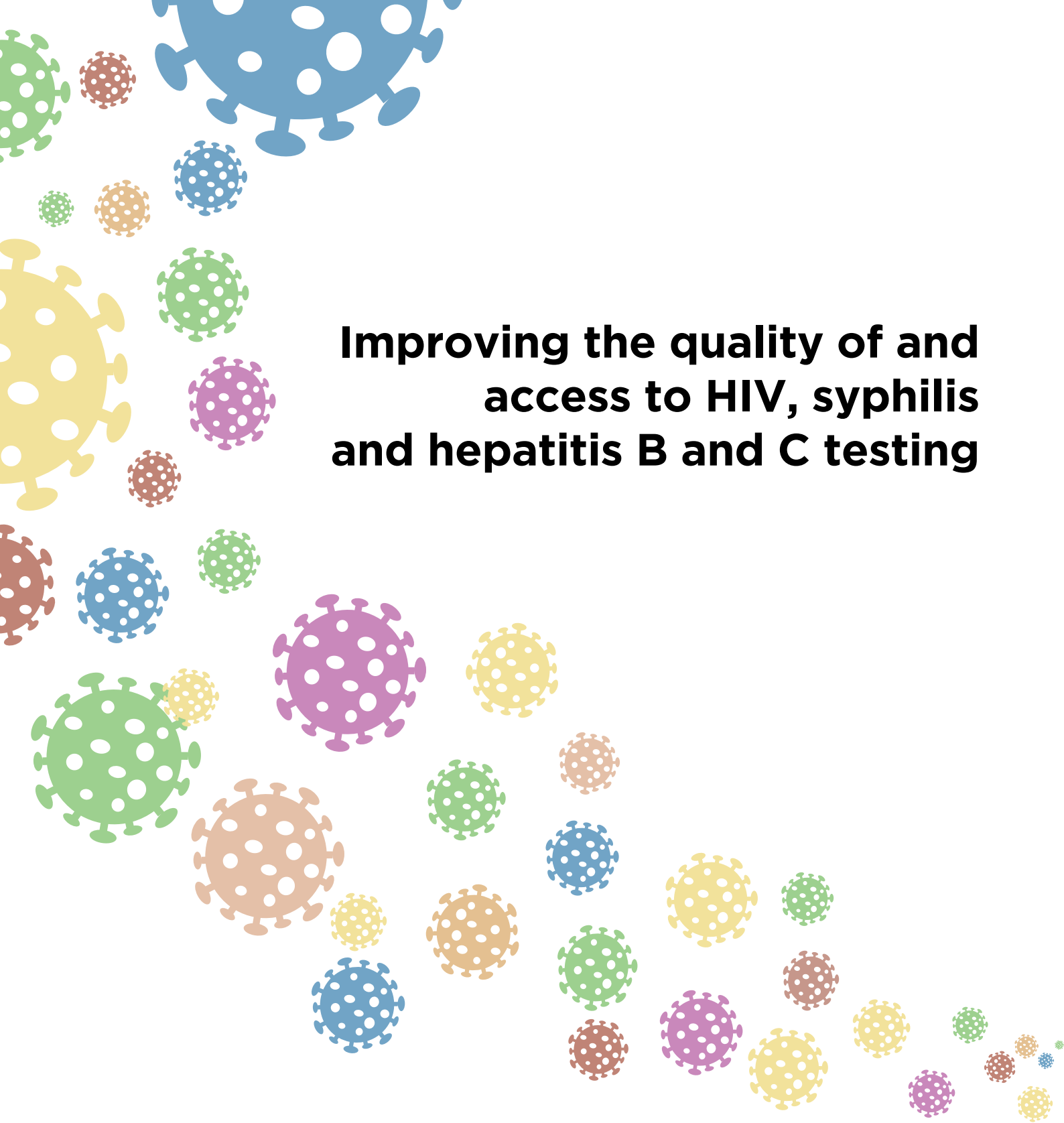
Improving the quality of and access to HIV, syphilis and hepatitis B and C testing



World Health Organization
Western Pacific Region

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Laboratory gap analysis in selected countries of the Western Pacific Region

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Executive summary

Background

Strengthening laboratory services has been identified as a priority in recent World Health Organization (WHO) strategies, including in the *Asia Pacific Strategy for Strengthening Health Laboratory Services* (2010–2015). However, countries can be overwhelmed by these tasks because the systems to ensure that laboratory testing is reliable, consistent and of high quality can be complex. Countries that conduct HIV, syphilis, hepatitis B virus (HBV) and hepatitis C virus (HCV) testing in the Western Pacific Region requested support to determine where their laboratory systems required strengthening and what activities should be undertaken to strengthen them.

The WHO Regional Office for the Western Pacific contracted the National Serology Reference Laboratory (NRL), Australia, a WHO Collaborating Centre, to support a gap analysis at sites that conduct HIV, syphilis, HBV and HCV testing. The WHO Laboratory Assessment Tool, published in 2012, was developed to assess national laboratory systems and those of individual facilities. For the gap analysis, this tool was adapted to focus on HIV, syphilis, HBV and HCV testing, and to collect information about licensing of laboratories, regulation and management of test kits, standards, quality management and quality assessment (Systems questionnaire). An additional questionnaire (Testing questionnaire) was developed to collect information on the current testing undertaken for diagnostic, blood screening and clinical management purposes (HIV only).

Methods

Seven countries in the Western Pacific Region were selected for participation in the gap analysis: Cambodia, Fiji, the Lao People's Democratic Republic, Mongolia, Papua New Guinea, the Philippines and Viet Nam. These countries were chosen as they represented the spectrum of laboratory systems development expected in the Western Pacific Region.

The two questionnaires, as Excel files, were emailed in February 2014 to either the WHO HIV country focal points or individuals who were selected by the focal points. Completed questionnaires were received from all seven countries between three weeks and three months after the date of distribution of the Systems questionnaire. Adequate data were not submitted until December 2014 for the Testing questionnaire.

Findings

The analysis showed that national systems to support HIV, syphilis, HBV and HCV testing varied widely by country, by pathogen and by degree of implementation. Systems that had significant gaps included the following:

Quality management systems (QMS): None of the countries had complete QMS in place. Only four of seven countries had a national body responsible for auditing laboratories. Mongolia and the Philippines each has one facility that is in the process of seeking accreditation; Viet Nam has six (for HIV only.)

External quality assessment schemes (EQAS): Participation in EQAS was in place in six of seven countries for HIV, three of seven for HBV and HCV, and two of seven countries for syphilis. This suggests that the quality of testing for HBV, HCV and syphilis is unknown in most countries. Where participation in EQA was in place, it was not always mandatory, and there was inconsistency between the requirements for "not-for-profit" and "for-profit" laboratories.

Regulation of diagnostics: Only one country, the Philippines, had systems to regulate diagnostics for all of the four pathogens. Viet Nam is presently developing a similar system, in the first instance for HIV only. Policies and procedures were more likely to be in place to ensure the quality and performance of HIV diagnostics than for the other three pathogens. Systems to regulate HBV and HCV diagnostics showed the greatest gap, with four of seven countries having very limited systems in place. In these countries, there were no processes to select diagnostics, which suggests that sites can select any product on the market regardless of its performance. In addition, three of these countries had no EQA in place for HBV and HCV and, as such, poorly performing assays and underperforming laboratories would be unlikely to be detected.

All seven countries reported experiencing problems in ensuring that test kits were always available.

There were differences in the way systems were applied for licensing and accreditation of testing sites, and participation in EQA between not-for-profit and for-profit laboratories. In some countries, these systems and procedures were applied only to not-for-profit sites. This can result in testing sites being outside of the regulatory and quality management systems, leaving their activities unmonitored and the quality of their test results unknown.

The gaps in systems varied between pathogens, with more systems in place to support HIV testing than for any of the other three pathogens. Systems to support HBV and