of research continues to be performed for the development of POC HIV tests, in tandem with the development of gold standard tests and new testing technologies. In microfluidics research, recent advances in multiplex diagnosis, label-free detection and lensless imaging have demonstrated high sensitivity and specificity for HIV detection.^{47–49} Lensless imaging work in particular has included hand-held prototypes no larger or heavier than a

mobile phone. Such devices also have the capability of transmitting test results wirelessly to ministries of health, health clinics and other end users to monitor trends in HIV infection and virologic status. Desai et al. review several other exciting research endeavours involving HIV tests that will be interesting for practitioners and engineers to monitor in the coming years.⁵⁰

Conclusion

Several low-cost and portable tools for HIV diagnosis and monitoring in low-

resource settings are currently in the pipeline or were recently introduced into the market. Ongoing field studies have shown that, unlike current gold standard tests, they provide same-day diagnoses in a reliable, rapid, affordable, simple and robust manner. POC diagnostic tests still need validation, so engineers, physicians and health workers should be aware of them so they can participate in their evaluation and improvement and ensure that the tests are ready for commercial use. ■

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ملخص

الأدوات منخفضة التكلفة الرامية إلى تشخيص الإصابة بعدوى فيروس العوز المناعي البشري ورصده في البيئات منخفضة الموارد

بعض الاختبارات منخفضة التكلفة مثل اختبارات التدفق الجانبي ومقاييس التقاط الممتز المناعي المرتبط بالإنزيمات وهي اختبارات مطبقة وذات أساس جيد. ولكن لم يتم تقديم الاختبارات الكمية المحمولة للرصد السريع لفيروس العوز المناعي البشري في نقطة الرعاية إلى السوق إلا مؤخرًا. وناقش في هذا الاستعراض، الاختبارات منخفضة التكلفة الرامية إلى تشخيص فيروس العوز المناعي البشري ورصده في البيئات منخفضة الموارد، بما في ذلك التكنولوجيا الواعدة المتاحة أو القريبة من السوق، لاستخدامها في نقطة الرعاية.

تمثل التكنولوجيات منخفضة التكلفة الرامية إلى تشخيص عدوى فيروس العوز المناعي البشري في البلدان النامية موضوعًا رئيسيًا للبحث والرعاية الصحية في البلدان النامية في الوقت الراهن. ومع الحاجة الكبيرة إلى زيادة الوصول إلى خدمات رصد فيروس العوز المناعي البشري ميسورة التكلفة في المناطق الريفية في البلدان النامية، تم تنفيذ قدر كبير من العمل في تطوير تكنولوجيات نقطة الرعاية ميسورة التكلفة والقوية وسهلة الاستخدام والمحمولة وذات الدقة الكمية الكافية بغيّة تمكين صنع القرارات السريرية. ولتشخيص عدوى فيروس العوز المناعي البشري، يتم بالفعل تنفيذ

摘要

在经济欠发达地区诊断和监测艾滋病毒感染的低成本工具

诊断和监测发展中国家艾滋病毒（HIV）感染的低成本技术是发展中国家当前研究和卫生保健的一个重大课题。随着发展中国家亟需更多惠及农村地区的廉价艾滋病毒监测服务，人们进行了大量的工作，开发廉价、强大、易用、便携并且定量准确性足够实现临床决策的床边技术。对于艾滋病毒感染的诊断，层析法和酶联免疫吸附试验等

一些低成本的检测已经存在并且非常成熟。然而，用于床边快速艾滋病毒监测的便携式定量检测只是在最近才推向市场。在这篇综述中，我们讨论了供经济欠发达地区艾滋病毒诊断和监测的低成本检测，包括市场上已有或者即将投入市场供床边使用的富有前景的技术。

Résumé

Outils à faible coût pour le diagnostic et le suivi de l'infection par le VIH dans des contextes de ressources limitées

Les technologies à faible coût pour diagnostiquer et suivre l'infection par le virus de l'immunodéficience humaine (VIH) dans les pays en voie de développement sont un sujet majeur de la recherche actuelle et des soins de santé dans le monde en développement. Tenant compte du besoin crucial d'accroître l'accès à des services de suivi du VIH dans les zones rurales des pays en voie de développement, beaucoup d'énergie a été consacrée au développement de technologies sur les lieux des soins, qui soient abordables, robustes, faciles à utiliser, portables et d'une précision quantitative suffisante pour permettre la prise de

décisions cliniques. Pour le diagnostic de l'infection par le VIH, des tests à faible coût, tels que des tests d'écoulement latéraux et des dosages immunoenzymatiques, sont déjà en place et bien établis. Cependant, les tests quantitatifs portables pour un suivi rapide du VIH sur les lieux des soins n'ont été que récemment introduits sur le marché. Dans cette étude, nous évaluons les tests de diagnostic et de suivi du VIH à faible coût dans des contextes de ressources limitées, y compris les technologies prometteuses pouvant être utilisées sur les lieux des soins, qui sont disponibles ou seront bientôt mises sur le marché.

Резюме**Малозатратные инструменты для диагностики и мониторинга ВИЧ-инфекции в условиях ограниченных ресурсов**

Малозатратные технологии для диагностики и мониторинга вируса иммунодефицита человека (ВИЧ) в развивающихся странах являются основным предметом текущих исследований и здравоохранения в развивающихся странах. Учитывая значительную потребность в расширении доступа к недорогим службам мониторинга ВИЧ в сельских районах развивающихся стран, была проделана большая работа в развитии технологий пунктов оказания помощи, которые доступны по цене, эффективны, просты в использовании, мобильны и обеспечивают достаточную точность количественных данных, необходимых для принятия клинических решений. Для диагностики ВИЧ-инфекции уже

используются и хорошо зарекомендовали себя такие недорогие тесты, как методы латерального потока и иммуноферментного анализа. Однако портативные количественные тесты для быстрого мониторинга ВИЧ-инфекций в пунктах оказания помощи были представлены на рынке только недавно. В данном обзоре рассматриваются недорогие тесты для диагностики и мониторинга ВИЧ-инфекции в условиях ограниченных ресурсов, включая технологии, перспективные для использования в пунктах оказания помощи, которые на данный момент доступны на рынке или близки к нему.

Resumen**Las herramientas de bajo coste para el diagnóstico y seguimiento de la infección por VIH en entornos con pocos recursos**

Las tecnologías de bajo coste para diagnosticar y controlar la infección por el virus de la inmunodeficiencia humana (VIH) en los países en desarrollo son un tema principal de las investigaciones en curso y la atención sanitaria en el mundo en desarrollo. Debido a la necesidad imperiosa de aumentar el acceso a servicios de seguimiento del VIH asequibles en las áreas rurales de los países en desarrollo, se ha trabajado mucho en el desarrollo de tecnologías de puntos de atención asequibles, robustas, de uso sencillo, transportables y suficientemente precisas desde el punto de vista cuantitativo como para permitir la toma de decisiones clínicas. Algunas de las pruebas de bajo coste para

el diagnóstico de la infección por VIH, como la prueba de flujo lateral y las pruebas de inmunoabsorción enzimática, ya están disponibles y bien establecidas. Sin embargo, las pruebas cuantitativas portátiles para realizar un seguimiento rápido del VIH en los puntos de atención se han introducido recientemente en el mercado. En la presente revisión hablamos acerca de las pruebas de bajo coste para el diagnóstico y seguimiento del VIH en entornos con pocos recursos, incluidas las tecnologías prometedoras disponibles o listas para salir al mercado para su uso en los puntos de atención.

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