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Improving Xpert MTB/RIF Assay Implementation in the Philippines National TB Control Program

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BACKGROUND

Despite the continuous efforts of the National TB Control Program (NTP) to increase case finding by expanding the number of laboratories and implementing other interventions such as active case finding for high-risk populations, TB case finding has remained below expectations. The introduction of rapid TB diagnostic technology such as Xpert MTB/RIF assay (or Xpert) in 2011 has improved TB detection, particularly of rifampicin-resistant TB (RR-TB) cases. RR-TB is currently used as a proxy indicator for the presence of multidrug-resistant TB (MDRTB). The TB detection rate using Xpert is 32% among new presumptive drug-susceptible TB cases, and 35% among drug-resistant presumptive TB cases; this is higher than the 15% positivity rate for TB diagnostic microscopy. Xpert was also able to detect RR-TB in an average of 35% of MTB+ cases.[1] The scale-up of Xpert services has increased the test's availability in the NTP laboratory services, with 207 sites established by the end of 2016. However, Xpert's performance capabilities in terms of case finding are not fully realized, due to a variety of issues affecting its implementation.

KEY ISSUES AND ANALYSIS

Limited Access to Xpert Sites

More than 50% of existing Xpert sites are situated in intermediate-level facilities such as district, provincial, or tertiary hospitals, or in specialized laboratories and tertiary medical centers; the rest are located in primary care units (e.g., rural health units (RHUs) or health centers). With this distribution, the number and location of Xpert sites remains inadequate to ensure universal access to rapid TB diagnostic tests and drug susceptibility testing. This inadequate access is a result mainly of long distances between the Xpert sites and referring health facilities. In Nueva Ecija, for example, the distance from a referring healh center to the referral laboratory ranges from less than a half-kilometer to almost 45 kilometers.[2]

Additionally, the high cost and variable availability of transport, especially in hard-to-reach rural areas, further limit access to services. Furthermore, the availability of Xpert services, particularly in primary care facilities, is not assured on a daily basis due to the shortage of medical technologists, who often are tasked with administering more than one laboratory per week.

Variable Performance of the Specimen Referral and Transport System

The performance of the specimen referral and transport system is unreliable. Poor packaging and transport expose specimens to damaging conditions, affecting their integrity before testing is carried out. Field observations showed that poor specimen packaging is common in primary care facilities because (1) the appropriate packaging supplies are not available, (2) health workers are not aware of proper specimen packaging techniques, and (3) health workers or patients often pay for the packaging supplies, leading to the use of poor-quality materials. These factors have led to specimen leakage or spillage from their primary containers, and subsequent contamination; specimens were exposed to heat, which can kill mycobacteria and lead to false-negative results; and specimen leakage has potentially exposed, or infected, people involved in specimen transport with the TB mycobacteria.

Under Programmatic Management of Drug-Resistant Tuberculosis (PMDT), specimen transport is adequately supported with donor funds (i.e., from the Global Fund). However, in DOTS primary care facilities, the system is loosely supported by funds from patients, health workers, and local government units. Public utility vehicles are commonly used for specimen transport from DOTS facilities, resulting in variable transport times, delays, and poor specimen handling.

Supply Management Problems

Stock-out of cartridges was experienced due to inaccurate quantification of supply requirements, resulting in the provision of lesser quantities than what was requested by testing facilities. The shortage of cartridges resulted in the testing of patients being limited; drug-resistant TB (DRTB) patients were preferentially tested whereas high-risk presumptive TB patients were excluded from testing. Additionally, improper transport during distribution tends to expose cartridges to heat and shocks during transit, potentially compromising quality. Storage conditions are also variable, especially at primary-level facilities, where temperature exceeds the recommended limit (28 °C). This exposes the cartridges to risk of damage, which can lead to erroneous test results.

Variable Quality of Tests

In 2015, the National TB Reference Laboratory (NTRL) reported that 5% of tests performed yielded errors or invalid results. This is the equivalent of 3,449 wasted cartridges. Most errors can be attributed to faulty operator practices; to cartridge quality, which can be due to poor distribution and storage; or to poor specimen transport conditions.[1] Faulty practices can be attributed to inadequate operator training, caused by a lack of training opportunities. Training quality has also been compromised by the lack of trainers, as well

as insufficient training equipment and supplies (i.e., Xpert machines and cartridges for training). There is no organized external quality assurance scheme for Xpert implementation, and the performance of regular maintenance activities at the facility level is also inconsistent.

RECOMMENDATIONS

A number of interventions are needed to address the performance gaps in the Xpert laboratory network, mainly in terms of strengthening laboratory support systems. The planned medium-term widespread expansion of Xpert is not likely to succeed in addressing accessibility and case finding issues without filling these systemic gaps. The following recommendations are considered strategic short-term interventions with long-term benefits, including improved access to testing and increased TB case detection.

- Strengthen the specimen referral and transport system to improve accessibility of Xpert services. The system should be supported with the necessary guidelines, funds, packaging materials, and training to address the problems in organization, financing, and processes such as specimen collection, packaging, and courier/transport services.
- Improve supply management capacity at all levels and stages of the management cycle, particularly quantification, distribution, and storage of supplies. Quality assurance of supplies must also be put in place.
- Strengthen the maintenance of Xpert laboratory equipment and facilities. A functional, regular maintenance program must be organized and implemented; maintenance tasks at the facility level assigned to operators should be regularly performed.
- Strengthen training and supervision of Xpert operators. Training quality should be improved by addressing the systemic gaps in the current Xpert training program, particularly in providing adequate practice time during training. Management of the Xpert training program should be strengthened by decentralizing some functions to the subnational level to address delays and backlogs in training.
- Improve the selection of Xpert sites under the expansion scheme. Use a carefully designed set of criteria to guide NTP managers in selecting new sites for Xpert expansion. Consider local TB burden, location of existing diagnostic (e.g,. X-ray) and treatment facilities, feasibility of specimen referral routes, and availability of transport in selecting the sites.

REFERENCES

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ABOUT SIAPS | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health.

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