Report

Fleming Fund: supporting surveillance capacity for antimicrobial resistance

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

**Russell Dacombe, Imelda Bates, Minakshi Bhardwaj, Selina Wallis, Justin Pulford**

**Capacity Research Unit,**
**Liverpool School of Tropical Medicine**

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# A. Executive 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.

# B. Introduction

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 surveillance in different contexts. This report covers six activities:

1. Identify laboratory-strengthening models through a systematic review of the published and grey literature and through consultation with existing contacts in LMICs and relevant research and development organisations.

2. Assess the strengths and weaknesses of each laboratory capacity strengthening model against a study-specific evaluation matrix.

3. Produce a report comparing and contrasting each laboratory strengthening model according to the evaluation matrix, identifying contexts in which each model has been successful and presenting barriers and enablers present in different contexts.

4. Identify different approaches for monitoring emergence and spread of resistance in different country settings, including the range of baseline data gathered.

5. Assess the different approaches to monitoring resistance in each country and determine the best models and mechanisms for surveillance, capacity strengthening and training in the different country/regional settings.

6. Produce a report documenting the different approaches for monitoring emergence and spread of resistance in each country and present the best models and mechanisms for surveillance, capacity strengthening and training in each.

The short project duration necessitated a focus on broad, high-level data to provide an overview. We have supplemented this with more detailed data collection for selected countries and from individuals. Much of the information collected applies to general laboratory activities but is also relevant for surveillance systems. To provide more in-depth information about how different surveillance models operate in different contexts, we have conducted a comparison of antimicrobial surveillance systems based on site visits to three LMICs. These countries - Ghana, Nigeria and Nepal - were selected because they represented at least two different continents and included a 'fragile' state. (see separate LSTM CRU report 2016 '*Supporting Surveillance Capacity for Antimicrobial Resistance: Regional Networks and Educational Resources'*)

# C. Methodology

## 1. Literature Search

### *1.1 Search strategy*

There are very few publications specifically focusing on anti-microbial resistance (AMR) surveillance laboratory activities, networks and systems. Publications with potential descriptions of, or references to, general laboratory capacity strengthening were therefore sought since these would also apply to AMR capacity and specific AMR-focused information was identified when available. Information was obtained from a search of the Medline, Web of Science, Global Health, PubMed, Google Scholar databases. The reference period for the search was January 1996 to June 2016. The search was limited to English language publications and was conducted using the following terms: laboratories, capacity strengthening, capacity building, scale up, accreditation, developing countries. Additional laboratory capacity strengthening publications were sought through a manual search of references listed in retrieved articles. A standard Google search was also conducted to identify the web presence of laboratory capacity strengthening initiatives and any associated documentation.

### *1.2 Model identification*

Retrieved publications, documents or reports were examined for references to laboratory capacity strengthening (including AMR-specific programmes) in low-middle income countries (LMIC) context. In the first instance, publication/document/report titles, abstracts and key words were reviewed against the following inclusion criteria: were within the reference period and had been implemented in an LMIC. When all selection criteria were present, publications/documents/reports were kept for full text review or excluded if they did not meet all stipulated selection criteria. All laboratory capacity strengthening models identified during the course of the full text review that related to LMIC were recorded on a specifically designed excel spreadsheet. In addition, LSTM staff sent formal requests through their existing professional networks to identify relevant laboratory capacity strengthening initiatives. Key informants (described below) were also asked to identify relevant initiatives and documents. Any additional LMIC laboratory capacity strengthening models identified were added to the excel spreadsheet.

### *1.3 Data extraction*

The research team developed and piloted a data extraction matrix designed to capture the information necessary to analyse each of the identified LMIC laboratory capacity strengthening models. The components of the data extraction matrix focused on specific topics for analysis including the geographical and political context, methodology used, enablers and barriers, indicators for success and the

evidence for these indicators being met. Research team members reviewed all documents pertaining to each of the identified LMIC capacity strengthening models and mapped information onto the data extraction matrix.

### 2. Key Informant Interviews

Key informant interviews (KIIs) were conducted with purposively selected laboratory capacity strengthening experts from international agencies and practising senior laboratory staff (managers and scientists). Potential KIs were identified during the literature search, through existing professional networks and by other key informants (i.e. 'snowball' recruitment). An introductory email was sent to all prospective KIs informing them about the study aims, requesting their participation and then inviting them to identify a date and time for possible interview. Prospective KIIs who did not respond to the email invitation were subsequently contacted by telephone, informed about the study and invited to participate. All interviews were conducted by telephone and Skype and followed a specifically-designed structured topic guide. The topic guide covered experiences and examples from their direct involvement in laboratory capacity strengthening programmes, types of activities, outcomes and challenges of the programme, and sustainability issues. KIIs were audio recorded when possible and when permission was granted and detailed written notes taken. The recordings were used to check the accuracy of the handwritten notes. KII data were entered on a study specific excel spreadsheet for subsequent analysis (further information is in annex 1).

## D. Findings

This section presents an overview of the findings including the major types of laboratory capacity strengthening models relevant for AMR that we found in the literature and through our expert interviews. The type of studies identified and their geographical coverage is summarised in annex 2. Models were grouped according to the three levels of operation for capacity strengthening, individuals, institutions (i.e. laboratories) and societal (i.e. national, regional and international) (2). Capacity strengthening models at lower organisational levels were often used as part of larger models at higher levels. For example training is present in the majority of models at all organisational levels. In some cases elements of some models at societal level were required to support lower level models. For example international external quality assurance (societal) is required for accreditation (organisational).

### *1. Overview of laboratory capacity strengthening models presented in the literature.*

Thirty thousand four hundred and eighty papers (including duplicates) we found after searching all five databases. Five hundred and thirty three papers were selected for abstract review and sixty papers were selected for data extraction.

The methods used in the studies identified were either narrative, time series or 'before and after' the intervention, which means that the level of evidence was low or very low for the effectiveness of the models described. Many papers described the delivery of multiple components making the assessment of the relative effectiveness of each component difficult.

### *2. Models focused on the individual level*

The predominant model for the capacity development of laboratory and related staff was training. Studies focused on individual level models are summarised in annex 3.

**Training**
Training of staff was often part of a larger capacity development model and will be discussed as part of those models. However there were a number of papers that concentrated exclusively on delivering training. These are described below according to the type of training.

**Field Epidemiology and Laboratory Training Programmes**
Three papers looked at a specific programme, the Field Epidemiology and Laboratory Training Programme (FELTP). The first FELTP started in Kenya in 2003 as a 2-year regional public health leadership programme(3). It initially covered Kenya, South Sudan, Ghana and Tanzania but has now expanded to cover 15 countries in sub-Saharan Africa. This has been achieved by franchising the course to institutions in other countries; there are now 10 FELTPs. The course focuses on four major scientific domains: epidemiology, public health surveillance, biostatistics and scientific communication. Students undertake short and long term placements in public health.

The Nigerian FELTP was reviewed from 2008-14 (4) assessing numbers of students enrolled and their involvement in key public health activities (e.g. outbreak response, polio eradication and surveillance). The assessment also considered the number of papers presented at conferences and examples of grants awarded. This was considered to demonstrate that course graduates were being used by the health system but the impact of this involvement was not specified. The cost of each FELTP was estimated at US$1-2 million comprising resident costs (e.g. research, books and tuition), programme costs (e.g. travel, supervision visits), technical support (CDC, Atlanta) and resident advisor salary (5).

**Short courses**
Two papers detailed short courses with specific outputs. On was an integrated management of malaria course (6) and one was to establish a system for monitoring the accuracy of results for commonly performed tests (7).

For the malaria course laboratory staff were assessed on the quality of the malaria slide and the sensitivity and specificity of the blood smear result. Participants were followed up at 6 weeks, 12 weeks and one year. All three indicators improved significantly at the first follow up and both sensitivity and specificity continued to

improve up to one year. The evaluations were combined with support supervision visits which involved the reinforcement of training and helped to achieve the results.

For the course for monitoring accuracy, supervisors trained laboratory staff over 18 months in common tests. During the last 6 months the accuracy of 11 tests were monitored which showed improvement in the accuracy of all tests.

A third paper presented a web based training tool for improving the accuracy of immunohistochemistry. The study measured concordance between a US and Nigerian based institution after an initial exchange of samples. Web conferences were then held to discuss discrepancies between the two institutions. On a follow up exchange of samples concordance improved (8). A fourth paper looking at cytology training was purely a description of the course so it was not possible to assess an impact (9).

From these examples repeated training courses delivered in conjunction with regular supervision appear to be effective at improving the skills of individual laboratory staff.

### *3. Models focused on the institutional (i.e. laboratory) level*

Studies that focused on strengthening laboratories (i.e. institutional level) areas summarised in annex 3. The majority of laboratory capacity strengthening papers focused on the testing and management of HIV or tuberculosis with funding primarily from USA sources (CDC and PEPFAR). The main focus of laboratory strengthening for individual laboratories was for tertiary medical laboratories to obtain and sustain ISO15189 accreditation. The core elements covered by ISO15189 are given in annex 4. For veterinary laboratories it was the related standard ISO 17025. Meeting the requirements set out in these standards means the laboratory has a functional Quality Management System (QMS) fit for use for medical/veterinary laboratories. QMS ensure that the services provided by an institution meet the requirements of the user. For diagnostic laboratories this focuses on accurate and timely results.

Capacity strengthening at primary or secondary level focused on improving the physical infrastructure and training staff in specific testing methodologies and good laboratory practice (GLP) and the establishment of quality assurance systems (QA) to monitor the quality of service. The establishment of QA systems is covered in section 4.

Approaches to strengthening the capacity of laboratories used a combination of the following components:

1. Inclusion of capacity strengthening of laboratories in policy documents
2. Engagement of laboratory management
3. Gap analysis of laboratories' capacity
4. Improvement planning

5. Physical infrastructure upgrading (buildings and equipment)
6. Human resource upgrading (training, restructuring)
7. Developing quality management systems
8. Monitoring quality (internal and external)
9. Accreditation
10. Sustaining accreditation

The degree to which it was possible to implement these components depended in part on the size of the laboratory, managerial commitment, funding and external structures such as procurement and servicing. The details of each component are discussed in the following section.

## 3.1 Laboratory capacity strengthening components

### 3.1.1. Policy documents

Many elements required for laboratories to become successfully accredited (e.g. procurement, hiring staff) are often beyond the control of the laboratory and cannot be achieved without higher-level support. A favourable policy environment where national laboratory strategic plans and guidelines for ISO15189 accreditation are endorsed and supported politically and financially were important for success (10, 11). However factors such as the decentralisation of services and the fragmentation of responsibility for laboratory services across multiple groups or government departments can block the implementation of these policies (12). The presence of a steering or advisory group for medical laboratories is useful to support the process of accreditation(13).

### 3.1.2. Engagement of laboratory managers

Accreditation requires alterations in the management structure and oversight from senior management as well as full commitment from the laboratory management team and higher-level institutional managers. Laboratories that sought ISO15189 accreditation independently generally achieved it quicker (1),(14) that those that were encouraged by external partners (15) indicating that management commitment is an important factor in driving accreditation.

### 3.1.3. Gap analysis

The majority of laboratories report undergoing a gap analysis using an external auditor either procured from a commercial supplier or provided by a donor funded programme (e.g. PEPFAR). Some accreditation projects used self-assessment checklists combined with support from external experts through activities such as workshops to help interpret the data generated. Evidence suggests that external input is important since unsupported use of the self-assessment checklist might lead to erroneous interpretations of compliance to the standard (16).

A baseline gap analysis was seen as critical for enabling laboratories to prioritise and address gaps. Regular audits were generally used to assess progress. Most gap analyses focused on benchmarking current laboratory systems against quality standards such as ISO15189 or a national equivalent.

Njelesani et al (17) developed a set of tools for identifying strengths and gaps in neglected tropical disease (NTD) regional laboratory systems. The tools incorporated ISO15189 standards but expanded this toolkit to document the laboratories' role in providing national and regional services to NTD control programmes (e.g. training and EQA) and participation in relevant networks and collaborations. This toolkit was implemented in four LMIC NTD laboratories to support the development of collaborative, individualised capacity strengthening plans and to track progress.

### 3.1.4. Improvement planning

Laboratories that achieved accreditation formulated plans to prioritise activities to meet the requirements of the standard. These plans were regularly revised as activities were conducted and the systems and capacity improved.

### 3.1.5. Physical infrastructure upgrading (buildings and equipment)

This component covers the construction and refurbishment of laboratory buildings at all levels of the health system. Improvements were made to accommodate new testing (e.g. molecular), stabilise utilities (i.e. electricity, water, communication), improve safety for staff and the public (e.g. signage and restricted access), environmental control (i.e. temperature and humidity), and to increase and modify space (e.g. to accommodate increased testing, specimen and record archiving, improve workflow and provide training).

This component includes equipping of laboratories to allow new or improved testing (e.g. automated blood culture), improved safety (e.g. fire extinguishers, autoclave) and security, introduced or expanded specimen and reagent storage (e.g. refrigerators and freezers), data transmission and storage (e.g. computers) and stabilised power supply (e.g. generator).

This infrastructure upgrading was often a very costly and time-consuming element of the process of capacity strengthening especially for laboratories needing a high specification, such as biosafety level 3 (18).

### 3.1.6. Human resource upgrading (training, restructuring)

Successfully accredited laboratories had all appointed a quality officer or unit to guide and monitor the process of accreditation. A full time quality manager was seen as important to drive the development of a QMS (11). This position is required by ISO15189 to be independent of the laboratory management structure, reporting directly to the head of the laboratory. ISO15189 also requires the establishment of other positions, such as a biosafety officer, all of which require significant investment in staff time and training.

A lack of detailed knowledge amongst laboratory staff and management around quality issues was commonly observed. Regular training for all staff was seen as important in establishing and maintaining a culture of quality within the laboratory (1), (19) . In some cases an external advisory group was formed to guide and monitor

progress (1). The WHO in collaboration with other partners has developed tools to support training in QMS (see section 3.5).

### 3.1.7. Developing and monitoring quality management systems

Once staff have received training and the management structure for QMS has been established, laboratories were able to put in place systems for monitoring and improving quality. Implementation was generally a stepwise process based on 'plan, do, act, and check' cycles characteristic of improvement planning (Section 3.1.4). Tools are available to support this process and examples are given in Section 3.5. Continuous benchmarking and formal documentation of progress against international standards could be a motivating factor for maintaining laboratories' commitment to progress to accreditation(11). Enrolment in international proficiency testing is a requirement of ISO15189. International schemes can be expensive so some countries, such as Thailand, India, Jordan, Pakistan and the Caribbean region have established their own schemes (11, 16, 20-22).

### 3.1.8. Accreditation

#### *3.1.8.1 Clinical Laboratories*

ISO15189 was the most common standard used by laboratories seeking accreditation (23). Countries such as Thailand, India and Argentina have developed and introduced their own national standards based on ISO15189 (21). However in Thailand only 80% of the standard's requirements have to be met to achieve accreditation, whereas for ISO15189 all have to be met. There were examples of both internally and externally initiated (e.g. donor) decisions to become accredited. Data from the literature indicated that accreditation took between 2-10 years with externally initiated processes taking longer. The lack of accrediting bodies within many LMICs is a barrier to timely accreditation. The increase in laboratories seeking accreditation has placed a strain on the accrediting bodies in some regions (e.g. South African National Accreditation System) and sourcing accreditation visits out of country also increases costs.

Other accreditation systems also exist such as the WHO accreditation scheme for polio laboratories and good clinical laboratory practice. Though the specifics of the standards vary they all have the same underlying principle of establishing a functional laboratory QMS.

#### *3.1.8.2 Veterinary*

Veterinary laboratories use the World Organisation for animal health (OIE)[1] standard (based on ISO 17025:2005) for accreditation but we could not find any published accounts of laboratories working towards this standard in LMIC. The OIE operates a twinning programme between its reference laboratories and LMIC partner laboratories. These projects address specific diseases but also broader issues such as improving diagnostic capacity. All projects are required to advance the

[1] http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/projects_completed_underway.pdf

partner laboratories to meet OIE standards. Currently LMIC with OIE accredited reference laboratories are: South Africa, Mexico, Argentina, Cuba, Thailand, Botswana, Senegal, Russia, Morocco, China, Brazil, India, Chile, Panama, Iran, Hungary.

## 3.2 Challenges in achieving and maintaining accreditation

In this section we present the challenges to achieving and maintaining accreditation present in the literature and raised by key informants. There is very little published evidence on how to sustain accreditation. The majority of published literature focuses on how laboratories can achieve accreditation, though as more laboratories become accredited more evidence may become available. Laboratories that did report on sustaining accreditation were private or donor funded (1), (14).

### 3.2.1 Adequate skilled staff

The process of accreditation is very labour intensive requiring the involvement of many staff in the development of documentation and increasing their time spent on recording requirements and other procedures. This, and the stringent infrastructure requirements, is partly the reason that ISO15189 accreditation has so far been limited to well-staffed tertiary level laboratories in LMICs.

The training given to laboratory staff to equip them to support accreditation also means they are highly attractive to other laboratories within the same sector and makes retention of these staff difficult (1). Skilled laboratory staff in many LMICs are in demand and there often exists a national market where both the private and non-governmental sector compete with the public sector for a small pool of staff (24). This movement of staff has been responsible for some laboratories being unable to maintain progress (25). However if they can be retained, these staff are a valuable asset for maintaining accreditation. Performance-based financial incentives have been raised as a possible way to retain staff (26)

### 3.2.2 Equipment maintenance/servicing

Equipment maintenance is often highlighted as a barrier to achieving accreditation. Many countries lack in-country expertise required to service laboratory equipment and have to source expertise internationally which is expensive and can lead to delays in servicing(27). A recent survey of eight microbiology laboratories in Kenya, including two reference level facilities, indicated that none of them had services contracts in place(28).

Better training and retention of biomedical engineers in LMICs has been raised as a potential solution to this issue.(29) Three papers specifically focus on the training of biomedical engineers. Abimiku (30) et al describe centralised training of biomedical engineers to support the PEPFAR funded ACTION programme in Nigeria which supports HIV diagnosis and management. This periodic training was done in collaboration with manufacturers. No results on the impact of this on equipment function were presented.

Hamel et al (31)describe the training of biomedical engineers in Nigeria to support HIV diagnosis and care. In this intervention on-site engineers were trained and provided periodic scheduled maintenance of equipment. The engineers received additional specialist equipment training out of country. The programme was reported to reduce equipment downtime and manufacturer service call outs, and increased the timely use of test reagents.

Makin and Keane analysed equipment repair requests from 60 hospitals in 11 LMIC where US trained biomedical engineer volunteers had been placed(32). These volunteers were able to put 72% of equipment back into service without imported spare parts. 99% of repairs were covered by 6 domains of knowledge (electrical, mechanical, plumbing, installation/training, power supply and motors). They found that only 107 skills would be required to get 66% of equipment back into service without the use of imported spare parts and presented a simplified training curriculum. Though this programme was not focused on laboratories, many items of equipment critical to an AMR laboratory were listed (e.g. microscopes, incubators, autoclaves). Investment in biomedical engineering capacity would have a wider impact on hospital services in addition to AMR and reduce costs associated with equipment malfunctions. However there is a risk of high turnover of trained staff highlighted by Abimiku et al(30).

#### 3.2.3. Procurement systems

The majority of laboratories in the public sector in LMICs do not have control over procurement. For those that do, a lack of in-country suppliers for specialist equipment and stringent and complex procurement regulations can result in very long lead times (1, 11). It is recommended that this be assessed as part of any initial capacity gap analysis (15).

#### 3.2.4 Funding

Laboratories that have achieved accreditation have either been private or donor funded laboratories. For the laboratory accreditation process to be successful it is important that the total cost of achieving accreditation is guaranteed up front. The large variability in time and resources required for laboratories to achieve accreditation makes securing these funds difficult. Also without direct budgetary control, the efficiency savings gained by implementing a QMS may not be properly documented or passed onto the laboratory.

### 3.3 Impact

A number of impacts from laboratory accreditation are described in the literature and these are summarised below.

#### 3.3.1. Reduction of wastage

Accredited laboratories report a decrease in wastage of laboratory materials such as reagents (1) that can contribute to, or entirely offset, the cost of accreditation (14).

### 3.3.2. Reduction in complaints

The improvements in reporting times and the reliability and accuracy of results has been attributed to a reduction in complaints. In Kenya, a reduction of 82% in the number of complaints was observed in the first 12 months after accreditation in Kisumu (1) and a similar reduction occurred at the Aga Khan hospital (14).

### 3.3.3. Improvement in pre-analytical, analytical and post analytical metrics.

Laboratories report significant improvements in these metrics (1), (14), (33). This is unsurprising as the purpose of a QMS is to monitor and improve these metrics.

### 3.3.4. Increase in demand for services

Laboratories report an increase in demand for services due to a perceived improvement in the quality of service(1) .

### 3.3.6 Improved human resources

As well as the generation of a highly skilled workforce in the laboratory, accreditation was noted to have fostered a better relationship between the laboratory and clinicians(14). This was thought to be due to the emphasis in the accreditation process on establishing clear communication with clients.

## 3.4 Costs associated with laboratory accreditation

Costs obtained from the literature are detailed below. All costs are adjusted for inflation[2].

### 3.4.1 Costs for accreditation

| Component | Source and cost (USD) | | | |
|---|---|---|---|---|
| | **Zeh et al (1) Kenya** | **Kibet et al (14) Kenya** | **Opio et al (13) Uganda** | |
| Gap analysis | 69,519 | - | | |
| Training | 35,223 | - | | |
| EQA | 16,372 | - | | |
| Accreditation | 19,070 | - | | |
| LMIS | 5,793 | - | | |
| Temperature monitoring system | 758 | - | | |
| **Total** | **146, 630** | **96,120** | **57,932 – 115,865** | |

### 3.4.2 Costs of sustaining accreditation

[2] CPI Inflation Calculator http://www.bls.gov/data/inflation_calculator.htm

| Component | Source and cost (USD) per year | | |
|---|---|---|---|
| | Zeh et al (1) Kenya | Kibet et al (14) Kenya | Elbireer et al (34) Uganda |
| Training | 15,293 | - | 2,591 |
| LMIS | 5,793 | | 3,872 |
| Preventative maintenance | | | 49,116 |
| Office supply costs | | | 608 |
| Personnel time | | | 97,077 |
| EQA | 24,558 | - | 23, 469 |
| QA reagents | | | 391,374 |
| Process improvement activities | | | 7,348 |
| Internal/external comparison testing | | | 1,180 |
| Accreditation | 35,478 | - | 17,380 |
| Temperature monitoring system | 1,307 | - | - |
| **Total** | **82,430** | **32,040** | **594,098** |

The lower cost of accreditation experienced by Kibet et al (14) was attributed to the availability of local QMS training where as Zeh et al (1) had to source training from outside the country. The costs in the Elbireer et al (34) study were seven times higher than Zeh et al (1), representing 32% of total laboratory expenditure, because they included many more components.

Kibet et al (14) stated that improved efficiency offset the cost of maintaining accreditation and estimated the cost savings to be $42,000 similar to the figure of $37,000 estimated by Elbireer et al (34). It is important to note that both of these laboratories required minimal physical infrastructure upgrades which could be a significant proportion of the costs for laboratories with less modern infrastructure.

### 3.4.3 Infrastructure, human resource and reagent costs

| Laboratory Type and Infrastructure Component | Source and cost (USD) | | | | |
|---|---|---|---|---|---|
| | Herva et al (1999)(35) Philippines | Paglia et al (2012) Tanzania | Paramasivan et al (18)* Lesotho | Dacombe et al (36)* Malawi | |
| Laboratory type | Microbiology | TB | BSL-3 | BSL-3 | |
| Equipment | 24,025 | 7,647 | 75,321 | 88,966 | |

| | | | | | |
|---|---|---|---|---|---|
| Building improvement | - | - | 107,754 | 148,039 | |
| Technical Assistance | 26,010/year | - | | 55,331 | |
| Reagent costs/year | 19,495 | | 324,421 | | |
| Human resource/year | 40,828 | | 104,778 | | |

* These studies look at the costs of setting up Bio-Safety Level 3 laboratories that have a high specification and construction costs.

### 3.5 Available tools and support for accreditation

The Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) tool was developed in 2009 by the World Health Organisation (WHO) to help laboratories to progress towards ISO15189 standard (19, 37). It is essentially a checklist to score compliance with ISO15189 using a five star system, with five stars indicating the laboratory is ready for assessment by an accrediting body (annex 5). The African Society of Laboratory Medicine is supporting a cadre of assessors to visit laboratories and certify their progress through the SLIPTA five-star system. A similar process is in place for blood transfusion services organised by the African Society for Blood Transfusion.

SLIPTA is supplemented by the Strengthening Laboratory Management Toward Accreditation (SLMTA) training model. It is directly linked to the SLIPTA audit process and provides educational material on QMS to help accelerate progress towards ISO15189(38-40). In 2014 the WHO launched an online tool, Laboratory Quality Stepwise Implementation (LQSI) tool to support laboratories aiming to attain ISO15189 accreditation (41). These tools have been extensively used in both sub Saharan Africa and the Caribbean. Some laboratories have also used the six sigma metrics for monitoring progress (14).

The OIE have developed a Performance of Veterinary Services (PVS) pathway for improving veterinary services that includes laboratory components (42) and is similar to the SLIPTA model. The pathway starts with the OIE conducting evaluations of countries veterinary services including laboratory components at the request of individual countries. This is followed by a gap analysis to identify and set priories for the veterinary programme. Specific activities are then undertaken to address these priority gaps[3]. This cycle is then repeated starting with another evaluation visit.

**Twinning**

There are a few examples of twinning of LMIC laboratories with a high-income institution. For example support was provided for 2 years to microbiology laboratories in the Philippines through the provision of equipment, reagents and

[3] http://www.oie.int/doc/ged/D14095.PDF

ongoing equipment monitoring, EQA and technical expertise(35). This intervention resulted in a large increase in the number of samples processed and improvement in concordance in species identification.

### 3.6 Limitations of the laboratory accreditation process

ISO15189 is a very good framework to improve the functioning of laboratories in terms of monitoring and improving the entire testing process from sample collection, testing, reporting and disposal. However even with intensive support and good leadership, achieving accreditation takes several years. It is also costly to undertake both in cash terms and in staff time limiting its practical application to large relatively well-funded facilities. It can also be costly to maintain, though the costs of this may be offset by efficiency savings through improvements in procurement and use of resources.

The implementation of the SLIPTA stepwise model partially offsets these problems but raises its own issues. Certification by SLIPTA assessors of the stage reached by a laboratory does demonstrate progress by a laboratory towards the ISO15189 standard. However it is not in itself a demonstration of a functional QMS as the score only reflects the number of requirements met and not if those requirements function together to improve quality. The same argument can be levelled at other accreditation programmes, such as the national scheme in Thailand, which only requires 80% of the ISO15189 requirements to be met. The LQSI tool does group requirements into four logical stages but its impact on laboratory quality remains to be investigated.

Since these models focus on the implementation and maintenance of a QMS, they do not directly address broader issues that are important for capacity strengthening such the relationship and role of the laboratories with their host institutions, regional collaborations and networks, and strategic planning to expand services and sustain funding (43).

## *4 Models focused on societal (i.e. national, regional and international) level laboratory strengthening*

Societal capacity strengthening for laboratories can be conceptualised as the creation of national, regional or international networks. However the activities carried out at each level are similar. Generally the bigger the scope of the network, the less in-depth the activities to support it can be due to increasing cost.

The activities required to build and support a laboratory network that have been presented in the literature (which is summarised in annex 3) are:

1. Engagement with policymakers
2. Gap analysis of laboratories intending to join the network
3. Upgrading of laboratory infrastructure, human resources and quality management systems

4. Standardization of laboratory methods, equipment and servicing across the network
5. Accreditation and regulation
6. Network coordination and communication

Since the Maputo declaration in 2008, national laboratory networks in LMICs have been developed in line with the establishment or strengthening of a tiered laboratory network (44). A national tiered network consists of four levels:

**National Tiered Laboratory Network**

| Level | Laboratory Type | Example |
|---|---|---|
| 4 | National Reference | HIV reference laboratory |
| 3 | Regional/Provincial | Tuberculosis microscopy QA laboratory |
| 2 | District | District hospital |
| 1 | Primary | Health post/centre |

-

The Level 4 laboratories should be linked to regional or international level laboratories for the purpose of quality assurance, specimen referral and technical assistance. For example internationally quality assurance of tuberculosis testing is managed through a network of supra-national reference laboratories that act as regional reference centres.

Many disease-specific programmes have established international tiered laboratory networks for example for rotavirus (45), HIV (46), polio (47), measles and rubella (48), and tuberculosis (49). The WHO HIVResNet Drug Resistance Laboratory network provides a typical example. This network operates a three tier international structure. Specialised drug resistance laboratories set standards for the network and provide technical assistance to other laboratories in the network. Regional drug resistance laboratories function as reference centres for countries that do not have a national drug resistance laboratory and provide training and technical assistance to national drug resistance laboratories within their region. National drug resistance laboratories provide specialist-testing service (in this case genotyping services) on nationally collected survey samples. All these laboratories are selected based on pre-defined criteria established by WHO (50). This structure is generally replicated in other international disease control networks.

### 4.1. Engagement with policymakers

Many studies cited the engagement of local health and government officials as important for the efficiency and success of their laboratory networks(51). Joint planning has often be used as an approach to ensure coordination between the development of networks and the countries involved (52). The development of laboratory strategic plans with clear goals and activities has been promoted by international organisations such as WHO. Strong relationships with the national ministry of health is important to mitigate possible threats to the network such as

the redeployment of skilled staff. Insufficient political commitment and lack of skilled human resources were raised by the majority of interviewees as major challenges facing laboratory capacity strengthening efforts.

## 4.2 'Gap analysis' assessments of laboratories within a network

Questionnaires are often used to analyse capacity gaps of large numbers of laboratories in a network (33), such as large multi-country networks, and are generally sent to a contact person within the laboratory to complete (17, 53). In one study in Thailand a QMS self-assessment was evaluated with follow up visits by the national accreditation body(16). This showed significant differences between the self-assessment and the accreditation visit indicating that the self-assessment approach may not be an accurate way of assessing the functionality of laboratory systems.

For networks involving smaller numbers of laboratories, site visits similar to the assessments used for institutional capacity have been conducted using tools such as checklists (28, 30, 52). Although time constraints mean these are often less detailed than the ones used for accreditation assessment they can be used for monitoring and evaluating laboratories in a network over time.

## 4.3. Upgrading of quality management systems, laboratory infrastructure and human resources

### 4.3.1 Establishing EQA systems

EQA is critical for a laboratory to be able to monitor and demonstrate the accuracy of its testing. Three types of EQA systems were identified from the literature and are summarised below.

***Panel testing***

Nine papers describe the setting up and/or operation of EQA programmes that involve a central laboratory sending samples to recipient laboratories which they test using their routine procedures (panel testing)(45, 48, 54-60). The laboratories send the results to the central laboratory which compares laboratories' results with the true results. Many EQA programmes look for concordance among participating laboratories to check the accuracy of the central laboratory's own results. Feedback is sent to participating laboratories about their performance but in some schemes, there may be significant delays. Since these systems can only detect errors but not the cause, laboratories that do not perform well are expected to have mechanisms in place to identify problems and take remedial action.

When EQA panel testing has been implemented as a stand-alone intervention without any supervision or remedial processes, it has not been shown to improve performance. However panel testing can be scaled up relatively easily making it ideal for EQA programmes requiring an international scope. When combined with other interventions such as on-site supervision and repeat training it is an important way

to achieve and monitor changes in performance of an individual laboratory and a laboratory network and could be applied in the context of AMR surveillance. The cost for the 2016-7 enrolment in the NEQAS AMR EQA is £402.

***Blinded rechecking***

Another model of EQA presented is the blinded rechecking of sample results by a second (normally higher tier) laboratory. This is most commonly used for slide based diagnosis (e.g. tuberculosis and malaria) but has also been applied to antimicrobial susceptibility testing (AST). Blinded rechecking can provide feedback to laboratories but like panel testing, time delays may be significant. Feedback will be non-specific as only the error can be detected in these systems not the root cause.

***Supervision***

Supervision of testing sites involves periodic assessment visits to each site by supervisors and has been used extensively in HIV, malaria and tuberculosis programmes(61-64). It is used in international networks such as the global rotavirus surveillance network (45). Supervisory visits enable the entire QMS of the laboratory to be assessed (generally using a standardised checklist) and has the potential to give rapid feedback to specifically address any root causes of errors that have been detected. Results of blinded rechecking of tuberculosis smear microscopy centres receiving on site supervision have shown an increase in laboratories with no errors detected. An HIV programme in Nigeria showed a significant reduction in sites registering non-conformities after the introduction of supervision combined with training and renovation (30). A HIV study involving laboratory supervision in 5 LMICs also demonstrated a similar reduction in errors over a four-year period (65). This suggests that on-site supervision does have a positive effect on testing quality. However due to the transport and personnel costs routine supervision may be expensive to operate and therefore can be difficult to sustain.

**4. 3.2 Training of staff**

Training of staff across a network of laboratories has been achieved using a number of different approaches alone or in combination(26, 66). These have included self-training using e-resources (67), on-site training (68) (26, 69, 70), centralised in-country training (26, 60, 66) and out-of-country training (65, 66, 69, 70). For technical and QMS training(30) the most common combination was centralised training followed by on-site training often combined with supervision visits. On-site training was preferred, as it did not take staff away from their workplaces.

In conflict zones centralised training has the advantage of providing training in a secure environment (66) with less risk to trainers though for participants, travel in conflict zones may pose additional hazards. Centralised training can also provide introductory technical training on a new technology platform before it is rolled out(51). However delays in roll out may reduce the effectiveness of this training since new skills will be lost quickly if there is no opportunity to use them in practice. Centralised training can also be structured to allow the sharing of experiences between groups in different locations. (31, 69)

Large country programmes have established in-country training centres housed at tertiary level facilities (26, 30) and trained a cohort of in-country trainers ('training of trainers') who are able to conduct on-site training (26), (66). Large regional training centres can also provide specialist laboratory training. For example, the African Centre for Integrated Laboratory Training, South Africa (26) focuses on technical training for tuberculosis and HIV but also provides general courses on QMS, biosafety and strategic planning. The application process involves in-country CDC laboratory directors.

### 4.3.3 Laboratory Infrastructure

Most national laboratory strengthening programmes involved some upgrading of physical laboratory infrastructure (29-31, 51, 65, 66). Many found the process time consuming and costly. Example costs of laboratory renovations are given in section 3.4. In Peru the upgrading of the tuberculosis network infrastructure was delayed by around 6 months due to government requirements (29). A trial in 5 LMICs reported that it took 2 years to renovate laboratories (65). In Peru local experts were trained in the design of laboratories to sustain the expansion of the network.

### 4.3.4. Standardization of laboratory methods, reporting, equipment and servicing across networks

#### *4.3.4.1 Standardization of methods*

Many networks develop standard operating procedures (SOPs) for common processes across the network such as testing and sample referral(45, 65). These are often produced by the networks' high level reference centres giving the advantage that the SOPs will be in-line with the latest knowledge. This also reduces the workload on less well staffed national and sub-national laboratories and allows for standardisation of training and reporting(51). Standardization of reporting is critical to ensure that the data the network generates can be validated and analysed. Many networks have introduced common electronic laboratory management information systems to address this (52, 67) and to help monitor QA (65). Staff training and routine validation processes are important components of these information systems.

#### *4.3.4.2 Integration of laboratory activities across vertical disease programmes*

Integration has been discussed as an opportunity to build on disease-specific investment in laboratory services, particularly in relation to HIV (26), for the benefit of other diseases. The expansion of activities which were initially set up as part of disease-specific programmes, such as on-site supervision, specimen transport, EQA and accreditation programmes, and staff training to incorporate other diseases is likely to be cost effective (71).

A study in Nigeria proposed a model for assessing integration (72). They split integration into two domains, physical/structural and virtual/service and presented specific components to be assessed under each domain. They carried out a series of interventions in 122 facilities mainly focused on the virtual/service domain which included establishing a common management structure, training and mentorship of

all laboratory staff and encouragement of regular staff rotation, making all equipment generally accessible and serviced, nomination of a quality manager to oversee all areas of the laboratory and distribution of an electronic laboratory management information system to all sections of the laboratory. These interventions were assessed after 3 months and the proportion of laboratories demonstrating some service integration rose from 53% to 82%. Although other impacts of this integration were not assessed it does present a framework to evaluate the process of integration in countries where there has been significant disease-specific investments in laboratories.

#### *4.3.4.3. Standardization of equipment and servicing*

A number of programmes have found the use of non-standard equipment a challenge(51, 64). Heterogeneous equipment makes it difficult to standardise methods and reagents and can therefore increase the cost and complexity of procurement. Procurement regulations which are put in place to ensure fair tendering and uncontrolled donation of equipment, can act as barriers to equipment standardisation. Strong governmental leadership and commitment is required to overcome these barriers because they need to be guided by a national strategy (73).

### 4.3.5. Accreditation/regulation

For reference level laboratories in a laboratory network, accreditation is desirable and often required. The costs involved put such accreditation schemes beyond the reach of lower level laboratories in LMICs which are often better served by well-supported QA systems, possibly managed by the reference laboratories, and monitored by regular on-site visits. The SLIMTA process offers a way to encourage laboratories to progress towards accreditation but the scoring system is not necessarily indicative of a functional QMS.

Many WHO disease specific programme networks accredit laboratories using their own criteria. For example the Global Measles and Rubella Laboratory Network uses seven performance criteria focusing on the timeliness of results, EQA panel test and rechecking concordance and implementation of a specified quality control procedure(48). At national level, peer networks for the development of QMS and educational visits to accredited laboratories for staff involved in developing QMS have been shown to be helpful (16). More countries need to be supported to develop their own regulatory systems for laboratories both to promote ownership and to release the pressure on existing accrediting bodies such as those in South Africa.

### 4.3.6 Network coordination

Regular communication through virtual and physical meetings has been raised as important for the functioning of a laboratory network. The Global Measles and Rubella Laboratory Network facilitate communication through regional laboratory coordination meetings every 1-3 years. Each region also has a dedicated laboratory coordinator whose role is to work with ministries of health to support and expand the network (48).

### 4.4 Challenges

The following challenges were identified through interviews and from the literature.

- The difficulty in securing political commitment and long term funding was a concern for ensuring the sustainability of laboratory strengthening projects. This is a particular problem when programmes are supported by external donors with time-limited funding since the cyclical and relatively short nature of grants does not fit with the long term commitment required to strengthen laboratories.

- In determining the direction and activities for strengthening laboratory capacity, there may be tensions between the nation's needs and donors' agendas. The focus should be on tests of public health importance and take account of clinicians' requirements.

- Insufficient numbers of suitably trained, qualified and motivated laboratory staff in LMICs was considered a major and common challenge. Better career pathways for laboratory staff and for encouraging women into senior laboratory positions may help to mitigate this problem.

- The cost of sending samples for EQA programmes is often very high and international regulations can be difficult to navigate(74). Some networks have tried to reduce shipment costs for example by using dried blood spots, which are exempt from dangerous goods regulations(48)

- In some LMICs private laboratories play an important role but their integration into disease surveillance and quality assurance networks has proved difficult. Their inclusion in confirmatory testing schemes has met with some success (48)

- The majority of service delivery is done by laboratories in the lower tiers but they are least able to access reagents, equipment maintenance and quality assurance schemes. It is therefore important for national surveillance and case management that they are incorporated into strong national quality, procurement, training, supervision and monitoring systems

- More systematic and robust ways of measuring the impact of laboratory strengthening efforts are needed to be able to better understand which approaches are most effective and in which contexts.

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Annex 1: Data from Key Informant Interviews

| Interview Number | Programmes involved in | Types of activities carried out | Outcomes | Challenges/Concerns |
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| 1 | Involved in two types of programs. 1) Health system perspective based, looking at lab systems and networks which involves strategic planning at national level. For example in Central Asia and former Soviet regions (Moldova, Uzbek, Turkmenistan etc). 2) Current situation analysis (SWOT) - doing system assessment which has two components- system one and a facility one. Africa Society for Public health score card for lab project. JEE Project parallel with global health security agenda which involves system analysis/SWOT and also policy and strategic analysis. Better lives for better health- EQA, training curriculum in Moldova, Tajikistan, Russia. The Facility based programs focus on QM, for example- using GLI and LQIS tools and involves direct implementation in Uganda (2008-2014). Another one in Tanzania and Vietnam | strategic planning, SWOT analysis, training of the mentors, trainers, quality management | Uganda-National TB laboratory became Supra-national reference lab with ISO 15189 accreditation with South Sudan and Somalia utilising services. | Sustainability and political commitment are key concerns. Also making them realise that it is 'their (local)' Quality management not ours and that teams are there for mentoring and not necessarily implementing. The difficulties of programs like SLPTA is that it parachutes people for quick service and hence challenges to local capacity building. If implementation is successful and robust system is achieved-challenges appear in terms of expectations (request for research) and workload, raising issues with regards to staff management or generate funds. Active lab leadership/manager is critical. For example Moses, director of TB program. For policy and strategic developments, not enough funds are available, or not properly trained staff to can take up advocacy for lab management and quality assurance, most LMICs do not have specific program |
| 2 | Started with TB lab strengthening work to develop National TB Lab quality management in Uganda and Vietnam. Was mentoring project but not necessarily embedded in the NTBL work. It involved technical training for one week/four times a year. It also involved distance monitoring, bringing TB labs for ISO15189 accreditation standards. The Global | | | Until Ebola happened lab capacity strengthening was not a major priority for the governments. Developing tools is not a major challenge but implementation is. Human resources are key concerns- work overload, continuity, and keeping |

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| | Laboratory Initiative (GLI) for TB was initiated to provide development and uptake of practical guidance and tools for high quality TB diagnostic networks. It provides a roadmap for taking step by step process for QM systems in TB. The GLI tool led to development of LQIS which is free tool in the form of a website that provides a stepwise plan to guide medical laboratories towards implementing a quality management system in compliance with ISO 15189. LQIS is more generic in nature, and contains a checklist that countries can flexibly adopt to their needs, and can be translated. Also provide training of using LQIS, introducing QM systems on site in different countries. Since ISO is expensive and difficult to achieve, the focus is only at national level or regional level labs. At primary health level- standardisation of tests, carrying out preanalytical assessment is important. Technical Assistance at lower levels is difficult as it depends on several other factors (context based). Donor money is usually only provided for national or central level | | | motivation about continuity to same high standards is very difficult. At PHC level, maintenance and supply of reagents, calibration of equipment is an issue. Equipment donation is not difficult and several organisations donate, however many times correct equipment is not received or other supply issues (reagents etc) to use equipment is not well thought. You need to work within the system you got, but challenges come from human resources- motivation of staff, political and organisational commitment. |
| 3 | 1. TB Supra national reference lab. It also has surveillance data on the emergence of TB resistance. Ref lab is linked with NRLs and provides support with QA of DST. It has formal agreements with national labs for support of new diagnostics. 2. Global Lab initiative with partner countries. 3 Expand TB involves rapid rolling out of new diagnostics at lower levels (?) | Various tools developed for partner countries such as biosafety, accreditation, effectiveness of the lab network, supporting consultants to provide training and technical assistance. The effectiveness of the programs | | WHO makes recommendations and countries roll out, costs are high and uptake of programs may not be as wide . Policy change at country level is challenging, for example GeneXpert for TB diagnosis. Ensuring sustainability is difficult- at the end of donor money, govts stop the run of the programs. The challenge is to have interventions at the lowest tier of health system, and point of care tests that are long term sustainable for local needs- where manufacturers need to optimise measurements. For example, in pulmonary TB point of care testing is an |

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| | | measured through several indicators- such as PT, improvement in case notification, RDT. | | issue. Manufacturers need to make too many manipulations with sputum samples, and quality management and biosafety needs to be maintained otherwise contamination is easy. WHO can only provide policy and implementation guidance but can not implement programs, has to rely on partners. |
| 4 | Recently have been involved in developing lab capacity in East Africa where there were gaps in TB control program (http://www.worldbank.org/en/results/2016/06/07/east-africa-public-health-laboratory-power-of-networking). Involved 5 countries- Rwanda, Tanzania, Uganda, Kenya, Burundi. All countries have high burden of disease out breaks and high burden of TB and emerging MDRTB. Designed a network of 32 labs, each country taking a lead one technical aspect. This also involved drug resistance monitoring. In last 5 years since 2009 Uganda and Rwanda have developed state of the art labs, and some got 1 or 2 stars for ISO15189 accreditation. Besides infrastructure, the project also helped in RDTs, preservice and in-service training. The network was developed on the premise of knowledge sharing between those five countries and support each other in different capacity building aspects. The harmonisation and standardisation of training programs, materials, SoPs were crucial for information exchange. Provide onsite training, training of trainers programs. FELTP is a gold standards training program for epidemiologists. ASLM focuses on strengthening lab workforce by training and certification through standardised frameworks. World Bank works only at tertiary level hospitals. It is important that the design of the programs should be simple but very focused. Offshoot research is | | | 1. Human Resources a key concern- quality of competencies is underdeveloped. Standardisation and harmonisation has a side issue of staff retention, they move to other places and there is 'labour mobilisation'. Turn over of HR is an issues. The relationships between scientists and clinicians is usually tense although things are improving, so it is preferable that programs should be integrated with hospitals.2. Measuring effectiveness and impact is very challenging. 3. Sustainability- both financial and institutional sustainability is key, maintaining capacity, and countries taking ownership of the programs and maintain capacity and create Centres of Excellence. Example of sustainability- Uganda Supranational Laboratory (NTBL) that provide support to 5 countries. Such activities require individual champions who have the drive and determination. |

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| | extremely important and powerful tool within programs to identify issues in local areas. Sometimes disease focused lab strengthening may not beneficial for expanding research. Also involved in developing lab capacity for NCDs. Phase 1 is diagnostics focused. For example- cancer related capacity. Only handful of hospitals do cancer diagnosis in urban hospitals or private sector hospitals. People arrive for diagnosis at very late stage or had very bad prognosis. Rolling out of basic pathology services at lower levels is considered. Proper biopsy and samples sent to referral labs within time is crucial. Telephathology programs are being considered using electronic computerised systems. For example- in Rwanda. Access to services, early prevention and detection of cervical cancer with other maternal health programs. | | | |
| 5 | Mixture of strengthening the service and research- combined both. 1995-2002 worked in Vietnam (UNAIDS_ in Ho Chin Minh infectious disease hospital. Based within hospital and laboratory, research lab based within routine lab- members keep rotating. New programs for supporting lab methods. For Vietnam settings very high quality lab. Same in Cambodia- children's hospital (2010-12), same setting microbial lab, introduce csf culture, culture for other things. focus on QC/QA. Similar thing currently in Philippines- infectious disease hospital in Manila, strengthening lab methods, routine testing. So working in routine diagnostic labs in different countries (Japanese govt fund) (WT fund). In Malawi and Vietnam worked on the laboratory part of the TB program to strengthen central ref labs to help them with surveillance of drug resistance of TB, and improving lab safety- physical structure and lab safety. WT funding lab research than strengthening- but can't do research without lab strengthening. UNAIDs have program | Cambodia Produced SOPs, Vietnam- training, training material, practical teaching, interpreting results. | Cambodia and Vietnam- believable results from the lab with high QA/QC. With TB in Malawi- MDRTB surveillance project, how much MDRTB was present. Completed survey. Opportunity to secure funding for refurbishing | 1. The lack of resources- in TB program, routine diagnostic labs. With WT funds in labs in Vietnam and Cambodia- able to achieve. But many labs struggle with resources to do tests or what they want to do. Resources for reagents, equipment to do safe job particularly TB labs which is big investment. 2.Access to the materials- access to QC strains, reagents. Information with regards to guidelines- for example if antimicrobial susceptibility testing that needs to be done according to guidelines. Two main system- EU system is free online and US CLSI which many use you have to pay. Labs can't pay for that and rely on old guidelines. CLSI revises every year and for each new edition you need to pay for it. |

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| | of lab strengthening for TB, for surveillance of MDRTB. Provided training at all levels (national/regional) | | lab. Vietnam- labs could do QA/QC based work (5 labs). | Labs part is often forgotten and neglected compared to the other parts of the system. Sometimes easier to focus on one labs, on national level- eg. Vietnam with 5 labs together challenging as each lab had different issues and problems, travelling around. Challenge to standardise methods across all labs. Funding and costings about national program, also within each lab- issues about what labs should be doing. One big issue with TB- safety in labs , particularly sensitivity testing, there are real risk to lab staffs. There are different approaches to address lab, for example - the lab is not perfect and completely safe from western lab point. One approach is to say that is what we got and we try to improve within the constraints of facilities available. Another approach is to say this is unacceptable. People from west criticise that it is unethical to do it in labs with limited facilities and should be based on western standards. My view is usually been first- that what ever we got lets try to make it safe as much as we can. BSL-3 level labs for developing countries are expensive to build and run and technically difficult and may not be within technical capability of local people. What WHO initially discussed that if you can't have BSL3 lab- can we have BSL2+ lab (more than BSL 2 less than BSL3). Not sure if WHO has produced new lab safety manual that |

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| | | | | suggests that. For TB lot of labs/countries struggle. One has to be realistic about what should be done. Try not to replicate western lab in resource poor settings. People do not trust the lab results in poor labs, as labs often do not have proper QC/QA. Even simple things like Malaria smear can't be done properly. So better to have a lab that can do few but good tests than lots of tests but not well. Focus on diseases of public health importance and not everything like a western lab would do. Should adapt to local situation but you can not adapt quality. have to stick to the quality. HR- salaries in govt labs not good, in Malawi- people move to private labs, or brain drain from south to north. For example a 1000 bedded govt hospital in Bangladesh did not have a functioning lab, but was surrounded by private labs increasing competition to attract patients (even entering wards) or through doctors nexus for business. Even private labs very bad quality. If you are doing surveillance for resistance, you need to also look into private labs because that is where people go. |
| 6 | Have worked previously with LSTM so LSTM aware of the programs involved in. There is a relative freedom to carry out projects of one's own interest, programs are donor driven in the US (a big limitation. Worked on both USAID and CDC funded projects. | | | Interview focussed on the different challenges in programs. USAID: programs are disease control based such as HIV/AIDS, TB, Malaria and lab component is embedded in it. CDC projects are stand |

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| | | | | alone and decided by CDC priorities rather than what is needed. Most US programs do not allow operational studies and emphasis is on service delivery, capacity building for returns. Sustainability is a concern although things are slightly changing, 10 yrs ago technical assistance and donors had to take ownership for sustainability but now countries are expected to take control. CDC started PEPFAR 1 in 2003, and PEPFAR 2 in 2008. The difficulty in PEPFAR is that it assumes that all countries should have same/similar lab conditions and ignores socio-economic and cultural conditions. The focus is on lab capacity inside the four walls of the lab, such technical development, linkages to quality management and accreditation stds etc and expect labs to come up with same stds in resource limited settings also. Example of Challenge in PEPFAR program in Kenya supported by MSH. Only oversight was provided by US and local Kenyan team was responsible for capacity building. However program was under the control of CDC, which developed national policy plan to implement taking a very top down approach without any ground work on local conditions. The focus in CDC is very much about technical component, biosafety issues. The program required training two key lab personnel at different sites who would further carry out the |

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| | | | | training for others. In Kenya despite the technical development in the labs, very hard to keep the staff motivated to carry on once the donors exit. MSH developed a leadership and management skills program for labs. It is not about labs per se but developing human resources so that there is an increased retention of staff and motivation to take ownership and capacity building from the countries. In Kenya political support and senior management support for staff motivation is lacking. WHO is dependant on donors and does not have its own money, so it focuses more on policy making, std setting. The Global lab initiative- designing tools for labs and then WHO relies on consultants to implement them locally. WHO-AFRO's lot of work is done by CDC, and although WHO West Pacific is more active but less attention is given to it. Sustainability is a key concern after donors leave. Programs are shut and countries do not take ownership for running the programs, due to the investments needed. Lab capacity strengthening is not just related to the structure of the lab alone but its sustainability requires substantial focus and planning about financial aspects- budgeting, leadership. In many poor countries the MoH rely on other ministries for budget (finance for example). Lab programs are more successful when they |

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| | | | | are embedded in system wide disease focussed programs. Access to labs is also difficult. CDC only focuses on top-half of the labs in the system and not lower levels. The idea of strengthening labs is not enough rather the focus should be about making diagnosis sustainable. For example with TB GeneXpert diagnostic technology- the tests are heavily subsidized by donors. Difference has to be covered by the countries. Lab capacity is technology focussed and most of the time staff do not meet patients. |
| 7 | Worked in WHO since 2004. Initially capacity building was integrated with infectious disease department but later created a specific unit for capacity strengthening of national labs. The focus in on epidemic born diseases just not HIV/NTD/TB/malaria. The focus has been on viral driven pathogens- H1N1/H5N1/Ebola but also have recent focus on plague and cholera. For example cholera in Haiti after the earthquake. Lyon Unit is not disease specific, Geneva unit is disease specific capacity strengthening. Take lab capacity strengthening in its entirety. Usually focus on NRLs or regional labs but occasionally hospital based labs also but diagnostic capacity strengthening only at national or provincial levels. Resistance capacity is included recently. AMR team is in Geneva but do not focus on lab capacity strengthening but we include lab capacity in our team. Within AMR- lab capacity at the interface between animal and human health. For example in Pasteur Institute a study in Cambodia focused on collecting specimens from animals (chickens?) to identify resistant strains in animals transferred to humans through food. The projects in WHO | | | Cyclical nature of grants is an obstacle for sustainability. Can not do much in one year. Only can buy equipment and reagents but to bring change in workforce/policies and programs need longer term investment and ownership for the local labs is important for sustainability.2. Many labs are more interested in research and publication with WHO rather than investing time and effort in lab capacity strengthening. 3. Sustainability is a key concern-needs lots of investment in every aspect of lab from workforce to infrastructure.4. To create market for labs-need for clinicians to understand its importance and they should demonstrate the use of lab and advocate it. Clinicians and lab managers are not |

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| | are both long and short term- depends on the donors and funding source. Major funders US govt, USAID, CDC, EC/EU, GIZ . French and Russian govts but never from DFID. Donors do not want to commit for 5 years in one attempt. Usually it is cyclical and every year grant is received. Only Gates foundation gave 5 yrs grant and followed by EC for three years. As with regards to Technical projects- 20 million USD spent in 15 years globally. Some strategic objectives have included- better organisation of NRLs, development of national lab policies, coordination of labs at national level. It involves- creating national units/bureau focusing only on lab capacity strengthening within ministries who have a lab systems information such as structure and type of lab, public and private, academic or hospital based, types of diagnostic facilities. There is a need for licencing mechanisms and registration processes for the labs. The system of twinning training/sandwiched training for researchers from resource poor countries in rich countries does not work because they go back to their local environment, difficult to identify motivated staff so onsite training with available resources is good. Immediate loss of capacity as soon as donors exit because countries do not take ownership for sustainability; and there is a dependency mode even for equipment and reagent supply (from abroad), corruption and personal interests take over a few times. Need for local supply chain and creating networks regionally. For example-in Yemen a director of a hospital lab had supply issues of reagents in his place but across the street supplies were maintained in his own private lab. Patients do not trust on lab reports also because of their quality so there is no demand and hence no importance for govt. Improvement can be brought from UHC and medical insurance for lab testing, so that patients do not need to | | | good in advocacy about labs so as to convince ministries for focus and investment. |

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| | pay out of pocket and a demand can be created for govt to oblige. Need for economic studies on demand side lab improvement. Lab strengthening not enough, how to finance labs with a focus on quality is more urgent. WHO also sends retired scientists as mentors and help labs to develop QMS systems, manuals and protocols. Another aspect of strengthening is in biosafety- developing biosafety manuals, in country guidelines and regulations.. Top 3 priorities (personally) would be-Support countries in short term, focus on mentoring doctors and coaching to scientists for lab capacity and making ministries to realise the importance of good lab data in treatment. In parallel, developing national policies and regulations for labs such as licencing only when a certain criteria is met. Third would be to develop insurance systems that include lab testing to stop out of pocket payments, create demand for lab tests so that there is an investment. Assessment of the effectiveness- by PT testing for example, accreditation achievement, number of labs participating annually in PT testing. WHO has done 12 yrs of PT testing but with catastrophic results-only one third of the labs could do proper susceptibility testing for bacterial pathogens. Reasons are same- outdated equipment, no reagents, lack of proper technical training for culturing; makes Antimicrobial susceptibility testing even more difficult. Viral labs better prepared than bacterial labs as donors focused only on viral labs as there were no vaccines or treatment for viral conditions compared to bacterial conditions for which we have antibiotics and secondly bacterial labs not important for rich countries so not big on their agenda for donation. | | | |
| 8 | GSK-Africa NCD open lab team launched a proposals back in Nov 2014 to identify projects | | | |

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| | that were undertaking more research how various NCDs impact the African patient under grant funding Go-GRAM(?). An explicit requirement of the grant was to have a capacity strengthening component. Five projects in five different institutions in Africa shortlisted (3 yrs funding) - each has capacity strengthening integrated into it by design. This could include funding a PhD or MSc as part of the project, consultancy or mentoring in particular area- for example linking GSK statistician with local statistician in research team to strengthening statistical component of an application, support and training in lab kits, advice on selection of various genetic markers. There is no standard type, we just provide support on the request. One project is started and the rest four are in the contracting stage. Each project fits in the WHO definition of NCD cluster. GSK scientists involved from the beginning- including writing a good protocol for the project. We have visited each country to establish relationship between GSK scientists and the applicant to start that person to person contact. M&E framework for each project developed, also for overall program to assess the impact of the project and impact on scientific knowledge, expertise building at individual and institutional level. Some indicators include- no. of people trained, number of training | | | |

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| | events, types and roles of people trained, no. of people enrolled in the program as a result of the grant GSK providing, number of workers trained on using equipment. Due diligence process was carried out- research environment was assessed on sites for initial start capabilities and identify what capacity building agenda of that project should be. At pregnant stage- From the institutions perspective- they were keen to portray institution in positive light that perhaps presented a risk that they might be obscuring some of the needs they might have so we needed to build a trust relationship where they were comfortable to open up. Many countries do not have experience of collaborating with private sector for building capacity. And to use private sector scientists for capacity building is an unfamiliar model for many countries so we had to convince that visits were not an audit rather to build relationship. From GSK side there were common themes (wrt to problems) that can be looked for future projects- institutional gaps (how to write good proposal, manage grant finances) and scientific gaps which GSK chose to focus on- technical support. Hoping that countries will build on training and continue after GSK exits. Trying to connect investigators with each other and try to create a network to give sustainability at the end | | | |

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| | of the three years once we finish. Encouraging south-south collaboration. Our strategy was to learn from doing and learning together, living through it. GSK working with two other funders for another set of calls on same principles- Newton fund program with South African MRC and UK have selected 7 projects in SA. | | | |
| 9 | Three different types of programs are conducted by AMREF. 1. Refresher course in laboratory services for lower level, technical staff. Conducted in Nairobi for 10 weeks, twice a year. Usually advertised on AMREF web pages, it is designed for district level or lower hospital lab workers. All disease types are focused and provide training in bacteriology, parasitology, serology, immunoassay etc. Normally 20-30 applications are received but can accommodate only 15. Participants need to find their own funds to attend.2. Medical Laboratory Practice and Management course: conducted for 5 and half months in three phases. Phase 1 involves 2 months of training and hand on practical sessions. Course material and self assessment checklist is provided for the tasks to be carried out. Phase 2 involves a two week residential training program in Nairobi using didactic approaches on leadership and mentoring. Phase 3 involves participants to develop action plans and implementation at their | training and mentoring- onsite facility based or a comprehensive program for all, designing training and diagnostic manuals, SOPs | | 1. Funding- for lower level courses where participants need to generate their own funds is challenging, even for lab management program sponsorship does not cover either local or international travels. Even after successful training implementation can be challenging because of lack of funds, therefore outcome and impact can not be measured. 2. Logisitical challenge- for lower staff training the technicians may need to close the lab for few days which is not feasible, and for international participants issues such as visas requirements, lack of proper paperwork etc are common. |

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| | respective institutions for which AMREF provides technical support. This course attracts participants from regional or national level laboratories, for example HIV/AIDS and TB referral labs and some places have put quality assurance system to lead to ISO certification. 3. AMRF carries out in country 2 weeks short courses designed based on the needs of the facilities. The trainers and facilitators provide onsite training, for example malaria microscopy. In 1997, external competency assessment of Malaria microscopy course was organised for competency assessment and also developed EQA programs at primary care levels where samples are sent with undisclosed results. | | | |
| 10 | 1. Involved several projects. With MSH- a Columbia University supported project in Rwanda, Burundi, DRC, Ivory Coast, Ghana. The focus was on HIV/TB. Work involved strengthening MoH capacity in general but also on lab techniques such as viral load. Also involved with PMTCT. 2. Another project involved was on NTB to strengthening MDRTB with Global Fund, MSH, PEPFAR. These involved both infrastructure development and renovating labs to 2nd or 3rd Biosafety levels. At central level the lab(s) were completely renovated at two levels- a city hospital and a peripheral level hospital to BSL level 3 for | | Establishment of panel testing in two hospitals in Rwanda, fully functional lab, use of GeneXpert machine for MDRTB. | Challenges are local, vary country to country. Some places need start up from scratch and other need improvement. Now PEPFAR and Global Fund do not support infrastructure development. 2. High turnover of staff, people train abroad and move abroad so we need to start again. People are dedicated to different projects or departments within the same facility so dedication for one is not there. But can't train all 3. Rwanda |

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| | TB. Capacity of NRL was developed with viral load for early infant diagnosis. And a separate Malaria molecular testing facility was created.. 5 central labs were also developed with package of testing facilities (more than TB). These involved technical training, local training with manufacturers for preventative training and standardisation of equipment across all the countries. MoUs were signed with manufacturers with annual maintenance. 3. Also involved in human resource capacity building with HIV/TB. This involved curriculum development for nurses at national level for pre-post training programs. Development of guidance on standardisation of equipment. 4. Involved in National policy on RDT for MDRTB, vertical programs for malaria/TB and focus on community level approaches. Developed lab materials for health care workers with Columbia university for rapid testing. Community level ToT program for NTBP which was a cascade program and support was provided to trainers for transport/accommodation when they cascaded training at community level. Within this program, in collaboration with Tropical Institute Belgium there was a sandwiched program to train medical doctors or scientists for BSL-3 level training for one month. In Ethiopia working with Institute of Public health to have NRL and HR capacity | | | is more organised in terms of supply and equipment maintenance compared to Ghana, Ethiopia and Burundi. No replacement or costs too high when equipment breakdown. 4. Effectiveness is hard to measure- use MSH tool for assessment which is similar to Makuto tool. MSH tool can be adopted according to the project. 5. Prioritisation of projects depends on fund and type of infrastructure needed. Sometimes also just do advocacy work which has no linkages with development of NRLs or some level labs in vertical programs. 6. Many times MoH programs have no linkages with lab development. MoH is usually dominated by clinicians who have not much interest in labs. 7. Countries do not take ownership and very much donor dependant (get used to advice from donors and technical experts) for example 68% of MoH staff in Rwanda are funded by external donors; but in |

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| | development in HIV/TB/malaria. This also involve establishing an MSc/PhD program at university hospital and sending candidates for training for sometime in specific techniques on virology, parasitology and microbiology. | | | MSH ownership is key focus on the programs. |
| 11 | Between Jan2012-Nov2014 was in WHO tech office in Lyon with lab strengthening biosafety team. Developing tools, training manuals, guidelines (QMS) , online SLIPTA tools, tool management guidelines. In country training involved assessment and training based on QMS rather than teaching basic lab techniques. How the tests should be done, SOPs, record keeping, rapid reporting tp clinicians. Provided country level training in Yemen and Sudan. The focus on the trainings have been for public health laboratories rather than clinical labs training. Majority of the cases MOHs do not understand the importance of public health labs. So we change the type of language we use for convincing ministries. For example-instead of saying that your lab achieved only 64% score on QMS which lot of ministries think is a good score, we state it means one in four samples is giving wrong diagnosis so as to convey the messages. WHO does not take money from donors if it does not wish to. However many donor agencies also have operational capacity, for example CDC who | Not involved in the assessment of the effectiveness of program. Though during the training, at the end of the session we ask for general comments and advice how things can be made better in training. WHO only provides service on request, countries sometimes carry out their | | Lack of women in lab leadership roles. For example in Yemen, Sudan, Egypt several women in the labs but most of them at what men perceived to be low level jobs. In low income countries such as Laos PDR- system is very basic so challenging to implement and train people, language barriers, infrastructure issues so even within all LMICs, situation is very different. 2. Country needs do not necessarily match with what donor wants. And as LMICs are dependant on future donations, they accept the donor money. Not an equitable partnership. For example, for one lab in Lao/Vietnam- 6 PCR were donated for 6 different diseases and working in silos . Donors sometimes also work in conflict with each other, and local labs struggle to balance different donor |

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| | can direct their own plans, plus also donate to WHO. For sustainability-local training and mentoring of the staff in good microbiology techniques. | own assessments. | | demands. Donor coercion exists. Donor money sometimes creates a patch rather than a comprehensive, systematic development of the lab. 3. WHO twinning program not very successful. The expectation that the stds of the labs in poor countries will be similar to rich countries is factually incorrect- and there is a brain drain. For example- during Ebola in Sierra Leone, people said there are more doctors of Sierra Leone outside Sierra Leone than in the country. There is a need for a system to be in place where career pathways of researchers should be tied with the grant to serve in-country for a certain period of time. ROSO- return to service obligation (as seen in Australian military). Government needs to provide an attractive environment to stop brain drain, mutual respect and appreciation, gender balance. |

Annex 2: Geographical coverage, disease context and operational level of capacity strengthening of studies found in the literature

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
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| 1 | Strengthening national laboratories health systems in the Caribbean Region | 2012 | Caribbean- St. Lucia, St Vincent, The Grenadines, Grenada, Antigua, Barbuda, St. Kitts and Nevis, Dominica, Barbados, Trinidad and Tobago, Belize, Suriname, Jamaica, the Bahamas, | HIV - PEPFAR | Societal |
| 2 | Building laboratory infrastructure to support scale of HIV/AIDS treatment, care and function | 2009 | Nigeria- 26/36 states in Nigeria | HIV/TB and Ois | Primary, secondary, tertiary |
| 3 | Animal health: harmonisation and distribution of pathogen detection and differentiations tools | 2008 | East Europe, Asia n(Pakistan/China), Middle East and Africa | animal pathogens-Transboundary animal diseases(Ringerpest, FMD PPR)CCHF | Regional and international |
| 4 | Standardisation of pathology laboratories in Pakistan: problems and prospects | 2009 | Pakistan | all | national |
| 5 | Laboratory quality improvement in Tanzania | 2015 | Tanzania | All/US Global Health Initiative (GHI) | Regional and district |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
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| 6 | Control and prevention of canine rabies: the need for building laboratory based surveillance capacity | 2013 | global | rabies | International, national and loval |
| 7 | World Health Organisation/HIVResNet drug resistance laboratory strategy | 2008 | International/global | HIV | WHO/national governments |
| 8 | Rapidly building Global Health Security Capacity-Uganda Demonstration Project, 2013 | 2014 | Uganda | TB, Cholera and Ebola/ | Primary, secondary, tertiary |
| 9 | Rehabilitaing public health infrastructure in post conflict setting: epidemic prevention and preparedness in Kosovo | 2001 | Kosovo | All infectious diseases/ WHO and IRC | Primary, secondary, tertiary |
| 10 | Strengthening tuberculosis diagnosis in a low-resource setting: experience learned in Dodoma, Tanzania | 2013 | Tanzania | TB/ | Regional |
| 11 | Non traditional security and infectious diseases in ASEAN: going beyond the rhetoric of securitisation to deeper institutionalisation | 2008 | ASEAN countries | Pandemic Influenza/WHO and national governments | National and regional |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| 12 | Building public health capacity in Afghanistan to implement the international health regulations: a role of security forces | 2010 | Afghanistan | All infectious diseases/WHO and USA | Primary, secondary and tertiary |
| 13 | Strengthening public laboratory service in sub-saharan Africa: Uganda case study | 2011 | Uganda | HIV and STIs/PEPFAR | National and regional |
| 14 | Capacity building of public health laboratories in Afghanistan: challenges and successes | 2014 | Afghanistan | All diseases/ US Naval Medical Research Unit 3 | Local and regional |
| 15 | Building laboratory capacity to support the global rotavirus surveillance network | 2013 | global | rotavirus diseases-diarrohea/ WHO | global |
| 16 | Expansion of global measles and rubella laboratory network 2005-2009 | 2011 | global | Measles and Rubella/ WHO | subnational, national, regional, global |
| 17 | Assisting cytopathology training in medically under-resourced countries | 2011 | Africa- Uganda, Nigeria, Kenya, Tanzania, South Africa | All/ | All levels |
| 18 | Impact of international laboratory partnerships on the eperformance of HIV/sexually transmitted | 2011 | China, India, Peru, Russia, Zimbabwe | HIV/STI (HSV2, syphilis, Chlamydia, gonorrhoea, | local |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | infection testing in five resource-constrained countries | | | trichonomas vaginalis/ NIH | |
| 19 | The World Health Organisation African Regional Laboratory Accreditation Process | 2010 | Africa | All infectious diseases/WHO | All levels |
| 20 | Building laboratory capacity to support HIV care in Nigeria: harvard/APIN PEPFAR, 2004-2012 | 2015 | Nigeria | HIV/PEPFAR | Primary, secondary, tertiary |
| 21 | Building capacity for the assessment of HIV drug resistance: experiences from the pharmaccess african studies to evaluate resistance network. | 2012 | South Africa, Zambia, Zmbabwe, Uganda, Kenya, Nigeria | HIV | |
| 22 | Surveillance of antimicrobial resistance in resource-constricted settings-experience from five pilot projects | 2010 | India (Delhi, Mumbai, Vellore) South Africa (Brits, Durban) | | |
| 23 | WHO global Salm-Surv external quality assurance system for serotyping of salmonella isolates from 2000 to 2007 | 2009 | Global | diarroheal illnesses/WHO | national |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| 24 | Developing laboratory systems and infrastructure for HIV scale up: a tool for health systems strengthening in resource limited settings | 2009 | Africa | HIV/PEPFAR | All levels |
| 25 | Strengthening systems for communicable disease surveillance: creating laboratory network in Rwanda | 2011 | Rwanda | All/ | all |
| 26 | Capacity building and predictors of success for HIV1 drug resistance testing in the Asia-Pacific Region and Africa | 2013 | Asia (India, China, South Korea, Japan, Thailand, Vietnam, Taiwan, Malaysia, Singapore). Africa (South Africa, Uganda) | HIV/ amfAR, Dutch Ministry of foreign affairs | All levels |
| 27 | Evidence-based approach to the maintenance of laboratory and medical equipment in resource poor settings | 2010 | China, Dominican Republic, El Salvador, Ghana, Haiti, Honduras, Nicaragua, Sierra Leone, Sudan, Tanzania, Ukraine. | | all |
| 28 | Impact of horizaontal approach in vertical program: continuous quality improvement of malaria and TB diagnostic services at primary level medical hospitals in the context of | 2013 | Ethiopia | HIV, malaria, TB/ PEPFAR | Primary care |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | HIV care and treamtment program in Ethiopia | | | | |
| 29 | Implementaiton of quality system approach for laboratory practice in resource-constrained countries | 2005 | Low resource countries | HIV/US CDC- Global AIDS Programme (GAP) | All levels |
| 30 | Working towar a sustainable laboratory quality improvement programme through country ownership: Mozambique's SMLTA story | 2014 | Mozanbique | All diseases/ WHO AFRO | central, provencial, district and health centres |
| 31 | Establishing PT scheme in developing countries: examples from Africa | 2012 | Africa | All/ German PTB | All levels |
| 32 | CLSI: building laboratory capacity in Africa | 2009 | global | HIV, TB, Malaria/PEPFAR | All levels |
| 33 | Public Health laboratory systems development in East Africa through training in laboratory management and field epidemiology | 2011 | Africa (Kenya, Tanzania, Ghana, Sudan, Uganda, South Sudan) | All infectious diseases/ | |
| 34 | The operation, quality and costs of a district hospital laboratory service in Malawi | 2003 | Malawi | HIV, malaria, TB | District level |
| 35 | Clinical laboratory networks contribute to strengthening | 2013 | Mali, Burkina Faso, Senegal | HIV, malaria, TB/French | |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | disease surveillance. The RESAOLAB project in west Africa | | | Development Agency (AFD), Fondation Merieux | |
| 36 | Improved clinical and laboratory skiils after team based, malaria case management training of health care professionals in Uganda | 2012 | Uganda | Malaria/Accordia Global health Foundation, IDI | |
| 37 | Laboratory capacity for diagnosis of foot and mouth disease in Eastern Africa: implications for the progressive control pathway | 2013 | Eastern Africa | Foot and mouth disease FAO/OIE | |
| 38 | A systmatic approach to capacity strengthening of laboratory systems for control of neglected tropical diseases in Ghana, Kenya, Malawi and Sri Lanka | 2014 | Ghana, kenya, malawi, SriLanka | NTD/DFID | |
| 39 | Training and service in Public Health, Nigeria Field Epidemiology and Laboratory training, 2008-2014 | 2014 | Nigeria | All diseases/FMOH | |
| 40 | Critical role of developing national strategic plans as a guide to strengthening | 2009 | Ethiopia | HIV/PEPFAR, Global Funds, Clinton Foundation | All levels |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | laboratory health systems in resource poor settings | | | | |
| 41 | Laboratory systems and services are critical in global health: time to end the neglect | 2010 | Resource poor countries | All diseases/PEPFAR, Global Funds, GHI | All levels |
| 42 | Country leadership and policy are critical factors for implementing laboratory accreditation in developing countries. A study on Uganda | 2010 | Uganda | All diseases/PEPFAR, Global Funds, Clinton Foundation | All levels |
| 43 | Antimicrobial resistance: capacity and practices among clinical laboratories in Kenya, 2013 | 2014 | Kenya | all infectious diseases | |
| 44 | Strengthening Laboratory systems in resource limited settings | 2010 | | | |
| 45 | Use of web based training for quality improvement between a field immunohistochemistry laboratory in Nigeria and its US based partner institution | 2013 | Nigeria | | primary |
| 46 | Strategy for strengthening scientific capacity in developing countries on | 2009 | | | |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | water and sanitation related issues | | | | |
| 47 | Improvement of Tuberculosis Laboratory capacity on Pemba island, Zanziber: a health cooperation project | 2012 | Tanzania | TB/Ivo de Carneri Foundation Italy | |
| 46 | Experience establishing tuberculosis laboratory capacity in developing country context | 2010 | Lesotho | WHO | National level |
| 47 | Capacity building in response to pandemic influenza threats: Lao PDR case study | 2012 | Lao PDR | Pandemic Influenza | |
| 48 | Medical laboratory quality and accreditation in Jordan | 2009 | Jordan | | |
| 48 | Role of Laboratories and Laboratory systems in effective tuberculosis programmes | 2007 | | TB | |
| 49 | Certification of TB culture and drug susceptibility testing laboratories through the revised National TB control programme (RNTCP) | 2012 | India | | |
| 50 | Capacity building efforts by the AFHSC-GEIS program | 2011 | global | All infectious diseases/USG- CDC, US Agency for | all |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | | | | International Development, DoD-GEIS | |
| 51 | Capacity building for zoonotic and foodborne diseases in the Mediterranean and Middle East Regions (an intersectoral WHO/MZCP proposed strategy) | 2010 | Mediterranean and Middle East | Zoonotic diseases/ | |
| 52 | Scale up of MDRTB laboratory services, Peru | 2008 | Peru | TB | |
| 53 | ASM LabCap's contributions to disease surveillance and International health regulations (2005) | 2010 | Botswana, China, Cote d'Ivoire, Guatemala, Guyana, Haiti, India, Kenya, Mozambique, Namibia, Nigeria, Rwanda, Tanzania, Thailand, Vietnam,Zambia, Zimbabwe | Infectious diseases/USAID, CDC | |
| 54 | The WHO/PEPFAR collaboration to prepare an Operations Manual for HIV prevention, Care and Treatment at Primary health Centres in High prevalence, resource constrained settings | 2009 | Sub-saharan Africa | HIV/PEPFAR | Primary care |
| 55 | POPs analysis reveals issues in bringing laboratories in | 2013 | Africa (Egypt, Ghana, Kenya, Mali, Mauritius, Nigeria, | POPs | |

| Study Number | Title | Year of publication | Country/Regional Context | Disease Context and funder | Operational level of capacity strengthening |
|---|---|---|---|---|---|
| | developing countries to a higher quality level | | Senegal, Uganda and Zambia), Central and South America (barbados, Brazil, Chili, Cuba, Ecuador, Jamaica, Mexico, Peru and Uruguay), South Pacific (fiji) | | |
| 56 | Laboratory capacity building in Asia for infectious diseases research: experiences from the South East Asia Infectious Disease Clinical Research Network (SEAICRN) | 2010 | Asia (Thailand, Vietnam, Indonesia, Singapore) | all infectious diseases (influenza in particular)/ NIH, NIAID, Wellcome Trust | National regional |
| 57 | The role of standards and training in preparing for accreditation | 2010 | | | |
| 58 | Improving quality management systems of laboratories in developing countries | 2010 | Uganda | All diseases/ WHO | |
| 59 | The SLMTA programme: transforming the laboratory landscape in developing countries | 2014 | Cameroon, Lesotho, Mozambique, Mozambique, Rwanda, Zimbabwe | WHO | All levels |
| 60 | Field experience in implementing ISO 15189 in Kimisu, Kenya | 2010 | Kenya | | national |

## Annex 3: Description of interventions and their results and impact found in the literature

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| 1 | Strengthening national laboratories health systems in the Caribbean Region(11) | Sensitisation meetings were held with MoH officials and laboratory directors. This was followed by a detailed laboratory assessment. Follow up assessment by PAHO | All the countries had capacity to carry out smear microscopy, haematology testing and clinical chemistry testing. 6 countries could perform in country HIV confirmation, 3 countries could roll out HIVRT and do viral load testing, 8 countries conducted CD4 testing. None of the countries conducted DNA PCR testing or HIV drug resistance testing. Clinical laboratory monitoring was challenging for 6 OECS countries including molecular testing, viral load quantification (fig2). Only 5.2% of the labs were accredited. All countries faced procurement and | Cumbersome process of testing and reporting results, long turn around times, Point of care diagnosis was non-existent, fewer infants receiving care and treatment. Quality assurance was weak, procurement challenges existed in all countries. There were several service interruptions leading to inaccurate diagnosis and monitoring of the patients. Tracking of the data was difficult, no standardised data collection or reporting of the results. |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | service contract challenges. None of the countries had government owned accredited lab and only 45% of the countries participated in EQA programs. Little above 20% countries had lab strategic plans or information systems | |
| 2 | Building laboratory infrastructure to support scale of HIV/AIDS treatment, care and function | Multifaceted approach included building lab infrastructure, management, and laboratory personnel training for a effective, integrated tiered referral lab network, adoption of appropriate technologies at all levels and a robust QA/QC program. | Development of 'Hub and spoke network model'. Hubs- tertiary care teaching hospitals, spokes as secondary hospitals, community clinics and health centres. Between 2005-2008 more than 237000 patients are counselled and screened for HIV and referred HIV+ clients to care, 70000 for basic care and support for HIV and 45000 for highly active ART regiments, 10000 for TB screening | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| 3 | Animal health: harmonisation and distribution of pathogen detection and differentiations tools | workshop on harmonisation and distribution of pathogen detection and differentiation tools. Involved presentation of different diagnostic tests for various animal conditions | 1. Spain- rPCR led to rapid performance, sensitive, reproducible and reduction in risk for carry over contamination. 2. Pakistan- confirmatory testing for bacterial and parasitic diseases in farm animals. | |
| 4 | Standardisation of pathology laboratories in Pakistan: problems and prospects | Narrative article | The article outlines the challenges in standardisation of labs at international level. These included lack of pathologists (2.6 per million), accessibility to medical literature and education. Import of IMDs from abroad with questionable quality assurance. No requirements for revalidation, and no federal authority for examination and certification of IMDs, No ISO 15189 accreditation | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | lab, costs of ISO accreditation but a national EQA program exists. Large number of small size labs competing with isolated large chain labs threatening business. | |
| 5 | Laboratory quality improvement in Tanzania | 1. 12 regional and district labs were selected as cohort for initial assessment . 2. Hands on activity based training was in three short sessions with three months gap. 3. Reaudit was conducted at different intervals | At the baseline assessment only 1 lab had one star which improved to 7 labs having one to three star scores. However post one year re-audit the scores declined for all labs who received stars, and only one star was received by 5/9 labs assessed. | Personal interest and commitment of lab managers and quality officer were important for success. Clarity in the intent of accreditation and worskshop was important. Importance of a mentor was critical as well as conducting intervention in local language. |
| 6 | Control and prevention of canine rabies: the need for building laboratory based surveillance capacity | a pathway for surveillance system characterised by standardisation and decentralisation, locally based coordination, interpretation and integration of differnet approaches was suggested | Proposed pathway for a global surveillance system for canine rabies | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| 7 | World Health Organisation/HIVResNet drug resistance laboratory strategy | narrative | Developing a network of individual laboratories based on capacity and expertise to perform specific duties supporting WHO recommended HIVDR surveys. The global network is organised on three levels, national drug resistance laboratories (NDRLs), regional drug resistance laboratories (RDRLs) and global specialised drug resistance laboratories (SDRLs) | |
| 8 | Consensus and accuracy in haematology laboratories of developing countries: the Jordinian experience | Study involved sending control specimens of whole blood and freshly prepared blood smears to 50 laboratories each month to determine PCV, Hb, RBC and WBC; and blood smears for counting differential WBC count after staining | Comparison of the re-calculated means of measured parameters between cell counter and manual methods showed manual methods gave lower mean values. The difference was significant for RBC and WBC. The percentage for Jordanian laboratories achieving medically useful analytical | The ways in which results were provided, clarity and accuracy became better because of the competition between different labs. However, using all methods mean as target value is not useful in places where manual methods are |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | performance was 99% (PCV), 97.2 (Hb), 99.5 (WBC) | dominant, as shown by this study where manual method results were lower than that of RBC and WBC cell counts |
| 9 | Rapidly building Global Health Security Capacity- Uganda Demonstration Project, 2013 | 1. Strengthening the public health laboratory system by increasing the capacity of diagnostic and specimen referral networks.2. enhancing communication and information systems for outbreak response 3. developing public health emergency operating center (EOC) | 1. Upgrading of cold-chain system for specimen, algothims for 3 priority specimen, distribution of SOPs, posters and case definitions. Overall improvements in organisational management, 10 labs improved documentation, 3 biorisk and biosafety. Overall the baseline scores changed from 20-36% to 34-55%. 2. Customised modules for each priority pathogen into DHIS-2. 3. SMS notification adn feedback for samples, sample tracking alerts. | 3 areas of focus for efficient and sustainable approach to enhance capacity building were identified- detection of health threats through laboratory and other systems, coordination of information and response through EOCs and prevention of avoidable threats. A need for holistic approach involved these three areas. Expansion of the system to other pathogens including Zika, Hep E et. |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| 10 | Rehabilitaing public health infrastructure in post conflict setting: epidemic prevention and preparedness in Kosovo | 1. Extensive consultations conducted between WHO, IPH, UNHCR to develop a program design, with WHO as lead agency to provide technical support. 2 WHO as lead agency coordinating with IRC to develop 6 focussed interventions | The interventions included: 1. Kosovo Health surveys-violant trauma main reason for 64% of deaths, vaccination coverage rate for children under 5 <20%, management of diarrheal diseases poor. 2% of the mobile accessed mobile health clinics run by NGOs. 2. Standardised case definitions and case-management protocols-clinical case management protocols were developed for 14 infectious diseases and distributed to health professional, primary care and poly clinics, and clinical epidemiologists. 3. Public Health Surveillance system- Infectious diseases surveillance and response commission comprising of epidemiologists, microbiologists, public | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | health managers from WHO, IRC and IPH was formed; with data analysis and interpretation at 6 regional IPH offices coordinated by central IPH office in Pristina. Training of IPH staff on surveillance systems, and national wide training of primary care clinicians on case definitions and surveillance forms. 4. Rehabilitation of Microbiology Laboratories- significant deficiencies in staffing, equipment and supplies were found in seven laboratories that were assessed. Training was provided for microbiological testing, and priority equipments and supplies were provided . 5 Establishment of community based public health education and | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | promotion campaign- Commission for health promotion was established with representatives from WHO, IPH and NGOs who developed policies and protocols for community outreach with focus on media campaign on HIV/AIDS, STIs, safe motherhood,violence against women. 6. Development of epidemic response capacity- 5 epidemic response teams (each with 4-5 members) were established at regional offices, workshop on epidemic preparedness and response was also organised. | |
| 11 | Strengthening tuberculosis diagnosis in a low-resource setting: experience learned in Dodoma, Tanzania | 1. Restructuring of the Tuberculosis section and separating it from the main lab. 2. Purchase of new equipments for implementing TB microscopy and culture. 3 Personnel training to improve quality of | 1. Three laboratory personnel were trained in TB diagnosis and biosafety procedures who further trained other DRH personnel. 2. | Cooperation program led to an increase in the number of samples and case detection rates |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | TB diagnosis, introduction of sputum microscopy, TB culture and external EQA. | Implementation of sputum smear microscopy led to an increase in reporting of TB cases from 11.2% in 2009 to 14.2% in 2010. 3. Introduction of TB cultures increased the positive confirmatory drug susceptibility testing. 4. DRH coordinated EQA was conducted for 10 peripheral labs. | |
| 16 | Non traditional security and infectious diseases in ASEAN: going beyond the rhetoric of securitisation to deeper institutionalisation | narrative | A. WHO and ASEAN funded networks incude. 1.Deploying resources for national and regional laboratories for speedy diagnosis of cases of human infection and stockpiling of drug and vaccines.2. Developing website of ASEAN-Disease surveillance Network. 3. Development og ASEAN Plus Three (APT) | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | framework. 4. Establishment of APT Emerging Infectious Diseases (EID) Program. 5. Development of East Asian Summit (EAS) and EAS Declaration on Avian Influenza Prevention, Control and Response. B. US-Funded REDI network for tracking, controlling and researching emerging infections. | |
| 17 | Building public health capacity in Afghanistan to implement the international health regulations: a role of security forces | 1. FETP- training program for two years.2 DEWS- syndromic surveillance system. 3. PRT- clinic construction, medical training, , purchase of medical equipment and text books, patient care. | | |
| 18 | Strengthening public laboratory service in sub-saharan Africa: Uganda case study | narrative | Capacity building pyramid is suggested utlising the resources from existing programs such as PEPFAR and SLMTA. This pyramid refers to a stepwise process leading to getting | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | WHO-AFRO accreditation based on SLMTA. | |
| 19 | Capacity building of public health laboratories in Afghanistan: challenges and successes | 1. Needs assessment was carried out with focus on human capital, infrastructure, management and training. . 2. Establishment of disease warning system sharing surveillance data with WHO, FAO, USAID. This also included lab based disease surveillance and research. 3. CPHL reserved as national reference lab for outbreak reports. 4. Training of laboratory staff | 1.After needs assessment space remodelling and renovations were done in CPHL to accommodate new equipment for diagnostics. Upgrading of provencial hospitals to conduct bacterial culture and serology.2. 300 laboratory sessions for 140 trainees at different sites. 76 days of internal training for 236 Afghan health care professionals using NAMRU-3 materials. 40 technicians, 4 field epidemiologists and 10 support staff were recruited to train exclusively under NAMRU-3 to perform diagnostic procedures following SOPs. 3.Disease early warning system sites increased from 123 in 2007 to 344 | Fulfilling of WHO IHR regulations by Afghanistan through huge leap in monitoring the burden of infectious diseases. Improved vaccination programs, decrease in mortality rates for young children from 257/1000 in 2002 to 191/1000 in 2008. Increase in life expectancy from 42 to 61 years |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | by 2013. 4. CPHL recognised by WHO as Afghan national influenza centre given the expanded capacity for pandamic flu. Improved diagnostic capacity ifn CPHL for other illnesses such as acute febrile illness, water diarrhoea and vector borne disease. | |
| 20 | Building laboratory capacity to support the global rotavirus surveillance network | supporting surveillance activities including sentinel site hospital selection, specimen and data flow management, lab performance monitoring and regional meeting planning. | 107 sentinel hospital laboratories, 36 national laboratories, 9 regional reference labs, one global reference lab has been established. Sentinel sites- enrol children<5 yrs hospitalised with acture gastroentritis and confirm, presence of rotavirus in stool. National labs- testing, speciment storage, selection and distribution of positive specimen for genotyping. Rotavirus regional labs (RRL)- bulk | 1.Establishment of a rotavirus laboratory technical working group in 2012 to increase standardisation of methods and procdedures. Standardisaton in genotying data collection, developing SOP for sample handling, storage and shipping; routine confirmation of subset of genotypes. 2. |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | genotyping. Global reference lab- technical support to RRL, training, QA, QC, provision of reagents and procedures. | Number of reporting countries increased from 44 (2008) to 64 (2011), sentinel hospitals from 132 to 185. Number of children enrolled- 41414 to 48947, detection rates from 36% to 41%, 5 globally prevalent genotypes identified, |
| 21 | Expansion of global measles and rubella laboratory network 2005-2009 | Network consisting of subnational level to global reference laboratory for surviellance of measles and rubella, in each WHO region. The network has focus on testing strategies, quality assurance and surveillance indicator, coordination and integration. | 1. By 2010- 690 labs attached to the network which follow standardised set of testing protocols, reporting procedures and strong focus on QA. National level-162, regional reference 19, global 3 and sub national 506. 2 Two to three regional labs selected in each region as centre for excellence. 4. Comprehensive evaluation of sampling techniques | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | using IgM detection, viral RNA detection, sequencing molecular surveillance, temperature stability and ease of use. 5. 220 laboratories globally participating in proficiency testing program at all levels. 5. Laboratories expanded detection and surveillance into yellow fever in central and western africa (23), Japanese encephalitis in SEAR (13), WPR (9), HPV (10). 173,000 test conducted for measles in 2009. | |
| 22 | Assisting cytopathology training in medically under-resourced countries | Suggestions are made for different ways of training cytopathologists to use FNB for diagnosis. These include-internet based distance learning courses, series of cytology tutorials run in-country by international experts periodically, Sandwich fellowships in the UK for medical trainees. telepathology for | Between 2007-2010 a series of Incountry cytology tutorials were organised, conducted by western experts. Uganda-2, Nigeria-2, Kenya-3, Tanzania-2, Ibadan-1, South Africa-1 | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | primary reporting or second opinions, shipping specimen | | |
| 23 | Impact of international laboratory partnerships on the eperformance of HIV/sexually transmitted infection testing in five resource-constrained countries | Pilot Ethnographic study was conducted in each country to identify high risk populations, specific venues they are located and identified popular opinion leaders. 2. Post pilot study trial was implemented- indepth risk behaviour assessment interviews at baseline at 12 months and 24 months involving 40-188 participants in each 20-40 community venues per country. 18147 participants recruited in 138 venues in 5 countries and 54438 specimen collected over 3 time points | The initital trial was conducted to find vulnerable population and social congrgating points and collect samples for QC/QA | |
| 24 | Impact of international laboratory partnerships on the eperformance of HIV/sexually transmitted infection testing in five resource-constrained countries | Post pilot study QC/QA was carried out with three major component. 1. personnel training of lab personnel before the trial and during the trial, on-site training 2. Manuals for the multi-country study. 3. ongoing QA monitoring of study procedures. For these 2 new labs were constructed in India and Russia, upgrading of two labs in China and Zimbabwe and use of US Military lab in Peru | 1. Training- 2nd training of lab managers had 100% results syphilis and trichomonas testing. 3 sites- 100% correct HIV EIA and WB testing. Two sites participating in CT/NG testing had 100% results. Proficiency panel results for in-country labs- majority of the countries had between 85 to 100% | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | results in panel testing for 7 diseases. Reference lab QA- 80-100% results were achieved. There was a continuous progression of the QA in the countries over the years of training and monitoring. | |
| 25 | The World Health Organisation African Regional Laboratory Accreditation Process | The WHO step wise accreditation process is desgined to address the gap between the requirements of ISO15189 and current status of labs in Africa. A systematic effective quality management system for lab testing, strong QA, QC and QI including pre-analytical and post analytical processes. | The key building blocks of accreditation process include 1. Standards and assessment tools- based on ISO15189:2007 (E) with 12 categorical sections for assessment on the basis of 110 clauses and 250 points. 2 Assessor and assessor training- drawn from labs in africa, the assessors will be trained in Kenya (english speaking) and Cameroon (french speaking) but can not assess their own country labs and not financially compensated.3. Equipment calibration and biosafety- | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | work with Field Epidemiology Network Lab in Uganda for training. 4. Laboratory Management training and Mentoring- Development of SMLTA which after initial assessment provides a series of training sessions to build national training teams for SMLTA in 12 countries for labs till facility level. 5. Proficiency testing- Dept of Bacteriology and Virology of Dantec Hospital, Dakar, Digital PT, National Institute for communicable diseases, national health lab services South Africa will provide PT for several diseases using serology, microbiology, chemistry, haematology and parasitological testing. | |
| 26 | Building laboratory capacity to support HIV | 1. A three level primary, secondary, tertiary network of laboratories was | 1. 35 laboratories were developed in total. 18 | 1. Significant impact was seen on overall |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | care in Nigeria: harvard/APIN PEPFAR, 2004-2012 | organised and linked for HIV testing and diagnosis. Primary care-rapid testing, blood samples. Secondary level-serology, CD4+, haemotology, clinical chemistry setting. Storage for VL, DBS. Tertiary level-large HIV ART programs at university associated hospitals. 2. Clinic selection after detail assessment from site visit, followed by needs assessment. 3. Standardisation in equipment procurement and training. Lab modifications for effective logical sample flow and processing, supply chain for test kits with two warehouses for distribution. 3 Trained on-site engineers (varying expertise) for equipemnt maintenance. 4. Electronic medical records system for data management linked by local computer networks for easy flow of information within each site. 5. Tertiary labs to provide trainings to staff at secondary and primary level. | major sites managed (8 tertiary and 10 secondary level labs). 7 labs designated as Centre of Excellence by Nigerian Ministry of Health. 2. All secondary and tertiary labs also had capacity for TB diagnosis, treatment and care, and two for MDR TB testing and using this for national TB control program. 3. Harvard/APIN PEPFAR supported labs conducted over 2.5 million tests and results for HIV from 2004-2012. EID testing expanded 10 fold from 2007 to 2008 with over 9000 HIV exposed infants tested. From 2009 testing was completely taken over by APIN | health system strengthening through a variety of approaches including training of the trainers, utlising centralised training conferences for assurance of standardisation and network exercise. 2. Electronic data management led to decrease in the transcription errors, turn around time, aggregate reporting at national level, development of treatment response utility system for comprehensive picture of treatment profile of individual patient and help in clinical decision making. 3. |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | | Harvard/PEPFAR labs subscribed to EQA and 6 labs were included in SMLTA roll out in 2010, with one lab achieving 5 star, five 4 stars. |
| 27 | Building capacity for the assessment of HIV drug resistance: experiences from the pharmaccess african studies to evaluate resistance network. | A network of 6 countries in Africa was developed with specific focus on HIVDR surveillance through population level assessment forHIV1 DR and patient follow up during 1 and 2 line ART (PASER Monitoring/PASER M). The chosen sites were given laboratory training in GLP, Good Molecular diagnostic Practices, sample handling and documentation using web based specimen track and trace system. A limited number of central reference labs were chosen for testing and ensuring standardisation and quality assurance. More than 2 EQA were done and PT was carried out before genotyping. 2. Central web based ViroScore Suite Database was used for all data sequences for storage and quality control. 3 To mitigate expensive costs of genotypig- a private public consortium ART-A was | During the 5 annual networking meetings 100 clinicians and 86 labs received training. PASER-M achieved 96% (n=3007) patient recruitment with 82% retained in the 12 months follow up . | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | developed for novel, simple diagnostic technology for HIV viral load testing, detecting and interpretation of HIVDR in clinics and labs. 3. Regular monitoring visits to sites were conducted that also included teaching and training of basic research skills to investigators, clinicians, nurses, lab technicians. Also followed by annual network meetings. | | |
| 28 | Surveillance of antimicrobial resistance in resource-constricted settings- experience from five pilot projects | 1. Three site in India (Delhi, Mumbai, Vellore) and two in South Africa (Brits, Durban) were chosen for study. All in urban areas attached to big hospitals, and Vellore also had access to rural settings. 2 Each site was given a framework protocol to collect community based AMR data every month for 12 months with one or two bacteria as indicators.3. E.Coli was used an indicator at 4 sites (3 India, I South Africa) and faecal from patients, urine was collected from pregnant women. The antibiotics tested included ampicillin, cotrimoxazole, chloramphenicol, nalidixic acid, ciprofloxacin. In South Africa, S. Pneumonia and H. Influenzae were obtained from sputa of the patients and | High resistance rates were found in all sites, and in Vellore no difference in settings was found between urban and rural populations. In Mumbai, the pre- and post antibiotic use in the samples did not vary signifcantly between groups. In Mumbai, Brits and Durban where samples were collected from different facilities, no difference was found in resistance rates. Data from two sites that distinguished commensals from pathogens showed | |

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| | | ampiclin, cotrimoxazole, chloramphenicol, and erythromycin. 4. Resistance was tested only for ABMs commonly used for treatment of infections in the community. | higher AMR rates among E. Coli causing UTI for all antibiotics tested. | |
| 29 | WHO global Salm-Surv external quality assurance system for serotyping of salmonella isolates from 2000 to 2007 | narrative | In 2000 WHO established Global Salm-Surv EQAS to enhancelab based surveillance of salmonella infections and other food borne diseases through enhanced serotyping of Salmonella species. 2. Assessment of laboratory capacities for correctly serotyping by shipping 8 blinded salmonella isolates to labs. Submission of results to EQAS web based reporting system with sercured individual passcode .3. Results are given as a report itemizing errors relative to the expected results and can be used by participants to evaluate accuracy of | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | current techniques and quality of anti-sera in labs | |
| 30 | WHO global Salm-Surv external quality assurance system for serotyping of salmonella isolates from 2000 to 2007 | 8 Salmonella strains were selected for each EQAS iteration. Except the strain for Salmonella serovar Enteritidis, all other strains were included once only in EQAS iterations in 2000, 01, 04, 06, 07. Testing instructions with participating laboratory record sheet on CD with Salmonella Agar stab cultures were sent to participating countries under IATA regulations. Results were submitted either online via secure site or fax or email. | 1. 249 labs in 97 countries participated in EQAS from 2000 to 2007. 44labs/35 countries in 2000, 96labs/55countries in 2001, 99 labs/61 countries in 2002, 127labs/72countries in 2003, 127 labs/71 countries in 2004, 130labs/66countries in 2006, 140 labs/68 countries in 2007 participated. 2. The average number of labs per EQAS iteration between 2000-07 was 102. 3. 125 labs participated in 3 tp 4 iterations and 92 in four or more.4. 54% to 92% labs performed serotyping on all 8 strains. 5. The percentage of correct serotyping was 76% (2000), 72%(2001), 91% | Important regional differences in serotyping results for Salmonella species. |

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| | | | (2002), 80% (2003), 88% (2007). Reporting of zero errors increased from 48% in 2000 to 68% in 2007. 6. The rate of errors ranged from 41% in 2006 to 3.6% in 2007 | |
| 31 | Developing laboratory systems and infrastructure for HIV scale up: a tool for health systems strengthening in resource limited settings | Role of PEPFAR 1 and 2 in strengthening laboratory systems for HIV scale up is described. The areas include 1. Human capacity development 2 infrastructure and logistics and supply chain management and development. 3. Quality assurance. 4. laboratory data collectionn and indicators. 5 harmonisation | Examples included 1. Human capacity development-African Centre for Integrated Laboratory Training in Jo'burg South Africa to provide south to south training. 2. Performance based financing in Rwanda for staff retention, pay increase for pharmacists in Botswana. 3. Infrastructure- National Laboratory Strategic Planfor Ethiopian Health and Nutrition Research Institute (EHNRI) where national reference lab, 4 regional hospitals, 6 regional labs are | |

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| | | | renovated. Rwanada 'common basket' fpr implementing partners to contribute and national central purchasing unit (CAMERWA). Supply issues in cold chain addressed by propane powered refrigerators in Nigeria.5. Quality Assurance- APIN counducts QA in Nigeria, National Institute of Medical Research in Nigerai is ISO certified. 6. Laboratory data collection and indicators- PEPFAR 2 and ICAP as tools for assessment. 7 Harmonisation- EHNRI Ethiopia oversees all standardisation process in the country working with US SCMS for procurement and maintenance of equipments. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| 32 | Strengthening systems for communicable disease surveillance: creating laboratory network in Rwanda | EQAS was conducted by WHO-AFRO, US CDC for Rwanda to assess national lab network | 1. Surveillance- After ISDR implementation in 2001, disease priorities were streamlined with 19 high priority diseases, staff training provided in testing, management through a series of workshops. 2. NRL is autonomous with diagnostic capacties for HIV, TB, Malaria, influenza, H5N1. Decentralisation of administrative function of NRL to expand capacity, management and use of surveillance at all levels, GIS use, bacteriology labs set up in 5 district hospitals. 3. Coordination and function of lab network. NRL equipped with PCR, flourance activated cell sorting, lymphocyte %age for infants. 4 reference labs and NRL connected to 34 | Improvements in strain isolations by NRL. For Cholera- from 46 specimen (2005), 17 (2006), 110 (2007). Dysentry- 11 (2005), none (2006), 110 (2007)Measles 188 (2005), 187 (2006), 132 (2007). Typhoid 42 (2006), 44 (2006), 132 (2007). Meningitis 20 (2005), 21 (2006), 22 (2007). The number of VCT sites 285 in 2007. QC results showed improved discordance rates to 0.8% in 2008. The QC for TB slide examination- increase from to 60 (2003) to 183 (2007) CDT sites participating in QC. |

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| | | | district hospital labs and 385 health centre labs at peripheral. Each with defined SOPs. 126 health centres with HIVRDT and exapnsion of PMTCT. 5. Training- 467 biotechnologists on lab detection of malaria, HIVrapid testing, SLP and biosafety in 2005. 969 lab personnel trained in integrated lab training in Malaria, TB, HIV, biochemistry and haematology (61 participants), CD4 counts (34 partcipants), dried blood spots (180), HIV specific testing at new VCT sites (223). 6 Supervision- 420 labs get assessment every year some more than once. 517 (2005), 862 (2006), 689 (2007). 7. External collaboration is maintained with each | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | partner by allocating specific facilities to avoid duplication. Establishment of TRAC allows integrated clinical planning and lab activities. National disease programs integrated with external lab ref systems such as Polio, measles (WHO AFRO and UVRI), MDRTB with IMTA Belgium for QC testing. QC panels for epidemic bacteria, malaria, TB microscopy , CD4 counts, ELISA and western blot received fro NIPH Southh Africa. | |
| 33 | Capacity building and predictors of success for HIV1 drug resistance testing in the Asia-Pacific Region and Africa | the intervention involved proficieny testing in genotyping by distributing nine 5-sample TAQAS panels (45 samples) to 19 labs in 11 asian countries and 2 african countries for testing using their standard protocols. Samples were sent biannually from NRL Australia and results were returned to NRL Australia. This was followed by a detailed protocol | 1. Eight laboratories reported results of all nine panels. 2 Questionnaire was completed by all but one lab demonstrating a wide variability in genotyping experiences. The average length of labs conducting genotyping | HIVDR genotyping was associated with the panel complexity and with lab performance factors such as detection of mixtures and agreement with TG but not with |

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| | | questionnaire to participating labs on testing methods. | testing was six years, 348 tests per year, sample turn around time was 14 days. 2. Majority of the labs(18/22)used locally assembled protcols.3. fourteen 4.labs required bachelor's degree qualifications or higher. 5. Only 6/22 outsourced sequencing. 6. Most 20/22 used an automatic base calling software and all reported manual checking and editing of automated base calls. 7. The peak height to call mixed bases was set at 20-30% by 19 labs. 8. Most labs (15/22) labs reviewed sequenced datra at sites associated with ARV resistance. 9. Fifteen used Stanford Database for resistance interpretationn in other three used IAS-USA or ANRS along with Stanford | differences in the lab use of commercial vs in-house tests or sequencing protocols |

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| | | | database. 10. A total of 144 data sets were returned by 23 participating labs, with 10 labs returning results upto five weeks past the turn around time. 136 datasets were suitable for assessment and . The median detection of DRMs in TGs in 7 plasma panels ranged between 88 to 98%. Three labs detected <80% initially but subsequently improved. | |
| 34 | Evidence-based approach to the maintenance of laboratory and medical equipment in resource poor settings | 1. between 2003-2008, approx 100 engineering students, biomed technicians and engineers (volunteers) gathered data on out of service medical equipment from 60 resource poor hospitals in 11 countries. The hospitals were of varied size, limited technical staff, and tech staff not qualified in BMET's in 11 countries. 2. It was followed by analysis of out of service equipments and repairs were attempted by volunteers using local spare parts (purchased or repaired), using basic repair tool kit and advice from expert | Total of 2849 engineering requests were analysed. Of those 2529 were medical equipments, 320 non medical equipments. 1821 were repaired and made in use (72%). 2. The type of devices included blood pressure devices (294), nebulisers (123), pulse oximeters (104), ECG (86), incubators (80), electro-surgery devices (77), | The results show that medical equipments repair do not require major import of spare parts to be returned to service upon repair. Lenghty post-secondary training for licences and engineering is not suitable for resource poor settings. |

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| | | engineers. Volunteers were not allowed to purchase or order parts from outside the country.3. Every peice was labelled repaired (only if returned for use) or not repaired ( included repaired but still not used upon return). 4. Detailed reports were filled by volunteers on each equipment and reanalysed by second engineering student, and selected cases by experienced and licenced engineers. | infusion pumps (77), autoclaves (74), microscopes (65), centrifuges (63), X ray devices (57), ventilators (57). 3. The six domains of knowledge required from documentation included- electrical, mechanical, power supply, plumbing, motors and installations or user training. A further 26 units/concepts/skills were identified in 6 domains needed for diagnosing the problem and executing repair. Within 26 units 107 further skills were documented in more than one repair in a basic unit. 4. of total 1704 documented, repaired pieces 1132 (66%) were put back in service using one of the 107 skills identified and using local spare parts. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| 35 | Impact of horizaontal approach in vertical program: continuous quality improvement of malaria and TB diagnostic services at primary level medical hospitals in the context of HIV care and treamtment program in Ethiopia | 1. Laboratory Quality Improvement tools were developed to assess and monitor the quality of both malaria nd AFB microscopy total testing process. The tools comprised of 100 closed ended questions divided into 12 sections with containing general and specific aspects.2. LQITs used in 5 Health Centres and one faith based hospital labs in Showa zone of Oromia region. 3 Data collected quarterly at baseline at all 6 sites | 1. Baseline scores for MALScore were between 42 to 61% for all labs (all labs were unsatisfactory). Similarly AFBScore was between 41 to 70%. (one Health centre was satisfatory). 2 Monthly follow up, onsite training and mentorship, documentation and quality assurace support provided help with improving lab services.2. 20 lab professionals recieved onsite training to address the gaps seen ins LQIT assessment. 3 At the end of 6th quarterly assessment the MalScore was between 88-90% and AFBScore between 88-95%. 4. The Human resources issued showed constant increases due to indentification of focal persons for malaria and AFB microscopy and | |

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| | | | refgular refresher training. 5. Safety- MalScore was 100% at baselinne, AFBScore improved from 67 to 82% with a development of TB infectious waste disposal protocol. 6. Regular improvements seen in lab process- slide prep, staining, maintenance, microscope, reading reporting of results. This was because of implementing SOP during 3rd and 4th quarter and poster display for WHO malaria staining process. . 7 Improvements in documentation of quality procedures into routine activities 8. Quality control section scored the lowest at baseline but showed improvement in quarter 4 due to introduction in SOP | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | for malaria and AFB quantifications | |
| 36 | Implementaiton of quality system approach for laboratory practice in resource-constrained countries | narrative | 1. Needs assessment is carried out by GAP team in the country at the invitation of the governement including review of the proposed country plan. 2 Seeking commitment from governments for strengthening lab program 's capability and capacity, followed by assessment of current lab practices at all levels to identify gaps and enable priorities.3. Big meeting of all laboratorians together to begin establishment of a national system of labs, national approach to QA, and better communication, training needs. | |
| 37 | Working towards a sustainable laboratory quality improvement | 1.In 2011 national lab technical working group (TWG) consisting of MoH personnel, partners was establish to build | 1. All eight labs completed three SLMTA workshops, 6 had complete exit audit | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | programme through country ownership: Mozambique's SMLTA story | framework for National lab quality improvement program.2. The TWG developed SLMTA implementation plan which included training, mentorship, supervision and audits; with dedicated coordinator and SLIPTA focal person. 3. Training toolkit was translated into Portugese and locally relevant implementation strategies were developed and local portugese FOGELA was created for this program. 4. This was implemented in phases and hierarchical approach with top-tier labs (NRL and central hospital labs) first enrolled. Post-training, the trained personnel became resource person for training, mentoring and supervising others. 5. Training was also given to 15 auditors using WHO-AFRO Auditor training curriculum. 6. 2011- new auditors with experienced auditors carried out baseline audits for the eight enrolled labs based on SLIPTA checklist | data, 2 had missing data or excluded from analysis. Overall improvement was seen in all 6 labs after 12 months of implementation- three labs (1 star), one lab (2 star), one lab (3 star). 2 The greatest areas of improvement were client management, customer service, corrective action, purchasing and inventory, and management reviews. The areas of least improvement were information management, equipment, facilities, safety, internal audit. 3. The National TB Ref Lab was best performinng with 3 stars. 4. At the end of the program 3 labs officially enrolled into SLIPTA program for review by auditors from ASLM. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| 38 | Establishing PT scheme in developing countries: examples from Africa | 1. In country PT schemes for food and water testing were organised and training of the personnel in SADC and EAC countries in Africa. 2. three samples for water PT schemes and two in food PT were distributed for same measurands. 3. Assessment was made using Z scores. | 1. Number of participants from 18 African countries participating in PT scheme for microbiological analysis of water- 23 (2008), 9 (2009), 33 (2010), 40 (2011). 2. Number of participants from 20 African countries participating in PT scheme for chemical analysis of water- 39 (2006), 47 (2007), 45 (2008), 54 (2009), 58 (2010), 54 (2011). 3. The data showed chemical analysis of water being outside the acceptable range in three samples. T | The use of low cost methods for analysis of the measurands is one factor for lack of insufficient quality of the participants results and corrective actions taken after failing in PT rounds. |
| 39 | CLSI: building laboratory capacity in Africa | narrative | 1. Two pronged approach is taken for capacity strengthening: LS strengthening and GHP. It supports individual countries and also national lab systems through standard development | |

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| | | | activities for its members. 2. Initial site visit for measuring existing capacity, is followed by needs assessment for identifying gaps and design a customised training program for best practices. 3. Implementation of selected improvements done through Mentor/Twinning program for 3 months where experts work with local lab professionnals to facilitate improvement strategies and prepare for accreditation, including self-assessment tools. 4. Each year two in-country lab leaders are given sponsorship to attend annual CLSI leadership conference. | |
| 40 | Public Health laboratory systems development in East Africa through | 25% of classroom instructions and 75% field assignments. The lab residents take course on epidemiology, bio stats, | | |

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| | training in laboratory management and field epidemiology | research methods, scientific communication , public health surveillance, computers in public health, lab methods in field, lab management and leadership | | |
| 41 | Measuring laboratory based influenza surveillance capacity: development of the international laboratory capacity review tool | 1. PHLs, CDC and SMEs in influenza collectively developed a tool to assist in assessing international lab capacities for testing influenza specimen and quality control management. The tool represented essential lab functions and practices of WHO NICs. The tool was organised in 9 categories containing questions to evaluate lab practices, identify strengths and develop recommendations. 37 assessments were done between 2009-11. 2. The tool contains 271 questions that fall into informational category or capacity related (180), an equipment table and training table. 2. 164/180 questions were used for quantitative analysis. 164 questions divided into 8 categories for analysis in capacity. | The tool was tested by SMEs and revised to add quantitative framework. The validation of the quantitative framework was done retrospectively. | |

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| 42 | The operation, quality and costs of a district hospital laboratory service in Malawi | A survey was carried out in Ntcheu district hospital to collect baseline data on the operation, quality and costs of the current district laboratory services in Malawi as a basis for the development of essential laboratory package. Data was collected on tests, workload and staffing levels; quantity and type of consumables required, inventory of euipments, quality of tests (cross testing at SSI Denmark and LSTM UK) for TB microscopy and malaria microscopy, haemoglobin measurement and blood tranfusion for grouping and compatibility tests; economic costings for resources used in the different tests, human resources costs. | 1. Tests, workload and staffing- 31203 tests were performed between 1997-98 (malaria microscopy-21%, TB 23%, Hb 13%, transfusion 26%). Average technician worked for 23.8 hrs/week comprisintg 2479 hrs/year against the required 3970 hrs for the work.2 All tests were carried out in the same room with poor ventilation and no safety cabinets, no autoclave or appropriate disposal of waste, cleaning and washing procedures for the lab were inconsistent.3. Quality of tests: Except Hb testing, the concordance between the test results and reference result was over 90%, for Hb it was only 37% (combined failure of all types of transfusion). 4. The economic costs of lab | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | for one year of study was US$ 32618, TB microscopy US$13547, transfusion and Hb measurement US$ 11 207, malaria $2708. | |
| 43 | Clinical laboratory networks contribute to strengthening disease surveillance. The RESAOLAB project in west Africa | RESAOLAB was established with support from AFD and Fondation Merieux. The three key areas of acitivity include training laboratory personnel, setting QA, strengthening epidemiological surveillance | 1. Training- a shared natrional strageic plan for continuous education of lab technicians was developed containing 9 modules. Till 2013 64 sessions with 25 participants in each have been conducted. Also available for self-training via GLOBE. 2. Setting quality assurance- shared national strategic plan for lab quality management was developed to define standards for personnel organisation, lab equipment, procedures, data processing, hygiene and security. Also identified 4 labs in each country for EQA. Till 2013, | RESAOLAB played key role duirng cholera outbreak in Mali in 2011. Other countries in region- Niger, Togo, Benin, Guinea have made requests to join RESAOLAB> |

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| | | | 350 supervised EQA conducted. 3. Strengthening the epidemiological surveillance- open source lab information and management system was developed for monitoring daily surveillance activity. Training workshop on how to use new tool was conducted in collaboration with WHO-AFRO. | |
| 44 | Improved clinical and laboratory skiils after team based, malaria case management training of health care professionals in Uganda | Integrated manamagemnt of Malaria, 6 day course was organised at 8 sentinel sites by JUMP. It included didactic and practical sessions, and partcipants included clinicians, lab professionals, health info assitants. A baseline observation of clinical care adn lab testing was done prior to training. 2. Three support supervision visits were conducted by JUMP team at approx 6 weeks, 12 weeks, one year post workshop to give feedback and perform onsite observation. 3. The evaluation involved | 1. 118 clinicians were trained, 101 observed (61 at baseline and once after training).2. Performance of 5 key skills for patients presenting with fever improved between baseline and three follow up visits. 3. History takingfor children < 5yrs and patient education for >5 yrs did not improve much in the one year follow up.4. Preparation of | |

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| | | the assessment of clinical skills and laboratory skills. | malaria smear improved significantly from baseline in each follow up visits. The sensitivitiy of interpreting smear results increased significantly (84%), specificity also increased (91%) (WHO standard was met for specificity (90%) but not for sensitivity). However, it was not possible to distinguish effects of JUMP from UMSP as they were jointly implemented at the same sites. | |
| 45 | Laboratory capacity for diagnosis of foot and mouth disease in Eastern Africa: implications for the progressive control pathway | 1. Cross sectional prospective survey was conducted to assess the lab capacity for diagnosis of FMD among the NRLs in 14 EARLN countries.2. Questionnaire was sent electronically to all labs. The areas of information sought- outbreaks and control strategies including response time, sampling, personnel, transportation issues, storage of samples, stage of PCP-FMD, control strategies, type and sources of vaccines, policies for FMD control | 1. 13/14 countries responded.2. All but one (Djibouti) experienced one outbreak in last five years. Outbreaks were reported by Vet officers in three countries (Uganda, Sudan, South Sudan). 9/13 countries outbreak were reported by vets and farmers. Seven countries | Limited lab capacity for FMD in terms of tests, equipments and skilled manpower |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | from twelve submitted samples inconsistently to WRLFMD. 2. Nine countries were below PCP-FMD stage 3, only one at stage 3. Only Kenya and Tanzania used pre and post-outbreak vaccinations. Only Kenya adn Ethiopia had vaccination plants, and rest imported from Bostwana and Kenya. 4. Majority 12/13 sampling was done durinng acute phase of outbreak. Except Puntland all countries personnel were trained in FMD sampling. Majorty reported sample collection between 100-1000. 5 All labs were able to conduct FMD diagnosis. The costs were US$50 per sample in most except Eritrea and Rwanda where cost for diagnosis was US$100 per | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | sample. Three countries used virus isolation (Eritrea, Kenya, Sudan), eight immunological detection methods, South Sudan also did antigen-ELISA and 3 used PCR. 6. None of the labs were accredited for FMD diagnosis but all except Burundi had SOPs for diagnosis. Only 4/13 participated in annual PT. Most NRL worked at BSL-2 for biosafety except Kenya and Ethiopia who worked at BSL-3. Five out of 13 did not regularly service equipment and only six calibrated equipment annually. Except Kenya all reported understaffing. | |
| 46 | A systmatic approach to capacity strengthening of laboratory systems for control of neglected tropical diseases in | 1. a three stage approach was taken to develop assessment and monitoring tools for NTDs- evidence from literature on lab strengthening at individual, organisation, national and international level and | Retrospective analysis of the tools was done after initial implementaion and tools were revised. The strengths and weaknesses | |

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| | Ghana, Kenya, Malawi and Sri Lanka | generating list of components necessary for optimal lab system for NTD and using this to design a questionnaire based tool for lab managers, a semi-structure interview guide, capacity gap checklist and a checklist of ISO15189 for onsite observations.2. The tools were implemented in labs of four countries of CNTD/LF programme . This included site/institution visit with two complementary members from LSTM visiting the institutions. 62 semistructure interviews were conducted (17 Malawi, 11 Ghana, 16 kenya, 18 Sri Lanka) with stakeholders. | in the four participating countries were analysed by the tools developed by LSTM. The categories included 1. people and management - Ghana ( skills and abilities match lab requirements), Malawi (young and expanding team to support), Kenya (flexible lab scientist capacity), Sri Lanka (34 full time staff). 2. Research support- Ghana (research office to see all research activities), Malawi and Kenya ( code of practice for research and institutional support for grant writing and funding, ethics committee), Sri Lanka (MoH ethics committe). 3. External interactions- Ghana (works with all stakeholders across all sectors locally/internationally), | |

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| | | | Malawi (offers of support from other labs), Kenya ( availabilty of local expertise and support for NTD lab development), Sri Lanka ( International Filariasis research group support). 4. Collaborations-all had strong links with other national institutions and policy makers. 5. All labs in four countries had the potential to provide support ot national and regional NTD control programs in diagnosis, vector analysis. Most laboratories were seen as preferntial collaborators. | |
| 47 | Training and service in Public Health, Nigeria Field Epidemiology and Laboratory training, 2008-2014 | 1. Two year course consisting of formal teaching and service activities. The competencies areas include epidemiology, public health surveillance, biostatistics and scientific communications as key areas with other optional courses. 2. Training is provided in four clusters of 4- | 1 Between 2008-14, 207 NFELTP residents were trained with 58% being clinicians, 26% lab scientists, 16% vets. 595 health workers trained from short courses which | The program has helped to address public health emergencies, and worked on the concept of one health bringing physicians, |

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| | | 6 weeks. Followed by exams and dessertation. Combination of didactic and seminar based teaching. 3. The program has three tracks- medical epidemiology, veterinary epidemiology, lab epidemiology and management. | included HIV program management, monitoring and evaluation, outbreak response and surveillance, vaccine preventable diseases, zoonoses, leadership and management, HIv/TB collaborations. | veterinarians, laboratorian togethes. Supported the scale up of ISDR capacity at federal and state level, residents help for analysing surveillance data and conducted basic research for program implementations. |
| 48 | Critical role of developing national strategic plans as a guide to strengthening laboratory health systems in resource poor settings | 1.EHNRI established a division of national laboratory system to strengthen public health integrated lab system in2005. It also developed a national plan containing 14 strategic objectives that are supported by various institutions to implement. 2. AHPL- established lab quality system plan, EQA for HIV serology chemistry and hematology, lab info system with referral links and network of clinical labs with regional and national ref lab. 3. ASCP- involved in developing training curriculum in chemistry, hemotology, CD4, preservice training curriculum for medical lab schools, standardisation of curriculum and help with setting NRL. 4. | 325 health centres providing ART networked with 105 testing sites. More than 4k DNA PCR performed at NRL. Development of 6 regional ref labs. Training in TB, malaria and other opportunistic infections. TB microscopy and smear testing developed. Evaluation of NSLP conducted | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | CLSI-technical support for developing and standardising lab operating procedures, lab layout, developing competency assessment tools for evaluating effectiveness of different training programs, preparing regional and hospital labs for accreditation. 5. SCMS-designing and implementing lab logistics management systems. 6 CU-ICAP- support 42 labs in AIDS prevention, treatment and care.7. I-TECH provides technical assistance to 32 hospital networks.8. CHAI helped to develop national quantificationtools for lab commodities. | | |
| 49 | Laboratory systems and services are critical in global health: time to end the neglect | recommendations | The need for developing comprehensive sustainable Lab systems is desbribed and elements of lab health systems. These include-framwork for training, retaining and career development; infrastructure development, supply chain, maintenance of lab equipment, specimen referral systems, | |

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| | | | QC/QA/QM, lab info system, biosafety and waste management. This also include establishing PPP. Establishing field epidemiology and lab training programs; building centres of excellence; Implementing affordable quality management and accreditation systems. | |
| 50 | Country leadership and policy are critical factors for implementing laboratory accreditation in developing countries. A study on Uganda | A reivew of the National Health Policy 1, Health Sector Strategic Plan 2, Nationa Health Lab Policy, Maputo Declaration on Lab services, Lab related technical reports of WHO. Followed by 20 key informant interviews- belonging to MoH, WHO country office, CDC office in Uganda, CPHL, AMREF | 1.The National Lab Technical and Policy Committee has the aim to provide leadership and coordination of lab services in Uganda, to develop national lab service policies, review standards and develop lab info management system. 2. Health sector strategic plan 1 and 2 focus on national lab network development.3 Uganda has active EQA in place with | A step wise accreditation is recommended with focus on specific diseases initially. Accreditation useful for standardisation and quality of services, complaince with international standards. WHO recommended accreditationn should be localised for Uganda and setting |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | three aspects- PT, onsite evaluation, retesting of specimen. Currently 3 PT schemes exist-NEQAS PT for HIV/malaria/TB/OI in 250 labs. PT scheme for CD4 testing. The second involves UKNEQAS which sends whole blood panels from UK for testing and results submitted online. Third is regional EQA focusing on primary health care labs in Uganda, kenya and tanzania. The second EQA- onsite evaluation is done from CPHL with LTC support. THE HIVRL and National TB Ref lab conduct retesting and rechecking as basis of EQA schemes.4. APHC registers private labs. 5. No National lab accreditation system yet exists in Uganda, but few (private Ebenezar lab) erolled in South African | nationnal accreditation guidelines and standards |

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| | | | National Accreditation System leading to ISO15189 eventually. The JCRC enrolled for CAP accreditation. However the costs for accreditation too high to afford by most labs ($50K to 100K) | |
| 51 | Antimicrobial resistance: capacity and practices among clinical laboratories in Kenya, 2013 | 1. Retrospective reviews of lab records ( bacteriology records) on AST for stool and blood cultures were carried out to determine AMR patterns, and key informant semi structured interviews to assess the lab capacity to perform culture and AST, practices and utlisation of results by clinicians.2. Eight public medical labs (two level6- national referral, four level 5-sub national, two level 4- district) were selected. The data was collected between Jan-Dec 2012 | 1. Seven were clinical labs and one public health lab. 7/8 labs participating in WHO/AFRO stepwise lab improvement scheme. Only 1/8 had facility for Campylobactor, one had no records and only 3/8 performed blood cultures. No lab had service contracts for equipmetn and only one reported validation report. 7/8 lab did not undergo any refresher training for microbiological techniques.7/8 labs had additional biochemical tests. 4997 stool and 4258 | 1. Inadequate capacity of bacterial culture and AST in all labs. 2. Expired cultures, samples and reagents were not regulaly disposed.3. Lack of approaved SOPs compromised reliability and accuracy of the results. Lack of clear guidelines in the labs leading to large wasting of resources. |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | blood samples were reported. 2. AST PRACTICES-5/8 lab had SOP for stool sample collection, 7/8 with culture processing SOPs, 5 with AST SOP. Five performed internal QC on media and reagent and 3 participated in external EQA (not for AST and culture). None had the capacility to isolate E.Coli, although 4 had reported organism obtained in them. 3. AMR PATTERN- Ampicillin and tetracycline resistance was shown in three Shigella species isolates. Sulfamethoxazole resistant was seen in Salmonella, and also absolute resistance by 4 Shigella species. MDR was seen in E.Coli, Shigella and Salmonella.4. INTERVIIEWS- eight | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | clinicians reported not utilising lab test results for patient management, the reason was- lack of antibiotics tested at labs were not available in hospital, delays in lab results, lack of feedback from lab. | |
| 52 | Strengthening Laboratory systems in resource limited settings | The research explored three areas of strengthening- lab systems, coordination of lab effforts, adoption of quality standards. 1. Three data sources were included- Gray literature, interviews with major donors, site visits to three countries. 2. Interviews were conducted with 19 donor agencies and site visits to Ethiopia, Kenya and Thailand. 3 During site visits, a total of 15 lab were visited and over 60 interviews with host government personnel. | 1. Laboratory systems- The capacity and quality of labs rapidly dropped in the lower levels. Lack of equipment, staffing etc were common issues. Incountry brain drain from govt to private sector was mentioned. Bureaucratic hurdles were issues with donor agencies. Kenya and Ethiopia lab system strategic plans were consistent with guidance documents. Fragemented responsibilities among different ministries for lab system development was | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | key to lack of progress. 2. Coordination-Challenges for host systems to comply with multiple funding agencies at the same time. Donor agencies priorities revolve around their own mission and vision which can be challenging for host nations. However, donor driven agenda can be problmatic for donors also, in terms of need to obligate for longer periods, need for clear exit strategy, more focus on infrastructure development and less on leadership. Donor funded labs very advanced but not integrated with public health labs of the countries and hence lack direct operational support from the govts. 3. Adoption of quality systems- Countries with central coordination committees often driven | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | by large programs such as PEPFAR or Global Funds are more successful in adopting standardised equipments. But equipment donations, small scale programs independant of national health strategy are challenge to standardisation as equipment donation can lead to manufacture monopoly, long term costs, reliance. 4. Thailand has comprehensive PT and national accreditation program (based on ISO 15189) but Africa focuses mostly on HIV testing. These rely on external QA programs such as UK (NEQAS), Canada (QASI) and Australian National Serology Ref Lab. | |
| 53 | Use of web based training for quality | The study was conducted at University of Chicago and IAMRAT using online | 1. OFI (one author) received training in US on | |

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| | improvement between a field immunohistochemistry laboratory in Nigeria and its US based partner institution | Immunohistochemistry (IHC) training seesions. After initial training (stage 1), first performance evaluation (stage 2) was conducted follwed by a review of the process and then a session of online training and discussion (stage 3), and second performance evaluation (stage 4). | IHC, returned to Nigeria IAMRAT to set up IHC lab and provide training to others, and shipping necessary equipments for the lab from US. Training in Nigeria was 12 weeks course including seminars, acadmic literature and hands on experience. Info on IHC service/lab was widely circulated in Nigeria. Samples of breast cancer tissues were referred to IAMRAT lab for IHC testing from several hospitals and stained slides were scored. Tissue microarray samples were constructed in Chicago with 232 tumor samples sent from Nigeria and IHC testing was performed.2. Results of the immunostaining were scored semi quantitatively by two pathologists at two | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | study centres. This was followed by initial concordance analysis of samples in Chicago and Nigeria (comparison). 3. The process of training and methods was reviews after concordance analysis and web based conference (skype) was performed. Discripencies in the analysis were seen in staining protocol, antigen retrieval procedures, scoring methods. Following this a joint evaluationof digital slides was conducted addressing technical issues. 4. Second evaluation of immunostaining was conducted and assesed in Chicago. The concordance between Nigeria slides and Chicago slides was seen to have improved. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| 54 | Strategy for strengthening scientific capacity in developing countries on water and sanitation related issues | The strategy is build on four corner stones 1.-providing means to researchers to attract funds to initiate new project: through training, and support, review of proposals by 10 international experts, workshops on revision of projects and follow up guidance and support from local organisations. 2. Facilitations in generating high quality results: training in research methods, site visits to GLP labs,support in equipment procurement, mobilising networks. 3. Dissemination and implementation of results: training in presentation techniques (oral/poster), mentorship, funds for publication costs, local dissemination workshop support. 4. Follow up on implementations: workshops and follow up grants on competitive terms. | IFS grantees and resource persons participate in training of the trainers who later disseminate program. A close contact with end-users is encouraged who are also participants in research (action research). New researchers are targeted with focus on gender balance, type of research topics. Continuous monitoring and evaluation is conducted in different phases; from initiation of new projects, access to equipments, key focal points at local level. | |
| 55 | Improvement of Tuberculosis Laboratory capacity on Pemba island, Zanziber: a health cooperation project | The infrastructure development was done in four different phases. Phase 1- identification of suitable space, checking of useful material, desgining lay based on WHO standards, testing of biosafety level 2 cabinet with centrifuge, microcentrifuge, incubator. Phase 2- Lab equipped with light micropscope, | Between 2007-2010 921 samples were sent to TB section of PHL-IdC from 14 peripheral labs in Pemba and since July 2009 26 peripheral labs in Unguja island. 121 pulonary TB cases were diagnosed. | A low cost intermediate lab set up within a short space of time. However, need to maintain supply of reagents, focus on |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | incubator, combined fridge and orbital shaker. Reagents and disposables for smear microscopy. Phase 3-Training of lab personnel in smear microscopy and solid culture on LJ media. Phase 4.- HR capacity building reinforcement by teaching training, monitoring and mentoring by internet. The diagnostic methods included smear preparation using ZN methods. The Internal quality assurance system was established but no EQA. | From 115 smear positive cases, 84 were culture positive, and by 2010 the smear positive to culture positive rates reached 100%. | transportation of samples, are important for optimal services. |
| 56 | Improvement of Tuberculosis Laboratory capacity on Pemba island, Zanziber: a health cooperation project | The infrastructure development was done in four different phases. Phase 1- identification of suitable space, checking of useful material, desgining lay based on WHO standards, testing of biosafety level 2 cabinet with centrifuge, microcentrifuge, incubator. Phase 2- Lab equipped with light micropscope, incubator, combined fridge and orbital shaker. Reagents and disposables for smear microscopy. Phase 3-Training of lab personnel in smear microscopy and solid culture on LJ media. Phase 4.- HR capacity building reinforcement by teaching training, monitoring and | Between 2007-2010 921 samples were sent to TB section of PHL-IdC from 14 peripheral labs in Pemba and since July 2009 26 peripheral labs in Unguja island. 121 pulonary TB cases were diagnosed. From 115 smear positive cases, 84 were culture positive, and by 2010 the smear positive to culture positive rates reached 100%. | A low cost intermediate lab set up within a short space of time. However, need to maintain supply of reagents, focus on transportation of samples, are important for optimal services. |

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| | | mentoring by internet. The diagnostic methods included smear preparation using ZN methods. The Internal quality assurance system was established but no EQA. | | |
| 57 | Experience establishing tuberculosis laboratory capacity in developing country context | FIND team conducted a needs assessment of NTRL and developed a multi-phase work plan for upgrade. Phase 1- developing training modules and manuals followed by upgrading training in sputum microscopy and refresher training in smear microscopy. QA program was established based on online evaluation, supervision and blind checking, LQAS sampling was put in place for EQA of smear microscopy across all health centres. Regular Panel testing carried out from samples obatained SNRL South Africa for EQA. Phase 2- NTRL renovated with BSL3 facility to meet WHO stds for handling liquid TB culture, TB solid culture and DST implemented with EQA provided by SNRL in South Africa. TB liquid culture, DST, rapid immunoassay based species identification, LJ media for isolation from solid culture, BACTEC-MGIT 960 TB system for liquid culture | 1. The TB diagnostic capacity increased from less than 100 to more than 700 culture per month by june 2008. 2. The validation of liquid culture method in Dec 2008 revealed the contamination rates 1.9% for solid and 7.8% for liquid cultures. There was 14% increase in the sensitivity of liquid culture compared to solid culture by immunochromatographic assay. Between Jan'08 and Mar'09, 8569 specimen were cultured including the use of LJ and MGIT with an overall contamination rate of | A high profile project attracted lot of attention and requests for training from other African countries, which could be stressful for the staff, and add to the workload who could miss out on different training opportunities. |

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| | | were introduced. Phase 3-activities to prepare for introduction of the LPA for detection of MDRTB began with construction of a clean room facility, followed by introduction of the assya and training of the lab staff. | 10.8%, with 87% culture positive.2 After validation and retraining LPA has started to be routinely used. 3Microscopic examination for smears increased from 900 to 85471 per month at 14 different microscopic centres and NTRL. Of these 33473 slides/14372 patients were examined at NTRL. | |
| 58 | Capacity building in response to pandemic influenza threats: Lao PDR case study | 1. GoL established a coordination entity in 2006- National Avian and Human Influenza Coordinating office (NAHICO) directly under PM office in 2006, which was later expanded in 2009 as National Emerging Infectious Disease Coordinating Office (NEIDCO) in May 2009. 2. NCLE held forum/meeting with WHO andUSCDC to develop a road map for NIC desgination. USCDC adn Pasteur provided training, oversight and helped to set QA standards to develop new strategies at NCLE for public health laboratory detection process. This included starting | 1. till 2011 294 influenza samples and viral isolates submitted to WHO GISRS. EQAP comptence ratings 90-100% for PCR, 80-100% for rPCR. Single molecular sequencing platform for both human and animal health laboratories (one health approach). 2. EWARN expanded from 33 to 144 districts in all 17 provinces. 3.Rapid | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | up PCR testing and training to local lab personnel (coinciding with H5N1 outbreak), participating in WHO EQA and with this contributing to WHOGISRS and WHO FLUNET. 2. Establishment of virological sentinel surveillance network to combine respiratory illeness with pandemic and seasonal influenza (EWARN). 3. Field Epidemiology Training (FET) initiative to develop technical cadre of public health professions networked throughout the country.4 Use of Real-time PCR to improve testing capacity. | recognition and response to outbreak due to timely verfication and follow up of carses to identify human clusters through training of the trainer approaches and decentralisation of reporting mechanisms. 3. Rapid recognition in outbreak and response time taken, decentralisation of outbreak reporting. 23 FET trained personnel to conduct outbreak investigations, pandemic containment, mitigation, adverse effects of immunisations, expansion of SARI and ILI surveillance. Exapnsion of the network to include other epidemics and outbreaks, for example Japanese encephalitis, human anthrax, dengue, cholera etc. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| 59 | Medical laboratory quality and accreditation in Jordan | narrative | 1. MoH responsible for running all 190 labs, distributed at peripheral, intermediate and central levels. Also Military medical services run 8, university hospitals 2, UNRWA 24, Charity based 15, Private sector 351. Licencing of the labs is mandatory by law, MoH has set up standards for quality control and assurance and by law all labs need internal QA and participate in EQA if existing. Focus on QC in training programs and last 10 years National External Quality Assessment Schemes were implemented in bacteriology, virology, parasitology and clinical chemistry. 2 Accreditation-new concept in Jordan and there are no regulations at | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | present for accreditation. Few labs have ISO9001:2000 and USO 15189:2007. Jordan Institute of Standards and Metrology (JISM) has specialised unit in accreditation (JAS) which is developing. Healthcare Accreditation subcommittee is constituted and tasked with planning of Jordan Health care Accreditation and Certification Commission (JHACC) which is responsible for accreditation and certification, and developed first draft of accreditation for hospitals. This draft implemented in 17 hospitals- 8 public, 5 private, 2 military, 2 university. | |
| 60 | Role of Laboratories and Laboratory systems in | narrative | Need for drug susceptibility testing is | |

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| | effective tuberculosis programmes | | emphasised in light of resistance. EQA programmes should focus on how smears are performed and interpreted. Given that LMICs do not have basic capacity for drug resistance surveillance (DRS) or MDRTB, appropriate use of current limited culture capacity should be encouraged. Use of NAAT for rifampin resistance is recommended, however with achieving robustness of the results. 'On the job' training for AFB microscopy and HIV rapid testing is encouraged for improving lab personnel capacity. TB cases reporting should be made mandatory and national TB programs and NRLs should ensure EQA for | |

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| | | | private labs. An integrated NRL is preferred than stand alone ref lab specific for TB. Microscopy labs in LMICs can invest in low cost fanboxes, relatively inexpensive than expensive biosafety cabinets. If suitably installed these provide similar level of protection. EQAs are expensive, an effective way of supranational EQA is through mentorship of NRLs and exchange of strains between them to measure performances. Research is encourged to be performed in the field labs in LMICs than established academic institutions , and helps to improve the capacity of operational field research. | |
| 61 | Certification of TB culture and drug | narrative | A formal application is made to the CTD for | |

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| | susceptibility testing laboratories through the revised National TB control programme (RNTCP) | | accreditation for C&DST (stds based on ISO15189), which after scrutinising forwards to NRL for further processing. The steps for accreditation involve- a preassessment visit by team of NRL for reviewing infrastructure facilities, C&DST equipment, qualified and trained personnel, SOP, technical procedures, workload capacity, biosafety and infection control measures. Based on initial assessment, customised recommendations are made. 2. Once labs comply with recommendations, labs are assessed for performance based on first 100 patient samples for culture and DST for contamination and proficiency for setting up | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | interpretatble DST tests. 3. NRLs provide external blinded proficiency testing for 20 panels for susceptibility testing for anti-TB drugs for assessment of accuracy in senstivity, specificity, positive and negative predictive value and certification is if >90% results are achieved. The overall time taken for the process is 6-7 months. The program is encourganing other labs, such as ICMR labs, medical colleges labs, private labs for C&DST accreditation. | |
| 62 | Capacity building efforts by the AFHSC-GEIS program | The AFHSC- GEIS sponsored activities invovled reovation existing labs, furnishing new scientific equipments, provision of new or enhanced diagnostic testing equipments, at overseas DoD facilities and US based influenza centres, which served as regional reference labs and host country labs. Over 80 MoHs, | 1 Capacity building initiatives by georgraphic regions. South East Asia (Bhuta, Cambodia, Lao, Nepal, Singapore, Thailand)- NIC and Military influenza lab equipment, reagent and | |

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| | | Agriculture and defence and other institutions in 74 countries were involved, including 52 National Influenza Centres, EID ref labs were supported in this program.Focus was on human health entities. Also invoved development of two new BSL-3 labs in Thailand (AFRIMS and NHRC) providing WHO and SOuth East Asia regional support in research and assist with outbreaks. Two BSL-2 labs were established in Cameroon to target Africa. 2. To support Influenza surveillance AFRIMS established viral/bacterial pathogen culture and molecular diagnostic capacity in Nepal equipped with rPCR for diagnosis. NAMRU-3 also established influenza Centres in Afghanistan, Iraq, Jordan and NMRCD in Columbia, Ecuador, Paraguay, Venezuela, and US-Army Medical Research Unit in Kenya. USPHCR South supported El Salvadore, Guatemala, Honduras, Nicaragua and Panama. 3. Training- in 2009 AFHSC-GEIS supported 18 organisations to conduct 123 training initiatives in 40 countries with 3130 | training, EID lab diagnositcs and disease surveillance system. Far East (Japan, Korea, Philippines)-NIC and Military influenza lab equipment, reagent and training, EID lab proficiency and equipment. East and Central Africa (Cameroon, Kenya, Tanzania, Uganda)- NIC & VHF lab equipment, reagent training and support, EID lab diagnostics. West Africa (Benin, Burkina Faso, Cote D'lvoire, Ghana, Liberia, Mali, Niger, Sierra Leone, Togo)- NIC&MoH influenza lab equipment, reagent and training support, VHF lab diagnostics and militariy EID lab diagnostic testing capacity. North Africa, Middle East and South West Asia ( | |

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| | | people trained to assist work compliant with IHR regulations. | Afghanistan, Egypt , Iraq, Jordan, Kuwait, Oman, Pakistan, Syria, Sudan)- NIC lab equipment, reagent and training support. Central Asia (Azerbaijan, Georgia, Mangolia)- EID and influenza lan equipment, reagent and training support. Europe (poland, Romania)- Military and acadmic influenza lab equipment, reagent and training support. Central and South America (Colombia, Ecuadore, El Salvadore, Guatemala, Honduras, Nicaragua, Panama, Paraguay, Peru)- NIC&MOH influenza lab equipment, reagent and training support, leishmania military reference lab equipement, reagent and training support. | |

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| 63 | Capacity building for zoonotic and foodborne diseases in the Mediterranean and Middle East Regions (an intersectoral WHO/MZCP proposed strategy) | Based on WHO's one world one health concept, Mediterranean Zoonosis Control Program (MZCP) is proposed, based on multi-disciplinary and multi sectoral collaboration and coordination as a core tool for preparedness to address global impact of endemic zoonotic and food borne diseases with particular emphasis on emerging and re-emerging conditions. 2. It involves knowledge sharing, promoting technologies, horizontal communication, public health training program and motivating community participation | The MZCP focuses on building robust public health and animal health system compliant with IHR and OIE standards. Activities include- mized traning groups of physicians, veterinarians, biologists, health and food inspectors, lab staff and other personnel. 2. Intercountry and national training courses on epidemiological surveillance of zoonoses and food borne diseases; food safety and HACCP systems and food security; environment and public health; seminars on intersectoral collaborationn and coordination in zoonotic and foodborne diseases and other relevant areas of interest. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| 64 | Scale up of MDRTB laboratory services, Peru | Between 1996-2000, PARTNERS consortium was establihed with help of US$ 45 million from Gates Foundation to achieve national coverage of MDRTB and replicate it at other places.2. Decentralisation of Rapid DST in 7 regional labs in order to obtain timely results. 3. Use of first line DST in regional labs and Second line DST at INS for high risk patients. Prior to that an assessment was carried out in two district hospitals for efficiency, biosafety facilities, needs of personnel training for the possibility of decentralisation. 4. The preparation phase-mobilising political commitment, infrastructure development, workforce development through Biosafety cabinet (BSC) training and certification. This involved inviting applications to become regional labs for DST and supporting two for renovations to see challenges in the process. In parallel, Training and validation for each DST method. 5. Implementation phase- DST incorporated into program services. Monthly review of aggregate data for contamination rates, culture growth, drug resistance with | 1. Between 1996-2006 the number of DST performed and mycobacterial cultures doubled.2. The monitoring phase showed that health personnel often failed to adhere to NTP norms for DST. Approx 50% of the DSTs in 2005 were for patients without an indication for DST, 28% of those were for patients with MDRTB, although there was an increase in demand for DST because of awareness of MDRTB and benefit of rapid realtime testing. | Responding in time and stepwise overlapping efforts to prevent delays-stepwise decentralisation and dedication to human resources. Coordination of NRL and NTBP with stable political leadership. Within DOTS model smear microscopy can be performed at health centres with local coordination with TB services. Operational research is important for understanding research and program conditions. |

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| | | supervisory visits from INS staff to regional labs, and also to provide training. 5. Monitoring phase- long term evaluation of reinforcement of NTP norms, appropriate use of DSTs and culture data, DST indicators and optimal DST methods should respond to changes in regional epidemiology as well as availability of resources. | | |
| 65 | ASM LabCap's contributions to disease surveillance and International health regulations (2005) | LabCap contributes to several programs. 1. LabCap- PEPFAR initiative- capacity building of global HIV and clinical microbiology laboratories in resource constrained countries. This also includes diagnostic capacity strengthening in HIV/AIDS related Ois, TB through technical assistance and mentoring onsite, needs assessment, development of QA/QC. SOPs and establishment of NRLs/NPHLs, referral networks, surveillance and outbreak response, optimisation of lab policies, assisting in accreditation and certification. 2. ASMLabCap- CDC training: two international courses on AFB smear microscopy EQA, MtB culture, DST, microbiology workshops. 3 IEIP | 1. ASM-PEPFAR: in Botswana, Coted'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, Tanzania, Vietnam, Zambia, DRC, Central Asian Republics, Ukraine. 2 LabCap-CDC training: Smear microscopy EQA Tanzania (participation from other English speaking countries in Africa), Senega (other French speaking countrie)l; DST in Cote d'Ivoire; microbiology workshops in Botswana, | Enables indegenious lab to more rapidly and effectively identify and respond to broad range of diseases, transferring QA skills |

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| | | initiatives: technical expertise and consultation in lab capacity building for clinical microbiology for respiratory condition and implementing actice surveillance for pneumonia. 4. ASM-PATH India: strengthening Intermediate Ref Lab (IRL) network to perform Mtb culture and DST and obtain national accreditation. 5. TB IQC with PATH USAID: providing extensive support to USAID operating units in the implementation of their TB programs through introduction and expansion of components of WHO recommended STOP TB strategy. | Kenya, Mozambique, Tanzania, Zambia; national workshop on enteric disease surveillance and response in Kenya. 3. IEIP initiatives: China ( PCR and non-PCR based evaluation and write SOPs), Guatemala (reivew blood culture processing and give recommendations; including using susceptbility testing via disk diffusion), Thailand ( evaluation of sample collection procedures, transport, processing and identification). 4. ASM-PATH India: evaluation of 8 states using IRL assessment tool, guidelines for preventative measures and biosafety manuals, recommendations for workshop. 5. IQC partnership: partnership through consortium of | |

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| | | | FIND, Partners in Health, MSH, UCSF, Brigham and Women's hospital to expand WHO STOP TB strategu. | |
| 66 | The WHO/PEPFAR collaboration to prepare an Operations Manual for HIV prevention, Care and Treatment at Primary health Centres in High prevalence, resource constrained settings | narrative | The operations manual describes principles, planning for integrated HIV services at PHC, services linkages integration triage, infrastructure, monitoring patients and programs, supply management, lab services, human resources, leadership and management, quality improvement. The tests needed by PHC include: rapid HIV antibody test with counselling, Rapid Syphilis test, malaria test, for infant diagnosis DBS and send out for virologic testing, Hb and hematocrit determination, urine dipstick for sugar and | |

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| | | | protein, rapid pregnancy test, malaria smear testing, TB smear microscopy, blood sample collection for CD4 and full blood count. At district level, additional tests such as AFB smear microscopy, Syphilis RPR, gram stains etc should be available. The supplies include: log books for HIV, STI, syphilis, DBS. TB sputum smear microscopy request form, TB registry book, Infant PCr lab requisition form with program monitoring data, CD4 request form, pregnancy test worksheet. | |
| 67 | POPs analysis reveals issues in bringing laboratories in developing countries to a higher quality level | 1. Initial needs assessment (questionnaire and interviews) was carried out in 18 labs on infrastructure, equipment, consumables, staff etc. Following which customised on site training was organised for each 18 labs for two weeks on POP analysis, QA/QC procedures and hands on lab training. 2 After training performance | 1. Lab infrastructure and environment- Lack of appropriate infrastructure (roads/lab windows/ appropriate lab temp) in Africa is detrimental for trace analysis with loss of compounds with low | Need for more inter-laboratory assessments of ionic PFAS in fish, food, water, sediment, human milk, |

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| | | of all labs were assessed by inter-laboratory study on dioxins (di), polychlorinated biphenyls (PCBs), non-di (ndl) PCBs, organochlorine pesticides. In addition labs also provided samples they analysed to the expert lab (mirror analysis). 3 The results of this performance were evaluated in a seried of workshops organised in different regions with focus on transfer of knowledge and discussion on challenges and successes. | boiling point and mass spectrometry. Fume hood capacity limited exposing technicians to chemicals and occupational health risk. Records of consumables, reagents not maintained. 2. Procurement of lab consumables and instrument maintenance- lack of consumables and lengthy ordering procedures leading to delays or stopping analysis. Use of alternatives and creativity to maintain lab at minimum level was seen ( replacing rotary evaporator with removing Soxhlet cooler but maintaining warming mantle for example). 3. Training and building up expertise and routine- lab expertise varied between | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | | different regions. Asia and South America the expertise were higher than Africa with knowledge on lab management and POP analysis. All labs recieved two weeks training on POP analysis, hands on onsite training in the labs but this was not sufficient to come to required standards, for which 6 months are needed for PCB and OCP analysis. Increasing fequency of POP analysis would help in training. 4. QC/QA- quality control and assurance particulary bad in South America and Africa and most labs were not accredited to ISO standards, performance criteria for methods and validation of studies were not set. | |
| 68 | Laboratory capacity building in Asia for | 1. One SEAICRN lab was established at Mahidol Univerisity,Thailand and | 1. Thailand- 5 labs, Vientnam 5 lab, Singapore | |

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| | infectious diseases research: experiences from the South East Asia Infectious Disease Clinical Research Network (SEAICRN) | reference labs for different aspects of research in the countries in order to carry out influenza and other infectious diseases related 32 RCT in these countries at international standards levels using RT-PCR. All 15 labs in 4 countries were developed to MDL level. 2. BSL-3 facility was established in Hospital for Tropical Diseases, Vietnam for isolation of H5N1 viruses and emerging pandemic influenza viruses, along with pyrosequencing facility to detect mutations and drug resistance.3. Onsite training was provided at all labs for realtime RT-PCR, molecular diagnostics and contamination prevention.4 All labs were enrolled in two different EQA programs and PT was performed for all sites before patient screening was allowed.5 Staff was given specific training for conducting RCTs and a centralised specimen labelling and database system was established for all SEAICRN trials.5. Clinical Laboratory quality improvement program was also initiated, involving assessment of each hospital clinical lab against international standards, equipment maintenance and | 1, Indonesia 4 labs were established. 2. All labs also use MDL for other activities such as HIV, Hepatitis, Menangitis, dengue, encephalitis.3. Traning courses: Phd (6 scientists enrolled), Masters (9) and 295 short term fellowships provided. | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | calibration, enrollement in EQA, assessment of training needs, review of ref values used, accreditation status. follow up was done through training, recommendations, developing SOPs, and document control systems, appointment of Quality officer in all hospitals. | | |
| 69 | The role of standards and training in preparing for accreditation | WHO-CDC-CLSI training toolkit has been developed to support trainers which can be localised and customised for national and local needs. For example: five major zonal labs in Tanzania have been supported to develop quality management systems. Done through onsite mentoring and series of workshops. Similar efforts in Ethiopia, Cote d'Ivoire | | |
| 70 | Improving quality management systems of laboratories in developing countries | 1. An assessment checklist was desgined to quantitatively define the situation in the lab in terms of observable measurable results. It can be used for supervisory visits, planning and evaluating lab improvement projects, and assessing training and effectiveness of SLMTA. It was subsequently adopted as WHO-AFRO checklist for lab accreditation. This checklist was field tested in Ethiopia and | The goal of pilot testing was to assess the efficacy of SLMTA program, specifically task based approach and multiworkshop delivery model, capturing lessons learnt, refining curriculum. Sample improvements were seen in Kawolo | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
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| | | Uganda by interviewing 22 lab managers from all the four levels (national, regional/provencial/district/community). The 10 modules in the toolkit for assessment resemble the key areas of SLMTA framework. The toolkit contains keys areas of work, desired outcomes adn tasks that managers need to perform. 3. The pilot included series of 3 workshops conducted by CDC ASCP facilitaors with 3-4 months gap. | hospital Mukano in terms of organising store room, Nkozi hospital Mpigi with regards to improving data collection, STI clinic Mulago in terms of implementing duty roster. | |
| 71 | The SLMTA programme: transforming the laboratory landscape in developing countries | 1. SLMTA curriculum covers 10 key competencies of a lab manager- productivity, work area, inventory, procurement, equipment maintenance, QA, specimens, lab testing, test results reporting, documents and record control. Total of 66 tasks define effective lab management and consitute objectives of SLMTA curriculum.2. SLMTA runs between 12-18 months involving a series of 3-4 day workshops utilising 44 instructional activities adn more than 100 job aids. Each activitiy is hands on, practice based learning experience for specific management tasks.3. Post training two types of improvement | Some examples from SLMTA include 1. Cameroon- used facility based decentralised model for training instead of one centralised program due to lack of resources. Lesotho- the schedule and frequency of training adapted to match existing mentorship timetables. Mozambique- SLMTA integrated in existing structure of MoH lab system. Rwanda- adoption of data driven advocacy by | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | projects are implemented-complicated projects requiring data collection before and after implementation and simpler 'just do it' type that can be implmented straightaway. This is supported by periodic supervisory visits or on-site mentoring guided by standardised tools.4. This is followed by formal lab evaluation component for accreditation under WHO-AFRO SLIPTA programme which is 5 stage preparedness scheme that recognises labs according to their compliance with ISO 15189 standard. 5. SLMTA can be organised and adapted to local environments | tracking number of tests not performed, funds required, and prospective revenue that can be generated. Cameroon-after initial SLMTA one hospital devised its won quality improvement teams for other units in the hospital. Zimbabwe- extensive resource challenges were met by manually writing and paper based system where computers were not available. 2. SLMTA adopted training of the trainers approach was scaling up. A teach back of assigned activities is conducted for receiving constructive feedbacks. 3. For SLMTA to run- a national lab policy and plan, a technical working group is pre-requisite, equally crucial is appropriate site selection | |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | with advise on small start and then scaling up. SLMTA requires three types of cadres- trainers to teach curriculum, auditors to perform internal audit, and mentors to facilitate projects. 4. Globally- outside africa 24 more countries from Carribean, Central and South America, and South East Asia have adopted SLMTA. | |
| 72 | Field experience in implementing ISO 15189 in Kimisu, Kenya | The journey towards accreditation involved 1. The lab conducted consultation (outsource) with Contract Lab Services who identified ISO 15189 as appropriate international accreditation. It conducted gap analysis in QMS and adviced on implementing ISO standards. Lab constituted independent Quality System Unit (QSU) to evaluate areas of improvement based on Contract Lab Services assessment. QSU developed various documents and systems- lab quality manual, quality policies, SOPs, staff competency assessment guidelines, | 1. Challenges in achieving ISO 15189: expensive and labor intensive, lack of trained personnel in QMS for GCLP, lack of professional in country trainers, equipement procurement from abroad, implementing safety standards. 2. Post achievement challenges- staff retention and move to other labs,, maintaining reliable supply of | 1. Creation of reliable and competent workforce, greater internal contrl and good tracking system, reliable infrastructure for tracing errors and complaints. 2. Timely identification of weaknesses and rapid resolution leading to reductions in operation costs and time savings.3. |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | complaint/incidence reporting systems, quality indicator systems, internal QA auditing system, documents and records control system. 2. Enrolment for EQA with CAP, Virology Quality Assurance Program, UKNQAS, Humane Quality Assurance Services. 3. Infrastructure and information systems were developed such as automated temperature monitoring and streamling sample reception, repository and tracking. 4. Initial Assessment done by US PPD prior to ISO assessment by SANAS to address the existing gaps. Followed by ISO 15189 accreditation. | commodities at manageable costs, increased workload and client demands,, continous nurturing of 'culture of quality'. 3. Essential elements of managing accredited lab involve-well organisaed lab management system, strengthening of QSU which improved QA standards, establishing a lab technical advisory commitee, establishing and monitoring lab quality indicators based on 7 areas of assessment ( Quality management, resource utilisation and financial performance, process efficiency and effectiveness, risk management and safety, client satisfaction, personnel performance and satisfaction, data | Accurate, reliable, quality and timely service delivery, reduction in sample rejection |

| Study Number | Study Title | Description of Study | Results | Implications/Impact/ Recommendations |
|---|---|---|---|---|
| | | | management), promoting continuous quality improvement. | |
| | | | | |

## Annex 4: Quality system elements of ISO15189 accreditation

List taken from Young (2010)(75)

1. Organisation and management
2. Quality management system
3. Document control
4. Review of contracts
5. Examination by referral laboratories
6. External services and supplies
7. Advisory services
8. Resolution of complaints
9. Identification and control of non-conformities
10. Corrective action
11. Preventive action
12. Continual Improvement
13. Quality and technical records
14. Internal Audits
15. Management review
16. Personnel
17. Accommodation and environmental conditions
18. Laboratory equipment
19. Pre-examination (pre-analytical) procedures
20. Examination (analytical) procedures
21. Assuring quality of examination procedures
22. Post-examination (post-analytical) procedures
23. Reporting of results

## Annex 5: Stepwise Laboratory Improvement Process Towards Accreditation

The primary focus of the SLIPTA is to improve laboratory Quality Management Systems (QMS) to prepare laboratories for accreditation to ISO15189. This is the international quality management standard specific to medical laboratories used in most high-income countries, including the National Health Service. The ISO 15189 standard is designed to ensure the accuracy and suitability of results produced by the laboratory. Though initially focused on TB and HIV the SLIPTA tool is generalizable and could be modified to address AMR laboratory surveillance capacity.

**Description of tool**
**Engagement of stakeholders**

The WHO regional office initially coordinates the establishment of Memorandums of Understanding (MOUs) with Ministries of Health and facilitates the establishment of regional Independent Evaluation Groups (IEGs). The IEG is the primary vehicle of engagement with governments. MoHs can only be supported through the SLIPTA process if they apply which demonstrates some degree of buy in to the process from the MoH. It is down to the MoH to select the laboratories for enrolment in SLIPTA.

**Laboratory audit**

Once enrolled a team of auditors will be sent to audit the countries selected laboratories within a year. The laboratories are audited using the following criteria:

1. Laboratory test results;
2. Number of tests annually: defined as total annual volume of tests performed by laboratory;
3. Internal quality control procedures implemented for all testing methods used;
4. Two most recent proficiency test results for each test performed;
5. WHO SLIPTA Checklist for the African Region.

The SLIPTA checklist audits the laboratory using the twelve laboratory quality system elements (QSE) to produce an overall score (table xx)

Table A5.1: Scoring of 12 QSE

| Section | QSE | Points available |
|---|---|---|
| 1 | Documents and Records | 28 |
| 2 | Management Reviews | 14 |
| 3 | Organization and Personnel | 22 |
| 4 | Client Management and Customer Service | 10 |
| 5 | Equipment | 35 |
| 6 | Internal Audit | 15 |
| 7 | Purchasing and Inventory | 24 |
| 8 | Process Control and Internal and External Quality Assessment | 32 |
| 9 | Information Management | 21 |
| 10 | Corrective Action | 19 |
| 11 | Occurrence Management and Process Improvement | 12 |
| 12 | Facilities and Safety | 43 |
| | Total | 275 |

Following the audit a list of errors (non-conformities) are presented to the laboratory and six weeks are given to allow the laboratory to present evidence that the non-conformities have been addressed. For serious non-conformities a follow up audit may be required. The laboratory will then be rescored and a star rating given and a certificate of recognition issued, valid for 2 years. This certificate does not equate to any type of accreditation.

Table A5.2: SLIPTA star grading

| Grade | 0 star | 1 star | 2 star | 3 star | 4 star | 5 star |
|---|---|---|---|---|---|---|
| Score | 0-150 | 151-177 | 178-205 | 206-232 | 233-260 | 261-275 |