

5 HIV AND SEXUALLY TRANSMITTED INFECTIONS

a Universal test and treat implementation: an update on the HIV testing services diagnostic algorithm in adults

The South African National Department of Health announced on the 10 May 2016 that it will implement the two major recommendations of the WHO regarding the timing of anti-retroviral therapy (ART) initiation, and on pre-exposure prophylaxis (PrEP) for HIV. These recommendations are: 1) treatment initiation in all age groups regardless of CD4 count ("Universal Test and Treat", UTT); and 2) prevention of infection using PrEP for high-risk populations in combination with other prevention measures. In South Africa UTT is to be implemented from September 2016 for all HIV-positive persons and PrEP will be provided to sex workers from June 2016, starting in 10 sex-worker programmes. These two policy recommendations are based on clinical trials and observational studies.

The implementation of UTT is likely to be complex as several operational requirements, including HIV diagnostic testing, need to be addressed. In South Africa, HIV Testing Services (HTS) are the key entry points for the continuum of HIV care and treatment. As part of the preparation for UTT, the DoH has updated the HTS policies and guidelines, which are now in line with the WHO HTS 2015 guidelines. The South African HTS diagnostic testing strategy remains a serial testing algorithm but changes aimed at improving the accuracy of results have been made as follows:

- If the screen and confirmatory rapid test are discrepant, guidelines recommend that both screen and confirmatory rapid test should be repeated. If the repeat rapid testing result remains discrepant, only then should a specimen will be sent to the NHLS laboratory for ELISA testing.
- ELISA testing at the NHLS laboratory must follow the standard diagnostic testing for HIV infection namely 4th generation ELISA/EC

testing. As before, any initial 4th generation ELISA test that is reactive must be confirmed using a second and different 4th generation ELISA platform. However, if the two 4th generation results are discrepant, a second specimen is to be sent in 14 days.

When discrepant results are observed using rapid tests, a tiebreaker test is no longer recommended. There is evidence to suggest tiebreaker tests may result in an increase in false-positive results. Also, current HIV rapid tests are likely to miss acute/early infections, and combination (antibody + p24 antigen detection) HIV rapid tests have not shown an improvement, most likely because of insufficient sensitivity in detecting p24 antigen. The HTS guideline does not include confirmation of HIV infection prior to initiation of ARV therapy.

In the South African HTS 2016 guideline, HIV self-testing is acknowledged as a potential way to increase test coverage, particularly amongst males, young persons, and other high-risk groups. The South African Pharmacy Council has approved over-the-counter distribution and use of HIV self-tests. Clearer guidance will likely be developed for self-testing following planned studies to assess acceptability, ease of use and access. The South African HTS 2016 guideline recommends that any reactive (positive) self-test result should be confirmed through standard HTS testing algorithms.

Source: Centre for HIV and Sexually Transmitted Infections, NICD-NHLS.