7. HIV TESTING TECHNOLOGIES

7.1 Factors to consider

The introduction of highly sensitive, specific, simple-to-use, rapid antibody tests that do not require sophisticated laboratory services, running water or electricity is an important advance. Accurate results can be available within a much shorter time than for traditional enzyme-linked immunosorbent assays (ELISA). The advantages of using rapid HIV tests for provider-initiated HIV testing and counselling – particularly for health facilities where laboratory services are weak – include visibility of the test and quick turn-around, increasing confidence in results and avoidance of clerical errors. Testing can occur outside laboratory settings, does not require specialized equipment and can be carried out in primary health facilities by appropriately trained non-laboratory personnel, including counsellors. However, trained laboratory supervisors are required for supervision and quality assurance, including quality control for testing and bio-safety. Tests selected should be of assured quality.

ELISA may be preferable in settings where large numbers of tests need to be performed, where immediate provision of test results is less important (such as for hospital inpatients) and in reference laboratories. ELISA allows large numbers of samples to be tested efficiently at one time but potential disadvantages include the necessary time to assemble enough samples to make a test run (approximately 40), the need for clerical rigour to unambiguously link individuals to test results and the reporting time of the results (half a day), which generally precludes outpatients receiving the test result at the same visit. ELISA tests are carried out using specialized laboratory equipment and therefore require certified laboratory staff to manage the test procedure, report results and maintain equipment.

Decisions on whether to use HIV rapid tests or ELISA for provider-initiated HIV testing and counselling should take into account factors such as:

- Cost and availability of the test kits, reagents and equipment
- Available staff, resources and infrastructure
- Laboratory expertise and personnel available
- Number of samples to be tested
- Sample collection and transport
- The setting in which testing is proposed
- Convenience
- The ability of individuals to return for results.

Definitive diagnosis of HIV infection in children younger than 18 months requires virological tests, as the presence of maternal HIV antibodies may complicate the interpretation of positive results of HIV rapid tests or ELISA tests. Virological testing depends upon complex procedures such as HIV-DNA or HIV-RNA polymerase chain reaction (PCR), is expensive and requires highly trained

staff. WHO promotes a centralized virological testing approach where specimens are collected on filter papers which are easily transported to a central laboratory, even in tropical conditions.

7.2 Testing algorithms

HIV testing should follow recommended CDC-UNAIDS-WHO HIV testing strategies[70] and relevant national HIV testing algorithms. Testing algorithms may involve serial (also called sequential) or parallel testing. ELISA-based algorithms are almost always serial in nature, while rapid test algorithms can be either.

With **serial testing**, if the result of the first test is negative, the HIV antibody test is reported as negative. If the test result is positive, the specimen is tested with a second test using different antigens and/or platform from the first. Tests that are exactly the same but sold under different names should not be used in combination. A second positive test result is considered to indicate a true positive result in populations with an HIV prevalence of 5% or more. In low prevalence settings where false positive results are more likely, a third confirmatory test may be required. WHO and UNAIDS recommend serial testing in most settings because it is cheaper and a second test is only required when the initial test is reactive.

With **parallel testing** – recommended only when using whole blood finger stick samples rather than venous blood – two tests are carried out simultaneously using assays based on different antigens and/or platforms. Concordantly negative or positive results are considered as true negatives or positives, respectively.

When two test results (serial or parallel) show dissimilar results (one is reactive and the other non-reactive), the tests results are described as discordant. Specialist laboratory advice may be required in cases of such test discordance.

In all cases, WHO and UNAIDS recommend that HIV tests used should have a sensitivity of at least 99% and a specificity of 98%. The specific test combinations need to be evaluated in the context in which they will be used before wide-scale implementation.

8. PROGRAMMATIC CONSIDERATIONS

Decisions on how best to implement provider-initiated HIV testing and counselling will depend upon an assessment of the situation in a particular country, including local epidemiology, the available infrastructure, financial and human resources, the available standard of HIV prevention, treatment, care and support and the existing social, policy and legal frameworks for protection against HIV-related discrimination. Where there are high levels of stigma and discrimination and/or low capacity of health care providers to implement provider-initiated HIV testing and counselling under the conditions of informed consent, confidentiality and counselling, adequate resources must be devoted to addressing these issues prior to implementation.

Decisions about whether and how to implement provider-initiated HIV testing and counselling should be made in consultation with all relevant stakeholders. The steps that may need to be taken to adapt the general recommendations in this document to national and local conditions are shown in Table 2.

Many settings with a high HIV burden face substantial human and financial constraints that limit the feasibility of implementing new health services on a large scale. As described in Section 4, it may be necessary to prioritize particular types of health facilities for the introduction of provider-initiated HIV testing and counselling, depending upon the social and epidemiological context and available resources.

Coordinated planning, training and procurement are important to help ensure synergies between provider- and client-initiated HIV testing and counselling approaches and will help to facilitate referral between different types of health services.

Table 2 Consultation and adaptation activities to implement provider-initiated HIV testing and counselling at country level

1. In countries considering the implementation of provider-initiated HIV testing and counselling, the Ministry of Health should convene a national consultation to plan an implementation strategy, including adaptation of this guidance document to local conditions. Participants should include:
   - National-level programme managers for HIV, tuberculosis and other clinical services
   - Ministries of justice, welfare, interior and finance
   - Health care providers
   - Regulatory bodies and health professional associations
   - Community- and faith-based organizations, including women's organizations
   - Most-at-risk populations
   - People living with HIV/AIDS
   - Human rights advocates
   - Private sector representatives
   - Representatives of legal and social support services.
2. Existing social, legal and policy frameworks should be assessed and reviewed to facilitate implementation of provider-initiated HIV testing and counselling and to protect the rights of patients, including advocacy and communication campaigns and social and legal support services.
3. Adequate resources must be planned and available for implementation, including for testing-related commodities, health care provider training and community preparedness and social mobilization.
4. Operational guidelines, protocols and codes of conduct for health care providers, training tools and education materials must be developed or adapted. These should be based on HIV epidemiology, available resources, ethical and human rights principles and legal and sociocultural contexts.
5. For countries choosing to implement provider-initiated HIV testing and counselling in a phased manner, priority settings for initial and subsequent scale-up should be selected.
6. Health care providers should be identified and trained.
7. Provider-initiated HIV testing and counselling should be incorporated into existing supervision, quality assurance and monitoring and evaluation systems.
8. Civil society should be engaged in ongoing monitoring and evaluation of provider-initiated HIV testing and counselling in health facilities.
9. At facility level, linkages should be strengthened between services to facilitate entry into HIV-related services following HIV testing and counselling, including community-based prevention, treatment, care and support services.

9. MONITORING AND EVALUATION

Monitoring and evaluation should form an essential and ongoing part of programmes to implement provider-initiated HIV testing and counselling. National monitoring and evaluation of provider-initiated HIV testing and counselling services should allow programme managers to:

- Monitor progress in implementation, including procedures for obtaining informed consent, ensuring confidentiality and providing counselling
- Identify problems, and refine and adapt implementation strategies
- Assess the effectiveness and impact of provider-initiated testing and counselling in terms of:
  - increasing access to HIV testing and counselling, and to test results
  - increasing access to and uptake of HIV-related prevention, treatment, care and support services
  - decreased morbidity and mortality
  - increased HIV awareness and treatment literacy
  - social impact (e.g. on rates of disclosure; on stigma and discrimination; and adverse outcomes).
- Assess cost-effectiveness and sustainability.
- Assess the quality of related laboratory services
- Assess the reasons that HIV testing and counselling is being recommended.

Monitoring and evaluation planning should aim, where possible, to utilize existing structures or mechanisms for collecting relevant indicators, rather than setting up independent systems. Standardized and simple data collection tools will enable comparability between sites and reduce burden on health care personnel. Appropriate training in data collection should be provided to health care providers and administrators.

As the amount of data in routine monitoring will always be limited, it is recommended to complement routine monitoring with focused evaluations on specific aspects of implementation. For example, quality assurance should be undertaken at the health facility level. Regular evaluations of health care provider performance and patient satisfaction (testing processes, pre-test information, consent process, post-test counselling) can help improve the effectiveness, acceptability and quality of HIV testing and counselling services.

Health facilities are encouraged to partner with non-governmental organizations and civil society groups in monitoring and evaluating provider-initiated HIV testing and counselling to ensure service quality and acceptability, including the maintenance of high ethical standards and human rights norms.

More detailed guidance on monitoring and evaluation of HIV testing and counselling, including provider-initiated HIV testing and counselling, is being developed by WHO and will be available in 2007.

APPENDIX

Additional resources

A broad selection of tools and guidance for implementing HIV testing and counselling in different settings, including provider-initiated HIV testing and counselling, may be found on the **WHO HIV Testing and Counselling Online Toolkit**. This web site is periodically updated with the latest HIV testing and counselling resources available (Web site: http://who.arvkit.net/tc/en/index.jsp;

PDF file: http://whqlibdoc.who.int/publications/2005/924159327X_eng.pdf).

The following documents and internet sites may also be useful resources for planning, implementing and scaling-up provider-initiated HIV testing and counselling services:

Antiretroviral therapy and clinical care

- Antiretroviral therapy for HIV infection in adults and adolescents: towards universal access - recommendations for a public health approach, WHO, 2006 revision. http://www.who.int/entity/hiv/pub/guidelines/artadultguidelines.pdf
- Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access - recommendations for a public health approach, WHO, 2006 version. http://www.who.int/hiv/pub/guidelines/pmtctguidelines2.pdf
- Antiretroviral therapy for HIV infection in infants and children: towards universal access - recommendations for a public health approach, WHO, 2006. http://www.who.int/hiv/pub/guidelines/paediatric020907.pdf
- WHO ARV Toolkit. Website: http://www.who.int/hiv/toolkit/arv/en/index.jsp, PDF version: http://whqlibdoc.who.int/hq/2003/9241591161.pdf
- WHO Integrated management of adolescent and adult illness (IMAI) and Integrated management of childhood illness (IMCI) - various documents. Web site: http://www.who.int/hiv/pub/imai/en/

Legal and policy issues

- Policy statement on HIV testing, UNAIDS and WHO, 2004, http://data.unaids.org/una-docs/hivtestingpolicy_en.pdf
- HIV/AIDS and human rights - international guidelines, UNAIDS and OHCHR, 1996. http://whqlibdoc.who.int/publications/1998/9211541301.pdf
- International guidelines on HIV/AIDS and human rights, 2006 consolidated version, UNAIDS and OHCHR. http://data.unaids.org/Publications/IRC-pub07/jc1252-internguidelines_en.pdf
- Handbook for legislators on HIV/AIDS, law and human rights, UNAIDS and IPU, 1999 http://whqlibdoc.who.int/unaids/1999/UNAIDS_99.48E.pdf

Beneficial disclosure and partner counselling

- Opening up the HIV/AIDS epidemic: Guidance on encouraging beneficial disclosure, ethical partner counselling & appropriate use of HIV case-reporting (UNAIDS Best Practice Collection, Key Material, UNAIDS and WHO, Geneva, November 2000). http://whqlibdoc.who.int/unaids/2000/UNAIDS_00.42E.pdf

HIV testing in women and girls

- Addressing violence against women in the context of HIV testing and counselling - a meeting report, WHO 2007 (forthcoming)
- Testing and Counselling for Prevention of Mother-to-Child Transmission of HIV (TC for PMTCT) Support Tools, CDC, WHO, UNICEF, USAID and PMTCT implementing partners. Web site: http://www.who.int/hiv/pub/vct/tc/en/index.html
- WHO Briefing Note -- HIV and Infant Feeding. Conference on Retroviruses and opportunistic infections. Los Angeles, 25-28 Feb 2007. http://www.who.int/hiv/mediacentre/Infantfeedingbriefingnote.pdf
- Sexual and reproductive health of women living with HIV/AIDS, WHO and UNFPA, 2006. http://whqlibdoc.who.int/publications/2006/924159425X_eng.pdf
- Prevention of mother-to-child transmission of HIV: generic training package, WHO and CDC, 2004. Web site: http://www.cdc.gov/nchstp/od/gap/PMTCT/
- Nutrition counselling, care and support for HIV-infected women, WHO, 2004. http://whqlibdoc.who.int/publications/2004/9241592125.pdf

HIV Testing and Counselling in TB Clinical Settings

- Interim policy on collaborative TB/HIV activities WHO/HTM/TB/2004.330 (http://www.who.int/tb/publications/tbhiv_interim_policy/en/index.html)
- *CDC and WHO tools on HIV Testing and Counselling in TB Clinical Settings 2007*
  - Module One: Introduction, Background, and Rationale http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%201_12.6.06.pdf
  - Module Two: Understanding the Provider-initiated and Delivered HIV Testing and Counseling Process in the Context of TB Clinical Settings http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%202_12.7.06.pdf
  - Module Three: Preparing the Provider to Perform PTC http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%203_12.12.06.pdf
  - Module Four: Administrative, Implementation and Standard Operating Procedures http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%204_12.13.06.pdf
  - Module Five: Clinical Considerations http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%205_12.6.06.pdf

- Module Six: Demonstration Clinic
  http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%206%20Demo_12.1.06.pdf

Most-at-risk populations

- WHO online sex work toolkit (Web site: http://who.arvkit.net/sw/en/index.jsp; PDF version: http://www.who.int/entity/hiv/pub/prev_care/sexworktoolkit.pdf)
- HIV prevention through harm reduction among injecting drug users
  http://www.who.int/hiv/idu/en/index.html
- Strategies for involvement of civil society in HIV testing within context of "3 by 5": Focus on marginalized communities, UNAIDS, 2004,
  http://data.unaids.org/Topics/Human-Rights/hr_refgroup3_06_en.pdf

HIV testing and children

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- Convention on the right's of the child general comment No 3: HIV/AIDS and the rights of the child, UN, 2003, Website: http://whqlibdoc.who.int/publications/2002/9291730254.pdf
- Integrated Management of Childhood Illnesses (resources). Website:
  http://www.who.int/child-adolescent-health/publications/pubIMCI.htm

Testing technologies

- Training package for HIV rapid testing, CDC and WHO, 2006.
  http://www.phppo.cdc.gov/dls/ila/hivtraining/default.aspx
- WHO Guidelines on HIV rapid testing, WHO (to be published)
- Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach, CDC and WHO, 2005
  http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf
- Revised recommendations for the selection and use of HIV antibody tests, UNAIDS/WHO, 1997
  http://www.who.int/docstore/wer/pdf/1997/wer7212.pdf
- The importance of simple/rapid assays in HIV testing, WHO/UNAIDS, 1998
  http://www.who.int/docstore/wer/pdf/1998/wer7342.pdf

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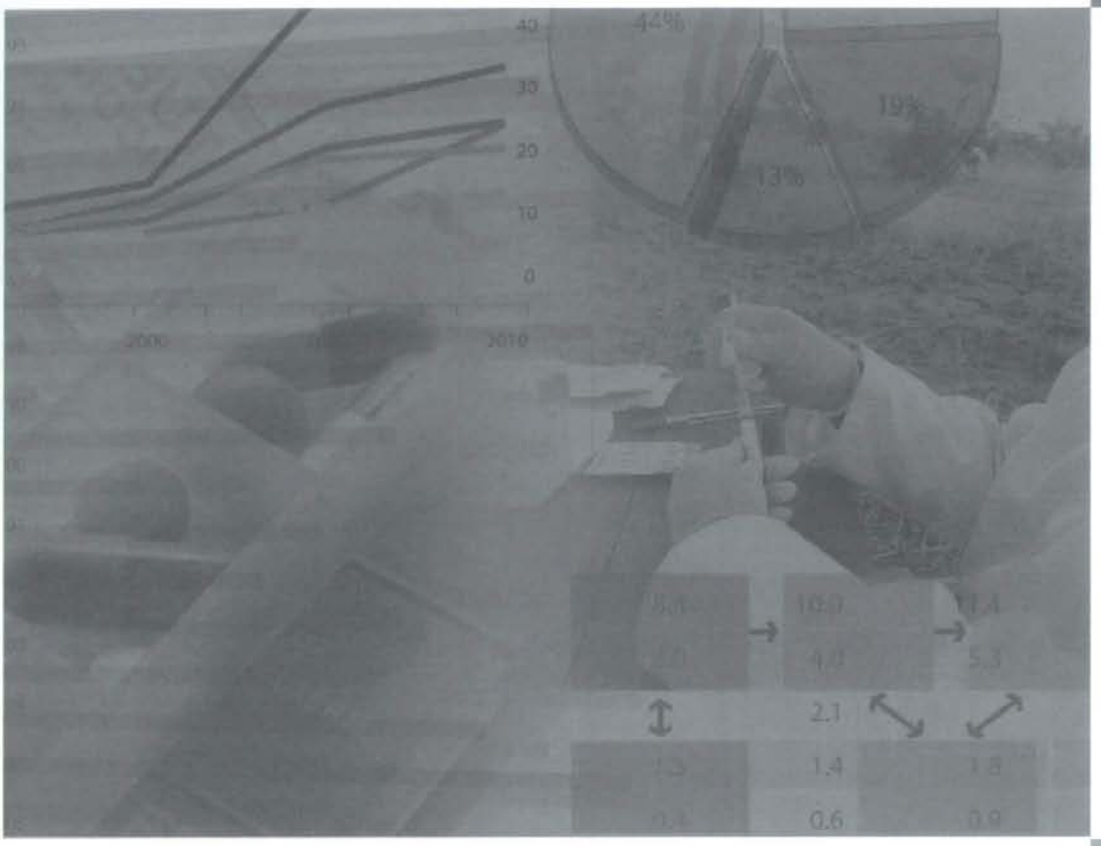

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