Meeting Report

Improving the Quality of HIV and Syphilis Point-of-care testing using the new WHO guidance Document (Biregional Asia-Pacific Workshop)

28–30 July 2015
Phnom Penh, Cambodia
MEETING REPORT

IMPROVING THE QUALITY OF HIV AND SYPHILIS POINT-OF-CARE TESTING USING THE NEW WHO GUIDANCE DOCUMENT

(BIREGIONAL ASIA-PACIFIC WORKSHOP)

Convened by:

WORLD HEALTH ORGANIZATION
REGIONAL OFFICES FOR SOUTH-EAST ASIA AND THE WESTERN PACIFIC
AND
UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION

Phnom Penh, Cambodia
28–30 July 2015

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The views expressed in this report are those of the participants of the Biregional Asia Pacific Workshop and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Improving the Quality of HIV and Syphilis Point-of-care testing in Asia and the Pacific in Phnom Penh, Cambodia from 28 to 30 July 2015.
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Keywords

Diagnostic tests, Routine / HIV infections / Syphilis / Total Quality Management/
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<tr>
<th>Abbreviation</th>
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<tbody>
<tr>
<td>ANC</td>
<td>antenatal care</td>
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<td>ART</td>
<td>antiretroviral therapy</td>
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<td>CD4</td>
<td>cluster of differentiation 4</td>
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<tr>
<td>CBO</td>
<td>community-based organization</td>
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<td>CDC</td>
<td>(United States) Centers for Disease Control and Prevention</td>
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<td>CTEI</td>
<td>costing tool for the elimination initiative</td>
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<tr>
<td>DALY</td>
<td>disability-adjusted life year</td>
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<td>DTS</td>
<td>dried tube specimen</td>
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<tr>
<td>EPTCT</td>
<td>elimination of parent-to-child transmission</td>
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<tr>
<td>EQA</td>
<td>external quality assessment</td>
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<tr>
<td>Global Fund</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
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<td>HCV</td>
<td>hepatitis C virus</td>
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<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HIVST</td>
<td>HIV self-testing</td>
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<td>HTC</td>
<td>HIV testing and counselling</td>
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<td>HTS</td>
<td>HIV testing services</td>
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<td>IVD</td>
<td>in vitro diagnostics</td>
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<td>KHANA</td>
<td>Khmer HIV/AIDS NGO Alliance</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MSM</td>
<td>men who have sex with men</td>
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<tr>
<td>MTCT</td>
<td>mother-to-child transmission</td>
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<td>NCHADS</td>
<td>National Center for HIV/AIDS, Dermatology and STD</td>
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<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
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<tr>
<td>NRL</td>
<td>National Reference Laboratory</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>PEPFAR</td>
<td>(United States) President’s Emergency Plan for AIDS Relief</td>
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<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
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<td>POC</td>
<td>point of care</td>
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<tr>
<td>PPTCT</td>
<td>prevention of parent-to-child transmission</td>
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<td>QA</td>
<td>quality assurance</td>
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<td>QAC</td>
<td>quality assurance cycle</td>
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<td>QC</td>
<td>quality control</td>
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<td>QI</td>
<td>quality improvement</td>
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<td>QMS</td>
<td>quality management system</td>
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<td>RDT</td>
<td>rapid diagnostic test</td>
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<td>RPR</td>
<td>rapid plasma reagin</td>
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<tr>
<td>RST</td>
<td>rapid syphilis test</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TPHA</td>
<td><em>Treponema pallidum</em> haemagglutination (test)</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<tr>
<td>VCCT</td>
<td>voluntary confidential counselling and testing</td>
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<td>WHO</td>
<td>World Health Organization</td>
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SUMMARY

The World Health Organization (WHO) regional offices for South-East Asia and the Western Pacific organized a three-day workshop on “Improving the Quality of HIV and Syphilis Point-of-care testing in Asia and the Pacific” aimed at mitigating the risk of misdiagnosis of patients and ensuring the quality of point-of-care testing in Asia and the Pacific. The workshop was convened at the Faculty of Pharmacy, University of Health Sciences in Phnom Penh, Cambodia from 28 to 30 July 2015.

Each session commenced with formal presentations on a selected topic followed by group breakout sessions, during which each country identified gaps in their ability to provide quality rapid HIV and syphilis test results and then proposed possible solutions. The participants represented 11 Asian and Pacific countries, as well as presenters, facilitators and organizers from WHO, United States Centers for Disease Control and Prevention (CDC) and partner organizations. The countries represented were Cambodia, Fiji, India, Indonesia, Lao People’s Democratic Republic, Mongolia, Nepal, Papua New Guinea, the Philippines, Thailand and Viet Nam.

The group work aimed at determining the current status of quality assurance of HIV- and syphilis-related point-of-care diagnostic testing. Participants were introduced to the new WHO guidance document *Handbook for improving the quality of HIV-related point-of-care testing*. The development and validation of appropriate testing algorithms for HIV and syphilis were also discussed. National implementation plans for strengthening quality assurance of HIV rapid/point-of-care testing were drafted.

The workshop addressed challenges to the implementation of quality management principles and quality assurance of point-of-care tests, including rapid diagnostic tests in laboratories, as well as testing outside of the laboratory in community health-care settings.
1. INTRODUCTION

The rapid scale up and decentralization of HIV point-of-care testing has resulted in testing being carried out in some settings without appropriate quality assurance (QA) measures, thereby increasing the potential risk of error.\(^1\) In addition, many countries in Asia and the Pacific have implemented, or will implement, testing strategies using rapid diagnostic tests (RDTs) for screening and for confirmation of HIV and syphilis test results. Some of this testing will be performed outside the laboratory. To ensure reliable and accurate test results, it is critical that QA and quality management principles are included in the planning, implementation and monitoring of testing.

Point-of-care tests, including RDTs, are generally easy to use and do not require technical expertise, cold chain storage, specialized equipment or a power source. As such, they can be employed outside the laboratory and conducted by non-technical staff. However, in these settings, it is imperative to have appropriate QA measures in place. Lessons learnt from the implementation of RDTs, particularly for HIV testing in non-laboratory settings, have shown that there are often weaknesses in the systems required to support good-quality testing. Commonly, there are limitations relating to human resources, and the training and supervision of staff. This results in poor workflow, poor trouble-shooting and staff not following the manufacturer’s instructions. In addition, relatively few QA activities are conducted to manage and identify process and testing errors. This has, for example, contributed to misclassification of HIV status, which has been reported recently across programmes and countries, resulting in incorrect care and treatment of individuals.

HIV-related point-of-care testing technologies have become widely available in the past few years and have the potential to play a major role in achieving the 90–90–90 targets\(^2\) set by the Joint United Nations Programme on HIV/AIDS (UNAIDS) through increasing access to diagnostics in developing countries. Therefore, maintaining a high quality of testing while increasing access is critical for better patient care.

The new WHO Handbook for improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results aims to address the weaknesses in current point-of-care testing QA programmes, identify key activities that will help in the development and implementation of sustainable high-quality HIV RDTs and HIV-related point-of-care-testing within laboratory and non-laboratory settings. The handbook seeks:

- to emphasize the importance of a continuous quality improvement (QI) for point-of-care testing;
- to strengthen existing QA/QI practices for point-of-care testing;
- to highlight the need for a cadre of quality officers and a network of point-of-care testers;
- to provide innovative QA/QI strategies; and
- to share a comprehensive package of established and new QA/QI tools for point-of-care testing.

The Handbook describes the quality assurance cycle (QAC), a three-phased process developed to assist health-care providers and stakeholders in planning, implementing and sustaining QA for HIV-related point-of-care testing.

1.1 Meeting organization

The meeting was organized in the form of a workshop hosted by the Faculty of Pharmacy at the University of Health Sciences in Phnom Penh, Cambodia from 28 to 30 July 2015. Each session commenced with formal presentations on a selected topic followed by group breakout sessions, during

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which each country identified gaps in their ability to provide quality rapid HIV and syphilis test results, and then proposed possible solutions. The 31 invited participants represented 11 Asian and Pacific countries. In addition, 34 presenters, facilitators and organizers from WHO, United States Centers for Disease Control and Prevention (CDC) and partner organizations also attended. The countries represented were Cambodia, Fiji, India, Indonesia, Lao People's Democratic Republic, Mongolia, Nepal, Papua New Guinea, the Philippines, Thailand and Viet Nam. The programme is given in Annex 1 and the list of participants in Annex 2.

1.2 Meeting objectives
The objectives of the meeting were:

1) to discuss the current status of QA for HIV-related and syphilis point-of-care diagnostic tests;
2) to introduce the new WHO guidance document Handbook for improving the quality of HIV-related point-of-care testing (released in 2015); and
3) to discuss the development and validation of appropriate testing algorithms.

2. PROCEEDINGS

2.1 Opening session
The opening ceremony was presided over by the chief guest – His Excellency Professor Eng Huot (Secretary of State, Ministry of Health, Cambodia), along with Dr Artur Ramos (US CDC representative, Cambodia), Dr Momoe Takeuchi (Office of the WHO Representative in Cambodia) and Professor Chheang Sana (Dean of the Faculty of Pharmacy, University of Health Sciences, Cambodia).

2.1.1 Objectives of the meeting and expected outcomes
As less than half the people in the Region are aware of their HIV status, the HIV response intends to increase diagnoses up to 90% by 2019 in order to initiate early access to treatment. The importance of community-based testing conducted by trained lay providers was identified as essential for this rapid scale up and decentralization of point-of-care testing. The need to mitigate the risk of misclassification of HIV status and ensure the quality of point-of-care testing conducted in Asia and the Pacific was highlighted by several recent reports of misclassification of HIV status. The expected outcomes included discussions on the current status of QA for HIV- and syphilis-related point-of-care diagnostic testing, introduction to the new WHO guidance document Handbook for improving the quality of HIV-related point-of-care testing, and the development and validation of appropriate testing algorithms for HIV and syphilis.

2.2 Session 2: Overview of HIV and syphilis point-of-care testing, quality management systems and challenges in Asia and the Pacific

2.2.1 Overview of HIV and syphilis point-of-care testing and availability of tests on the market and future tests
A comprehensive overview was provided on the performance and potential utility of recently developed dual HIV/syphilis RDTs. Syphilis can increase the HIV viral load and subsequent mother-to-child transmission (MTCCT) of HIV, both HIV and syphilis are diagnosed using serology, both require treatment intervention and partner management, and dual rapid tests would be useful, particularly in the antenatal care (ANC) setting. In the South-East Asia and Western Pacific Regions, 170 000 pregnant women contract syphilis annually and, if untreated, 52% pregnancies will have an adverse outcome. Appropriate intervention can reduce the transmission of HIV from mother to child to <2% and, although half of the HIV-infected infants will die within 2 years of birth without treatment, this can be substantially reduced by providing antiretroviral therapy (ART) to both mother and child. It has been demonstrated that both testing and treatment for syphilis in the ANC setting is highly cost-effective in both low- and high-prevalence situations.
Three dual HIV/syphilis assays are currently undergoing WHO prequalification. They have undergone laboratory evaluation in China and Nigeria, are being field tested in Zambia, and piloted in China, Colombia and Nigeria. The preliminary data indicate a higher sensitivity for HIV than syphilis. The introduction of these dual tests offers potential opportunities to improve the quality of ANC by facilitating the uptake of testing and treatment, increasing the efficiency of testing and procurement, and allowing for the introduction of common QA and quality control (QC) processes.

Potential challenges will include the need to have both dual and single tests available for clients not wishing to be tested for both analytes, integrate them with established HIV testing algorithms, and develop integrated training and QA systems.

2.2.2 Key findings of the gap analysis on laboratory services in the Western Pacific

Key findings were presented of a laboratory gap analysis conducted in selected countries of Asia and the Pacific, in order to improve access to and quality of testing for HIV, syphilis, and hepatitis B and hepatitis C. The work was commissioned by the WHO Regional Office for the Western Pacific and was conducted in collaboration with the National Reference Laboratory (NRL), Australia.

The aim was to gather information on testing, determine gaps in laboratory systems and recommend activities for strengthening these systems. The gap analysis was conducted using two questionnaires completed by the Ministry of Health, WHO Regional Offices for South-East Asia and the Western Pacific, NRL and other central laboratories. The countries chosen to represent the spectrum of systems development expected in the Western Pacific Region were Cambodia, Fiji, Lao People’s Democratic Republic, Mongolia, Papua New Guinea, the Philippines and Viet Nam. The two questionnaires covered the following topics:

- Support systems
- National standards, regulation of test kits, licensing and auditing of laboratories, quality management systems (QMS) and external quality assessment (EQA)
- Testing performance
- Testing strategies, algorithms and test kits used for diagnostics, blood screening and clinical management.

Laboratory systems varied from country to country but in each country were the strongest for HIV. All countries reported a national body responsible for HIV testing and an HIV reference laboratory, but no country had uniformly implemented functional QMS, particularly for auditing and accrediting laboratories. Only one country regulated test kits for all four pathogens and three countries had no policies to ensure the quality of test kits procured for hepatitis B virus (HBV), hepatitis C virus (HCV) or syphilis. These three countries had no external EQA scheme in place to detect poor performance of these test kits.

All countries had EQA in place for HIV; however, participation was not always mandatory or enforced, and varied between 25% and 95%. Private facilities tended to fall outside the regulatory and QA systems, and were consequently unmonitored and the quality of testing unknown. Only four of the seven countries had EQA for HBV and HCV, and only two of the seven countries had EQA for syphilis. National testing strategies for HBV and HCV did not exist in most countries, with only one test used and no requirement for confirmatory testing. One country did not test for HCV at all.

Support was recommended for implementation of basic QMS, and development of national EQA systems with universal mandatory participation. National strategies and guidelines are required for HBV, HCV and syphilis testing, which build on the current HIV models, and policies and systems are needed for regulation and procurement of test kits, along with scaling up of HIV viral load testing.

2.2.3 Current status of quality assurance of point-of-care diagnostic tests

This presentation provided the results obtained from the survey questionnaire distributed to the Ministry of Health/AIDS control programmes in 12 countries (those participating in this workshop...
and Myanmar). The questions were designed to identify deficiencies that need to be addressed in the QA programmes for HIV and syphilis in each of the countries. The questionnaire focused on the following areas related to HIV – policies, proficiency testing programmes, testing algorithms, test result turnaround times, types of samples, use of standardized logbooks, who can perform rapid HIV testing, where rapid testing is offered, HIV testing and counselling (HTC) service settings and tracking of discordance between tests.

All countries reported having current policies in place for the use of rapid HIV tests; they were all using rapid HIV tests and had the capacity to provide proficiency programmes for rapid HIV tests. All countries allowed rapid HIV tests to be performed in laboratories by laboratory personnel. However, many countries did not support testing by doctors or lay counsellors, or testing outside the laboratory or community health-care facility sites.

Most countries use serum or plasma as the sample source, with some using whole blood (sometimes finger-prick). None of the countries advocated the testing of oral fluid specimens. CDC encourages the use of finger-prick blood testing, investigation of oral fluid specimens and use of dried tube specimens (DTS) for EQA. The percentage of testing sites participating in proficiency testing varied from 15% to 100%. CDC recommends that all countries should aim for 100% participation and this is particularly important for monitoring all HIV testing sites, especially new facilities or existing facilities that are just starting to offer rapid testing. It has been universally observed that quality improves at sites that participate in proficiency testing programmes. Only three countries reported tracking discordance rates between tests used in their algorithms (2–3% discordance seen). It is recommended that tracking discordance be implemented to identify issues with testing algorithms and poor-quality testing.

All countries should:

- have HIV point-of-care testing at a wider range of site types (with testing by more health-care professionals);
- investigate the use of cheaper, safer and more convenient samples types (finger-prick, oral fluid);
- expand proficiency testing to all sites involved in HIV point-of-care testing;
- have mechanisms for corrective action at sites that fail proficiency testing;
- use standardized registers as a tool to monitor QA (track discordance rates); and
- use DTS to reduce the cost of proficiency testing programmes.

### 2.2.4 Quality assurance in Cambodia

Cambodia is moving towards HIV epidemic control, with the number of new infections dropping dramatically. For progress in this area, QA is important.

Laboratory support for pre- and post-ART testing is in place, including haematology, biochemistry, CD4 count, viral load, emerging infectious diseases and drug resistance genotyping at multiple laboratory sites.

The current challenges are the fact that there are no QA programmes for HTC and community-based testing sites. There is no follow up on discordant results between HTC and voluntary confidential counselling and testing (VCCT) sites, and there are insufficient rounds of proficiency testing for VCCT sites. There is too long a turnaround time between EQA events and feedback and corrective action reports, and there are constant stock-outs of reagents.

Going forward, Cambodia wishes:

- to develop a QA programme for HTC and community-level sites;
- to improve the QA programme at VCCT sites by performing regular site visits;
- to undertake corrective actions and provide training to VCCT sites reporting inaccurate proficiency testing results;
- to follow up on discrepant results between HTC and VCCT sites;
• to increase the number of proficiency testing rounds to VCCT sites and include HTC facilities;
• to decrease the time taken to release proficiency testing reports to participating facilities, by implementing an e-proficiency testing programme;
• to improve inventory and procurement systems at facility level to reduce stock-outs; and
• to improve the system for procurement of reagents so that expiration dates are longer and distribution is better.

2.3 Session 3: Achieving uptake and coverage through community based approaches

2.3.1 WHO recommended community based testing approaches and best models

Community-based testing approaches have been recommended by WHO and include multiple service delivery approaches (Fig. 1). These, the WHO guidelines available and the test for the triage approach were discussed. To achieve the ambitious treatment target set out in the 90–90–90 targets, there is a need to adopt new testing approaches. Currently, only 51% of individuals infected with HIV in the Region are aware of their status and this needs to be increased to 90% by 2020. More comprehensive data need to be collected on the number of tests conducted (denominator), in addition to more accurate data on the number of reactive results obtained.

The coverage and uptake of HIV testing services (HTS) is low among men, adolescents, women who are not pregnant and other key populations. In many countries, there is a lack of infrastructure to scale up access to HTS and there are often policy restrictions on lay testers, the use of RDTs and the need for western blot confirmation. Community-based HTS have been found to be highly acceptable to clients, resulting in earlier diagnosis and increased linkage to care, as well as being able to reach often overlooked populations.

Test for triage is a strategy to support the expansion of community-based testing. A single RDT is conducted in the community as a single test (A0), but does not replace the first screening test (A1) that is required in the national testing algorithm. The full national testing algorithm, which includes test A1, should be conducted if A0 is positive. Some potential challenges with this approach include the fact that there will be a high rate of false-positive results in low-prevalence settings, and it will be necessary to ensure that clients understand the meaning of their test results. HIV self-testing (HIVST) offers a huge potential for scale up and is being tried in many countries. It is highly acceptable to clients and the sensitivity is ≥91.7% and specificity ≥97.9%. The difficulty will be to ensure linkage to care and put regulations in place to ensure the quality and reliability of testing.

Fig. 1: Service delivery approaches to HIV testing

HTS: HIV testing services; PITC: provider-initiated counselling and testing; STI: sexually transmitted infection; TB: tuberculosis; VCT: voluntary counselling and testing
The critical issues for HTS, especially for community-based testing, are given below:

- Need to make strategic choices:
  - making difficult choices about the mix of testing approaches, for better cost–effectiveness, earlier diagnosis, and linkage to and impact on care, including ANC testing in different epidemic settings;
  - reinforcing appropriate testing in specific clinical settings;
  - increasing access by supporting community testing;
  - prioritizing index partner and family testing.

- New approaches:
  - testing provided by trained lay providers (new WHO recommendation);
  - testing for triage (new testing strategy);
  - HIVST (push for implementation and monitoring).

- Preventing misdiagnosis:
  - focusing on QA;
  - re-emphasizing re-testing for all positive persons before ART initiation.

Two examples of how these testing strategies have been successfully introduced were highlighted by participants from Myanmar and Cambodia.

### 2.3.2 Community based testing in the Western Pacific Region: example from Cambodia

The presentation provided an overview of community-based testing in Cambodia, including its coverage and outcomes. Key populations are targeted (transgender persons, sex workers, men who have sex with men [MSM] and ANC attendees) using branded programmes that market condoms and lubricants through to integrated family planning. KHANA (Khmer HIV/AIDS NGO Alliance), a nongovernmental organization (NGO), has fully trained lay counsellors who carry out a risk assessment, conduct finger-prick rapid HIV testing and confirm reactive results for inclusion of clients in treatment and care.

Up to May 2015, 52.2% of most-at-risk populations were tested by finger-prick and 0.7% were HIV reactive, 99% were on treatment (37% pre-ART and 38% on ART). A total of 28% of individuals were lost to follow up, 0.5% died and of those diagnosed with HIV, 57% had a CD4 count of <500 cells/mm3 and 43% had a count of ≥500 cells/mm3. Figure 2 illustrates their care cascade.
Fig. 2: HIV care cascade (KHANA, Cambodia)

**ART:** antiretroviral therapy; **VL:** viral load

The QA and QI tools that are in place include the following:

- **Counselling checklist:** to improve the quality of counselling during training and field implementation. Counsellors are assessed on how well they explain the benefits of HTC, the quality of health information, emotional support, etc.
- **Processing checklist:** to improve the quality of the practical aspects of finger-prick testing. Counsellors are assessed on whether all materials (buffer, test kits, needles, etc.) are prepared during outreach, and how well they follow the protocol for storage of test kits and for drawing blood, etc.
- **Temperature monitoring sheet:** to ensure that test kits are stored in good conditions (2–30 °C).

The primary challenges include poor infrastructure, limited QA, lack of control over test kit procurement, high staff turnover, and the fact that mainly low-risk populations are tested and not those at high risk. Cambodia intends to recruit more lay counsellors and target pilot programmes to more high-risk populations.

### 2.3.3 Issues around HIV self-testing: examples from China and how to set up quality assurance systems

Expanding HIV testing is a priority in China, as 70% of those with HIV do not know their status and MSM comprise one third of China’s new HIV cases. Decentralized HIV testing outside government settings has become increasingly common with community-based organizations (CBOs) accounting for over half of all newly identified HIV cases in China. China has a large MSM population (2–8 million) with a high HIV prevalence (6–7%), and 85% of MSM engage in sexual activity with multiple homosexual partners, and only 43% consistently used condoms.

Homosexuality remains a sensitive issue in Chinese culture (many MSM conceal their orientation, with less than one third disclosing their orientation to their parents). The average marriage rate among MSM is 17%, which is much higher than other countries belonging to the Organisation for Economic Co-operation and Development (OECD). MSM in China tend to get married to cover their...
homosexual orientation, or opt to adapt a bisexual lifestyle and exhibit a heterosexual identity publicly. The main barriers for MSM to get tested include a lack of perception of HV risk, fear of a positive result that could result in discrimination, and staff inadequately trained to engage and retain MSM in care.

HIVST is feasible, acceptable and growing, with a current rate of 20%, but faces many concerns about accuracy, and many clients prefer supervised testing (performing the test was not as much of a concern for clients as reading the results). Self-testing kits are available but the information provided with the test kits is very general, with no confirmatory testing guidelines discussed, and no or poor counselling and referral to care and treatment opportunities. All HIVST kits were sold by private companies or individual sellers, at an average price of US$ 39 (between US$ 19 and 46), and all Chinese HIVST brands sold were approved by the State Food and Drug Administration and Chinese CDC, but there is poor market control because they are not part of the Chinese national HIV testing guidelines/algorithm.

Pilot studies of self-testing showed a 6% positivity rate in Guangzhou compared with a 15% rate in Beijing. This appears to be a promising approach, and it is recommended that collaboration between agencies be encouraged and key steps taken to increase QA for the self-testing approach.

2.4 Session 4: HIV & other point-of–care testing quality management systems: Global perspective

2.4.1 Expanding HIV and syphilis testing, linkages to care and treatment. WHO HIV testing guidelines

Moving towards the 90–90–90 targets for 2020 was the subject of this presentation. The first “90” is the most challenging – how to get people living with HIV to come for testing and then to initiate ART to achieve the second and third “90” targets.

The key issues covered in the new consolidated guidelines on HTS include:

- recommending and supporting HTS by trained lay persons
- provision of guidelines on how to certify testers and do QA to ensure correct results, possibilities for new ways of QA by volunteers on site
- the human rights issue of quality of HIV testing
- the 5 Cs principles: consent, confidentiality, counselling, correct results and connection
- how to implement the above.

There has been a significant increase and improvement in HTS globally. The success of prevention of mother-to-child transmission (PMTCT) programmes has resulted in high testing rates among ANC attendees, but the prevalence of HIV among women is often low. The problem is among men, especially in high-prevalence countries, where HIV infection rates are higher in men than women. There are four highlights from the new guidelines:

- 1: HTS by trained lay providers for programme expansion
  - Evidence showed increasing uptake and the quality was not different from testing by healthcare providers if lay providers were well trained and provided with good QA programmes.
  - Some countries may require national policies to support testing.
- 2: Improving quality; reducing misdiagnosis
  - More than 50% of countries did not follow current WHO HIV testing strategies.
  - Retesting should be done to avoid misdiagnosis.
  - Retesting of inconclusive cases should be done after 14 days to verify HIV status, especially before starting ART to minimize HIV misdiagnosis.
- 3: Universal versus targeted HTS approaches
  - Universal HTS for ANC attendees is cost–effective in low- as well as high-prevalence settings.
  - If resources are limited, a targeted approach could be adopted as an interim measure.
- 4: HIV self-testing
Not enough information is available as yet, so it is not yet recommended.
HIVST has been implemented in some countries and some studies are ongoing.

- HIVST cannot provide a final diagnosis and cannot be included in the national algorithm, but may be important in the future.

**2.4.2 Update on comprehensive approach to improve the quality of HIV testing: PEPFAR perspective**

This presentation advised on how to improve the first “90” with confidence to support the 90–90–90 targets. It includes key pillars of a comprehensive QI programme because proficiency testing alone is not enough.

Policy engagement is important to ensure sustainability of testing quality and proficiency, and guidelines and strategic action plans for improving HIV testing quality are needed. Strengthening human resources for uptake needs a national competency/certification programme for testers, not only for non-laboratory but also for laboratory technicians/officers to ensure quality services. A strategy is also needed on how to implement training effectively.

Proficiency testing should be conducted to assess laboratory performance in test methods and compare data with other laboratories in the same programme. The assessment should also review the best use of available resources to fill in human resource gaps and ensure completeness of the QA cycle, which would result in timely reporting, follow up and corrective actions. A standard register is needed for ongoing monitoring, including enough information for traceability – such as kit names, lots, results, discordance; and information to address the problems, if any.

The site QMS includes tools for site assessment; a step-wise certification process similar to a laboratory accreditation programme; a simple checklist that is easy to follow.

Monitoring the quality of RDTs includes the prequalification process, monitoring the quality of test kits, using the right test kits, issue of inventory, stock-in and stock-out.

The site QMS can be applied to any point-of-care testing, not only HIV. An additional test is the oral fluid test; this requires training, an appropriate swab technique, standard operating procedure (SOP), quality, and systems for additional/confirmatory testing when reactive.

Continuous QI requires Ministry of Health engagement and resource allocation for sustainability. There is a need for countries to develop and implement a policy for the quality of HIV testing and other RDTs. Improving the accuracy of testing relies on the implementation of a comprehensive approach based on innovation, is data driven and involves local partners for maximum impact.

During the ensuing discussion, it was stated that 2.6–10.3% of diagnoses are incorrect. The majority of these errors are due to poor management, incorrect testing, user error or clerical/technical errors, and only a small proportion are due to test kit cross-reactivity with other analytes.

**2.5 Session 5: Policies and plans to support quality rapid diagnostic testing**

**2.5.1 Introduction to “Handbook for Improving the Quality of HIV-related Point-of-Care Testing”**

The recently released WHO *Handbook for improving the quality of HIV-related point-of-care testing* was introduced. A continuous cycle of QA is outlined in Fig. 3.

Assuring the quality of HIV testing means also assuring the quality of every step of the process and all procedures. The *Handbook* is intended for all audiences involved in policy development, planning, implementation and actually carrying out HIV rapid testing.
The cycle of implementing QA involves the following three phases, with specific activities for each phase.

**Fig. 3: Continuous cycle of quality assurance**

1. **Planning phase**
   - Engage the leadership.
   - Establish the team for QA coordination.
   - Define roles and responsibilities.
   - Define standards.
   - Conduct situational analysis.
   - Select and assess sites.
   - Develop an implementation plan.
   - Develop policies.
   - Plan human and financial resources.

2. **Implementation phase**
   - Develop and implement training and certification of testing staff.
   - Conduct site supervision and drive accreditation.
   - Implement process control (QC).
   - Generate QA-related documentation.
   - Strengthen logistics for QA.

3. **Sustenance phase**
   - Plan and allocate resources.
   - Increase national ownership.
   - Mobilize communities.
   - Implement sustainability-focused monitoring and evaluation.
   - Improve advocacy.

Tools, checklists, SOPs, job aids and other information can be found in the Handbook appendices. A step-wise process for improving the quality of HIV-related point-of-care testing is also given. Tools for rating testing sites for QA activities range from not recognized to level 1, level 2 and level 3. There is also a QA model for human resources.
2.6 Session 6: Systems to support quality point-of-care testing and interface with the HIV elimination programme

2.6.1 Diagnostic considerations for HIV and syphilis surveillance and public health interventions

HIV surveillance calls for collaboration between laboratories, clinicians, the Ministry of Health and the public. The three key elements of surveillance are:

- evaluation
- planning
- advocacy.

Surveillance data can be used to evaluate programmes, plan for outbreaks and expand testing, needle exchange programmes, etc. Surveillance can support the test-and-treat cascade by identifying people living with HIV, undiagnosed infections and the incidence of infection.

Self-testing can help increase surveillance efforts by expanding access; however, some false-negative results will occur, particularly with oral fluid testing, and not all people with reactive results will be linked to care. Making data available to the national HIV programme is becoming increasingly important and there are challenges with obtaining accurate data on the number of tests performed and the number of reactive results when self-testing is implemented.

New testing options using RDTs should be considered to support surveillance, such as case reporting, and there are opportunities to use VCCT data for surveillance by collecting both positive and negative tests.

2.6.2 Overview of a quality assurance cycle for external quality assessment programmes

The differences between QA, EQA and QC were highlighted in this presentation. QA covers the entire process, from a patient entering the clinic until they are provided with a test result by a clinician, while EQA ensures only the quality of testing at a particular facility (i.e. from receipt of a sample until a result is released), and QC ensures only that a particular assay is performing to specification. The importance of lot release when using RDTs was also emphasized due to the significant variation seen from batch to batch with rapid tests. The QMS was also covered, including documents, training, equipment maintenance, stock inventory, secure data systems, logistics, safety, compliance with regulations and participation in proficiency programmes.

2.7 Session 7: Strengthening capacity for reliable and accurate point-of-care testing

2.7.1 Training, certification, supervision of testers and standardization of scripts for reporting results to clients

Several measures need to be put in place prior to implementing point-of-care rapid testing for HIV/syphilis. The implementation of a pilot study for the WHO Treatment 2.0 programme in Viet Nam was used as an example. This was an extremely successful pilot due to the incredible enthusiasm of the Vietnamese participants, and is currently being rolled out to cover further districts.

One cannot just decide to implement rapid testing in a community health-care setting by providing test kits and training. One first needs to ensure that there is support from the Ministry of Health and donors, and set up a cascade of roles and responsibilities from the top down. Prior to even selecting point-of-care testing sites, one needs to ensure that a fully validated testing algorithm is in place, and that the supply of test kits to the screening and confirmatory testing sites can be guaranteed. There needs to be training material in the form of presentations that include everything – from an overview of HIV, safety, performing the tests and sending samples for confirmatory testing, obtaining samples and participating in the EQAS provided to all reference, provincial and district laboratories, as well as point-of-care testing sites. Hard copies or electronic copies of all SOPs and forms need to be provided to the relevant sites, and should include everything from counselling, sample collection, testing, data referral, training checklists, work aids in the form of flow charts, audit/test site visit forms, inventory control forms. A process needs to be put in place to monitor the performance of point-of-care testing
sites for an initial period, during which all reactive and a percentage on non-reactive samples are retested by the supervising laboratory.

Once all the implementation procedures, paperwork and training have been put in place, one can then audit potential point-of-care testing sites and assess their suitability and requirements for testing. After providing all the essential requirements and training, the point-of-care testing sites should also receive training on trouble-shooting from both a technical and clinical perspective.

2.8 Session 8: Monitoring the quality of test kits and ensuring continuous supplies
Session 8 covered issues related to logistics to ensure continuous supplies and monitoring of the quality of test kits.

2.8.1 Approval and management of test kits – WHO prequalification process and applications in the assessment pipelines, and post-market surveillance
The speaker gave an overview of the WHO prequalification process, applications in the pipeline and the requirement for QA systems. There is a lack of regulatory control for in vitro diagnostics (IVDs), both pre-market assessment and post-market surveillance. The stringency of regulatory assessment depends on the risk related to their use, and procurement policies of global health agencies act as a de facto regulatory control. Global efforts have been made to harmonize regulations for IVDs to facilitate market entry with common sets of requirements.

The role of WHO is to issue normative guidance on when and how to use IVDs for clinical decision-making (i.e. Consolidated guidelines on HIV testing services launched at the International AIDS Society meeting in July 2015), to prequalify IVDs (i.e. assess quality, safety, performance), which is undertaken by the WHO Prequalification Team, and to increase in-country capacity to effectively regulate and monitor the quality of IVDs in their market.

WHO prequalifies IVDs for HIV, hepatitis C, hepatitis B, HIV/TB, malaria and human papillomavirus (HPV). This is based on an assessment of a manufacturer’s dossier that must demonstrate that the IVD conforms to the essential principles of safety and performance of medical devices. The new procedure implements staged inspections to ensure that the manufacturer conforms to ISO 13485:2002 requirements and includes the following:

- Stage 1 inspection (may be desktop or one day on-site)
- Stage 2 inspection (initial on-site inspection)
- Follow up (to review if corrective action plan has been implemented)
- Re-inspection (of pre-qualified products) – maximum 2 action plans (to address nonconformities) for review.

Laboratory evaluation is conducted jointly with CDC. After prequalification, the following steps are taken:

- Post-market surveillance, which is a WHO post-qualification activity, and includes reactive and proactive measures, through complaint reporting and pre-distribution/post-distribution lot verification testing.
- Post-qualification also includes mandatory manufacturer notification to WHO of changes to the product or the QMS.

2.8.2 Testing strategies and algorithms for HIV and syphilis; and validating testing algorithms

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Disease prevalence and test kit performance has an impact on the accuracy of the results delivered to patients. The different technologies available in rapid test formats were outlined and the characteristics determining test performance were discussed. The need for a highly sensitive screening assay (>99%, according to WHO recommendation) and highly specific confirmatory assays (>95%, according to WHO recommendation) was outlined.

The effect of disease prevalence on the positive and negative predictive values of test kits results was discussed. By using assays in the correct combination, these positive predictive values could be greatly improved. It was suggested that validating testing algorithms relies on the amount of information that countries have on certain test kits and the use of these test kits in combination in their particular region. Some countries will have data on local test kit evaluation, while other countries may need to rely on WHO prequalification data or data from the United States Agency for International Development (USAID). Peer-reviewed published results are also available on many of the test kits and their performance in different combinations and in different settings. If there is very little information on a test kit, it may be necessary to perform a full evaluation requiring thousands of samples, whereas if there is a significant amount of information about a test kit and its performance in conjunction with other test kits (particularly in the region of interest), minor validation alone, constituting several hundred samples, may be adequate.

Any new testing algorithm implemented in any region will require stringent monitoring for an initial period of time, and this will include retesting of all reactive samples and a proportion of negative samples. In general, validating algorithms requires access to adequate data, examining data for good test combinations, conducting pre-implementation testing as necessary, validation in the field and monitoring.

2.8.3 Other HIV point-of-care testing for early infant diagnosis, CD4, viral load and oral fluid: what are the requirements for quality assurance systems?

The WHO/CDC Syphilis Serology Proficiency Programme provides services to improve the regional capacity and quality of syphilis serological testing worldwide, particularly in low- and middle-income countries. This is done to ensure accurate and high-quality testing for quality service provision, accurate surveillance, and verification of elimination of MTCT of syphilis.

Five DTS are shipped to participants three times a year and they are then provided with a confidential graded report and a certificate of participation.

2.8.4 Robust Data Management Systems

Managing data is of crucial importance for improving the accuracy of HIV testing. There is an increasing need for robust data management systems, preferably electronic systems, given the difficulty in managing data using paper-based logbooks. Three e-tools have been developed for improving the quality of testing.

Tool 1 – Logbook data analysis tool

This tool allows the user to use the standardized register data for ongoing monitoring. It has simplified data entry and the data can be used to look at the agreement rate between different HIV tests and compare their performance. It can also be used for mapping test site performance and analysing variables such as invalid test results or test kit consumption.

Tool 2 – Data management for proficiency testing

This tool includes SOPs for proficiency testing. It allows for online reporting of results, analysing reported data, and generating reports for the performance of proficiency testing.

Tool 3 – e-tool for site assessment

This can be used as a site assessment tool for step-wise certification. The data from laboratory audits are captured and can then be analysed and used to provide feedback in the form of maps or graphs.
summarizing information, such as the distribution of sites at different levels or the performance distribution by site type, etc.

In summary, the e-tools can be used for completing the quality cycle by using data to monitor the performance and quality of HIV testing, allowing corrective actions without any delay, and then tracking the outcome of the corrective actions.

**Summary report of the meeting and draft recommendations**

The key issues that were covered during the three days were summarized and presented, along with the draft recommendations. These were discussed and refined with inputs from the group members.

The conclusions and recommendations of the meeting were compiled into the Phnom Penh statement to improve the quality of HIV-related testing in the Asia Pacific (Annex 3).

**Group breakout: Country-specific implementation plans**

Members from each country along with the facilitators drafted an implementation plan to strengthen QA for HIV point-of-care testing according to their national context, needs and priorities, based on a template that was provided to the countries (Annex 4). The implementation plan included milestones and organizational responsibilities, and any technical assistance required.

2.9 Closing session

Representatives from CDC Cambodia and NCHADS made closing remarks.

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**3. CONCLUSIONS AND RECOMMENDATIONS**

3.1 Conclusions

The conclusions from the workshop are summarized in “The Phnom Penh statement on improving the quality of HIV-related diagnostics in the Asia Pacific” (Annex 3).

3.2 Recommendations

3.2.1 Recommendations for Member States

**Recommendations for policy-makers**

To ensure reliable and accurate HIV-related point-of-care testing results for better patient care and management:

1) Strengthen QA for HIV-related point-of-care testing, including syphilis, within WHO Member States in the South-East Asia and Western Pacific Regions.
2) Adapt the WHO *Handbook for improving the quality of HIV-related point-of-care testing* to strengthen QA at the country level.
3) Develop/update policies, guidelines and plans for quality HIV-related point-of-care testing, including validation of testing algorithms.
4) Strengthen sustainable logistics for quality HIV-related point-of-care testing.
5) Ensure adequate government resources towards sustainable quality HIV-related point-of-care-testing.
6) Establish QA guidelines for HIV-related testing at the point of care;
7) Institutionalize capacity development for quality HIV-related point-of-care testing.

**Technical recommendations**

To enable the implementation of the QAC approach in countries:

1) Ensure that a QA programme for HIV-related point-of-care testing is implemented at all testing sites, including for community-based testing.
2) Use innovative approaches to improve data collection, analysis and information management of HIV-related point-of-care testing for timely corrective and preventive action.
3) Implement practical, continuous QI approaches to achieve laboratory or site certification/accreditation in a step-wise manner.

3.2.2 Recommendations for WHO

WHO support was requested for the following:

1) provision of technical assistance and support; and
2) facilitating communication and support from the Ministry of Health and key stakeholders through an online group for information exchange, and providing peer support to countries needing it.
### Day 1 (Tuesday) 28 July 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
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<tr>
<td>8:00 am</td>
<td>Registration</td>
<td>WHO/CADU</td>
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<tr>
<td></td>
<td><strong>Session 1: Opening Ceremony</strong></td>
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<tr>
<td>8:30 am</td>
<td>Welcome of participants Group photo</td>
<td>WHO representative, UHS representative MoH representative</td>
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<tr>
<td>9:15 am</td>
<td>Objectives of meeting and expected outcomes Introduction of participants</td>
<td>Naoko Ishikawa, WHO Western Pacific Region</td>
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<tr>
<td>9:30 am</td>
<td><strong>Morning tea break</strong></td>
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<tr>
<td></td>
<td><strong>Session 2: Overview of HIV and syphilis point-of-care testing, quality management systems and challenges in Asia and the Pacific</strong></td>
<td>Moderator: Naoko Ishikawa Rapporteur: Kevin Soli</td>
</tr>
<tr>
<td>10:00 am</td>
<td>Overview of HIV and syphilis point-of-care testing and availability of tests on the market and future tests</td>
<td>Lori Newman and Rosanna Peeling, WHO headquarters</td>
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<tr>
<td>10:15 am</td>
<td>Key findings of the gap analysis on laboratory services in the Western Pacific</td>
<td>Kim Wilson, NRL Australia</td>
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<tr>
<td>10:30 am</td>
<td>Current status on quality of assurance of point-of-care diagnostic tests</td>
<td>Kyle Bond, CDC HQ</td>
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<tr>
<td>10:45 am</td>
<td>Quality assurance in Cambodia</td>
<td>Mom Chandara, NCHADS</td>
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<td>11:00 am</td>
<td>Q&amp;A</td>
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<td><strong>Session 3: Achieving uptake and coverage through community-based approaches</strong></td>
<td>Moderator: Linh-Vi Le Rapporteur: Thomas Rush</td>
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<tr>
<td>11:10 am</td>
<td>WHO-recommended community-based testing approaches and best models</td>
<td>Anuj Sharma, WHO South-East Asia Region</td>
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<tr>
<td>11:25 am</td>
<td>Community-based testing in the Western Pacific Region: example from Cambodia</td>
<td>Ny Socheat, KHANA Cambodia</td>
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<td>11:40 am</td>
<td>Issues around HIV self-testing: examples from China and how to set up quality assurance systems</td>
<td>Andrea Shahum, UNC USA</td>
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<td>12:00 am</td>
<td>Q&amp;A</td>
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<td>12:15 pm</td>
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<tr>
<td></td>
<td><strong>Session 4: HIV and other point-of-care testing quality management systems: global perspective</strong></td>
<td>Moderator: John Nkengasong, Rapporteur: Chonticha Kittinunvora</td>
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<tr>
<td>1:30 pm</td>
<td>Expanding HIV and syphilis testing, linkages to care and treatment. WHO HIV testing guidelines</td>
<td>Naoko Ishikawa, WHO Western Pacific Region</td>
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<tr>
<td>1:50 pm</td>
<td>Update on comprehensive approach to improve the quality of HIV testing: PEPFAR perspective</td>
<td>Mireille Kalou, CDC HQ</td>
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<td>Group breakout</td>
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<td>4:00 pm</td>
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**Day 2 (Wednesday) 29 July 2015**

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<tr>
<td>8:00 pm</td>
<td>Introduction to <em>Handbook for improving the quality of HIV-related point-of-care testing</em></td>
<td>Mercedes Perez Gonzales, WHO HQ</td>
</tr>
<tr>
<td>8:30 am</td>
<td>Diagnostic considerations for HIV and syphilis surveillance and public health interventions</td>
<td>Rebecca Guy, Kirby Institute Australia</td>
</tr>
<tr>
<td>8:45 am</td>
<td>Overview of a quality assurance cycle for an external quality assessment (EQA) programme and standardization of scripts for reporting results to clients</td>
<td>Kim Wilson, NRL Australia</td>
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<tr>
<td>9:00 am</td>
<td>Q&amp;A</td>
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<td>10:00 am</td>
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<td>Summary report of breakout session</td>
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**Session 7. Strengthening capacity for reliable and accurate point-of-care testing results**

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<tbody>
<tr>
<td>1:30 pm</td>
<td>Training, certification, supervision of testers</td>
<td>Kim Wilson, NRL Australia</td>
</tr>
<tr>
<td>1:45 pm</td>
<td>Step-wise process for improving the quality of testing sites</td>
<td>Mireille Kalou, CDC HQ</td>
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<tr>
<td>2:00 pm</td>
<td>Group breakout</td>
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**Breakout groups**

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<th>Group</th>
<th>Country/Region</th>
<th>Facilitators &amp; note takers</th>
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<tbody>
<tr>
<td>1</td>
<td>Lao People’s Democratic Republic, Nepal</td>
<td>Kyle Bond, Anuj Sharma</td>
</tr>
<tr>
<td>2</td>
<td>Indonesia, Papua New Guinea, Cambodia</td>
<td>Artur Ramos, Kevin Soli</td>
</tr>
<tr>
<td>3</td>
<td>Mongolia, Viet Nam, Fiji</td>
<td>Van Nguyen, Thomas Rush, Kim Wilson</td>
</tr>
<tr>
<td>4</td>
<td>India, Philippines, Thailand</td>
<td>Chonchita Kittinunvorakoon, Naina Rani, Mukta Sharma</td>
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### Day 3 – (Thursday) 30 July 2015

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<tr>
<td><strong>8:30 am</strong></td>
<td>Approval and management of test kits – WHO prequalification process and applications in the assessment pipeline; post-market surveillance</td>
<td>Mercedes Perez Gonzales, WHO HQ</td>
</tr>
<tr>
<td><strong>8:50 am</strong></td>
<td>Testing strategies and algorithms for HIV and syphilis &amp; validating testing algorithms</td>
<td>Kim Wilson, NRL Australia</td>
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<tr>
<td><strong>9:10 am</strong></td>
<td>Syphilis</td>
<td>Lori Newman</td>
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<tr>
<td><strong>9:30 am</strong></td>
<td>Managing data for improving the accuracy of HIV testing</td>
<td>Amitabh Adhikari, CDC HQ</td>
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<tr>
<td><strong>9:50 am</strong></td>
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<td>Group breakout</td>
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<tr>
<td><strong>1:45 pm</strong></td>
<td>Summary and recommendations</td>
<td>Anuj Sharma, WHO</td>
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<tr>
<td><strong>2:30 pm</strong></td>
<td>Group breakout* – country-specific implementation plans</td>
<td>Countries</td>
</tr>
<tr>
<td><strong>3:30 pm</strong></td>
<td>Feedback of country plans</td>
<td>Countries</td>
</tr>
<tr>
<td><strong>4:30 pm</strong></td>
<td>Workshop summary and closing remarks</td>
<td>NCHADS representative, CDC representative</td>
</tr>
<tr>
<td><strong>5:00 pm</strong></td>
<td><em>End of Day 3</em></td>
<td></td>
</tr>
</tbody>
</table>

*Day 3: Group breakout (country-specific implementation plans)*

<table>
<thead>
<tr>
<th>Country</th>
<th>Group facilitators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>Artur Ramos</td>
</tr>
<tr>
<td>Fiji</td>
<td>Mercedes Perez Gonzales</td>
</tr>
<tr>
<td>India</td>
<td>Naina Rani</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Rosanna Peeling</td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td>Kyle Bond</td>
</tr>
<tr>
<td>Mongolia</td>
<td>Kim Wilson</td>
</tr>
<tr>
<td>Nepal</td>
<td>Mirelle Kalou</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>Kevin Soli</td>
</tr>
<tr>
<td>The Philippines</td>
<td>Naina Rani</td>
</tr>
<tr>
<td>Thailand</td>
<td>Naina Rani</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Van Nguyen, Thomas Rush</td>
</tr>
<tr>
<td>Time</td>
<td>Topic</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>8:00–8:30</td>
<td>Registration</td>
</tr>
<tr>
<td>8:30–8:45</td>
<td>Objectives of the meeting: part 2</td>
</tr>
<tr>
<td>8:45–9:10</td>
<td>The challenge of the elimination of the vertical transmission of syphilis and HIV in Asia and the Pacific</td>
</tr>
<tr>
<td>9:10–9:40</td>
<td>Overview on availability of dual rapid tests and validation of dual RDT</td>
</tr>
<tr>
<td>9:40–10:00</td>
<td>Feasibility of using dual HIV and syphilis rapid tests</td>
</tr>
<tr>
<td>10:00–10:30</td>
<td>Tea break</td>
</tr>
<tr>
<td>10:30–11:00</td>
<td>Testing algorithms for dual HIV and syphilis rapid tests</td>
</tr>
<tr>
<td>11:00–11:30</td>
<td>Review of test products (ongoing field evaluations)</td>
</tr>
<tr>
<td>11:30–12:00</td>
<td>Steps required in the planning, implementation and monitoring of elimination programmes</td>
</tr>
<tr>
<td>13:30–14:00</td>
<td>How to train to implement the dual rapid HIV/syphilis test:</td>
</tr>
<tr>
<td></td>
<td>-Procedure and interpretation</td>
</tr>
<tr>
<td></td>
<td>-Demonstration</td>
</tr>
<tr>
<td>14:00–14:30</td>
<td>Other aspects referred to elimination of congenital syphilis:</td>
</tr>
<tr>
<td></td>
<td>treatment of maternal syphilis and resistance to penicillin</td>
</tr>
<tr>
<td>14:30–15:30</td>
<td>Group discussion: benefits, opportunities, and challenges for the introduction of dual tests, algorithms, cost, quality and next steps</td>
</tr>
<tr>
<td>15:30–15:50</td>
<td>Tea break</td>
</tr>
<tr>
<td>15:50–16:20</td>
<td>Feedback of group discussions</td>
</tr>
<tr>
<td>16:20–16:40</td>
<td>Unresolved issues and next steps CLOSING</td>
</tr>
</tbody>
</table>
Annex 2. List of participants

1. PARTICIPANTS

CAMBODIA

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US CDC/ VIET NAM

Thomas Rush, Lab Advisor, US CDC, Vietnam, ijn5@cdc.gov
Annex 3. The Phnom Penh statement on improving quality of HIV-related diagnostics in Asia Pacific

We, participants of the Asia Pacific Workshop on Improving the Quality of HIV and Syphilis Point-of-Care Testing (28–30 July 2015, Phnom Penh), namely national managers for HIV and sexually transmitted infections (STI) programme, maternal and child health (MCH) programme, and laboratory programme from Member States of the World Health Organisation (WHO) South-East Asia and Western Pacific Regions, U.S. Centers for Disease Control and Prevention, technical partner organizations and WHO:

Recognize that the South-East Asia and Western Pacific Regions have endorsed the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 treatment targets to lay the groundwork to end the AIDS epidemic by 2030;

Recognize the 1996 UNAIDS declaration of quality of HIV testing as a human right;

Note significant gaps in quality of HIV-related diagnostics in the South-East Asia and Western Pacific Regions despite significant progress made thus far to increase access to quality HIV testing;

Acknowledge the need for reliable and accurate test results for HIV-related conditions to ensure no positive cases are missed nor HIV negative cases falsely classified, and for retesting of all patients with HIV positive results to be absolutely certain of their status before initiating treatment;

Acknowledge that the recently published WHO Consolidated Guidelines on HIV Testing Services and forthcoming Handbook for Improving the Quality of HIV-Related Point-of-Care Testing will help to address the gaps;

Resolve to adapt recommendations from the above-mentioned guidelines in Member States of the South-East Asia and Western Pacific Regions;

Resolve to create a national coordination team (or technical working group) on access and quality of HIV-related point-of-care testing to facilitate the implementation of these guidelines and mechanisms to collect and analyse performance towards achieving the 90-90-90 treatment targets;

Member States to:
1. acknowledge that access to high quality HIV-related testing is a human right for all residents in the South-East Asia and the Western Pacific Regions;

2. adapt the WHO Handbook for Improving the Quality of HIV-related Point-of-Care Testing to strengthen quality assurance at the country level;

3. develop or update policies, guidelines and plans for quality HIV-related point-of-care testing including validation of testing algorithms;

4. strengthen logistics around the provision of quality HIV-related point-of-care testing;

5. ensure adequate government resources towards sustainable quality HIV-related point-of-care testing;

6. establish quality assurance guidelines for HIV-related testing at point-of-care;

7. institutionalize capacity development for quality HIV-related point-of-care testing;
8. ensure that quality assurance programme for HIV-related point-of-care testing is implemented at all testing sites, including community based testing;

9. use innovative approaches to improve HIV-related point-of-care testing data collection, analysis and information management for timely corrective and preventive action; and

10. implement practical and continuous quality improvement approaches to achieve laboratory or site certification/accreditation in a step-wise manner.

Phnom Penh, Cambodia | 30 July 2015
Annex 4. Country implementation plans

Cambodia

<table>
<thead>
<tr>
<th>What?</th>
<th>Who?</th>
<th>When?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revise VCCT, HTC SOP based on WHO Handbook QA/QC of point-of-care testing (preliminary discussion)</td>
<td>TWG: NCHADS, US CDC, NIPH</td>
<td>August 2015</td>
</tr>
<tr>
<td>Revise checklist for point-of-care testing</td>
<td>TWG: NCHADS, US CDC, NIPH</td>
<td>September 2015</td>
</tr>
<tr>
<td>Revised training package for supervisors</td>
<td>TWG: NCHADS, US CDC, NIPH</td>
<td>September 2015</td>
</tr>
<tr>
<td>Select and train supervisors</td>
<td>TWG: NCHADS, US CDC, NIPH</td>
<td>October 2015</td>
</tr>
<tr>
<td>Identify facility to generate QC, proficiency testing materials</td>
<td>NCHADS, US CDC, NIPH</td>
<td>November 2015</td>
</tr>
<tr>
<td>Develop schedule for sites visit</td>
<td>TWG: NCHADS, US CDC, NIPH</td>
<td>October 2015</td>
</tr>
<tr>
<td>Site-monitoring visits</td>
<td>NCHADS and partners</td>
<td>Quarterly visit</td>
</tr>
<tr>
<td>Improve feedback mechanism through meetings, phone call, training, supervision</td>
<td>NCHADS and partners</td>
<td>Immediately after visits, or quarterly</td>
</tr>
<tr>
<td>Define facility for performing post-market evaluation</td>
<td>NCHADS and partners</td>
<td>October 2015</td>
</tr>
<tr>
<td>Develop SOP and panels for lot release</td>
<td>NCHADS, NIPH</td>
<td>January 2016</td>
</tr>
<tr>
<td>Ensure that our point-of-care testing facilities are received and implement QC</td>
<td>NCHADS, NIPH</td>
<td>November 2015</td>
</tr>
</tbody>
</table>

Technical assistance and recommendations

- Technical assistance from US CDC Cambodia and HQ
- Electronic checklist
- Electronic management of EQA programme at NIPH
- Development of serum panels for evaluation of test kits

HTC HIV testing and counselling, NCHADS National Center for HIV/AIDS, Dermatology and STD, NIPH National Institute of Public Health, point-of-care testing point-of-care tests/testing, QA quality assurance, QC quality control, SOP standard operating procedure, TA technical assistance, TWG Technical Working Group, US CDC United States Centers for Disease Control and Prevention, VCCT voluntary confidential counselling and testing

Fiji

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsibility</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review and revise current testing policy</td>
<td>Hospital labs and feedback to MOH for approval</td>
<td>1 year</td>
</tr>
<tr>
<td>Seek financial commitment</td>
<td>MOH Funding agencies (SPC)</td>
<td>1–2 years</td>
</tr>
<tr>
<td>Site selection and certification</td>
<td>MOH</td>
<td>6 months</td>
</tr>
<tr>
<td>Reviewing existing QA-related documentation (SOPs, job aids…)</td>
<td>Main hospital</td>
<td>3 months</td>
</tr>
<tr>
<td>POC testing at community level (nursing stations): recruitment of personnel Training</td>
<td>MOH, NRL, national quality manager</td>
<td>Depending on funding 1 year from time funding is secured</td>
</tr>
</tbody>
</table>
Establish a post-market surveillance system | NRL, main hospital labs | 6 months
---|---|---
Establish a monitoring system specifically for point-of-care testing (EQAS, site supervision) | NRL, main hospital labs | Depending on start of community testing
Establish a referral system for linkage to care | Nursing director | Depending on start of community testing

EQAS external quality assurance scheme, MOH Ministry of Health, NRL National Reference Laboratory, point-of-care testing, QA quality assurance, SOP standard operating procedure, the Secretariat of the Pacific Community

**India**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy level – advocacy for point-of-care testing QA for HIV and related infections</td>
<td>MOH (NACO and MH of NHM)</td>
<td>Sep 2015</td>
</tr>
<tr>
<td>Adaptation of the guidelines with country’s context</td>
<td>MOH and stakeholders</td>
<td>Dec 2015</td>
</tr>
<tr>
<td>Planning and budgetary allocation</td>
<td>MOH (NACO and MH of NHM)</td>
<td>Dec 2015</td>
</tr>
<tr>
<td>Capacity building of health-care providers Procurement and logistic and supply chain management</td>
<td>MOH (NACO and MH of NHM)</td>
<td>Apr 2016</td>
</tr>
<tr>
<td>Scale up the implementation plan</td>
<td>MOH (NACO and MH of NHM)</td>
<td>July 2016</td>
</tr>
<tr>
<td>Monitoring and evaluation of the programme</td>
<td>MOH (NACO and MH of NHM)</td>
<td>Oct 2016</td>
</tr>
</tbody>
</table>

**Technical assistance**
- From WHO, CDC and other UN aid agencies for technical and financial assistance
- To sensitize policy-makers for commitment, adequate resource allocation and implementation to strengthen the quality assurance mechanism

**Indonesia**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible institution</th>
<th>Timeline</th>
<th>Need from support</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Updating the policy for EQA &amp; post-market surveillance (PMS)</td>
<td>MOH</td>
<td>Q3–Q4 2015</td>
<td>WHO, CDC, NRL, CHAI</td>
</tr>
<tr>
<td>2. Develop the guidelines for QA &amp; PMS (adaptation of WHO Handbook &amp; SPI checklists)</td>
<td>MOH</td>
<td>Q3 2015</td>
<td>WHO, CDC (online)</td>
</tr>
<tr>
<td>3. Develop EQA &amp; PMS implementation plan: referral labs for HIV, STI, hep B, (C) including M&amp;E plan</td>
<td>MOH &amp; TWG/ experts</td>
<td>Q4 2015</td>
<td>WHO, CDC</td>
</tr>
<tr>
<td>4. Training of trainers for EQA providers (national and 6 regional labs)</td>
<td>MOH</td>
<td>Q2 2016</td>
<td>WHO, CDC and NRL Australia</td>
</tr>
<tr>
<td>5. Phased implementation by labs</td>
<td>MOH</td>
<td>Q3 onwards 2016</td>
<td></td>
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<td>---------------------------------</td>
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<tr>
<td>6. Monitoring/supervision of the implementation</td>
<td>MOH &amp; TWG</td>
<td>Q4 2016</td>
<td>WHO, CDC</td>
</tr>
</tbody>
</table>

**Technical assistance and recommendations**
- Policy updates on quality HIV-related testing and PMS, and to review the national action plan (national consultation workshop, Q1 2016)
- Training national and referral labs (EQA provider)
- Monitoring implementation

EQA external quality assurance, hep hepatitis, M&E monitoring and evaluation, MOH Ministry of Health, NRL National Reference Laboratory, PMS post-market surveillance, QA quality assurance, TWG Technical Working Group, US CDC United States Centers for Disease Control and Prevention

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**The Lao People's Democratic Republic**

1) Implementation of EQA for HIV serology
2) Improvement of quality of HIV testing
3) Evaluation of new HIV testing strategy and algorithm

**Technical assistance and recommendations**

1) WHO
2) US CDC
3) NRL
4) TGF

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**Papua New Guinea**

- **Key stakeholders**
  – National Department of Health
  – HIV Technical Working Group
  – Central Public Health Laboratory (NRL)
  – WHO, CDC–PEPFAR, UNAIDS
- **Establish HIV & syphilis QA technical team**
  – Consult key stakeholders
  – Develop terms of reference
  – Funding | technical assistance
- **Policy/guideline**
  – WHO *Handbook*
  – Quality assurance
  – External quality assurance
  – ISO 15189 | ISO 15190 | accreditation

**Need for technical assistance and recommendations**

- **Technical assistance**
  – Guidance on policy development
  – CDC Global AIDS Program (GAP) Thailand | Viet Nam | Atlanta
  – ISO 15189 Accreditation | SLIPTA | SLMTA
  – Training | QA
• **Recommendations**
  – Network with WHO Regional Offices for South-East Asia and Western Pacific
  – Interactive support from WHO Regional Office for Western Pacific, WHO headquarters & CDC Atlanta
    - Step-wise approach to quality cycle
    - Scale up of lay tester training
    - Community-based testing


**Mongolia**

- MOH-approved kit list needs to be developed.
- We need more staff and implement training at provincial and district levels (due to inadequate staff numbers and high staff turnover).
- We need to implement site audits at the provincial and district levels using the modified WHO checklist. Audits to be conducted by the National Centre for Communicable Diseases (NCCD).
- Expand the coverage of EQA and QC to 50 additional national sites (51 currently enrolled).

**Need for technical assistance and recommendations**

- Additional funding for test kits (currently MOH and Global Fund)
- Training on QA (potentially from NRL Australia)
- Training on pre-market evaluation of test kits
- Training on post-market monitoring of test kit performance
- Technical assistance on how to go about accreditation/certification

EQA external quality assurance, Global Fund Global Fund to Fight AIDS, Tuberculosis and Malaria, MOH Ministry of Health, NRL National Reference Laboratory, QA quality assurance, QC quality control

**Nepal**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible</th>
<th>Timeline</th>
<th>TA needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sensitization of stakeholders and orientation on the WHO <em>Handbook</em></td>
<td>NCASC &amp; NPHL</td>
<td>In the next couple of weeks</td>
<td>None</td>
</tr>
<tr>
<td>2. Adaptation of the WHO <em>Handbook</em></td>
<td>Lab Task Force &amp; Treatment, Care and Support TWG</td>
<td>Next 6 months</td>
<td>WHO country office</td>
</tr>
<tr>
<td>3. Adaptation of WHO standardized checklist for site certification</td>
<td>Lab Task Force &amp; Treatment, Care and Support TWG</td>
<td>Next 6 months</td>
<td>WHO Country Office, FHI 360, Global Fund</td>
</tr>
<tr>
<td>4. Dissemination of country-specific handbook and checklists</td>
<td>NCASC &amp; NPHL</td>
<td>Within a year</td>
<td>WHO Country Office, FHI 360, Global Fund</td>
</tr>
<tr>
<td>5. Introduction of EQAS/proficiency testing programme using dried tube specimens</td>
<td>NPHL</td>
<td>Pilot phase in 3 months and scale up within a year</td>
<td>WHO Country Office, NRL Australia, FHI</td>
</tr>
</tbody>
</table>
The Philippines

1. Advocacy with the government and other stakeholders
   Timeline: August–October 2015
   Responsible: TTI-NRL

2. Identification and resolution of possible barriers to and limitations for implementation, ex. Licensure, RA 8504
   November–December 2015
   Responsible: Stakeholders: DOH, NEC, SACCL-NRL, TTI-NRL, ARG, AIDS Council, LGU, UNAIDS

3. Strengthen the programme by unification and coordination of all stakeholders involved.
   Timeline: March 2016
   Responsible: Department of Health

4. Human resources: capacity building, including community lay providers
   Timeline: March 2016
   Responsible: DOH (TTI-NRL, SACCL-NRL)

5. Implementation of HIV point-of-care testing
   Timeline: August 2016
   Responsible: DOH (TTI-NRL, SACCL-NRL)

6. Provision of continuous support during operationalization of the project.
   Timeline: March 2017
   Responsible: DOH, kit manufacturers, customs

Need for technical assistance and recommendations

- From WHO, CDC, UNICEF and other development partners
- Follow-up meeting and training from WHO/CDC
- Main stakeholders to be involved
- Funding, training, policy designing and development, recommendations
- WHO point person assigned in Manila
  - to communicate with
  - to help with policy construction
  - to advise
Thailand

<table>
<thead>
<tr>
<th>Activities</th>
<th>Responsible person</th>
<th>Timeline</th>
<th>Challenge</th>
</tr>
</thead>
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<tr>
<td>Establishing community-based testing (CBT) policy</td>
<td>MoPH</td>
<td>First 6 months</td>
<td>Related regulation revising</td>
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<tr>
<td>Guidlines for establishing CBT</td>
<td>MoPH</td>
<td>First 6 months</td>
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<tr>
<td>Quality assurance (follow routine QA programme)</td>
<td>MoPH</td>
<td>2016</td>
<td>Budget</td>
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<td>Develop laboratory certification (site supervision)</td>
<td>MoPH</td>
<td>2016</td>
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<td>Pilot study</td>
<td>MoPH</td>
<td>2017</td>
<td>Find partner supporting</td>
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<td>- Training</td>
<td>Stakeholder, e.g. MT council, health insurance office</td>
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<tr>
<td>- Data system collection</td>
<td>Stakeholder, e.g. regional center</td>
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<td>- Evaluation pilot study</td>
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<tr>
<td>Implement CBT</td>
<td>MoPH</td>
<td>2018</td>
<td>Government funding support</td>
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</table>

Technical assistance and recommendations
- Policy advocacy
  - Programme implementation
  - Programme allocation
- Sharing evidence and regional data

Viet Nam

- Pre-market evaluation of HIV RDTs, including lot release 2015–16 (MOH, NICVB)
- Post-market surveillance 2015–16 (MOH, NICVB, TWG, reference labs)
- Develop QA guidelines for POC HIV testing 2015–16 (MOH, TWG, reference labs)
- Training on supervision and monitoring 2015–16 (MOH, reference labs)
- Expansion of POC diagnosis at district level being piloted (MOH, reference labs, WHO, CDC)

Technical assistance and recommendations
- WHO
- CDC
- NRL Australia

For development of policy/plan and guidelines, and piloting innovative approach for expansion of HIV testing to reach 90 targets
Annex 5. Dual rapid diagnostic tests towards the elimination of parent-to-child transmission of HIV and syphilis

Immediately following the three-day training workshop, WHO conducted a one-day working meeting on “The Use of RDTs in the Elimination of Mother-to-Child Transmission of HIV and Syphilis”. The meeting involved countries who were interested in introducing/validating the new dual RDTs, which have not yet been WHO prequalified.

Session 1: Objectives of the workshop

Objectives
(i) to review the current evidence and experience with dual RDTs for HIV and syphilis;
(ii) to discuss the feasibility of using RDTs to facilitate the elimination of parent-to-child transmission of HIV and syphilis in Asia;
(iii) to discuss algorithms for RDTs and steps for QA to be implemented;
(iv) to discuss the steps required in planning, introducing, implementing and monitoring the use of RDTs in the context of elimination programmes; and
(v) to develop a plan for introducing/piloting dual rapid tests and documenting experiences.

Expected outcome
(vi) draft plan to introduce dual rapid tests in each country
(vii) available resources identified to support implementation of dual rapid tests (toolkits, teams with dual rapid test experience, technical assistance).

Session 2: Elimination of the vertical transmission of syphilis and HIV in Asia and the Pacific

The elimination of the vertical transmission of syphilis and HIV in Asia and the Pacific was discussed.

The presentation provided an overview of the commitment to PMTCT in the Asia-Pacific region from 2010 until 2015, including the recent conceptual framework for EMTCT of HIV/syphilis (commitment of eight countries to the “dual goal” of eliminating new cases of paediatric HIV and syphilis, and two countries to the “triple goal” of eliminating HIV, syphilis and hepatitis B).

It graphically described the trend of new HIV infections among children in the Asia-Pacific Region. Although it shows an overall decline (27% decline since 2000), the progress is not fast enough to end AIDS by 2015. In addition, there is significant variation among and within countries.

The presentation provided data from WHO of estimated HIV testing and counselling coverage among pregnant women in low- and middle-income countries in 2005 and during the period 2009–2013. Most recent data from both South-East Asia and the Western Pacific Regions still show low coverage (30% and 62%, respectively).

Data on syphilis testing at ANC sites were shown among seven countries of the Asia-Pacific region during the period 2008–2012, pointing out the limited information available, but noticeably high screening coverage in Fiji, Malaysia and Mongolia.

Current PMTCT policies and practices were summarized separately in the Western Pacific and South-East Asia Regions. In most of the countries in both regions, there was a trend of switching to B or B+ options.

The process of validation of the step-wise EMTCT process in the Asia-Pacific region was explained, including the pilot step in 2012 (in Cambodia, Malaysia, Sri Lanka and Thailand) followed by a meeting of the Regional Core Group in 2014.
The advantages and potential issues were discussed of dual RDTs for HIV and syphilis:
- pros: better uptake, efficiency (human resources, time, cost), better health outcomes
- issues: available diagnostics (current, future), testing algorithms, field evaluation, cost.

**Session 3: Overview on availability of dual RDTs and validation**

**Estimating the maternal and child syphilis burden and costing tool for HIV and syphilis**

Syphilis in pregnancy is a public health problem in many developing countries and, based on disease burden estimates at country level, the cost of preventing and eliminating new cases of paediatric HIV and syphilis can also be estimated.

There are existing tools to support countries to estimate the disease burden of maternal syphilis and its adverse outcomes, and to estimate the costs of preventing and eliminating new paediatric HIV infections and congenital syphilis:

1. Flowchart of the model to estimate disease burden/adverse outcomes, approved by the Child Health Epidemiology Reference Group (CHERG) (published in PLoS Medicine)
2. Excel-based tool to estimate disease burden/adverse outcomes (available on the WHO website)
3. Costing tool for EMTCT (CTEI), developed by the National Center for Global Health and Medicine (NCGM) (available on the Asia Pacific UN PPTCT Task Force website).

**Summary:**
- There are Excel-based tools available for estimating the number of cases of maternal syphilis and its adverse pregnancy outcomes, and estimating the costs for PPTCT/EPTCT of HIV and syphilis.
- The estimation outputs are critically influenced by the availability and quality of demographic and service data, including unit costs and parameter assumptions.
- The estimation results can be used to support the country for planning (directing), monitoring and evaluating the PPTCT/EPTCT programmes.
- These estimations are best led and done by the government.

**Overview of the availability and validation of dual rapid tests for HIV and syphilis**

Shifting attention to PMTCT of HIV resulted in limited syphilis screening, causing higher paediatric mortality due to syphilis than HIV. The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) now supports dual RDTs for HIV and syphilis, and integration of both programmes. In countries with limited PMTCT programmes, implementing dual RDTs offers to improve data from both diseases (HIV and syphilis).

The 2004 Health development report cited lack of access and unaffordability as the two major reasons why services fail (pointed out the importance of long distance to the nearest medical facility in selected resource-limited countries). Only 25% of pregnant woman get tested for syphilis and 15% of them receive treatment in an appropriate time frame (complete cascade: 75% accessing ANC, >50% accessing ANC early in pregnancy, >25% tested for syphilis, >18% are given results, >15% get treatment).

Three rapid point-of-care dual HIV/syphilis tests are commercially available, with several others in the pipeline at an estimated cost range of between US$ 1.5 and 3.0. Multisite laboratory performance evaluation in the following countries has been conducted/is in process: Ethiopia, Ghana, Togo, Myanmar, Kenya, Mexico, and Lao People’s Democratic Republic.
Rapid syphilis test for screening has been introduced in seven countries: China, Haiti, Uganda, Tanzania, Zambia, Brazil and Peru. The rapid syphilis test toolkits (details available on the WHO website) can be adapted for the introduction and implementation of the dual tests.

Summary:
- Three rapid point-of-care dual HIV/syphilis tests are commercially available, with several others in the pipeline.
- The performance and operational characteristics of these tests are acceptable in laboratory-based evaluations.
- Toolkits for the introduction and implementation of rapid syphilis tests that are already available can be adapted for the dual tests.
- New challenges arise with the organization of QA for POC tests when testing is decentralized. Building EQA systems with the laboratory is critical to ensure quality, timeliness and reliability of results.
- Connectivity solutions from diagnostic equipment/readers can link test results to central databases for surveillance, monitor the quality of tests and testing, and improve supply chain management.
- RDTs have been shown to increase the efficiency of health-care systems.

Country experiences: lessons learnt from country evaluation of dual RDTs

Data collected during country evaluations of dual HIV/syphilis RDTs were presented. Reasons why we should care about HIV and syphilis coinfections in pregnancy include the following:
- Both are STIs that cause a substantial health burden for mothers and infants.
- Syphilis may increase the viral load of HIV-infected persons.
- Syphilis in HIV-infected mothers may increase the risk of MTCT of HIV.
- Both have evidence-based, scalable interventions using an antenatal services platform.
- Both need early access by all pregnant women to ANC to succeed.
- Both are tested using serology and both have existing, widely used single point-of-care tests.
- Both infections also require management of partners.

After manufacturer test development, the process of credentialing (independent evaluation) for the dual HIV/syphilis test includes the following steps:
- performance in the laboratory (phase I)
- performance in the field (phase II)
- introductory studies (phase III)
- operational research – e.g. cost, impact (phase IV).

Introduction of dual HIV/syphilis RDTs among pregnant woman in antenatal clinics:
- potential opportunities: improves the quality of ANC, facilitates the uptake of HIV and/or syphilis testing; detection of syphilis-positive, HIV-negative women allows identification of women at increased risk of acquiring HIV; detection of syphilis-positive, HIV-positive women allows identification of women at increased risk of HIV transmission; facilitates procurement processes, common processes for QA and QC; combining the two would be cost saving and increase efficiency;
- potential challenges: could limit the ability of providers to tailor diagnosis, known HIV-positive patient may not desire repeat testing, may increase complexity of procurement as both single and dual tests may need to be available, need to integrate into established HIV testing algorithms, and to develop integrated training and QA systems.
WHO research activities for evaluation of dual HIV/syphilis RDTs were introduced. It was highlighted that Nigeria and China had completed phase II (laboratory-based evaluation) for three brands, for which four outcomes were measured: sensitivity, specificity (comparison with reference tests), repeatability (between two readers), and stability (between two reading times).

Preliminary results of the CDC evaluation of single treponemal and dual HIV/treponemal tests concluded that positive agreement was greater for HIV antibodies than for treponemal antibodies, and using banked sera could have affected the performance of treponemal assays.

Preliminary results from phase III (field performance) evaluation in Zambia showed high provider acceptability and client acceptability of dual rapid tests. An ongoing study from phase III B (introduction study) in China and Colombia aims to determine uptake of HIV and syphilis testing and treatment by ANC attendees after dual HIV/syphilis RDT introduction, explore acceptability by ANC attendees and health workers, and determine workload and cost implications.

**CDC process for rapid test kit validation and update on ongoing field evaluations**

The CDC validation process and ongoing field evaluations for rapid test kits were described in detail. CDC with USAID has established a validation process to ensure that HIV RDT kits are adequately evaluated (but it is intended only for procurement of the RDT kits in programmes supported by the United States President’s Emergency Plan for AIDS Relief [PEPFAR]).

Evaluation of dual HIV/syphilis RDTs is performed by collaboration between two CDC branches (International Laboratory Branch and Laboratory Reference and Research Branch). Laboratory-based validation has three steps:

- **Step 1: product dossier** – includes product information, summary of internal/external evaluation, approvals of the United States Food and Drug Administration (FDA) or similar agencies of other countries;
- **Step 2: technical evaluation** – needs initial testing of 100 specimens followed by full testing of ~1000 specimens. Comparisons of two additional lots are also done using dilution panels (100 specimens), and inter-reader (3 readers) comparison using dilution panels (100 specimens);
- **Step 3: validation report preparation.**

**Summary:**
- Preliminary field evaluation results are very promising.
- Ongoing laboratory testing is done to determine confirmatory and performance characteristics.
- Ongoing QA is critical and should be implemented and monitored at all levels of testing.
- Qualitative data analysis (information obtained from both providers and patients) is ongoing to better understand the acceptability, feasibility and cost–effectiveness of the test.

**Discussion**

**Q&A session:**

1. What would be the lowest acceptable sensitivity for syphilis testing from a blood specimen?
2. A: No lower than 80% (oral fluid has very low sensitivity ~20% due to a small amount of antibodies in saliva).
3. How expensive was the QA system in Peru?
4. A: A syphilis testing panel was added to DTS used for HIV (funded by the Global Fund), which did not add any cost to the system. Supervisors performed site visits every 2 months initially, and
later every 6 months, if the centre performed well. Of note, providers reported difficulties in seeing faint lines on the test, which was found to be related to uncorrected vision issues.

5. Do you have any experiences with a situation when a laboratory has no Internet connection service?
6. A: I recommend working with the private sector to get connection.
7. What steps are needed to perform EQC?
8. A: One cannot do anything about “control lines” (internal controls), which are a part of the test, but positive/negative tests can be run at each site. There are published examples of the same health-care workers (from very remote areas) who had high concordance with syphilis results but lacked in sensitivity for HIV tests because they were “afraid of HIV positivity” – meaning that they did not call the test positive until the line was “very positive”.
9. What would be more costly with respect to QA? – adding a single RDT syphilis test to existing HIV testing or switching to a dual RDT for HIV/syphilis?
10. A: Adding a new test, regardless of whether it is sequential or done at the same time, will cost more money. Additional comments to this question:
   - If using a new dual RDT for HIV/syphilis, make sure it is in accordance with your original HIV algorithm.
   - WHO provides evidence in the prequalification system for tests but does not recommend a specific diagnostic algorithm as it is context specific.
   - PEPFAR provides financial support only for HIV but dual HIV/syphilis tests can be used with additional benefit to include testing for syphilis.
   - Dual RDTs for HIV/syphilis do not distinguish between HIV-1 and HIV-2.
     The relatively low sensitivity for the syphilis test among pregnant women might miss “old infections” but this is acceptable because it is most important to not miss cases with high syphilis titres, which have the highest transmission risk.

Session 4: Dual HIV and syphilis rapid test - Practical session

A practical session provided an overview of the use of the dual rapid HIV/syphilis tests, and demonstrated the test procedures and their interpretation.

- General QC/QA steps:
  - It is important to check expiration dates (officially recommended that the test should not be used if it is close to its expiration, although use within 1–2 months from expiration date can be considered if there is a good external quality control for both positives and negatives for each box.
  - Each test package has to contain a desiccant. If missing, use a new test package.
- The test can be kept out of the package for only a few hours (shorter in a high humidity environment) and has to be used within 1 day.
- At laboratory level, it is recommended to avoid contamination during sampling and run a maximum of 10 tests at one time.
- Any lines, including very faint ones, are considered reactive.
- Very high humidity shortens the time of test stability and therefore it is recommended to not read the test results after 1 hour of the post-window period.
- Interpretation of test result for clients:
  - “+” should be reported as a “reactive test” and needs a confirmatory test (avoid using term “positive”).
  - “–” means non-reactive and should be reported as a “negative test”.

Session 5: Testing algorithms for HIV and syphilis RDTs and quality assurance

- Algorithms for syphilis screening:
  - 10 options for testing algorithms were shown (available on the website4);
  - rapid plasma reagin (RPR) test: requires trained personnel, is more costly due to the need for a refrigerator, uses only serum specimens, minimum of 8 slots to run the cartridge, and might result in overtreatment of pregnant women (due to higher false-positive results);
  - rapid treponemal test: might result in overtreatment of pregnant women (those with a history of syphilis due to lifelong antibody persistence in spite of therapy) but this is accepted as there are adverse consequences if it is not treated.

- Performance of syphilis screening algorithms:
  - sensitivity and specificity of algorithms from different antenatal syphilis screening and treatment approaches (single rapid syphilis test [RST], clinic RPR, dual RST against laboratory Treponema pallidum haemagglutination [TPHA], dual RST against laboratory RPR) used in Peru, Tanzania and Zambia were summarized in the table.

- Cost–effectiveness of syphilis screening:
  - The most cost–effective screening algorithm is a treponemal-based RST, which identifies 54–66% of true cases at the initial visit.
  - There are some concerns about overtreatment, as treponemal tests fail to distinguish between past and current syphilis. Sequentially combining tests or using new dual treponemal and non-treponemal RSTs could greatly help to solve this problem. However, this would require a budget expansion of >38% above what is needed for the single RST at current prices.

Univariate sensitivity analysis showed that, for the dual RST to achieve the same cost per disability-adjusted life-year (DALY) averted as the single RST, the dual test price would need to drop from US$ 2.50 to US$ 2.07 in Tanzania, US$ 1.67 in Zambia, and US$ 1.24 in Peru.

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