

# Under the microscope: how to improve quality of laboratory equipment and diagnostics in Africa

Crown Agents Technical Manager David Whybrew offers some thoughts on maximising the efficiency and effectiveness of the medical laboratory



Well-functioning diagnostic technologies and laboratory services are vital factors for effective disease control. They detect and diagnose disease more rapidly and at an earlier stage; they allow for more targeted and effective treatment options; they enable more efficient monitoring of chronic diseases; and they help to limit healthcare spending. Major scale-up efforts over the past decade to combat the three major diseases in Africa – HIV/AIDS, malaria, and tuberculosis (TB) – have helped increase recognition of the importance of effective and affordable diagnostic equipment and services. There is a growing collective acknowledgement that initiatives to improve access to medicines must be supported by effective diagnosis and subsequent monitoring of patients, if treatments are to be successful and infection rates are to be brought down.

While treatment of HIV/AIDS, malaria, and TB has advanced rapidly in recent years, the advancement of high quality, affordable and appropriate laboratory equipment and diagnostics has been somewhat overlooked, leaving it as something of a Cinderella figure in health spheres. Progress in improving access to diagnostics and laboratory equipment has been slow in many African countries: the laboratory networks are weak, staff training is insufficient and infrastructure is often under-developed. Only around 8% of laboratories in sub-Saharan Africa meet international accreditation standards, with most rural laboratories facing poor infrastructure and insufficient staffing and equipment while catering for anywhere from 5000 to 15 000 people.<sup>1</sup> National governments are keen to build their diagnostic capabilities, but most lack the laboratory networks and national reference laboratories that are critical for the accurate testing and analysis of samples.

So why is implementing such systems so tricky? When it comes to quality there is no set system of agreed international standards that laboratory equipment needs to meet, unlike electrical standards, for example, or the standard formulae that exist for pharmaceuticals. The Maputo Declaration – championed by the World Health Organization (WHO) in 2008 and agreed on by governments, multilateral agencies, development partners, professional associations, and

academic institutions – sought to address laboratory challenges that limit the scale-up of services for TB, malaria, and HIV diagnosis and care.<sup>2</sup> The declaration demonstrates the stakeholders' attempts to set standards that will improve the level and consistency of diagnostics equipment across Africa. It aims to move the stakeholders towards agreement on what systems and capacity they need in order to ensure that diagnostic networks can meet countries' health policy priorities.

As part of its own steps to help implement the Maputo Declaration, WHO launched a prequalification programme for diagnostics in 2010, known as PQ Dx.<sup>3</sup> Under the programme, WHO maintains prequalification lists of diagnostics products that have been evaluated against certain criteria and state the levels of quality and operation that they have achieved. The lists are laying the foundations for networks of independent knowledge upon which WHO member states, UN agencies, procurement agents, and other partners can gauge their selection of test kits and technologies that are suitable for use in resource-limited settings. The PQ Dx has concentrated primarily on diagnostic equipment for HIV/AIDS, malaria, and TB control programmes and complements WHO's existing prequalification structure for medicines and vaccines.

While the PQ Dx is addressing the front end of the need to raise equipment standards, it can only fulfil a small part of what must be done to improve the overall quality of laboratory equipment and other diagnostic supplies. For any piece of equipment, it is critically important that installation, commissioning, and training



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are included in any contract with the supplier, and that a separate after-sales servicing and maintenance agreement is put in place. These 'terotechnology' requirements need to be built into procurement processes and tender documents and appropriate contracts need to be put in place and effectively managed. The role of local agents becomes particularly important given this need for 'after-sales service' of equipment. In addition, it is important that any equipment is properly registered in country, and where appropriate it is beneficial for equipment, reagents, and supplies purchased to be compatible with any existing equipment to encourage the considerable benefits of harmonisation and ensure effective utilisation by staff. If systems are not in place to ensure that compatible reagents are available or that adequately skilled staff – or relevant skills training – are accessible for future servicing and maintenance, then the long-term value and effectiveness of equipment will be limited.

Given the complexities in supplying safe, reliable, and appropriate laboratory equipment and diagnostics, there must be high-level and efficient coordination between all stakeholders involved in the chain. Each of the stakeholders – including procurers, end users (such as laboratory managers and medical professionals), programme managers (such as health ministries), and funders – has an important role to play in achieving the programme goals and complying with the relevant national health policies. Through its role as procurement

agent, Crown Agents has served in a coordination role on a range of successful disease control projects across Africa, providing a crucial link between all the players involved through the challenges and helping to avoid potential pitfalls of the processes, enabling the supply and roll-out of laboratory equipment and diagnostics that help to save lives and improve health efficiently and economically.

While the gulf between the standards and systems for diagnostic equipment and supplies and those for treatments in Africa has grown in recent years, efforts are increasing to improve laboratory systems and capacity. There are also increased efforts to develop new tools and technologies that bring diagnostic services closer to the point of care. In Malawi, for example, a new machine has been developed by the University of Cambridge that offers viral load testing, CD4 counts, and early infant diagnosis for HIV, on-site in the country's poor, rural communities.<sup>4</sup> This machine could eliminate the need for samples to be sent long distances to testing laboratories – journeys that can take many months and often see samples spoiled or lost during the process. Implementing the groundwork and necessary support structures to raise the standards of laboratories and diagnostics in African countries are long-term tasks – marathons not sprints. The vision is now strong, however, among governments, health agencies, donors, and other partners to ensure that diagnosis is brought on par with treatment and cure in the efforts to save lives across the continent.

### References

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