Laboratory strengthening

Building laboratory capacity to promote universal access to quality diagnosis and expand services for drug-resistant TB in India

THE IMPORTANCE OF LABORATORY STRENGTHENING

India has the highest number of incident tuberculosis (TB) cases in the world and is home to one-fifth of the world's multidrug-resistant TB (MDR-TB) cases. Functioning laboratories are critical to diagnose the disease, including drug-resistant forms, so that people who have TB can access the lifesaving treatment they need as quickly as possible while reducing the risk of infecting others. Laboratories also help monitor how patients are progressing through their treatments.

The Indian government developed a national laboratory accreditation strategy under the National TB Laboratory Scale-up plan to provide quality-assured diagnosis, improve laboratory safety, expand diagnostic technologies, and link laboratories across the country. Strengthening laboratories is also a key component of India's Revised National TB Control Program's (RNTCP) efforts to expand programmatic management of drug-resistant TB services nationwide.

APPROACH

In collaboration with the Foundation for Innovative New Diagnostics (FIND), the World Health Organization (WHO), and other partners, PATH provided intensive technical assistance to RNTCP to introduce newer rapid diagnostics for MDR-TB, ensure adequate biosafety and infrastructure, facilitate national accreditation, build laboratory networks nationwide, and strengthen external quality assurance. The work was funded by the US Agency for International Development.

IMPLEMENTATION

Laboratory accreditation

At the request of the Central TB Division (CTD) in April 2009, PATH launched a collaborative initiative with the American Society for Microbiologists focused on national accreditation of selected Intermediate Reference Laboratories (IRL). Initial assessment visits conducted in six state IRLs identified critical activities that each laboratory needed to undertake in order to achieve accreditation for the performance of routine culture and drug-susceptibility testing.

Infrastructure upgrades

In order for laboratories to carry out quality assured MDR-TB testing, they must have infrastructure and equipment that meets national and international standards. Since 2010, PATH has worked with FIND, WHO, and local government partners to upgrade selected laboratories with line probe assay (LPA) capacity and ensure that biosafety level 3 (BSL-3) requirements are met.

Technical support

PATH/Lesley Reed

To identify gaps in the laboratory strengthening process and work with staff to provide tangible solutions, PATH and the CTD convened a series of IRL experience sharing workshops. During the workshops, microbiologists, RNTCP consultants, and other laboratory specialists shared lessons learned, provided feedback to their peers, and participated in technical sessions on such topics as new technologies and good laboratory practices. Targeted follow-up training was provided for laboratory managers and microbiologists on topics such as logistics (reagents and chemicals) management, human resource management, equipment maintenance, recording and reporting, accreditation procedures, quality assurance, and laboratory information systems. Support was provided

for initial infrastructure assessment; finalization of laboratory layout; coordination with the national reference laboratory, CTD, and state departments; and accreditation in solid culture.

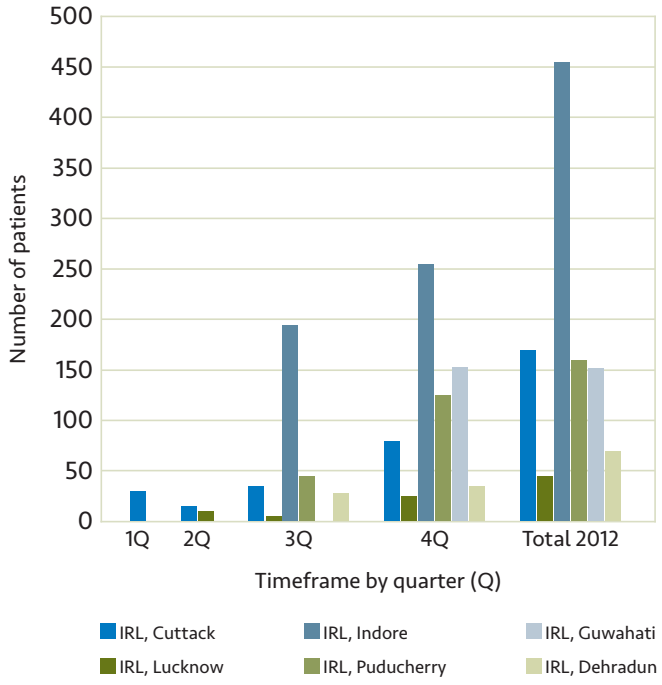
RESULTS

PATH established two BSL-3 facilities in in the state of Andhra Pradesh—IRL Hyderabad and the Blue Peter Public Health & Research Centre (BPHRC). These facilities now carry out liquid cultures, which are preferably used for follow-up. Between the last quarter of 2010, when the first BSL-3 lab was set up, and the end of 2012, there was exponential growth in the number of follow-up specimens were inoculated in BPHRC as well as the number of specimens in IRL Hyderabad. From the last quarter of 2010 to the end of 20123,196 follow-up specimens were inoculated in BPHRC and 7,036 specimens in IRL Hyderabad.

PATH also supported RNTCP and state governments, along with FIND and partners, to establish LPAs in 12 laboratories. Eight more laboratories are in the process of being upgraded with LPA capacity and will be ready by 2013. In the year 2012 alone, the first six labs to be upgraded conducted 6,825 LPA tests for drug-culture susceptibility, of which 1,041 cases were diagnosed as MDR-TB.

By the end of 2013, PATH will have contributed to infrastructure upgrades in 20 laboratories. These facilities have designs that are now in line with national and international standards of infection control, as per WHO guidelines.

FIGURE 2:
Drug-resistant TB patients diagnosed with LPA, 2012



LESSONS LEARNED/WAY FORWARD

As a result of collaborative and well-documented support for laboratory strengthening, a number of important programmatic lessons should be considered for future laboratory strengthening projects:

- Equipping laboratories with newer diagnostics and ensuring that requirements for BSL-3 are met are both strategies to increase the number of MDR-TB cases safely diagnosed. In the year prior to a project-supported laboratory upgrade in Andhra Pradesh, 68 MDR-TB patients died before they could access treatment. Following the upgrade, the laboratory diagnosed more than 300 patients with drug-resistant TB and placed the majority of them on treatment.
- IRL experience sharing workshops are critical forums for microbiologists, laboratory technicians, RNTCP officials, and partners to share lessons learned and challenges, facilitate solidarity, articulate technical assistance requests, and develop clear recommendations for improving laboratory strengthening efforts throughout India.
- Implementers should advocate for resources to assess the outcomes of trainings and to monitor follow-up steps by trainees as they use what they have learned.
- Laboratory upgrade and certification is a complex process that requires a series of consultations and coordination among various departments at the state level, including IRLs and the CTD. Close collaboration with national and state TB authorities is critical to ensure coordinated and efficient laboratory strengthening efforts.

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