PLAN AND ESTABLISH A SAMPLE REFERRAL NETWORK FOR TB DIAGNOSIS

PROGRAMME MODULE 3 (PM3)

global laboratory initiative
advancing TB diagnosis

MODULE CONTENTS

- Why specimen referral networks are crucial to the TB diagnostics network
- Strengths and weaknesses of specimen referrals
- Understanding the current referral network(s)
- Coordination/supervision of current sample referral network(s)
- What should be incorporated into the design of an efficient/effective specimen referral network
- Other uses for the specimen referral network
- Costs
- In-sourcing vs. outsourcing
- M&E

© Sam Nuttall

LEARNING OBJECTIVES

- At the end of this module, you will be able to:
- Understand specimen referral networks as it relates to TB diagnostic networks
- Explain the strengths and weaknesses of specimen referral networks
- Put in place structures for ongoing coordination and supervision for all stakeholders
- Understand how your national testing algorithm affects your referral networks
- Begin to (re-)design a functional referral network
- Consider the implications of integration

WHY FOCUS ON SPECIMEN REFERRAL NETWORKS?

- Referring a specimen, instead of a patient, takes the burden off of the patient to reach the laboratory
- Strong networks can possibly leaded to improved equity in coverage
- Referral networks provide linkages between patients, clinicians and laboratories

WHY FOCUS ON SPECIMEN REFERRAL NETWORKS?

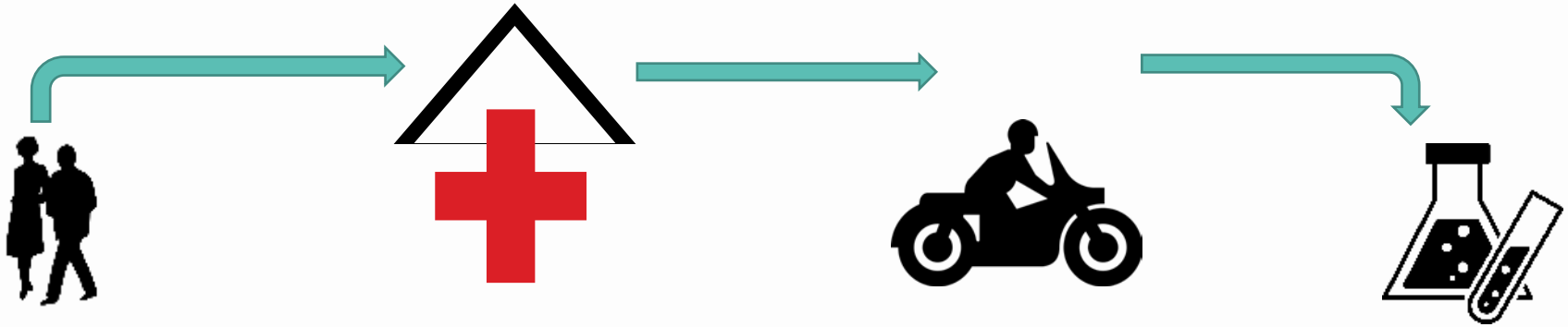
- Enables access to diagnostics at peripheral levels of health system
- Reduced patient cost and time to access services
- Improved cost efficiency of services (avoid placing staff and under-utilised equipment at lower levels)
- Requirement for sophisticated laboratory infrastructure for some TB tests (e.g. culture/DST)
- Referral networks must include mechanisms reporting results back to clinicians as well as referral of specimens for testing

REFERRAL NETWORK PROCESSES

- Consultation
- Specimen Collection
- Packaging

- Specimen pickup
- Reliable and safe transport by appropriate method

- Sample reception/ Recording
- Analysis
- Issue results



PATIENTS | CLINIC | TRANSPORT | LABORATORY TEST

- Reliably transport back results

- Results receipt/ recording
- Issue results to patient
- Treatment options, if necessary

EXAMPLES OF SPECIMEN REFERRAL MODELS

Type	Description	Benefits	Drawbacks	Examples
Dedicated outsourced courier system	System created for specimen transport; other small items/reports may be carried but focus is on specimens; run by service provider	Highly specialised, can specify biosafety, TAT, quality, measures to be met; logistics expert is responsible for system	Highest cost option, causing financial sustainability to be questionable but operational sustainability and quality should be high	Riders for Health (i.e. Lesotho, Malawi, Nigeria, Liberia, Zimbabwe)
Non-dedicated outsourced transport/logistics system	Logistics system already exists but can also carry specimen transport	Can be more efficient in terms of costs and logistics routes; logistics expert is responsible for system	Biosafety and quality control can be a concern where there is other cargo/passengers and training may not have been offered to drivers	FedEx, DHL, National Post System, Public Bus systems (i.e. Kenya, Ethiopia)

EXAMPLES OF SPECIMEN REFERRAL MODELS

Type	Description	Benefits	Drawbacks	Examples
In-house dedicated courier system	System is created for the purpose of specimen transport; other small items/reports may be carried but focus is on specimens; run by MoH	May be less expensive if using existing assets and equipment and HR	May take HR away from health-tasks and focus them on logistics, although they may not be logistics experts; long-term sustainability in terms of management and operation is questionable	Uganda's integrated specimen transport system1
In-house non-dedicated transport/ logistics system	Vehicles in the health system are used to transport specimens	Can be less expensive since using existing assets and HR	May have issues with quality control/rejection rates as specimen transport is not necessarily priority	Using ambulances to transport samples when possible; clinical outreach teams bring back specimens (i.e. Rwanda)

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3827263/

GOALS OF A SPECIMEN REFERRAL NETWORK

- Establish a system to transport patient specimens and return results (where needed)
- Well-coordinated, standardised, reliable, timely, consistent, quality-controlled, efficient
- Cost-effective and sustainable
- Reduce TAT from specimen collection to the return of results
- Increase access to laboratory services at the primary health care level
- Offer fully comprehensive service to transport blood, sputum, malaria slides, or any other referral sample

CURRENT STATUS OF SPECIMEN REFERRAL NETWORKS IN LMICS

Strengths

- Increased focus on specimen transport through GLI and the Global Health Security Agenda (GHSA)
- Availability of GIS maps & mapping software that could be adapted to meet the needs of the TB programme

CURRENT STATUS OF SPECIMEN REFERRAL NETWORKS IN LMICS

Strengths

- Guidelines/trainings on specimen transport specifically:
  - GHSA National Laboratory System Action Package http://www.cdc.gov/globalhealth/security/actionpackages/national_laboratory.htm
  - World Health Organization Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1
  - GLI Training Package Module 3: Collection and Transporting Sputum Specimens http://www.stoptb.org/wg/gli/TrainingPackage_XPERT_MTB_RIF.asp

CURRENT STATUS OF SPECIMEN REFERRAL NETWORKS IN LMICS

Weaknesses

- Lack of understanding and comprehensive view of specimen referral networks in a country
- Weak coordination/supervision
- Lack of tools to properly design an efficient network
- Fragmented design and implementation, i.e. TB-only
- Lack of understanding of true costs of the system
- Weak monitoring and evaluation, including quality control
- Insufficient focus on biosafety/biosecurity

UNDERSTANDING OF CURRENT TB DIAGNOSTICS REFERRAL NETWORK

- To provide access to TB diagnostics within a tiered laboratory network, there must be a referral network in place
- This referral network can refer patients or specimens
- Within one country, there may be multiple referral mechanisms depending on tier, region, funding available, transport options, etc. This can lead to **FRAGMENTATION**, because often the NTP or NRL are not aware of all the specimen referral methods in the country

UNDERSTANDING OF CURRENT TB DIAGNOSTICS REFERRAL NETWORK

- **STAKEHOLDER COORDINATION** is critical. It is important to understand which partners are supporting what specimen referral mechanisms and their costs, coverage, efficiency/effectiveness,
- To understand TB (and other disease) referral networks, perform a landscape assessment and mapping of networks across all diseases

NATIONAL TESTING ALGORITHMS IS IMPORTANT FOR EFFICIENT SPECIMEN REFERRAL NETWORK

- To design an effective specimen referral network, you must start with the national testing algorithm and understand HR/equipment placement and coverage of current specimen referral mechanisms
- Stakeholder coordination is important in this process
- Mapping the network is helpful during specimen transport design and new equipment introduction

NATIONAL TESTING ALGORITHMS IS IMPORTANT FOR EFFICIENT SPECIMEN REFERRAL NETWORK

- Referral of sputum specimens from collection points to first line diagnostic, either AFB microscopy or Gene Xpert
- Consideration of referrals from community level or from facilities
- Referral of rifampicin-resistant specimens tested in peripheral sites by Xpert MTB/RIF / Xpert Ultra to NTRL or SRL for second line DST

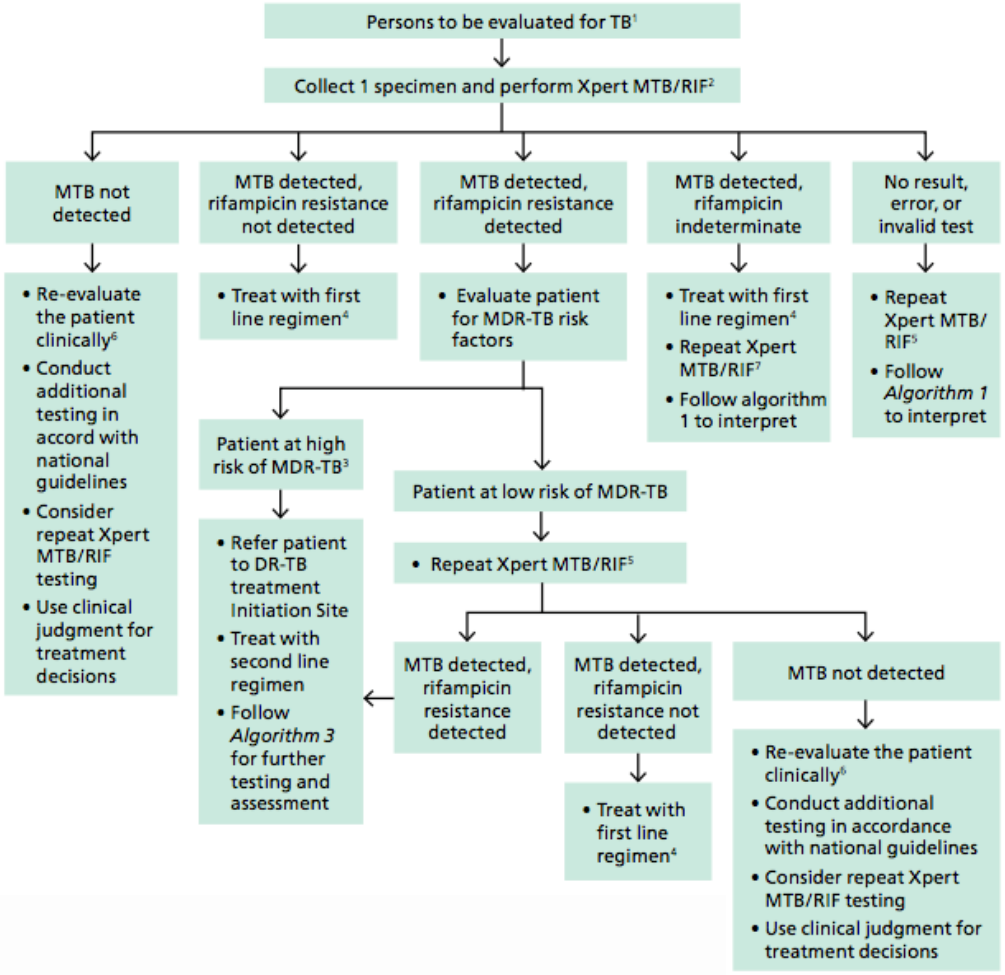
CONSIDERATIONS FOR DESIGNING AN EFFICIENT SPECIMEN REFERRAL NETWORK

Consideration	Options
Will sputum specimens for testing need to be referred?	If "No", the patients should already be at a facility with testing capability or else they will have to travel to the laboratory
If the specimen need to be referred, by whom and by what means will this be done?	Referred by the collecting facility, the laboratory, or a third party transporter via public transport, facility vehicle, personal vehicle, etc.
Where will the specimens be collected from patients and where is the laboratory?	Determine referral pathways for each collection point

CONSIDERATIONS FOR DESIGNING A EFFICIENT SPECIMEN REFERRAL NETWORK

Consideration	Options
How many collection points and laboratories exist?	Identify number of collection points and laboratories in network
What is the time and distance between the collection point and the laboratory?	Depends on road conditions and on transport mode
Will these specimens go directly to the testing laboratory or will hubs be utilised?	Identify need for the use of hubs either for further testing or for logistical purposes
At each laboratory what staff, equipment, reagents are available for testing and on which days is testing offered?	Laboratory capacity needs to be known to determine when specimens are collected, picked-up and dropped off at the laboratory

DIAGNOSTIC ALGORITHM FOR UNIVERSAL PATIENT ACCESS TO RAPID TESTING



[1] Persons to be evaluated for TB include adults and children with signs or symptoms suggestive of TB or with a chest X-ray with abnormalities suggestive of TB. This algorithm may also be followed for the detection of MTB using CSF, lymph node and other tissue specimen from persons being evaluated for extrapulmonary TB. For persons being evaluated for TB who are HIV positive and have CD4 counts ≤100 cells/µl or are seriously ill, see Algorithm 4.

[2] Programmes may consider collecting two specimens upfront. The first specimen should be promptly tested using the Xpert MTB/RIF test. The second specimen may be used for the additional testing described in this algorithm. For persons being evaluated for pulmonary TB, sputum is the preferred specimen.

[3] Patients at high risk for multidrug-resistant TB (MDR-TB) include previously treated patients including those who had been lost to follow-up, relapsed, and failed a treatment regimen; non-converters (smear positive at end of intensive phase); MDR-TB contacts; and any other MDR-TB risk groups identified in the country.

[4] Patients should be initiated on a first-line regimen according to national guidelines. A sample may be sent for molecular or phenotypic DST for isoniazid if the patient has been previously treated with isoniazid or if there is a high prevalence of isoniazid resistance not associated with rifampicin resistance (i.e., isoniazid mono- or poly-resistance) in this setting or for DST for rifampicin if rifampicin resistance is still suspected.

[5] Repeat Xpert MTB/RIF test at the same testing site with a fresh specimen. Interpret the result of the repeat test as shown in this algorithm. Use the result of the second Xpert MTB/RIF test for clinical decisions.

[6] Further investigations for TB may include chest X-ray, additional clinical assessments, clinical response following treatment with broad-spectrum antimicrobial agents, repeat Xpert MTB/RIF testing, or culture.

[7] Repeat Xpert MTB/RIF test at the same testing site with a fresh specimen. Use the rifampicin result of the second Xpert MTB/RIF test in this algorithm for a decision(s) regarding choice of regimen (first line or second line regimen).

Reference: GLI model TB diagnostics algorithms
http://www.stoptb.org/wg/gli/

COUNTRY TESTING ALGORITHM

Customise according to country context - Country testing algorithm

MAPPING THE SAMPLE REFERRAL NETWORK

- The following information is needed to map current networks:
  - Location of health facilities (GIS) – level and services
  - Location of laboratories (GIS) – test menu
  - Existing referral pathways between health facilities and laboratories and from lower level to higher level laboratories
  - Number of tests performed per laboratory
  - Disaggregated epidemiological data

MAPPING THE SAMPLE REFERRAL NETWORK

- The following information is needed to map current networks:
  - Much of this information may already be available in-country
  - Check within MOH planning department, universities or partners
  - Various software can be used to visually represent information on a map
  - Specialised mapping software is also available, but may require training and/or technical support

OTHER CONSIDERATIONS FOR EFFICIENT SPECIMEN REFERRAL NETWORK

- Return of paper results should use the same specimen referral mechanism, but electronic or mobile delivery of priority results should be considered
- Biosafety and quality of packaging and transport processes
- Consideration of flexibility and responsiveness of system to include outbreaks and surveys
- Dedicated logistics role to manage and coordinate specimen referral network
- Integration, where possible, with other specimens and disease programmes, should be considered

OTHER CONSIDERATIONS FOR EFFICIENT SPECIMEN REFERRAL NETWORK

- **Recommendation**: the design of a specimen referral network is a highly-specialised and technical area → outside expertise should be utilised during this phase

OTHER USES OF THE SPECIMEN REFERRAL NETWORK

- Benefits: the system can become more efficient
- Risks: the system becomes overloaded with other priorities and specimen referral suffer in terms of quality, biosafety, turnaround time
- Use for EPTB specimens, surveys
- Integration with non-TB systems such as specimens for HIV monitoring, surveillance systems, outbreak response, etc.
- Reverse logistics: transport of PT samples and other supplies/data

DOCUMENTATION FOR SPECIMEN REFERRAL NETWORKS

- Overarching documents
- National testing algorithm, National guidelines/policies related to referrals, Laboratory handbook (if available)
- Formal service agreements/contracts if the transport/logistics are outsourced
- SOPs and job aids
- Specimen collection strategies, packaging, sample transport methods, results return method

DOCUMENTATION FOR SPECIMEN REFERRAL NETWORKS

- Logs and forms
- Referral forms and registers, tracking slips/chain of custody forms, transport logs
- M&E
- Referral data
- Performance indicators and trackers

COORDINATION OF EXISTING SPECIMEN REFERRAL NETWORKS

- Coordination of networks can be achieved through the use of a national, integrated sample transport technical working group (IST TWG)
- Should be an off-shoot of the National Laboratory TWG
- Inclusion of specimen referral mechanisms representing all specimen types/disease programmes is encouraged even if the systems are not integrated, as sharing ideas, standardising reporting, etc. are useful
- The IST TWG should meet regularly and should be governed by written terms of reference

COORDINATION OF EXISTING SPECIMEN REFERRAL NETWORKS

Customise according to country context – Insert country specific figure for disease programmes (HIV, NTP, emergency outbreak response, disease surveillance)

EXERCISE 1: CREATING YOUR IST TWG

Purposes

- To discuss how to implement an IST TWG to coordinate and supervise specimen transport mechanisms across a country

Total time

- 55 minutes: 30 minutes small group discussion, 15 minutes report to large group, 10 minutes group discussions

Process

- In groups of 4, write down terms of reference (TOR) for a national integrated specimen transport technical working group (IST TWG), including:
  - Frequency of meeting
  - Lead person
  - Partners/stakeholders to include
  - Standardised metrics/indicators for each partner to report
  - Other topics?
- Report back on key items included in the TORs

EXERCISE: DEBRIEF

- What do you think is crucial to the IST TWG?
- Were there certain items that were discussed in your group but not included in the TOR?
- Who would need to convene this group and issue these TORs?
- Do you think that the IST TWG could be an all-inclusive and integrated working group across disease programmes, laboratory staff, etc.?

COSTS TO SET UP AND OPERATE A SPECIMEN REFERRAL NETWORK IN-HOUSE

Setup

- Programme specification
- Build programme infrastructure
- Motorcycle, specimen transport equipment and riding gear procurement
- Recruitment and training

COSTS TO SET UP AND OPERATE A SPECIMEN REFERRAL NETWORK IN-HOUSE

Running

- Fuel and parts
- Refresher training
- Replacement of equipment and gear
- Staffing (local): management, technical, drivers, specimen transport couriers
- Office and vehicle management units
- Insurance, outreach maintenance, programme management and oversight
- Replacement fund for assets/equipment (or depreciation expense)

OUTSOURCING VS. INSOURCING SPECIMEN REFERRAL NETWORK

In-sourcing – running the specimen referral system "in-house" where all operations, staff, etc. are performed by the public health system

- Benefits: Control over all aspects of the system
- Drawbacks: Difficult to manage, management time intensive, need logistics expertise, which is often not easy to find in public sector

OUTSOURCING VS. INSOURCING SPECIMEN REFERRAL NETWORK

Outsourcing – contracting a service provider to refer specimens and return results

- Benefits: Utilise logistics/transport/courier expertise so the MoH can focus on health issues, total costs are easier to identify
- Drawbacks: Perceived (even if not true) high-cost of the system, still need to manage the contract/service provider, may not be a widely-acceptable practice in your country

Hybrid model – certain aspects of the system may be outsourced (e.g. maintenance of the vehicles used for transport) or outsourcing transport outside cities and insourcing within large cities

INCLUDING M&E INTO THE SPECIMEN REFERRAL NETWORK

- M&E is very important for the specimen referral network and should be considered during the design phase
- Monitoring of the network includes quality control, as quality can be affected during specimen collection, packaging, transport, etc.
- It is difficult to monitor and evaluate a specimen referral system due to the challenge in tracking individual specimens, lack of detailed rejection logs at the laboratory, and incomplete cost. This can lead to **data challenges**!

KEY INDICATORS FOR SPECIMEN REFERRAL NETWORK

- Access to diagnostics measured by testing volumes in the laboratory
- Turnaround time from specimen collection to return of results
- Quality of specimens received measured by rejection rates at the laboratory
- Efficiency of the system, measured by a unit cost such as cost per specimen transported or result issued

EXERCISE 2: UNDERSTANDING TAT

Purposes

- To gain a better understanding of how the national testing algorithm and specimen transport availability affect the movements of a patient and their specimens/results
- To look for ways to improve the patient experience and take a more “patient-centered” approach

Total time

- 55 minutes: 30 minutes small group discussion, 15 minutes report to large group, 10 minutes group discussions

Process

- Working in groups of 4, using the current national algorithm, draw out every step in the specimen transport process. Starting from the patient arriving at the clinic through treatment initiation. Include all visits to the clinic as per the algorithm (i.e. spot-morning-spot requires 2 visits)
- Examine the overall process and make notes where improvements could be made to benefit the patient
- Share your process map with the group

EXERCISE 2: DEBRIEF

- Were you surprised by the amount of patient movement required in your system?
- Is the patient movement acceptable? Why or why not?
- Do you think there is a high risk of loss-to-follow-up based on your process map?

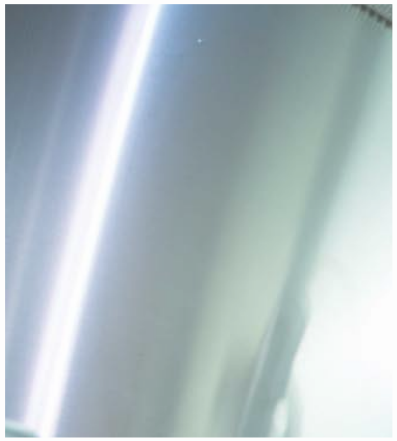
DISCUSSION QUESTIONS

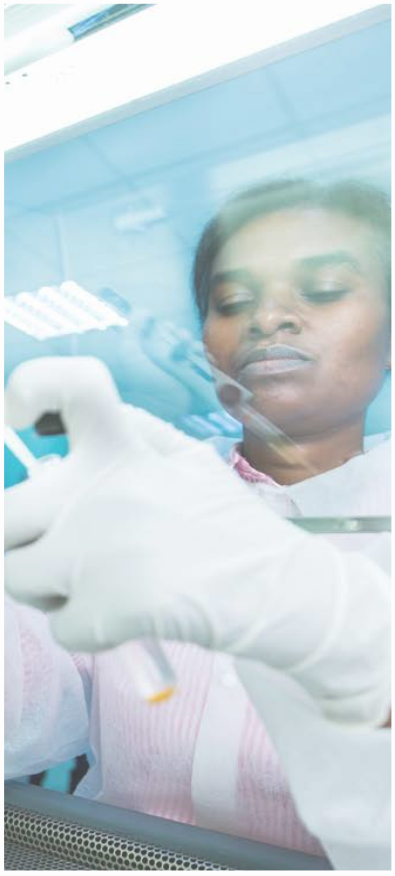
- Give two reasons why specimen referral networks are important
- What are two weaknesses in specimen transport systems?
- What is fragmentation referring to specimen referral networks?
- What does IST TWG stand for and what are the benefits of creating one?
- What is the basis for your specimen referral network design?
- What documents are crucial for the design phase?
- What are other uses of the specimen transport network?
- What is one key performance indicator for your specimen transport network?

KEY MESSAGES

- Specimen referral networks are an important aspect to increase access to the TB diagnostics network and potentially reduce out-of-pocket expenditure from patients
- However, these networks are fragmented, un-coordinated, not standardised and can be inefficient
- We must understand what networks exist, and provide the proper coordination, supervision, quality control and safety measures
- We also must consider re-designing these networks for integration and efficiency purposes over time
- There is no one-size-fits-all solution and external technical support may be beneficial during assessment, design and implementation

global laboratory initiative
advancing TB diagnosis





THANK YOU