

[Discussion Brief: Building Capacity for Diagnostics in Resource-Limited Settings](#)

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In the health delivery system, the laboratory provides diagnostics and plays an important role in disease control, patient care, and disease surveillance. However, laboratory services are often neglected in health delivery systems in poor and developing countries. Laboratories often have shortages of skilled staff, are poorly funded, often fail to meet safety standards and thus fail accreditation, and experience weak supply chain management systems. Many developing countries also do not have a national policy on laboratory services which further compromises the quality of laboratory services. In this virtual expert panel, members and experts in 37 countries exchange experience and offer input on various challenges.

Key Points

1. Public Health Needs and Capacity Limitations

- [Sandeep Saluja](#), a clinician working in remote areas in India, has to do most of the lab work with minimal assistance. Low cost point-of-care tests would reduce workload in such settings.
- National reference laboratories are often not properly included (or even completely omitted) in national health budgets. Consequently, they rely on sporadic sources of external funding for their consumable costs. National laboratories do not work in sync with other public health disciplines.
- There needs to be more support for the training of public health laboratory scientists. Professional development will bring about more informed leadership and better strategies in this discipline.
- Outbreaks such as that of Ebola/Marburg VHF in Uganda, the need for lab confirmation of malaria for treatment, and the emergence of MDR-TB have emphasized the need of quality lab in many countries.
- Given the increase in MDR-TB and the turnaround time for TB culture and DST, molecular methods seem to be the best way forward. Unfortunately, with the exception of rifampicin, the molecular tests are not yet adequate for drug susceptibility testing and thus laboratories still have to do TB cultures despite safety risks.
- A sorely needed rapid diagnostic test is needed for gonorrhea and Chlamydia as lab professionals are limited to the syndromic approach outlined by the WHO, which has been shown to lead to over treatment.

2. Rapid Diagnostics Tests Impact on Laboratories, Supply Chain

- Regulation of the sale of diagnostics should be reinforced to ensure their safety and efficacy.
- Guiding principles to assist governments in establishing regulatory controls for diagnostics and other medical products in their countries are critical.
- Supply chain management should be part of laboratory training curriculum, as it is done with Pharmacy students. Laboratory staff needs to grasp the basics of forecasting and managing logistics.
- HIV test algorithms need to reflect and match with supply chain realities at point of care to avoid stock-outs and interruption of services.
- Supply chain management and procurement need to be decentralized.

3. International Organizations and Initiatives

- [The African Society for Laboratory Medicine](#) is dedicated to improving lab services across Africa.
- [The Affordable Access for In-Vitro Diagnostics](#) by the London School of Hygiene & Tropical Medicine.
- [International Medical Device Regulators Forum](#)
- [The Latin America IVD Association \(ALADDIV\)](#): a regional forum for regulators, researchers, and ministries of health representatives to promote the convergence of regulatory standards and procedures
- [The Pan African Harmonization Working Group](#) (medical devices)

Key references

- [A Regulatory Program for Medical Devices: An International Guide. WHO, 2001 \(PDF\)](#)
- [Performance of the 2007 WHO Algorithm to Diagnose Smear-Negative Pulmonary TB in a HIV Prevalent Setting](#)
- [WHO 2011 Handbook for laboratory quality management systems. \(PDF\)](#)
- [WHO/AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation. 2012 \(PDF\)](#)
- [Increasing access to diagnostics through technology transfer and local production. 2011 WHO \(PDF\)](#)
- [Laboratory preparedness in the context of WHO-recommended MDR-TB diagnostic Algorithms \(PDF\)](#). Jerod Scholten, KNCV. DRTB Network 2013
- [GHDonline search results page for: Laboratory](#)
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