Access to laboratory testing at primary health facilities in Malawi, Uganda and Zimbabwe

Introduction

Decentralisation of HIV treatment to lower level health facilities is vital for increasing access to treatment. The 2013 WHO guidelines make this even more imperative, as more people are considered eligible for antiretroviral therapy (ART). These guidelines also make recommendations on the use of laboratory testing for diagnosis, assessing eligibility and monitoring patients on ART. This brief examines the availability and use of laboratory tests, based on a survey of 53 primary care health facilities in Malawi, Uganda and Zimbabwe, of which 30 provided ART services.

What laboratory tests are needed?

Most diagnosis of HIV is now carried out through simple point-of-care tests. DNA PCR virus tests are required for diagnosing HIV in infants.

CD4 tests are used in many settings to assess eligibility for treatment. Simple point-of-care tests are currently being piloted in Mozambique, but for now CD4 testing elsewhere relies upon specialised machinery and trained laboratory staff, although some of these machines are relatively simple and battery powered.

Once patients are on ART, the 2013 WHO recommendations say that they should be monitored every 6-12 months with routine viral load tests. If these are not available then routine CD4 and clinical monitoring should be carried out, with viral load testing being targeted at confirming treatment failure. For monitoring side-effects the guidelines say that symptom-directed laboratory monitoring can be used for those receiving ART, rather than routine tests for toxicity. Tests that may be needed for when patients develop symptoms from either HIV or as side-effects of treatment include haemoglobin (for anaemia), white cell counts and blood chemistry tests to assess renal and hepatic function and lactic acidosis.

In addition to tests related to HIV and ART, health facilities also need access to laboratory tests for diagnosing pregnancy, malaria, tuberculosis and other common conditions.

About the baseline survey

As part of the Lablite project, a baseline survey was carried out of 81 purposively selected health facilities in Malawi, Uganda and Zimbabwe. These facilities were from different geographical regions and facility levels, and were at different stages of ART provision. This brief focuses on the results from the 53 primary care facilities that were surveyed. Detailed questionnaires were administered to the in-charge nurse or clinician of the facility, or a representative. They included questions on the services provided by the facility and human resources. It was carried out between September 2011 and July 2012.

Key Points

- Decentralisation of HIV treatment to primary health facilities is essential to increase coverage of ART
- There is limited access to laboratory tests at primary health facilities in Malawi, Uganda and Zimbabwe
- Simple, cheap point-of-care tests need to be developed to improve access to tests for monitoring before ART as well as diagnosis of illnesses
- Lack of laboratory tests for monitoring treatment response should not be a barrier to initiating ART

Availability and use of laboratory testing for diagnosing HIV and assessing eligibility for ART

HIV antibody tests

The baseline survey found that all the facilities surveyed reported providing rapid HIV tests. However, stockouts of test kits were reported by 10/16, 5/21 and 2/16 primary health facilities in Malawi, Uganda and Zimbabwe respectively. The median duration of stockouts was 14 days out of the last 90 days, ranging from 3-30 days.

DNA PCR for early infant diagnosis

Early infant diagnosis depends upon access to PCR testing. PCR is available off-site at 9/11, 14/21 and 13/13 primary facilities for which data was available in Malawi, Uganda and Zimbabwe respectively.

CD4 testing for assessing eligibility for ART at facilities that provided ART on-site

In Malawi 2/9 facilities had CD4-testing on-site and 3/9 facilities were able to refer patients to an alternative facility. Only 4/9 primary health facilities in Malawi regularly used CD4 tests prior to initiation, and the remainder only used CD4 tests in selected patients.

In Uganda all ART-providing primary health facilities collected samples on-site and transported them to a reference laboratory. 1/6 primary health facilities regularly used CD4 tests in all patients prior to initiation, 4/6 only in adults, and 1/6 did not regularly use CD4 tests prior to initiation.

In Zimbabwe 13/15 primary health facilities providing ART collected samples on-site and transported them to a reference laboratory, while 1/15 referred patients for CD4 testing, and 1/15 had no access to CD4 tests. 9/15 sites used CD4 tests regularly prior to initiation in all patients, 4/15 in selected patients, and 1/15 did not use CD4 tests regularly prior to ART initiation.

Table 1: Policies for CD4 monitoring of patients on ART at primary health facilities

Country	Policy for CD4 monitoring of patients on ART
Malawi	3/9 facilities: if clinically indicated 6/9 facilities: not regularly used
Uganda	5/6 facilities: every 6 months 1/6 facilities: every 12 months
Zimbabwe	10/15 facilities: every 6 months 1/15 facilities: every 12 months 1/15 facilities: if clinically indicated 2/15 facilities: not regularly used

Availability of laboratory tests for monitoring patients on ART

CD4 monitoring of patients on ART in primary health facilities who provide ART

Table 1 summarises the reported policies for CD4 monitoring of patients on ART in primary health facilities. At the time of the survey, CD4 monitoring was not supported by the national guidelines in Malawi.

On average the number of CD4 tests conducted per month was low, given the numbers of adults on ART and the number of adults initiating ART. While facilities may have policies for the frequency of CD4 monitoring of patients on ART, the number of CD4 tests actually carried out at these facilities in practice does not always match. By looking at the number of CD4 tests carried out by facilities where the number of adults on ART is stable (less than 5% initiating ART per month, so most CD4 tests will be for monitoring), we were able to estimate the frequency of CD4 tests actually carried out. In Uganda both sites that met this criteria were carrying out enough tests (through sending samples to a referral lab) for each adult on ART to be tested every 6 months. In Zimbabwe, 1/ 4 facilities were testing each adult approximately every 1 to 2 years, while the remaining 3/4 were only doing enough CD4 tests to test every adult less than once every 2 years.

Viral load testing

Data from Malawi, Uganda and Zimbabwe show that viral load testing was rarely available at primary health facilities. No ART-providing primary health facility surveyed provided viral load tests, and only 1/9 facilities in Malawi and 1/15 in Zimbabwe could refer patients for viral load tests.

Toxicity testing

Primary health facilities that provided ART had very limited on-site laboratory testing capacity. Haemoglobin tests were available on-site at 5/9, 5/6 and 2/15 of ART-providing primary facilities in Malawi, Uganda and Zimbabwe respectively. 1/9, 1/6 and 8/15 facilities were able to refer patients for haemoglobin tests. White blood cell counts were only available on-site in 2 primary care facilities (1 in Malawi and 1 in Uganda), and by referral in 2/9, 2/6 and 9/15 facilities. Only 1/9, 2/6 and 8/15 primary care facilities were able to refer patients for liver function tests (none could test on-site). Access to urea and creatinine tests was similar.

Drug resistance testing

None of the facilities surveyed in any of the countries carried out drug resistance testing.

Challenges of carrying out laboratory tests

Even where health facilities do provide laboratory tests, services are vulnerable in several ways. The number of trained laboratory technicians and assistants is low. Only 6/16, 14/21 and 1/16 primary care facilities in Malawi, Uganda and Zimbabwe had laboratory technicians or assistants. Stockouts of test kits and reagents, and machines breaking down are also considerable problems.

Approaches to monitoring patients on ART

Access to laboratory testing for monitoring of people on ART in Malawi, Uganda and Zimbabwe is limited, even for CD4 testing. Viral load monitoring is unavailable in nearly all facilities surveyed. The DART and ARROW trials have shown that both adults and children can have good outcomes on ART with clinically-driven monitoring. Health economic work linked to these trials found that routine CD4 monitoring at current prices is not cost-effective. Lack of access to laboratory tests should not be a barrier to starting people on ART.

Simple point-of-care tests could help to increase access to CD4 testing, if they are cheap enough (<$4 a test) and not dependent on machinery or laboratory technicians. These are likely to become available in the next few years.

Viral load monitoring is more problematic, as it is much more expensive than CD4 testing and point-of-care tests are likely to take longer to become available. In the meantime, MSF have adopted an approach of using dried blood spots and pooling samples to make viral load testing more feasible and affordable. However, this approach has not yet been validated, and it is not clear how whole blood viral load relates to plasma viral load. The costs of viral load testing will need to be drastically reduced, and techniques developed that do not require complex machinery and highly trained laboratory staff, before routine viral load monitoring can become a reality for patients of primary health facilities in many parts of sub-Saharan Africa.

Conclusions

The new WHO guidelines have dramatically increased the number of people eligible for ART. In order to get these people on treatment decentralisation is essential. The baseline survey carried out as part of Lablite in Malawi, Uganda and Zimbabwe has shown that while HIV tests are available from all primary health facilities surveyed, CD4 tests are less universally accessible, and viral load tests are not available. Access to laboratory tests for early infant diagnosis, monitoring of patients prior to initiating ART, investigating suspected toxicity and confirming treatment failure needs to be improved.

However, health economic analyses based on the ARROW and DART results, and on several models, have found that while coverage of treatment is below 100% of those in need of it, more lives will be saved by using the available resources to put more people on treatment than by carrying out routine laboratory monitoring of those already on treatment.

While we wait for the development of simple, affordable point-of-care tests, implementation of the new WHO guidelines on routine laboratory monitoring with viral load testing will be very difficult to implement at primary health facilities. Lack of access to laboratory monitoring should not be a barrier to starting people on treatment.

Recommended reading

Chan, A. K., D. Ford, et al. (2014). "The Lablite project: a cross-sectional mapping survey of decentralized HIV service provision in Malawi, Uganda and Zimbabwe." BMC Health Serv Res 14: 352.

World Health Organisation (2013). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva, World Health Organisation.

Kekitiinwa, A., A. Cook, et al. (2013). "Routine versus clinically driven laboratory monitoring and first-line antiretroviral therapy strategies in African children with HIV (ARROW): a 5-year open-label randomised factorial trial." Lancet 381(9875): 1391-1403.

Keebler, D., P. Revill, et al. (2013). "Cost-effectiveness of different strategies to monitor adults on antiretroviral treatment: a combined analysis of three mathematical models." The Lancet Global Health.

Mugyenyi, P., A. S. Walker, et al. (2010). "Routine versus clinically driven laboratory monitoring of HIV antiretroviral therapy in Africa (DART): a randomised non-inferiority trial." Lancet 375(9709): 123-131.

Recommendations

- ART programmes should focus resources on getting more people onto treatment through decentralisation.
- Clinically-driven monitoring can help to achieve this in the absence of cheap, feasible point-of-care tests.
- Supply chains need to be strengthened to avoid stockouts of HIV test kits and laboratory reagents.
- Funders should encourage the development of tests that can be used in primary health facilities without relying on machines or laboratory technicians, at a price that is cost-effective.

About Lablite

Lablite is an implementation project investigating strategies to roll out HIV treatment safely and cost-effectively in sub-Saharan Africa. The project is working closely with ministries of health in three countries in Africa (Malawi, Zimbabwe and Uganda). It aims to inform national and international policy on how best to use the limited funds available to increase coverage of HIV treatment. Lablite is funded by the UK Department for International Development.

See more at: http://www.lablite.org