PLAN AN INTEGRATED DIAGNOSTIC APPROACH

PROGRAMME MODULE 8 (PM8)

global laboratory initiative
advancing TB diagnosis

MODULE CONTENTS

- What is a multi-disease integrated diagnostic approach?
- What are the benefits of a multi-disease integrated diagnostic approach?
- Ten key considerations for planning and implementing an integrated approach

© John Rae

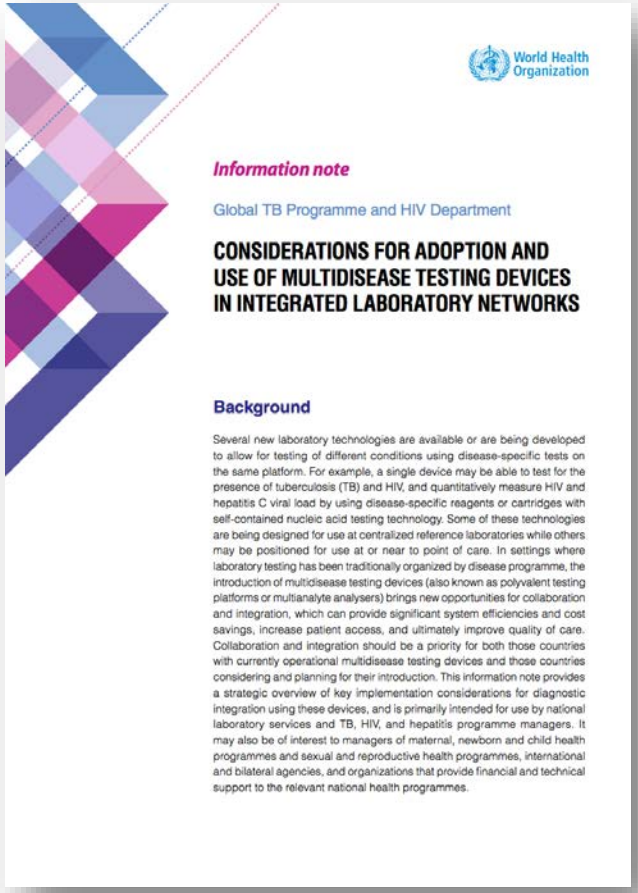
LEARNING OBJECTIVES

- Define a multi-disease integrated diagnostic approach
- List the benefits of adopting a multi-disease integrated diagnostic approach
- Provide examples of an integrated diagnostic approach
- Understand and be able to apply ten key considerations for planning and implementing an integrated approach

WHAT IS AN INTEGRATED DIAGNOSTIC APPROACH?

- A multi-disease integrated diagnostic approach is the use of a **single platform** for testing for **different clinical conditions** using **disease-specific tests**
- For example:
  - The GeneXpert instrument can be used to detect TB and determine rifampicin resistance (Xpert MTB/RIF assay), as well as for early infant diagnosis of HIV. Tests to quantitatively measure HIV and hepatitis C viral load are also under WHO evaluation for potential endorsement

MULTI-DISEASE TESTING DEVICES IN INTEGRATED LABORATORY NETWORKS



World Health Organization

Information note

Global TB Programme and HIV Department

CONSIDERATIONS FOR ADOPTION AND USE OF MULTIDISEASE TESTING DEVICES IN INTEGRATED LABORATORY NETWORKS

Background

Several new laboratory technologies are available or are being developed to allow for testing of different conditions using disease-specific tests on the same platform. For example, a single device may be able to test for the presence of tuberculosis (TB) and HIV, and quantitatively measure HIV and hepatitis C viral load by using disease-specific reagents or cartridges with self-contained nucleic acid testing technology. Some of these technologies are being designed for use at centralized reference laboratories while others may be positioned for use at or near to point of care. In settings where laboratory testing has been traditionally organized by disease programme, the introduction of multidisease testing devices (also known as polyvalent testing platforms or multianalyte analysers) brings new opportunities for collaboration and integration, which can provide significant system efficiencies and cost savings, increase patient access, and ultimately improve quality of care. Collaboration and integration should be a priority for both those countries with currently operational multidisease testing devices and those countries considering and planning for their introduction. This information note provides a strategic overview of key implementation considerations for diagnostic integration using these devices, and is primarily intended for use by national laboratory services and TB, HIV, and hepatitis programme managers. It may also be of interest to managers of maternal, newborn and child health programmes and sexual and reproductive health programmes, international and bilateral agencies, and organizations that provide financial and technical support to the relevant national health programmes.

- This training module is based on guidance provided in the *WHO Global TB Programme and HIV Department information note: Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks*
- http://www.who.int/publications/guidelines/tuberculosis/en/

WHY AN INTEGRATED DIAGNOSTIC APPROACH?

- Multi-disease testing devices (polyvalent testing platforms or multi-analyte analysers) enable:
  - Collaboration and integration between programmes
  - Significant system efficiencies and cost savings
  - Increased patient access
  - Improved quality of care
- Collaboration and integration should be a priority for both those countries with currently operational multi-disease testing devices and those countries considering and planning for their introduction

TEN KEY CONSIDERATIONS FOR A MULTI-DISEASE INTEGRATED DIAGNOSTIC APPROACH

1. Coordinated planning led by the Ministry of Health (MOH)	6. Ensuring capacity for supervision, monitoring and conducting trainings
2. Regulatory approval and validation	7. Clinician training and demand generation
3. Product and site selection	8. Inventory management & procurement
4. Integrated specimen referral systems	9. Quality management systems (QMS)
5. Standard operating procedures (SOP) and trainings for end-users	10. Data management and integration

1. COORDINATED PLANNING LED BY THE MOH

- Essential to the adoption and use of multi-disease testing devices is a country-led coordinated process to:
  - Develop a strategic plan for multi-disease testing
  - Map testing sites to understand location, instrument capacity and current workload of instruments
  - Build integrated specimen referral networks

1. COORDINATED PLANNING LED BY THE MOH

- To do this, countries should:
  - Establish an internal coordinating mechanism (such as technical working group (TWG)) with representation from all relevant disease programmes to support integrated planning and implementation
  - Identify funding streams and seek synergies across disease-specific funding to ensure complete implementation of plans and continuous service delivery

2. REGULATORY APPROVAL AND VALIDATION

- Regulatory approval requirements for diagnostic devices and assays vary by country
- Opportunities for streamlining regulatory approval processes should be considered, including:
  - An abbreviated regulatory process may be possible for new tests to be introduced which run on an already approved diagnostic device (or vice versa: an already-approved test to be validated on a new device)
  - Coordinate in-country validation among relevant disease programmes to avoid parallel efforts and reduce cost and delay in introduction of new tests

3. PRODUCT AND SITE SELECTION

Selection of devices and sites for deployment/integration at existing testing sites should be lead by MOH with representation from all relevant disease programmes and stakeholders

Countries should employ a data-driven approach to understand needs of all disease programmes and establish a cost-efficient plan to achieve service delivery needs

3. PRODUCT AND SITE SELECTION

To do this, countries should:

- Map all testing sites for potential device placement in the country based on target patient populations across diseases and testing volume needs for all tests
- Mapping should account for expected device capacity (*i.e.*, number of tests per day or per shift), and existing device deployment
- Assess unused capacity of existing devices and potential for integration before procuring additional devices

3. PRODUCT AND SITE SELECTION

Consider the following when selecting sites for placement of multi-disease testing devices:

- Infrastructure needs (space, electricity, temperature, *etc.*)
- Specimen referral systems
- Patient access to treatment for each disease being tested
- Equipment, cartridge or reagent disposal requirements
- Biosafety requirements for handling of specimens for all planned test types
- Maintenance requirements
- Human resource requirements

4. INTEGRATED SPECIMEN REFERRAL SYSTEMS

- Establish integrated specimen referral systems for all specimens using multi-disease testing devices.
    - e.g. developing integrated system from the start, or adding new specimens to an existing single-disease referral system
- Specific requirements may be needed for certain specimens, e.g. biosafety considerations for specimens for TB or Ebola testing
- Understand the timing and demand for testing of various disease programmes (*e.g*. TB and HIV clinic operating hours, specific clinic days, outreach events *etc.*)
- Plan specimen collection and transport so as not to overwhelm testing sites or transportation system

5. STANDARD OPERATING PROCEDURES AND TRAININGS FOR END-USERS

- Engage laboratory staff and clinicians from all relevant disease programmes in the consultative process for the development of the SOPs
- Ensure that the SOPs address instances of potential capacity shortfall at the testing site *e.g.* which priority specimens would be tested first, while remaining specimens would be referred to another site or temporarily stored until testing capacity is available
- Train all persons currently performing disease-specific tests on multi-disease testing devices across all test types used in the setting

5. STANDARD OPERATING PROCEDURES AND TRAININGS FOR END-USERS

- All end users should be trained in:
  - Specimen collection and handling (including biosafety precautions)
  - Patient management and test counselling (*e.g.* HIV viral load)
  - Test procedures
  - Following national testing algorithms
  - Interpretation and reporting of results

5. STANDARD OPERATING PROCEDURES AND TRAININGS FOR END-USERS

- All end users should be trained in:
  - Servicing and maintenance of the instrument
  - Quality assurance
  - Waste disposal specific to each assay's reagents and cartridges
- Assess competency (proficiency) of end-users at the end of training and regularly thereafter (*e.g.* annually)

6. ENSURING CAPACITY FOR SUPERVISION, MONITORING AND CONDUCTING TRAININGS

- Establish an integrated approach to quality assurance, including routine monitoring and supervision of facilities across the different test types to maximize efficiency and harmonise support, and alignment of shipment of proficiency test panels
- Select individuals at national and regional levels to perform supervision and monitoring of testing sites using multi-disease testing devices
- Advanced trainings on supervision, monitoring and conducting trainings may be required
- The roles and responsibilities of selected individuals should be clearly defined across the programmes

7. CLINICIAN TRAINING AND DEMAND GENERATION

- Train clinicians and primary care providers on:
  - All types of tests available
  - Utility of each test in clinical management of patients
  - National testing algorithms for each disease
  - Procedures for requesting the tests
  - Interpretation of results for all types of tests
- Develop materials for sensitization of clinicians and primary care providers collaboratively across disease programmes and with clinician and primary care provider input

8. INVENTORY MANAGEMENT & PROCUREMENT

- Integrate forecasting of orders to account for all test types across disease programmes
- Integrating forecasting and procurement allows for:
  - Cost savings from increased volumes and price negotiation with manufacturers
  - Savings on shipping, storage and transport of reagents
  - Integrated systems to monitor stocks and expiry dates of reagents
  - Ability to track consumption and wastage
- Ensure adequate storage space is available at facilities and plan frequency of ordering and delivery of test kits accordingly

9. QUALITY MANAGEMENT SYSTEMS (QMS)

- Integrate QMS for multi-disease testing devices to ensure more cost-efficient and effective implementation
- The QMS should include:
  - Regular on-site supervision
  - Quality indicator monitoring
  - Calibration, servicing and maintenance
  - Internal quality controls, external quality assessment (EQA) and post-market surveillance (if appropriate)
- While there are test-specific requirements for each of these elements (e.g. test-specific indicators and EQA), planning and implementation should be integrated wherever possible

9. QMS

Coordinate service and maintenance requirements for multi-disease devices across disease programmes, including:

- Define roles, responsibilities and timelines for service and maintenance across disease programmes
- Consider the volume of testing performed across all diseases when scheduling service and maintenance
- Negotiate costs with the manufacturer in a way that creates efficiencies across programmes (*e.g.* coordinate service provider site visits for maintenance to all testing sites in a particular region)
- Ensure service and maintenance is well documented and monitored for each device

10. DATA MANAGEMENT AND INTEGRATION

- Install diagnostic connectivity software that is able to accept and use data from all test types from a multi-disease testing device
- Connect the device with the laboratory information management systems (LIMS) and electronic registers to allow for automatic integration of data
- Configuration should allow selected users across disease programmes to have access to relevant data
- Define patient confidentiality rights and data use standards across the programmes
- Negotiate data use agreements across programmes for multi-disease testing devices

EXERCISE: PLAN AN INTEGRATED DIAGNOSTIC APPROACH

Purpose

- To plan an integrated multi-disease testing device laboratory network

Total time

- 60 minutes – about 30 minutes discussion in small groups, 10 minutes to report back to the large group, 20 minutes group discussion

Process

- Divide into 4 groups. Discuss and document the following:
  - What opportunities exist for establishing a multi-disease testing device laboratory network in your country?
  - What are the key concerns for collaborations between different programmes? How may these be addressed?
  - What challenges to collaboration exist, and how may these be overcome?
- Share your findings with the group

DISCUSSION QUESTIONS

- What is an integrated diagnostic approach?
- Give one example of an integrated diagnostic approach?
- List three considerations for selecting and placing multi-disease testing devices?
- List five key competencies for users of multi-disease testing devices?
- Give two benefits of integrating forecasting and procurement for multi-disease testing devices?

KEY MESSAGES

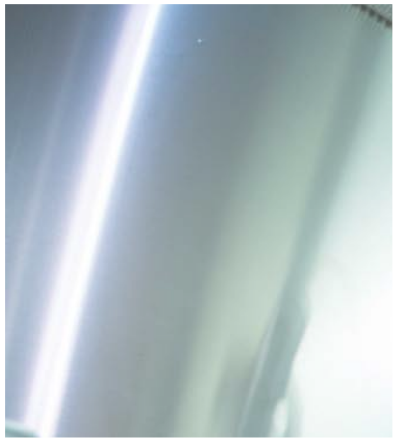
- An integrated diagnostic approach is the testing for **different clinical conditions** using **disease-specific tests** on the **same platform**
- Multi-disease testing devices can provide significant system efficiencies and cost savings, increase patient access and improve quality of care

KEY MESSAGES

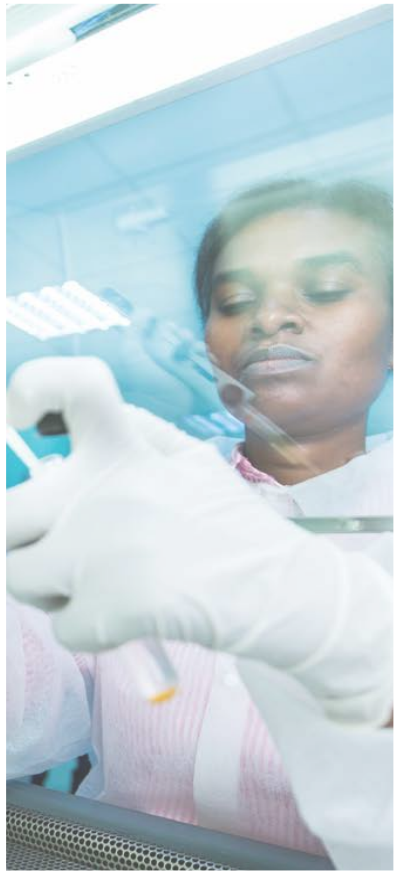
- Ten key considerations for a multi-disease integrated diagnostic approach include:

1. Coordinated planning led by the Ministry of Health (MOH)
2. Regulatory approval and validation
3. Product and site selection
4. Integrated specimen referral systems
5. Standard operating procedures (SOP) and trainings for end-users
6. Ensuring capacity for supervision, monitoring and conducting trainings
7. Clinician training and demand generation
8. Inventory management & procurement
9. Quality management systems (QMS)
10. Data management and integration

global laboratory initiative
advancing TB diagnosis



© John Rae



THANK YOU