

## **An analysis of approaches to laboratory capacity strengthening for drug resistant infections in low and middle income countries**

### **Summary**

The purpose of this study was to identify and compare in broad terms laboratory capacity strengthening models in low and middle income countries (LMICs) focusing on enablers and barriers to success in relation to anti-microbial resistance (AMR) surveillance in different contexts. There is very little published information that focuses specifically on laboratory models for AMR surveillance. These models will require a combination of general approaches to strengthening the capacity of laboratories and their systems and networks, coupled with specific microbiological and other techniques needed for AMR. Due to the lack of AMR-specific information we sought information from electronic databases of publications from 1996-2016. This data was supplemented by interviews with key informants with relevant expertise including in AMR surveillance, microbiology and laboratory systems to provide in-depth information about the various types of AMR surveillance laboratory activities, outcomes and challenges, and sustainability issues.

A data extraction matrix was used to capture the information necessary to analyse the various LMIC laboratory capacity strengthening models identified in the literature. Models were grouped according whether they were focused on individuals, institutions/laboratories and or the higher societal (i.e. national, regional and international) level. For individual staff the predominant model for enhancing their skills was training. This included through short courses focused on specific diseases such as malaria, or on generic skills such as tracking test accuracy. Repeated training in conjunction with regular supervision appeared to be effective at improving the skills of individual laboratory staff.

The majority of programmes aimed improving the effectiveness of laboratories as institutions were focused on HIV or tuberculosis and were funded by external agencies. These programmes mostly aimed to achieve accreditation for the laboratory against international standards (generally, ISO15189 for clinical laboratories and ISO 17025 for veterinary laboratories).

The types of topics covered which are all relevant for AMR surveillance included policies, laboratory management and planning, accreditation, quality systems and monitoring, laboratory capacity gaps, buildings, equipment, and human resource management and development. Successfully accredited laboratories had all appointed a quality officer or unit to guide and monitor the process of accreditation. The financial cost of an individual laboratory to achieve accreditation varied but was approximately £50,000 - £150,000. There are several resources available to support the accreditation process for clinical and veterinary laboratories including a stepwise improvement process which can help laboratories to monitor their graduated progress in implementing quality systems.

Infrastructure upgrading was often a costly and time-consuming component of strengthening laboratory capacity especially for those needing high specifications such as biosafety level 3. The associated costs and complexity mean that only a few tertiary level facilities are able to achieve international accreditation and it is beyond the reach of most lower level laboratories where the bulk of the workload is incurred. The lack of accrediting bodies within many LMICs is also a barrier to

timely accreditation and the increase in laboratories seeking accreditation has placed a strain on the few existing accrediting bodies in some regions such as South Africa.

Despite the challenges to achieving accreditation, it has many benefits relevant for AMR surveillance. These include a decrease in wastage of laboratory reagents (1) which can contribute to offsetting the cost of accreditation, a reduction in complaints, increased demand for services, and improvements in pre-analytical, analytical and post analytical metrics. In contrast to the recent effort that has gone into achieving accreditation in LMIC laboratories, there is very little published evidence on how to sustain accreditation status logistically and financially and more work is needed to document the logistics and costs and to balance this against the benefits, particularly in the context of AMR surveillance.

For models that focused on 'societal' level – i.e. the creation, consolidation or expansion, of national, regional or international laboratory networks – the following factors emerged as important: engagement with policymakers, assessments of laboratories participating in a network, upgrading of infrastructure, staff and systems, standardisation of methods, equipment and servicing, accreditation and regulation, and network coordination and communication. The WHO HIVResNet Drug Resistance Laboratory network provides an example that may be useful for AMR surveillance. This international network involves three tiers with the highest level supra-national laboratories setting standards, and providing a specialist testing service (e.g. genotyping) and technical assistance to other laboratories in the network which themselves are selected according to pre-defined criteria.

Overall the models we have identified, which are mostly from disease-specific programmes, suggest that a combination of training, supervision, site visits and panel testing for laboratories will provide the best way of ensuring an effective AMR surveillance system. To achieve this, the laboratories need to train, retain and motivate skilled staff. Each laboratory should operate within a tiered laboratory network with clarity around reporting channels, and the roles and responsibilities of all those involved. Strong commitment by government is needed to establish and coordinate an effective AMR surveillance system across a country, to ensure appropriate linkages with international bodies and to coordinate activities of the private laboratories and external donors.

This was a three-month study commissioned under the theme of '*An analysis of approaches to laboratory capacity strengthening for drug resistant infections in low and middle income countries*'<sup>1</sup>. It complements the work performed at the same time under the theme '*Supporting surveillance capacity for antimicrobial resistance: Regional Networks and Educational Resources*'. As the studies were conducted in a short time frame it is recognised that they are not entirely comprehensive; they are intended as starting point to help inform the UK government and its partners of areas of greatest need and how it may best build laboratory and surveillance capacity in LMIC contexts. This is an independent study commissioned by the Wellcome Trust and funded by Department of Health as part of the Fleming Fund.



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<sup>1</sup> <http://europepmc.org/grantfinder/grantdetails?query=pi:%22Bates+I%22+gid:%22202960%22>