Early Infant Diagnosis of HIV

Module 1: Introduction to EID and Point of Care EID Testing

POC EID Training Toolkit
v. May 2019

Agenda

1 Learning Objectives

2 HIV and HIV in Infants: What you need to know

3 Country Specific: Testing Algorithm, POC Testing SOPs and the Role of the Health Care Provider

Learning Objectives

1

By the end of this module, participants should be able to:

- Review the basics facts of HIV and HIV diagnosis in infants
- Describe the importance of early detection of HIV infection in infants
- Understand country specific testing algorithms and protocols
- Understand the role of Health Care Providers on early infant diagnosis of HIV

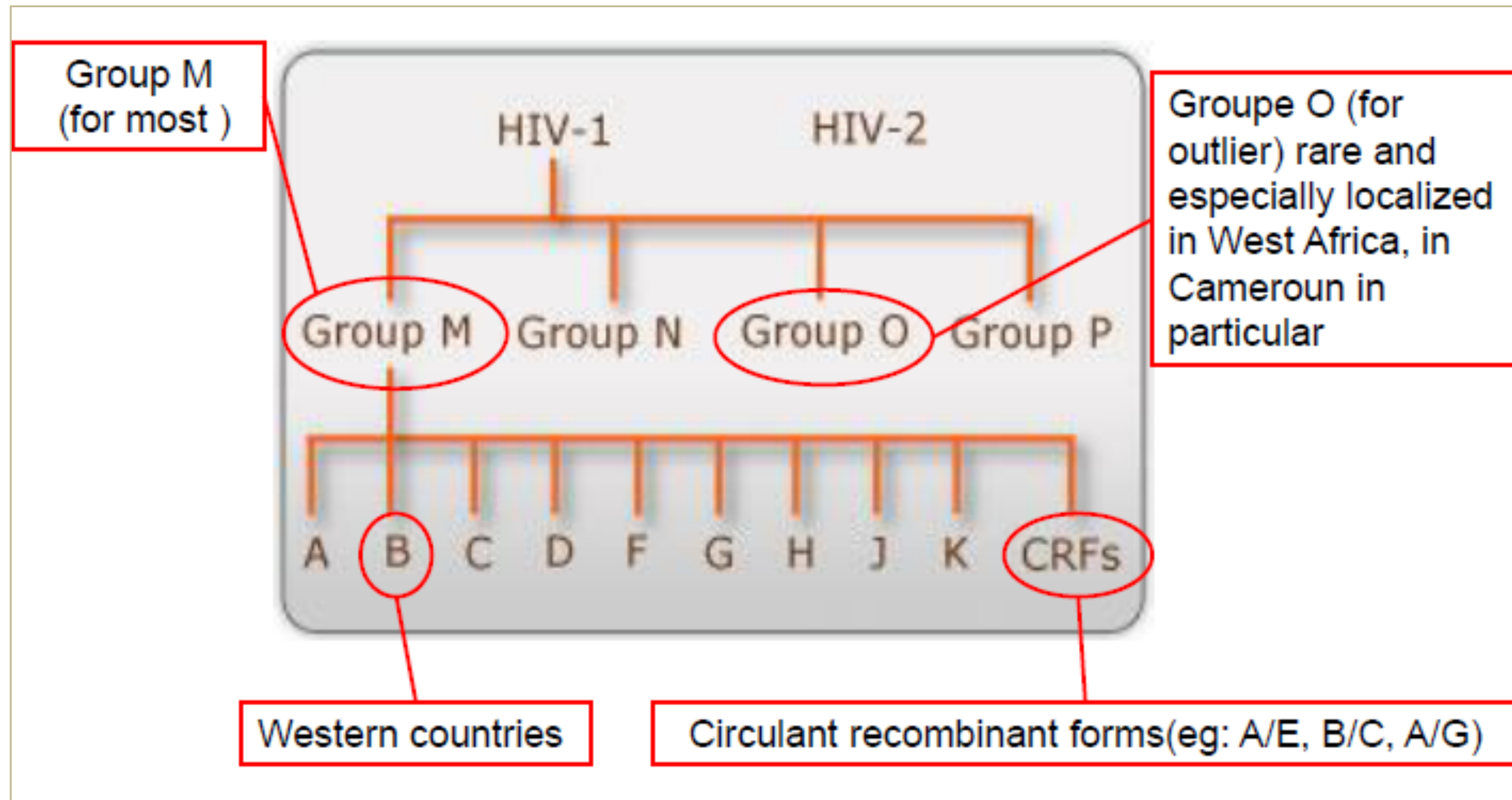
Agenda

1. Learning Objectives
2. HIV and HIV in Infants: What you need to know
3. Country Specific: Testing Algorithm, POC Testing SOPs and the Role of the Health Care Provider

What is HIV?

- HIV refers to the human immunodeficiency virus. There are two types of HIV: HIV-1 and HIV-2.
- HIV-1 is responsible for the vast majority of HIV infections globally
- HIV-2 is rare and localized mostly in West Africa and parts of Western Europe

HIV Groups and sub groups

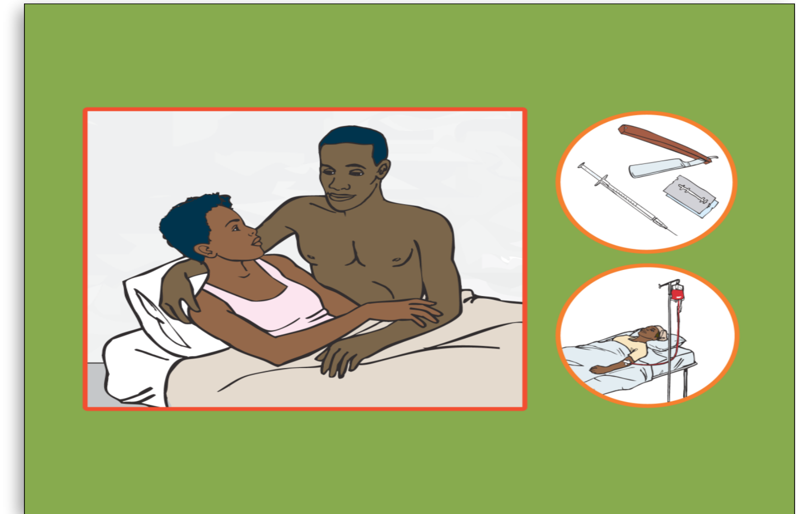


Source: Adopted from Alere presentation

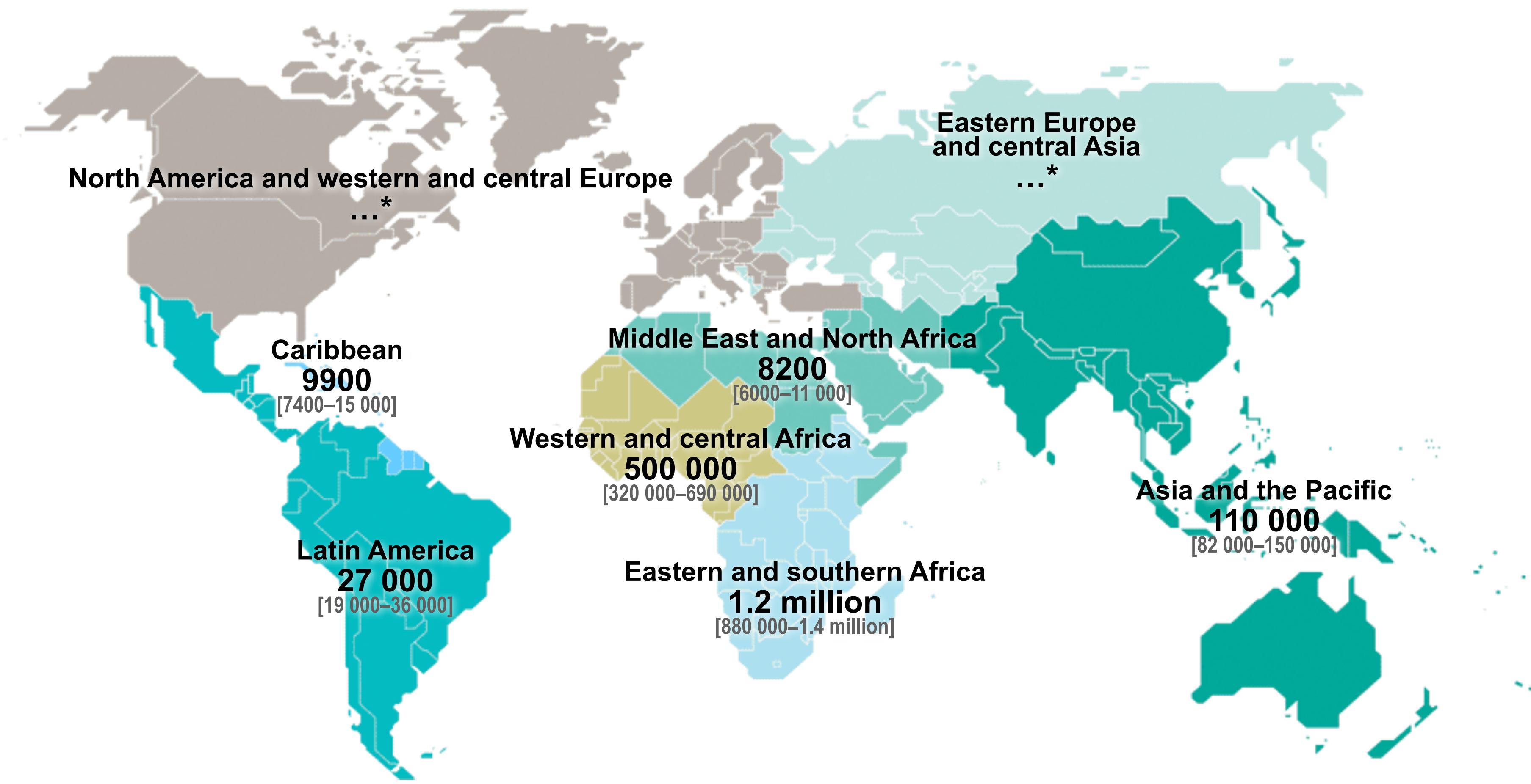
Basic Information on HIV: Transmission channels

The virus can be transmitted/passed through body fluids including: semen, breast milk, blood and secretion from mucous membranes

- Unprotected sexual contact with an infected partner
- Transfusion with HIV-infected blood
- Injection using needles or syringes contaminated with HIV-infected blood
- Accidental cuts in a hospital setting with blood contaminated sharp instruments
- Exposure of broken skin or wound to infected blood or body fluids
- Mother to child transmission



1.8 million estimated children (<15 years) living with HIV in 2017

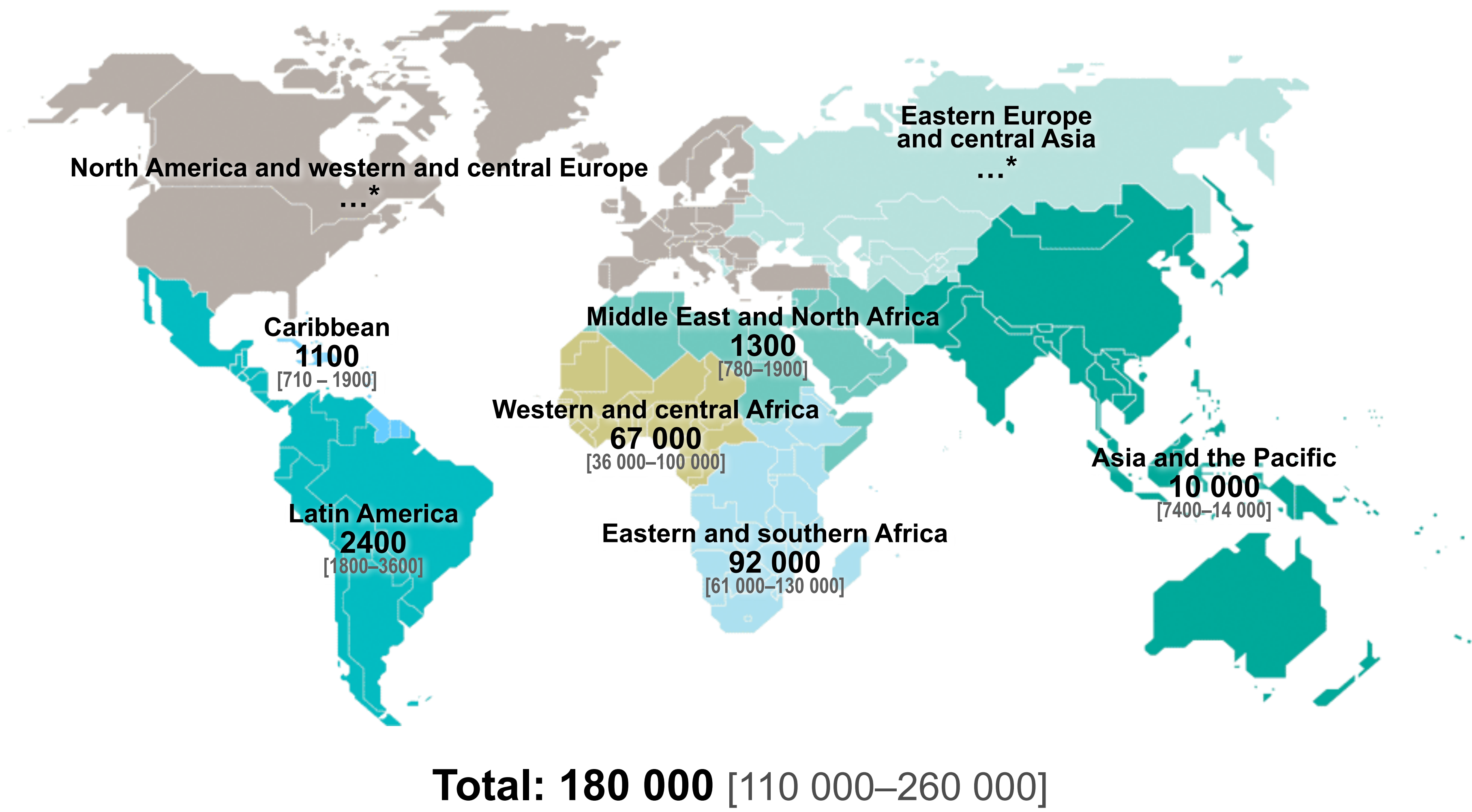


Total: 1.8 million [1.3 million–2.4 million]

*Estimates for children are not published because of small numbers.

Source: UNAIDS, 2018

180,000 estimated new HIV infections among children (<15 years) in 2017

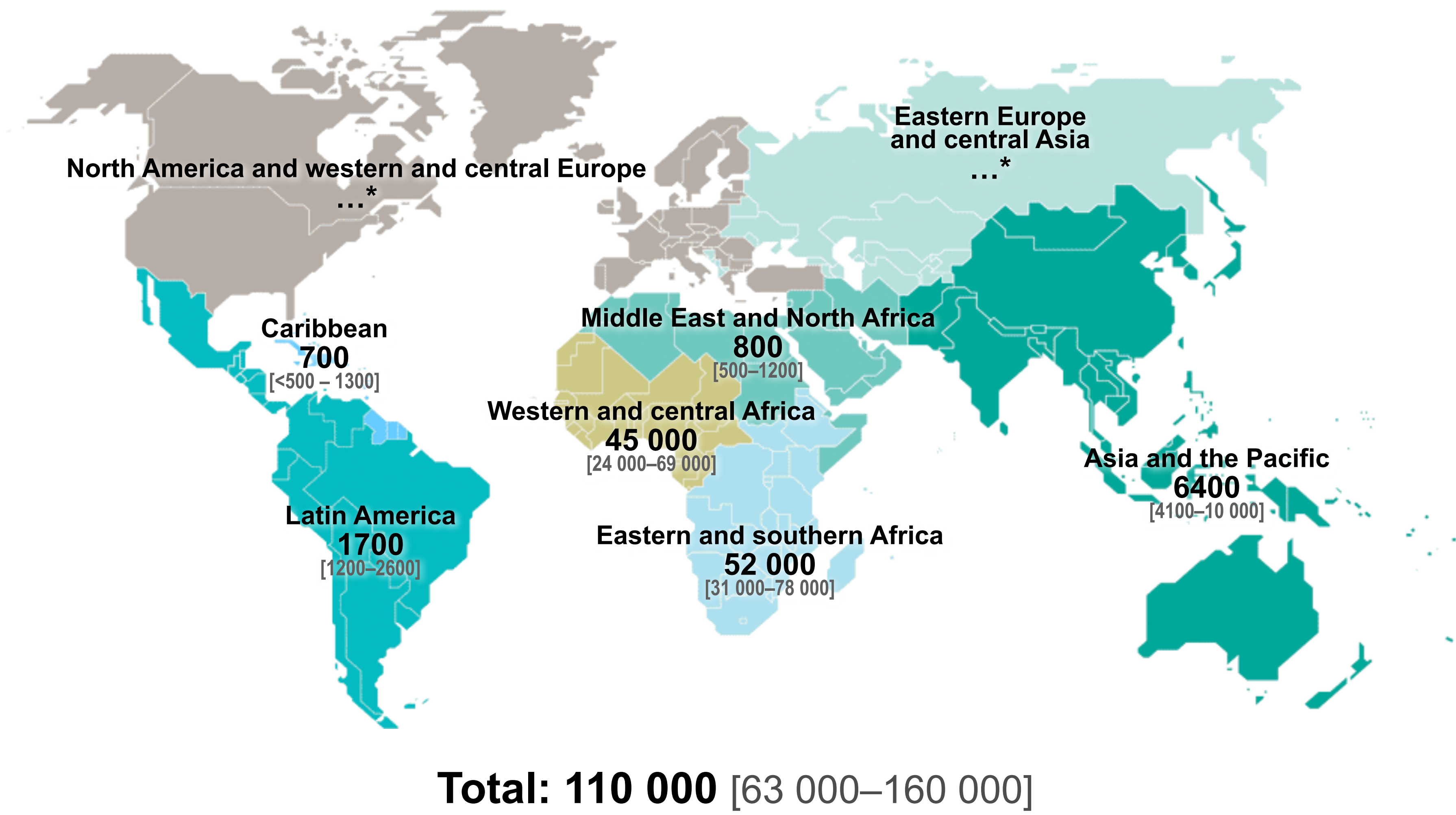


Total: 180 000 [110 000–260 000]

*Estimates for children are not published because of small numbers.

Source: UNAIDS, 2018

110,00 estimated deaths in children (<15 years) from AIDS in 2017

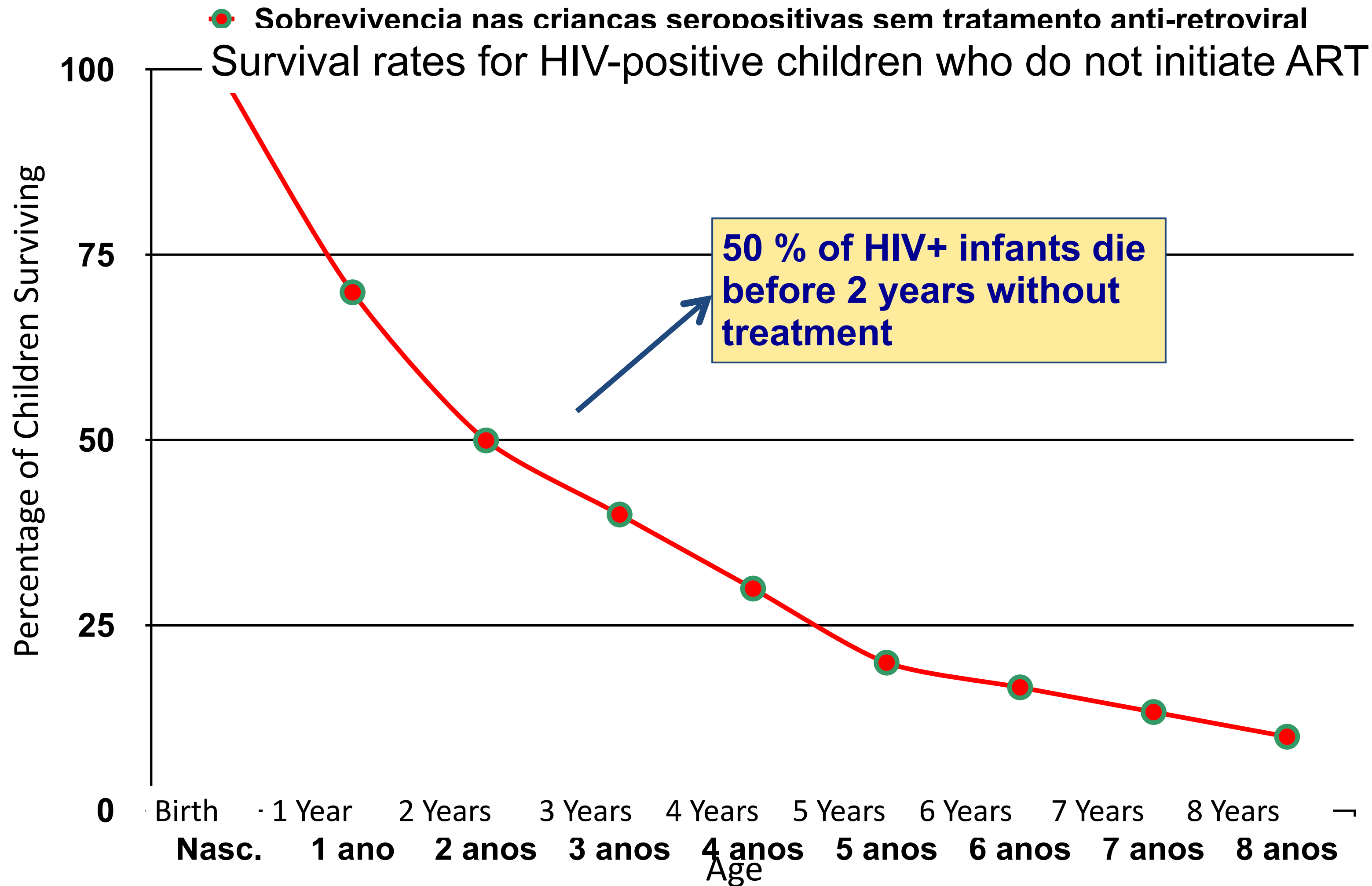


Total: 110 000 [63 000–160 000]

*Estimates for children are not published because of small numbers.

Source: UNAIDS, 2018

EID is an emergency test due to high mortality among HIV-positive infants not on ART



Newell et al. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. Lancet. 2004 Oct 2-8;364(9441):1236-43.

Challenges with diagnosing HIV in infants

2

- Children and infants exhibit accelerated symptoms of AIDS compared to adults
- Left untreated, HIV mortality is 30% by age 1, 50% by age 2 and 75% by age 5
- Clinical staging of disease may be too late for effective treatment
- Risk of transmission persists through breast feeding feeing; diagnosis is a multi-year process
- Before 18 months of age HIV serological test (e.g. rapid diagnostic tests) are unreliable

Diagnosing HIV in Infants – Why Rapid Tests Don't Work

Reminder: Rapid tests look for HIV antibodies

HIV-positive mothers pass antibodies across the placenta to the fetus._

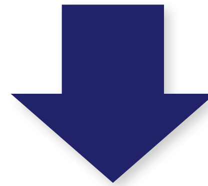
The standard rapid test cannot accurately diagnose infants until the age of 15 - 18 months, the earliest age at which the mother's antibodies are no longer present in the infant's blood.

By this time, many HIV-infected infants will have died.

Transfer of maternal antibodies complicates infants HIV diagnosis

Early Infant Diagnosis (EID) uses nucleic acid testing to look for HIV genetic material

HIV infections in infants CAN be accurately diagnosed using virological nucleic acid testing (NAT) -- in the past this was a challenging test to perform…



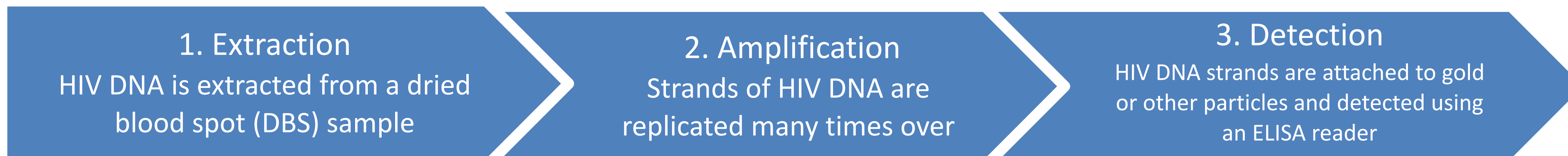
Dried Blood Spot (DBS) is now available to make NAT easier. DBS samples are easy to prepare and can be stored and transported to testing facilities without refrigeration.

DBS testing in conventional laboratory networks expanded access to EID Testing, but only 51% of HIV-exposed infants were tested before 2 months of age in 2015.

Source: WHO Information Note: Novel Point of Care Tools for EID of HIV, July 2017

EID Testing – How Conventional Testing Works

- Used to test HIV-exposed infants for HIV
- Searches for nucleic acids – DNA or RNA – NOT human antibodies
- Provides a qualitative test result (reactive/non-reactive)
- There are unique infrastructure and equipment requirements
- Testing is a complicated, multi-step procedure



- Testing is a lengthy process (up to 8 hrs) → there can be quality concerns
- Testing is typically performed at a few central labs, while samples are collected from many clinics across the country via sometimes unreliable sample transport networks
- Long processing in the lab and unreliable sample transport =

Long turnaround time for results to return to facilities and caregivers

The WHO provides recommendations for when, how and where to diagnose HIV in infants (1 of 3)

2

HIV virological testing should be used to diagnose HIV infection in infants and children below 18 months of age (strong recommendation, high-quality evidence)

Virological testing should be conducted at 4-6 weeks or at the earliest opportunity thereafter for all HIV-exposed infants (strong recommendation, high-quality evidence)

Addition of nucleic acid testing (NAT) at birth to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants (conditional recommendation, low-quality evidence)

Virological test results should be returned as soon as possible to the clinic and child/mother/caregiver, but at the very latest within four weeks of specimen collection. Positive results should be fast-tracked to the mother-baby pair as soon as possible to enable prompt initiation of ART. (strong recommendation, high-quality evidence)

WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and prevention HIV infection: Recommendations for a public health approach. 2016.

The WHO provides recommendations for when, how and where to diagnose HIV in infants (2 of 3)

ART should be started without delay for infants with an initial positive virological test result and, at the same time, a second specimen is collected to confirm the initial positive virological result. Do no delay ART. Immediate initiation of ART saves lives and should not be delayed while waiting for results of the confirmatory test. (strong recommendation, high-quality evidence)

Nucleic acid testing (NAT) technologies that are developed and validated for use at or near to the point of care can be used for early infant HIV testing (conditional recommendation, low quality evidence)

HIV exposure status should be ascertained for all infants with unknown or uncertain HIV exposure being seen in health-care facilities at or around birth or the first postnatal visit (usually 4-6 weeks) or other child health visits ((strong recommendation, high-quality evidence)

Consideration can be given to replacing the RDT at 9 months with NAT in the interest of minimizing challenges of interpretation and simplifying the infant testing algorithm (strong recommendation, high-quality evidence)

WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and prevention HIV infection: Recommendations for a public health approach. 2016.

The WHO provides recommendations for when, how and where to diagnose HIV in infants (3 of 3)

2

Consideration can be given to replacing the RDT at 9 months with NAT in the interest of minimizing challenges of interpretation and simplifying the infant testing algorithm (strong recommendation, high-quality evidence)

Higher Yield Entry Points: In generalized epidemic settings, infants and children with unknown HIV status who are admitted for inpatient care or attending malnutrition clinics should be routinely tested for HIV.
(strong recommendation, low-quality evidence)

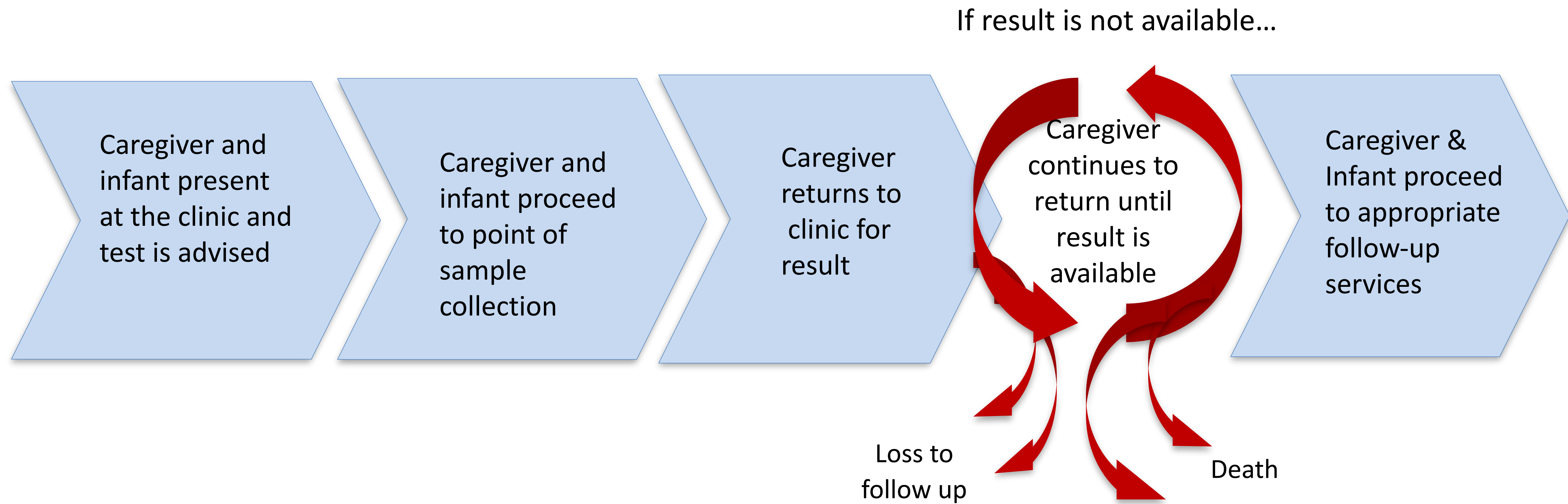
Lower Yield Entry Points: In generalized epidemic settings, infants and children with unknown HIV status should be offered HIV testing in outpatient or immunization clinics.
(conditional recommendation, low-quality evidence)

An indeterminate range should be used to improve the accuracy of nucleic-acid based early infant diagnosis assays (strong recommendation, moderate-certainty evidence)

WHO. HIV diagnosis and ARV use in HIV-exposed infants: A programmatic update. 2018
WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach. 2016.
WHO. Interim Guidelines: Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV. 2018

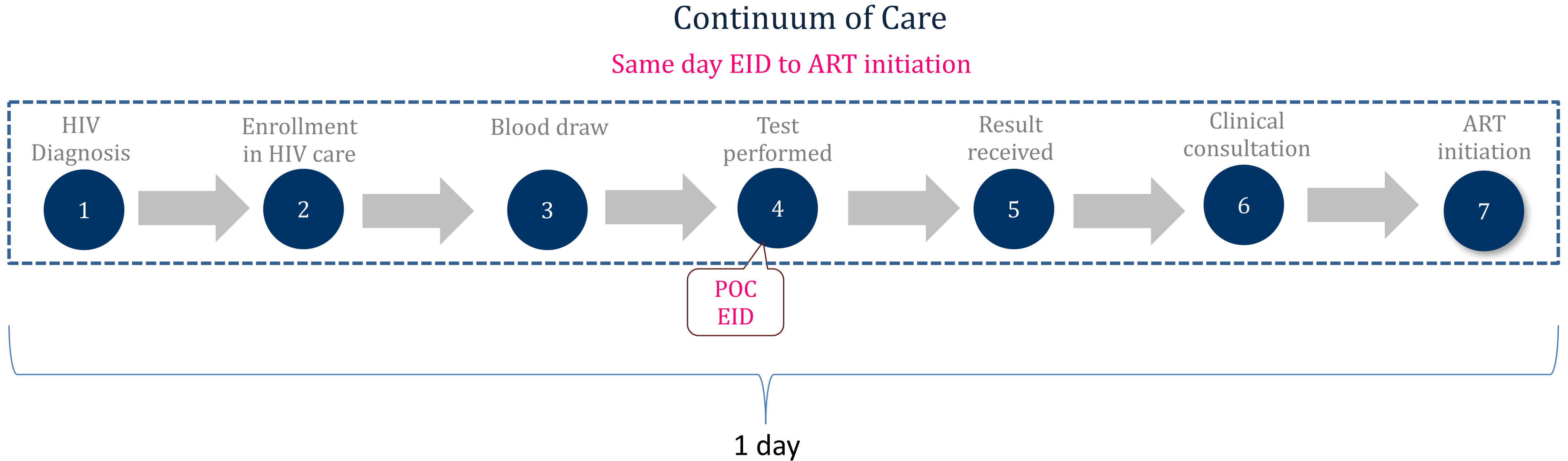
Infants are vulnerable to delays in diagnosis due to long result turnaround times

Each delay contributes to increase risk of mortality for this vulnerable population



Referral-based conventional EID often takes >60 days for results to be returned to the facility/ caregiver, and many results are never returned at all

Point of care (POC) testing transforms the provision of HIV diagnosis by allowing same day sample collection, testing, result return, and treatment initiation



POC EID can return results within the same day, allowing faster treatment initiation for HIV+ infants and more caregivers to receive the test results

POC testing overcomes challenges related to conventional EID to provide significant public health benefits for HIV-infected infants

- Referral-based conventional EID faces delays due to the need to batch samples for transport and analysis
- In study settings and routine use, POC EID has been shown to:
  - Reduce result turnaround time to <1 day
  - Increase ART initiation rates
  - Reduce time to ART initiation

Health workers should proactively identify HIV-exposed and infected infants outside of PMTCT

2

[Before the training begins, update this slide with the appropriate names of entry points in the local health system – the names for these clinics may vary by country, but should include any ward where infants may present for care]

HIV exposed infants may present at any entry point to the facility:

- Mother-baby care point
- PMTCT
- Nutrition ward
- Young Child Clinic / Under-5 clinic
- Pediatric inpatient clinic
- TB Clinic
- Immunization / EPI
- Outpatient department

Infants with unknown HIV status who present at the health facility should be routinely tested for HIV

Step	Action
1. Check child health passport of every infant for mother's HIV status	• If mother is HIV-positive, counsel and refer for infant POC EID testing
2. Check mother's health passport if no indication from child passport	• If mother is HIV-positive, counsel and refer for infant POC EID testing
3. If mother's HIV status unknown, perform a rapid HIV test on her	• If mother is HIV-positive, counsel and refer infant for POC EID Testing
4. If unable to HIV test the mother, perform a NAT on the infant	• If mother is HIV-positive, refer to immediate ART care and her infant for POC EID Testing

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National EID clinical algorithm

3

[Before conducting training, insert country-specific EID testing algorithm here. During training, carefully review the algorithm, including the infant's age when each test should be conducted and the type of test that should be conducted. Emphasis should be given to completing the entire EID algorithm through the end of the exposure period (3-months after cessation of breastfeeding)]

Example: POC EID Testing SOPs

[Before conducting training, update this slide with an example that aligns with local EID SOPs]

ELIGIBILITY

Based on the EID national testing algorithm for molecular testing (EID NAT)

TRIAGE*

If there are more than four clients, triage based on the following criteria:

- Sick children – the sicker children given testing priority
- Distance to the facility – those having to travel furthest given testing priority
- Willingness of the caregiver to stay around for the test and results – personal judgement of the end user, taking in to consideration the other clients in queue

POC EID TEST RESULTS

1. HIV-1 detected, perform a confirmatory test using a new sample
   - If detected return results to client, and manage the client according to National HIV Guidelines.
   - If NOT detected on repeat test, collect DBS and send to molecular lab for test rerun; retain the infant/child on preventive therapy until DBS results are out.
2. HIV-1 undetected, manage client according to National HIV Guidelines.

*Validate during clinical system training session

As health care providers, what role do you play?

- Identify HIV exposed infants at all points of entry to the facility
- Provide sufficient pre-and post- counseling
- Collect sample and perform the test using POC EID device onsite
- Ensure positive results are confirmed using a new sample
- Refer and/or provide care and treatment when eligible
- Ensure infants complete the entire EID algorithm to obtain final HIV status
- Monitor patient progress throughout subsequent visits
- Follow up defaulters and provide counseling
- Monitor adherence to care and treatment

Helping the vulnerable children for an AIDS free generation

Photo source: WHO Information Note: Novel Point of Care Tools for EID of HIV, July 2017

Questions?

Thank You!

Acknowledgments

The development of the POC EID Training Package was made possible thanks to Unitaid's support.

Unitaid accelerates access to innovation so that critical health products can reach the people who need them.

Assuring Quality Testing

Module 2: Lab Systems and POC Testing

POC EID Training Toolkit
v. May 2019

Agenda

1. Learning Objectives
2. POC Quality Management Systems
3. Safety and Waste Management
4. Connectivity and Data Management
5. Supply Chain and Device Management

Learning Objectives

1

By the end of this module, participants should be able to:

- ❑ Understand the critical role of the laboratory system for POC testing
- ❑ Explain the systems approach to laboratory quality assurance and its benefits
- ❑ Identify the essential elements of laboratory quality systems and how they apply to POC testing; recognize key factors that may compromise the quality of POC testing
- ❑ Understand the importance of safety practices and waste management
- ❑ Understand the importance of correct documentation for data collection, supply chain and device management

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1. Learning Objectives
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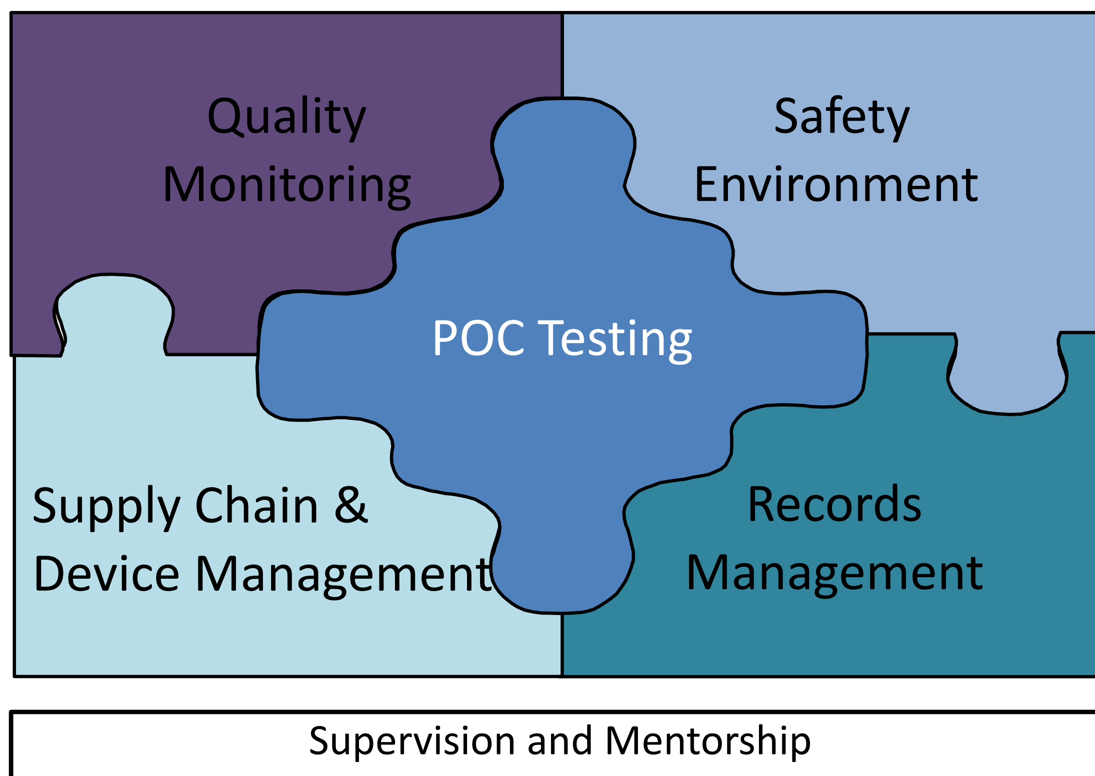
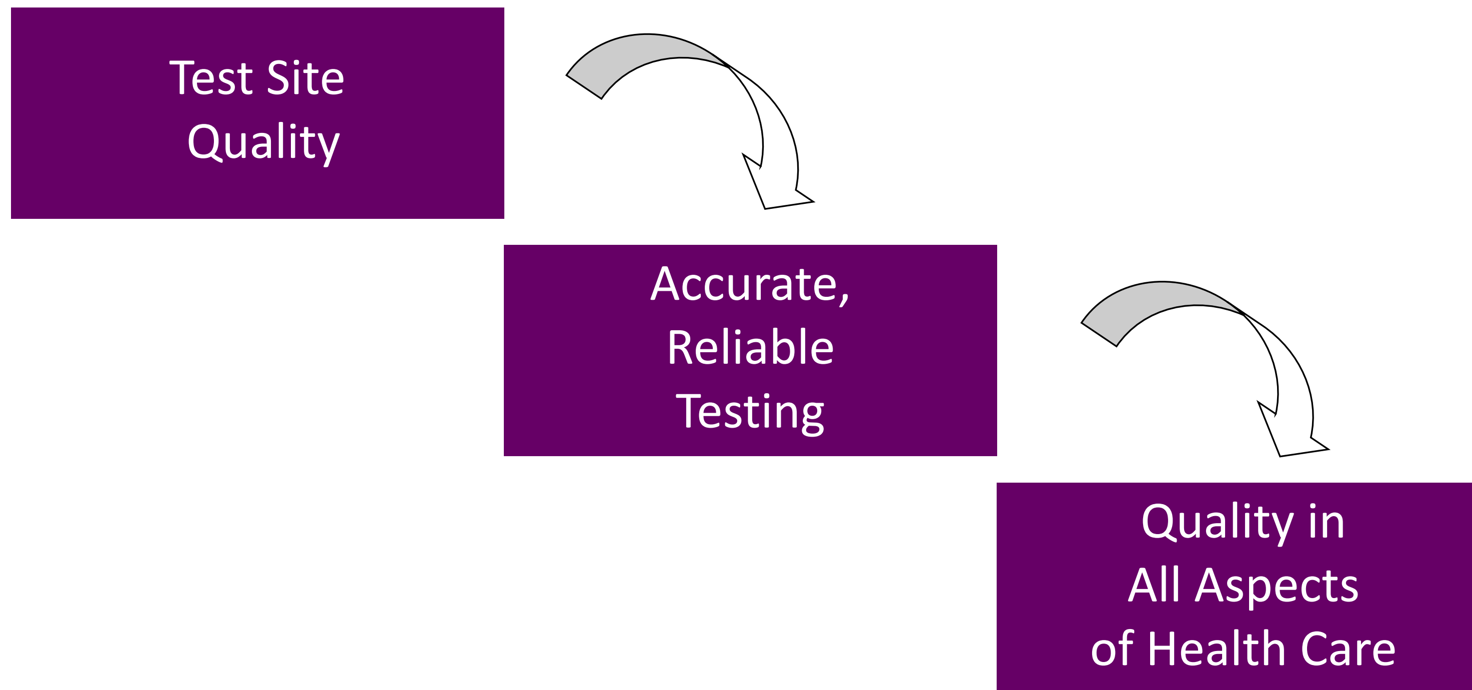
Facilities need strong lab systems to sustain quality POC testing



What Is “Quality?”

- The ability of a product or service to satisfy stated or implied needs of a specific customer
- Quality is achieved by conforming to established requirements and standards

Why do we care about quality?



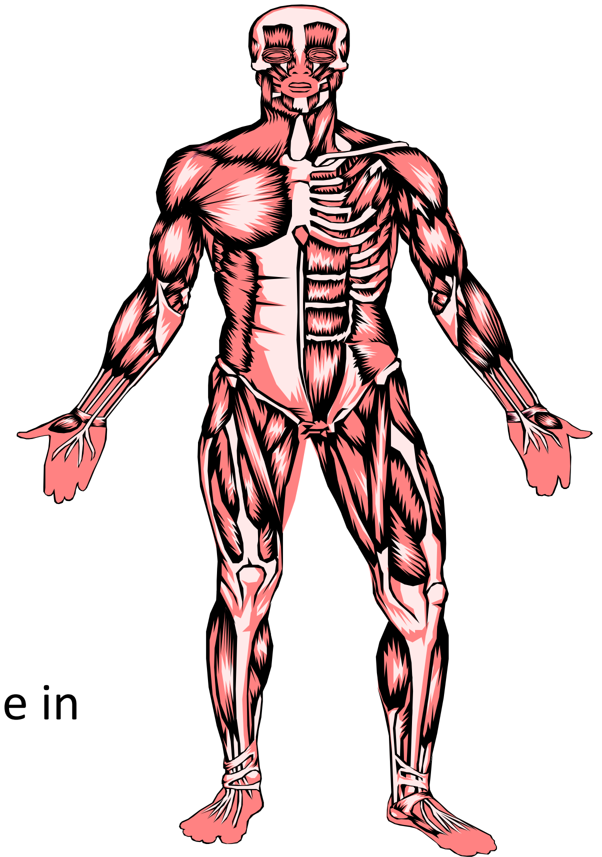
What is a ‘Systems Approach’ to quality?

2

- Considers all components within a system
- Identifies the connection and relationship (e.g., cause and effect) among the components

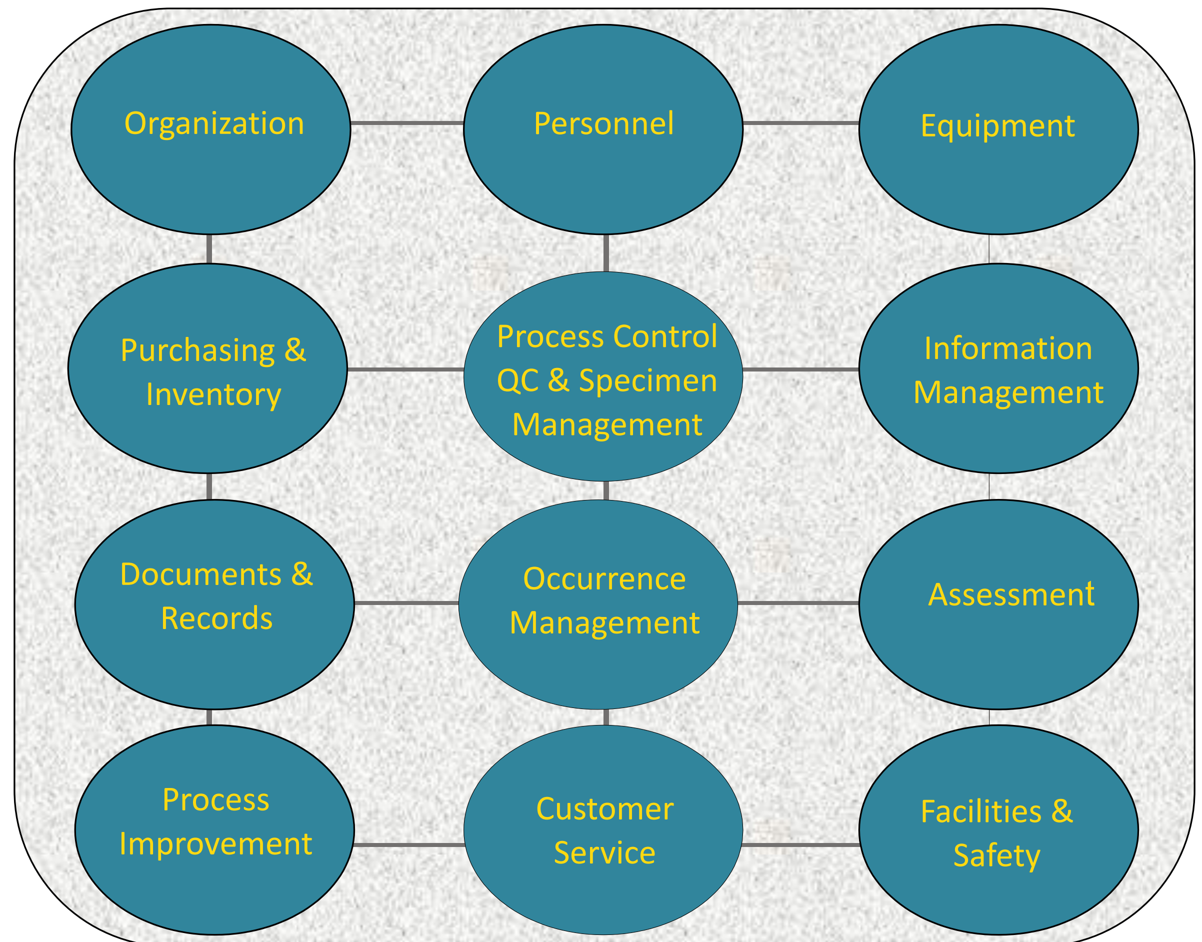
Example: The human body

→ A headache may be caused by a problem somewhere else in the body



The organizational structure, responsibilities, processes, procedures, and resources for implementing quality management of the laboratory or testing site.

In other words…all activities contribute to the quality of testing, directly or indirectly!



Who is responsible for quality?

- Laboratory management <u>and</u> program staff establish and oversees quality assurance procedures
- Test site personnel implement the quality assurance procedures
- Everyone is responsible for maintaining quality in testing

Comparison of QA approaches for POC testing

2

QA Approaches	External Quality Assessment (EQA) Panels	Internal Quality Control (IQC)	Duplicate Testing/ Inter-laboratory Sample Testing	Connectivity	Mentorship
Technology and Systems					
Instrument/device performance	✓	✓	✓	✓	✓
Patient identification	X	X	X	X	✓
Sample & reagent storage conditions	X	X	X	X	✓
Sample transportation conditions	X	X	X	X	✓
Inter-laboratory comparison	✓	X	✓	✓	✓
User					
Overall technical procedure	✓	✓	✓	✓	✓
Sample handling	X	✓	X	X	✓
Reagent application	✓	✓	X	✓	✓
Sample collection	X	✓	X	X	✓
Sample application	✓	✓	X	✓	✓
Result interpretation or reading	✓	X	✓	✓	✓
Data processing (records)	✓	X	X	✓	✓

Quality Assurance vs. Quality Control

2

	Quality Assurance	Quality Control
Definition	Activities to ensure processes are adequate for a system to achieve its objectives	Activities to evaluate a product or work result
Examples	• • Establish standard operating procedures for sample collection & testing • • Define criteria for acceptable samples	• • Analyze known QC samples before a patient sample to determine if a test is valid • Decide if a sample is acceptable for testing

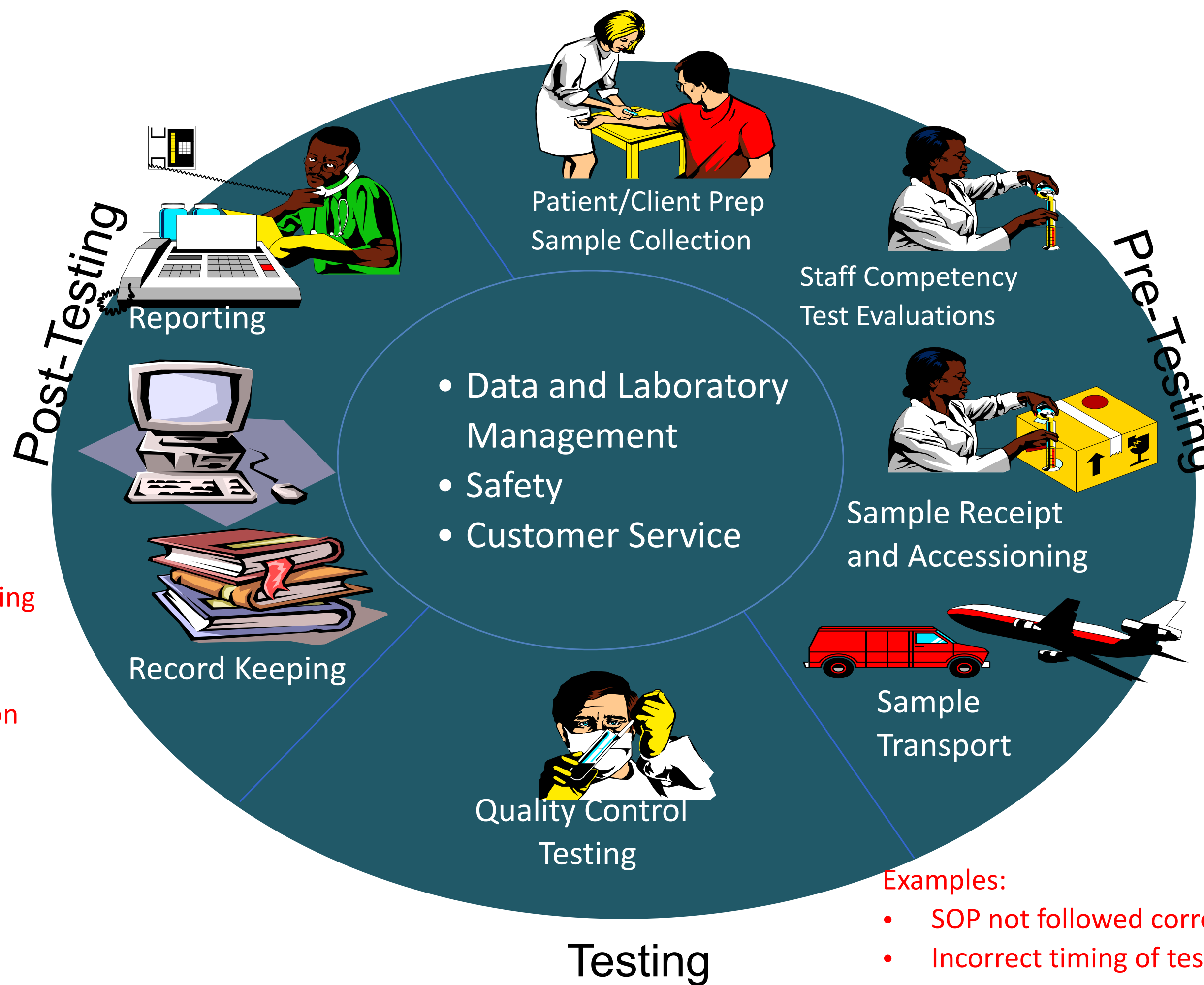
Why do errors occur?

Some causes include:

- Individual responsibilities are unclear
- No written procedures – SOPs/job aids are not available
- Written procedures are not followed
- Training is not done or not completed
- Test kits not stored properly
- QC or EQA is not performed
- Equipment is not properly maintained

Errors can occur at any time throughout the testing process

Errors can occur at any phase of the testing process



Examples:

- Specimen not labelled properly
- Specimen stored incorrectly
- Test kits stored incorrectly

Examples:

- Transcription error in recording test result
- Record not legible
- Report sent to wrong location

Examples:

- SOP not followed correctly
- Incorrect timing of test
- Incorrect reagents used

Trouble shooting errors

What do I do when an error occurs on my POC device?

- In case of an issue, a message will be displayed (often, with an error code)
- Refer to the Operator's Manual and look for the error code, follow the recommended corrective actions
- If the problem persists, contact supervisors
- In case of a discordant result, refer to SOPs or contact supervisor

How can we avoid errors and POC testing downtime?

- Make sure POC test cartridge is filled properly following the SOP (exact volume, no air bubbles)
- Ensure there is no sample leakage/spills before closing the lid and running the test
- Make sure NO vibration/machine movements while test is running
- On mPima, make sure channel window is clean (no dirt and smudges)
- On GeneXpert, do the Xpert Check or calibration check once a year or as needed

Site supervision and mentorship help to identify testing issues early in order to take corrective and preventive actions

Assessment report

- Generated from POC Database on testing and error trends or equivalent report
- To be used during site supervision

Supervision

- Carried out by trained lab tech/lab coordinator using the POC supervision and mentorship checklist
- Occurs every quarter or every 6 months

Mentorship

- Carried out by trained lab tech as needed
- Based on the supervision/data report findings and EQA performance

Summary: Why is a Quality System important for POC testing?

- Quality is the foundation of everything we do
- The Quality System sets the standard for the level of quality the facility will achieve
- Prevents misdiagnoses that affect the quality of life of the clients/patients
- Allows facility to meet client/patient expectations
- Provides means to prevent, detect and correct problems/errors – monitors all parts of testing system
- Is the core of a monitoring, evaluation, & improvement system consistent between testing sites
- Reduces costs by reducing wastage

Even the simplest test is not foolproof!!!

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1 Learning Objectives

2 POC Quality Management Systems

3 Safety and Waste Management

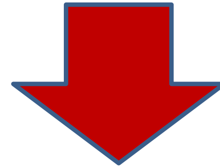
4 Connectivity and Data Management

5 Supply Chain and Device Management

What is a biohazard and why is it important to take safety precautions in the lab?

A biohazard is a biological agent, infectious material or derived products capable of causing harm to humans, animals and plants

Coming in contact with biohazards – such human blood or blood products – is potentially dangerous



Safety involves taking precautions to protect you, your colleagues, the client/patient or the environment against infection

Laboratory safety is achieved through administrative controls, engineering controls, the use of personal protective equipment, practices and behavior

What are universal or standard precautions?

Universal precautions are the recommended physical requirements, procedural actions and precautions for safe work with human pathogenic materials or microbes in healthcare, laboratory and other work environments

Every specimen should be treated as infectious

Apply safety practices throughout the testing process

Pre-Testing

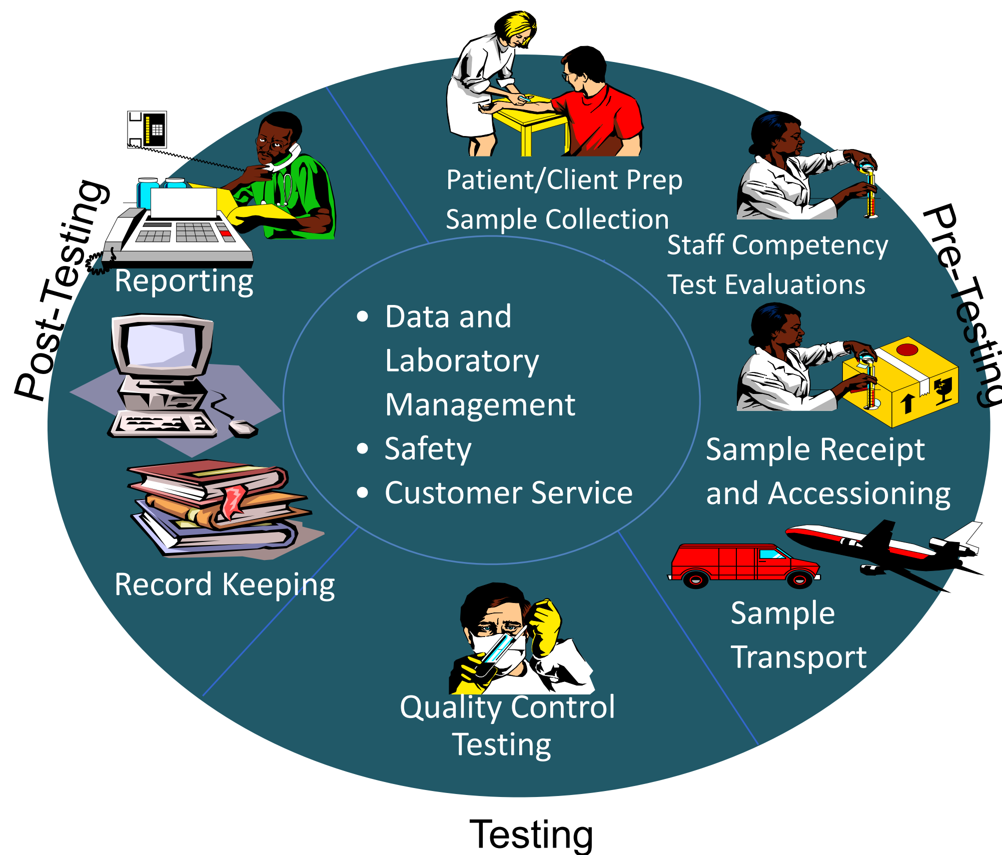
- Specimen collection
- Specimen preparation
- Specimen transport

Testing

- Testing

Post-Testing

- Disposal



Develop safe work habits

Handwashing is the simplest, most effective means of preventing infections if done properly and frequently
– US Centers for Disease Control

- Wash hands before and after collecting samples from each patient
- Washing hands before and after conducting testing
- Wear a fresh pair of gloves with each patient
- Wear a laboratory coat or apron
- Dispose of contaminated sharps and waste appropriately, and immediately after testing

Develop safe work habits (cont.)

- Pipetting by mouth is strictly forbidden
- Never eat, drink or smoke at the test site
- Keep food out of the laboratory/ testing site refrigerator

Develop safe work habits (cont.)

DO-

Develop safe work habits (cont.) 3

DO NOT

Contamination can occur in a number of ways

Personal Protective Equipment (PPE) can prevent contamination

- Gloves
- Lab gowns/coats
- Eye protection-Goggles
- Respiratory protection-Mask
- Face Shields
- Head cover
- Foot wear
- Up-to-date vaccinations (e.g. Hep B)

Shower

Eye washer

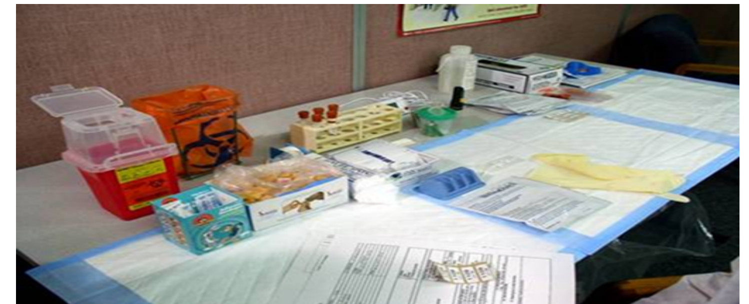
Fire Safety

PPE

Waste Disposal

Maintain a clean working area and work surfaces

- Keep work areas uncluttered and clean
- Disinfect work surfaces daily
- Restrict or limit access when working
- Keep all necessary supplies ready
- Store supplies in a safe/secure area
- Keep eye wash units in working order and within expiry date
- Keep hand washing basin/sink clean and uncluttered



Disinfect work areas with bleach

Disinfection: Use of chemical agents to destroy harmful organisms on inanimate objects

Chlorine compounds or Alcohol (70%)

- Kills germs and pathogens
- Keeps work surface clean
- Prevents cross-contamination
- Reduces risks of infection

Sharps and waste containers – Don'ts

3

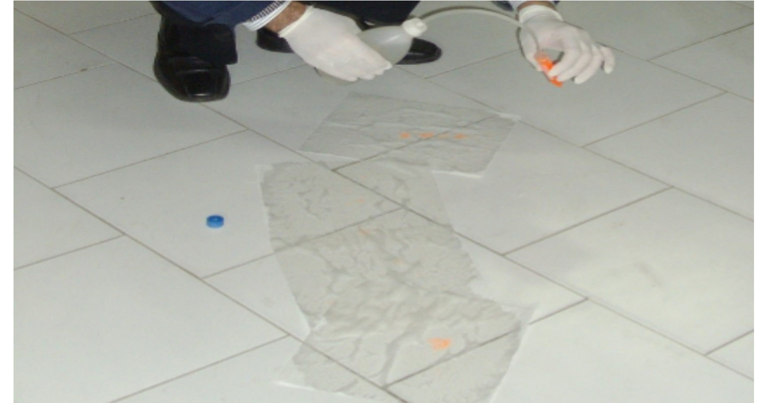
Do NOT:

- Break, bend, re-sheath/re-cap or reuse lancets, needles or syringes
- Shake sharps containers to create space
- Allow sharps containers to get full
- Use a container that is not puncture-resistant, leak-proof
- Place the sharps container far away from work surface

Good practice for handling sharps

- The use is responsible for disposal of sharps
- Users must dispose of sharps after <u>each</u> test
- Users must place sharps in sharps boxes
- <u>Do not</u> drop sharps on the floor or in the office waste bin
- Place sharps container near your workspace
- Seal and remove when box is ¾ full
- Incinerate all waste

Emergency Response – spill and splash



What to do in the event of contamination

Personal contamination

1. Alert co-workers
2. Clean exposed surface with soap/water, eyewash (eyes), or saline (mouth)
3. Apply first aid and treat as an emergency
4. Notify supervisor. Write occurrence report
5. Report to medical clinic for counseling/ treatment (e.g. PEP)

Surface contamination

1. Alert co-workers
2. Define/isolate contaminated area
3. Put on appropriate PPE
4. Remove glass/lumps with forceps or scoop
5. Apply absorbent towel(s) and wet with water to spill; remove bulk & reapply if needed. Then dry the area with absorbent paper towels to ensure all residual liquid are removed
6. Apply disinfectant to towel surface (10% bleach or 1% v/v Sodium Hypchlorite
7. Allow adequate contact time (15-20 mins)
8. Remove towel, mop up; clean with alcohol or soap/water
9. Properly dispose of materials
10. Notify supervisor

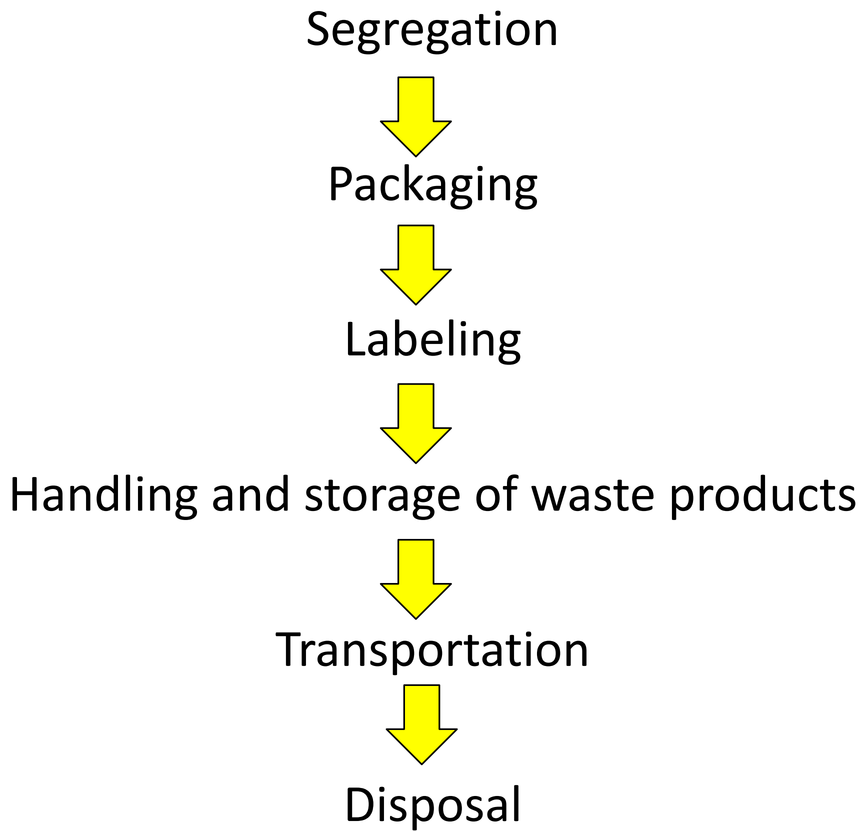
Waste management

Waste is any material that is “discarded” or intended to be discarded

Waste management is the collection, processing, recycling, disposal, monitoring and transport of waste materials

Safety signage

Waste management process



Incineration of waste

Incineration is the complete burning of contaminated waste or bio-waste at high temperatures (>1000 ℃) to destroy hazardous substances and kill micro-organisms

Incineration:

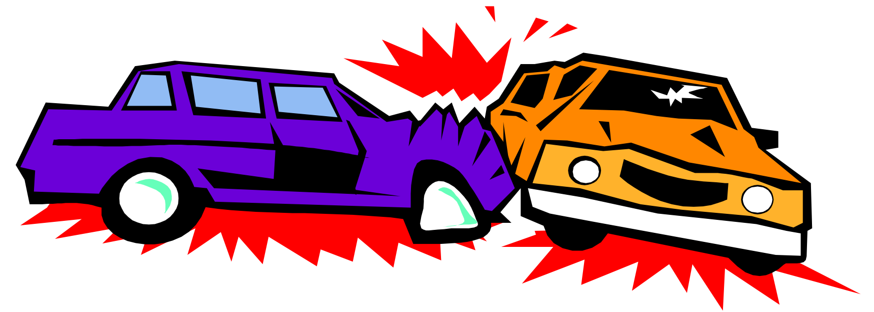
- Is effective against potential re-use
- Protects environment
- Must be supervised

Used POC/near POC cartridges are contaminated waste and should be incinerated

Note: Check and follow manufacturer's instruction for the disposal of cartridges to ensure it is not harmful to the environment

Reminders

What can cause injury --- e.g. needle prick?



- Lack of concentration
- Inexperience
- Lack of concern for others
- Improper disposal of sharps and waste

Adhere to safety precautions to protect you, your colleagues, family, the client and the environment against infection

Agenda

1. Learning Objectives
2. POC Quality Management Systems
3. Safety and Waste Management
4. Connectivity and Data Management
5. Supply Chain and Device Management

Data/record management

4

Record Management is the mechanism that ensures information is captured correctly, kept confidential, and is available and accessible when needed.

If using paper based records…

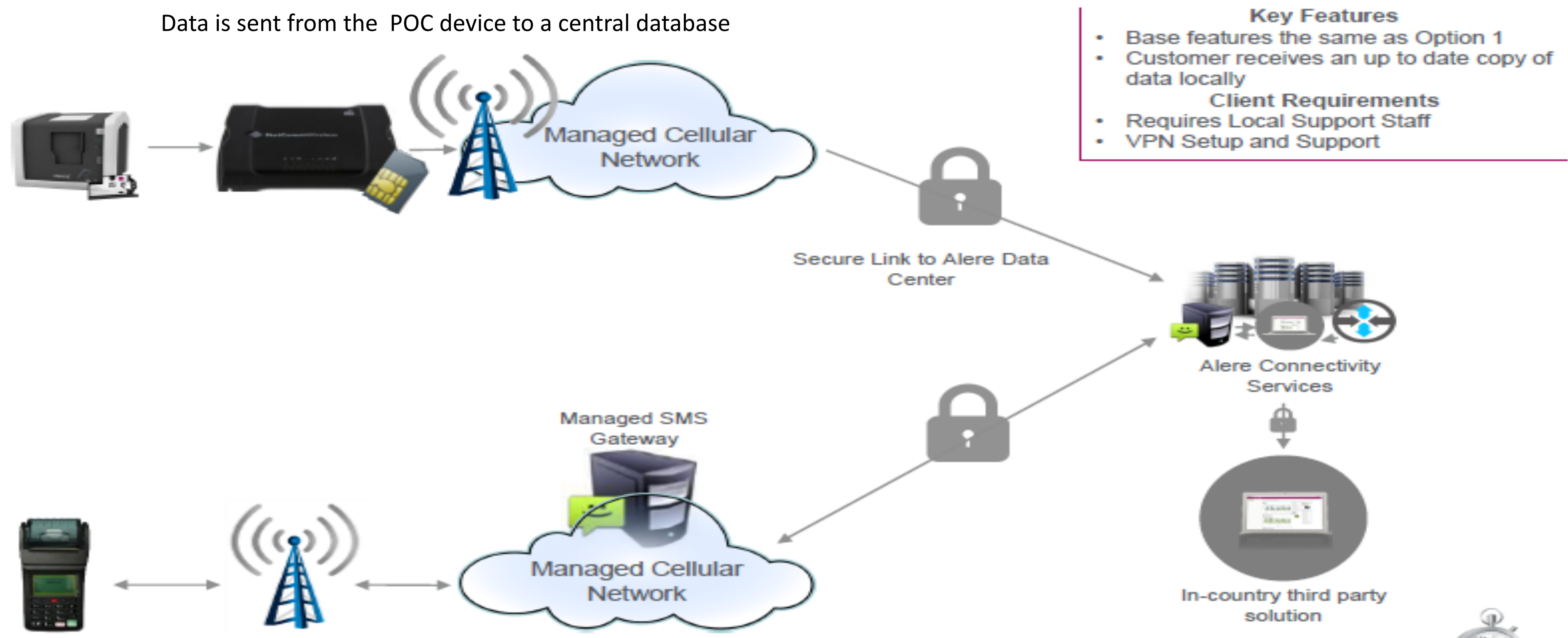
- ➢ The register and logs used in the lab or clinic that record tests that are performed, and can be used to trace patients records when necessary

If using electronic records...

- ➢ Testing data should be routinely transmitted to a central database for back up
- ➢ This system simplifies reporting, monitoring and evaluation

Connectivity provides visibility to monitor and manage the performance of POC devices, and speeds result transmission from centralized testing sites back to the facility

4



Agenda

1. Learning Objectives
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5. Supply Chain and Device Management

Supply chain management

Inventory management for POC testing is critical to ensure uninterrupted testing services

For POC testing, inventory needs to be tracked for:

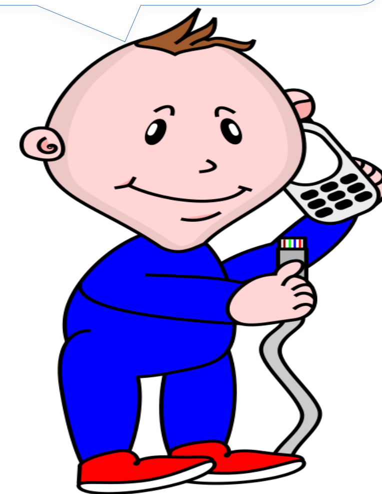
- Reagent cartridges
- Sample collection materials

Supplies for POC commodities should be integrated into the facility's existing inventory management system

[Before the start of the training, optional to insert language about the local inventory management system and how POC commodities will be incorporated in the local supply chain]

Error and service reports

- If you encounter an error, refer to the device user manual for guidance
- If you encounter three (3) errors consecutively, stop and report (and arrange for service data export) to national support team:
    - MOH-Laboratory contact No. [Before training, fill in telephone number]
    - Partner Support contact No. [Before training, fill in telephone number]
    - Distributor's contact No. [Before training, fill in telephone number]
- If the POC device is down, needs service or a swap-out device is required, contact the national support team for advise and next steps



Summary

- Quality Testing is the backbone of results reliability , this prevent misdiagnosis that affect the quality of life of the clients/patients
- Adherence to safety precautions will protect you, your colleagues, family, the client and the environment against infection
- Connectivity allows data to be transmitted from POC devices in the field to a central point, where the data can be monitored centrally, simplify data aggregation and allow for timely reporting
- Reliable supply chain and device management systems ensure uninterrupted testing and increase productivity

Questions?

Thank You!

Pre-testing Errors

Examples	Preventing and detecting errors before testing
• Specimen not collected properly • Specimen mislabeled or unlabeled • Wrong Specimen/Specimen Container • Specimen stored inappropriately before testing • Specimen transported inappropriately • Test kits stored inappropriately	• Check storage and room temperature • Collect appropriate specimen • Use of appropriate Specimen Container • Select an appropriate testing workspace • Check inventory and expiration dates • Review testing procedures • Record pertinent information, and label test device

Testing Errors

Examples	Preventing and detecting errors during testing
• SOPs not followed • Operators not trained or competent to perform the test • Incorrect timing of test • Results reported when control results out of range • Improper measurements of specimen or reagents • Reagents stored inappropriately or used after expiration date • Insufficient sample collected • Incorrect reagents used	• Ensure the device runs everyday • Ensure all operators are trained and have appropriate certification • Perform and review Quality Controls (QC) – run standard controls, if necessary for the platform • Follow safety precautions • Conduct test according to written procedures (Follow SOP) • Correctly interpret test results

Post-testing Errors

Examples

- Transcription error in recording and reporting
- Report illegible
- Report sent to the wrong location
- Information system not maintained

Preventing and detecting errors during testing

- Re-check patient/client identifier
- Write legibly and ensure an up to date recording
- Clean up and dispose of all waste accordingly
- Package PT panels/specimens for re-testing, if needed

Acknowledgments

The development of the POC EID Training Package was made possible thanks to Unitaid's support.

Unitaid accelerates access to innovation so that critical health products can reach the people who need them.

Clinical Systems

Module 3: Workflow improvements to facilitate POC EID testing

POC EID Training Toolkit
v. May 2019

Agenda

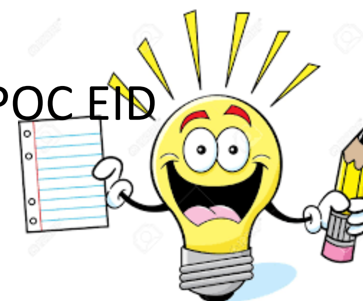
1	Learning objectives
2	Changes required to maximize the impact of POC testing
3	Adjusting lab and clinic workflow
4	Summary

Learning Objectives

1

At the end of this module, participants will be able to:

- Determine the way that their facility will refer infants for POC EID testing to ensure patients get same-day results and results are acted upon the same day
- Assign responsibility for patient referrals and documentation
- Discuss the changes to patient and laboratory workflow, referral, and documentation of results that will be required to successfully introduce POC EID testing at the facility



Agenda

1. Learning objectives
2. Changes required to maximize the impact of POC testing
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4. Summary

Why is POC testing important when we have referral-based conventional testing?

2

Referral-based conventional technologies have formed the backbone of national testing programs for many years. However, their ability to expand access has been hampered by systems challenges, including unreliable sample transportation networks, sample integrity issues, instrument failures, and laboratory network workflows.

→ POC early infant diagnosis (EID) that provides NAT testing at the point of care allows HIV-exposed infants to be tested, diagnosed and quickly linked to life-saving care and treatment

Source: Excerpts from Key Considerations for Introducing Point of Care Diagnostic Technologies in National Laboratory Programmes: forthcoming resources, July 2016

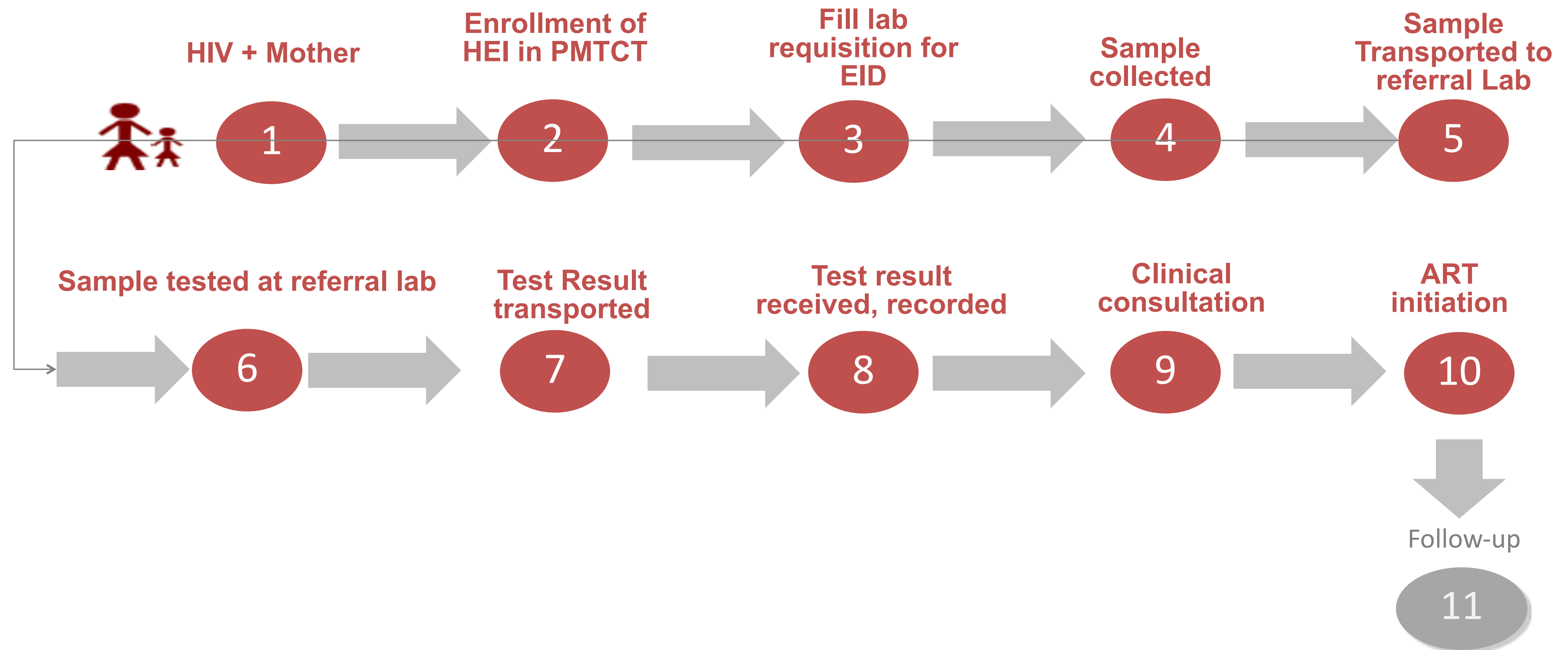
Activity: Current Clinic Flow for EID Testing

2

- ❑ Divide the participants into 2 groups
- ❑ Use flip chart and markers, draw the existing patient flow for EID testing
- ❑ Each group will have 10 minutes to establish the current patient flow at the facility and assign someone from the group to present the patient flow to the full group
- ❑ Present the patient flow in 5 minutes

Example of current clinic flow for referral-based EID

2



How can a clinic maximize the effectiveness of onsite POC EID?

2

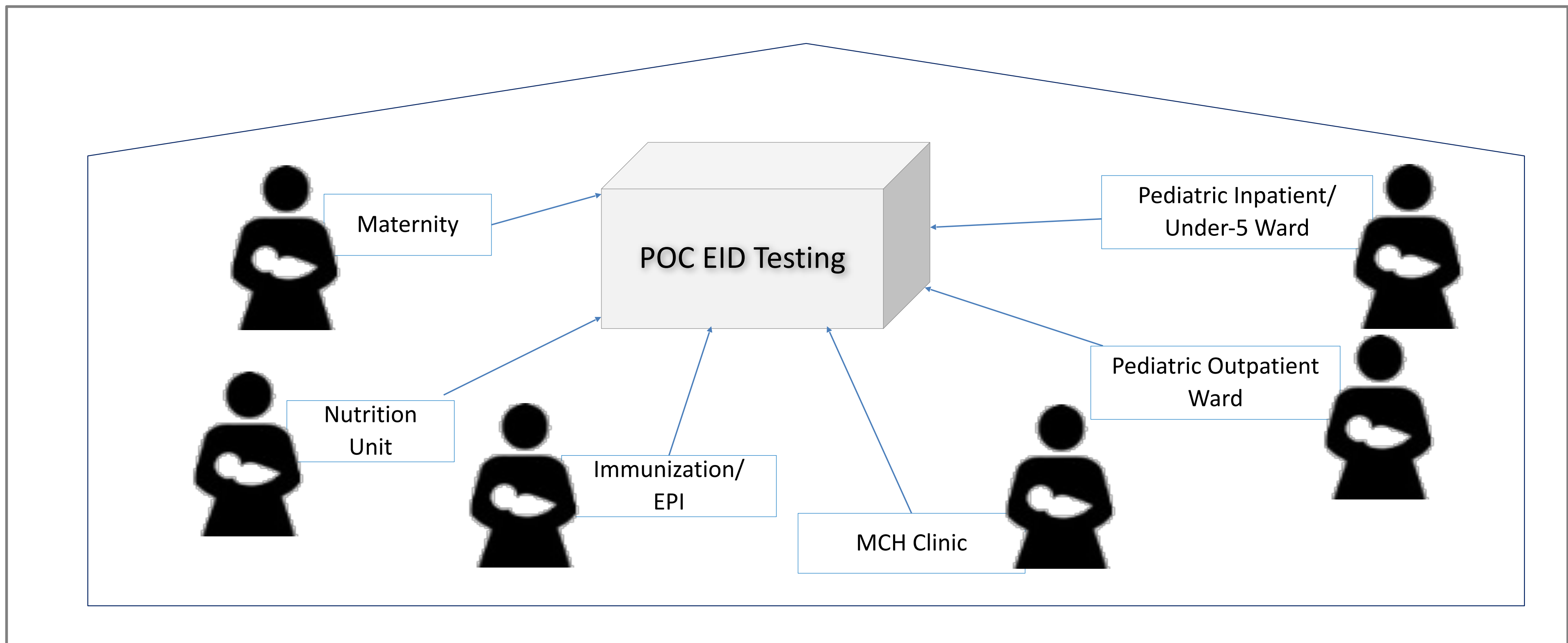
Adjustments in patient flow and laboratory systems are necessary to achieve the full patient impact of point-of-care testing.

- Introducing point-of-care testing makes it possible for patients to get their test results the same day they are tested and to have those results acted upon immediately.
- Same day result return reduces the time between when an infant is diagnosed with HIV and when they initiate treatment, improving their chances of survival.

HIV-exposed infants should be identified through multiple entry points throughout the health facility

2

POC EID samples received from multiple entry points



[Before the training begins, update this slide with the appropriate names of entry points in the local health system – the names for these clinics may vary by country, but should include any ward where infants may present for care]

What is required in the clinic to maximize the effectiveness of POC EID?

2

1

Adjust clinic flow to accommodate same day testing, result return and clinical action

- Start testing early in the day to maximize the number of patient that can be tested
- Refer patients from triage to allow testing to begin earlier in the day

2

Review clinic and/or laboratory schedules to make sure testing is available as many hours per day and days per week as possible

3

Prioritize patients for testing to manage testing volumes

4

Manage data effectively to ensure all results reach patient records

5

Maintain open communication between the lab, mother-infant paird clinic and the ART clinic to address challenges that arise

Agenda

1. Learning objectives
2. Changes required to maximize the impact of POC testing
3. Adjusting lab and clinic workflow
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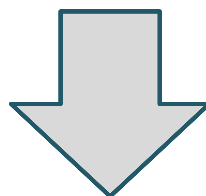
Activity: Adjusting clinic workflows

3

Group 1: Clinic flow for HIV-exposed infants, Lab and clinical schedules

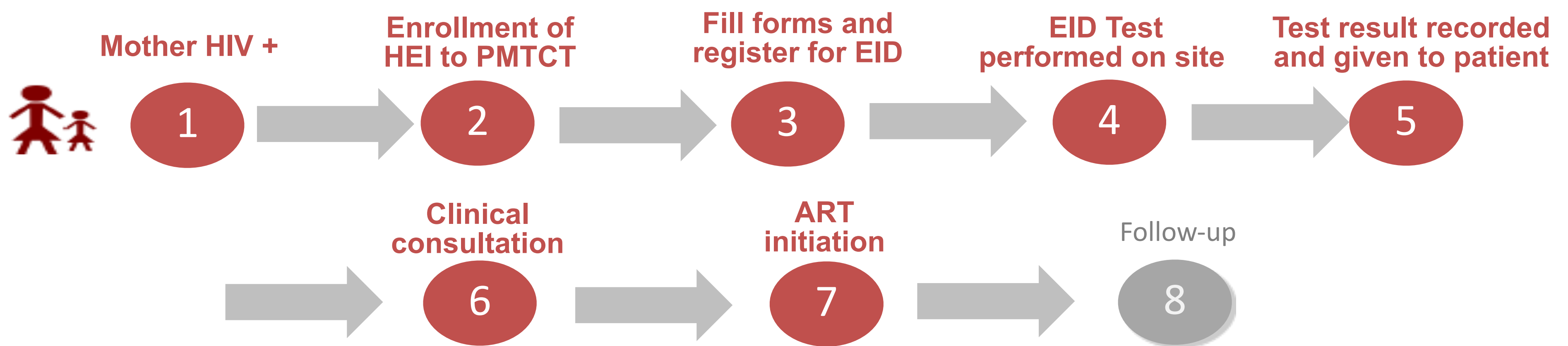
Group 2: Prioritize patients for testing and managing testing volumes, and show process for data management

→ For this discussion include the roles of health care workers who are in contact with patients and their responsibilities are.



Groups should create flow diagrams that can be implemented in the clinics and include the roles and responsibilities of all key health care workers

Possible clinic flow for POC EID



Adjusting clinic flow: what changes will individual staff members need to make?

3

1

Discussion Questions:

1. Where will we collect samples for POC EID? Is the collection site the same as the testing site?
2. If the site are the same, who will conduct pre-counselling for the mother/caregiver? Who will do the triage so that testing can begin early?
3. Who will fill out the POC EID register and/or lab forms?
4. Will there be a HCW assigned to do all EID tests for the day or will anyone available do the test?
5. Will the HCW doing the tests write the patient results into the patient record or will anyone available do the recording?
6. How will we ensure that the mother/caregiver has received the result and that results are acted on by the clinician on same day?

mPima: Examining clinic schedules to increase the hours per day and per week that patients can be tested

3

2

Discussion Questions:

On the mPima device, 8 patients can be tested in 8-hour shift. Thus, in health centers with high patient volumes, it is important to make sure testing is available all day, every day so that many patients can be tested.

Making POC EID testing available all day may require coordination between the clinic and lab:

- Could the clinic open earlier?
- Will the clinic be open for EID testing all day, five days a week?
- Will it be possible to test all patients needing POC EID during the hours the clinic is open? If not, how will the remaining patients get tested onsite?
- Will the clinic be able to collect samples for next day testing given the acceptable storage time and temperature requirements (24h at 18-28̊C)?

GeneXpert: Examining clinic/lab schedules to increase the hours per day and per week that patients can be tested

3

2

Discussion Questions:

On the GX device, 4 patients can be tested every 90-120 minutes. Thus, in health centers with high patient volumes, it is important to make sure testing is available all day, every day so that many patients can be tested.

Making POC EID testing available all day may require coordination between the HIV clinic, TB clinic and the laboratory:

- Could the lab open earlier?
- Will the lab be open for TB, EID and VL testing all day, five days a week?
- Will it be possible to test all patients needing the tests during the hours the lab is open? If not, how will the remaining patients get tested onsite?
- Will the lab consider testing the remaining samples the next day following the “first sample in, first sample out principle?

Prioritizing patients and managing patient volumes

3

3

Discussion Questions:

Introducing POC testing will change the way patients receive tests. Due to the volumes that can be tested on the POC device, patients may need to be prioritized for testing, though every effort should be made to ensure all patients can be tested on-site and can receive same-day test results.

- → How will the health facility prioritize EID samples when there are too many to run in one day?
- → How will the facility prioritize different types of tests (EID, VL, TB) and sample types (DBS, whole blood, plasma, sputum)?

EXAMPLE OF PATIENT TRIAGE FOR EID SAMPLES

1) Sick children – the sicker children are given testing priority

2) Distance to the facility – those having to travel furthest are given testing priority

3) Willingness of the mother/caregiver to wait for the test and results, requires personal judgement of the operator, taking in to consideration the other clients in queue

NOTE: If using GeneXpert device, if there are still more clients, HCWs can collect DBS samples and send to the lab for testing the next day

Data Management – Ensuring results reach patient records

3

4

Discussion Questions:

1. What "checks" will be in place to ensure all patient results are entered into patient records?
2. What "checks" will be in place to ensure all POC tests and results are recorded in the designated logbook in the clinic/lab?
3. What "checks" will be in place to ensure all results are entered legibly and in the correct format into logbooks and patient records/charts?
4. How will HCWs ensure all results correctly shared with the patient/caregiver?

Remember: No documentation = No work done

Collaboration is necessary between the lab, mother-infant care points and ART clinics to address issues that may arise

3

5

Discussion Questions:

Introducing POC testing increases the amount of coordination that is needed between the lab/testing point and the clinics. Patients may need to move between the lab/testing point and the designated clinics on the same day, and patient results will be ready at the site throughout the day rather than all at once. Thus, it is important that the clinics and the lab/testing point communicate and collaborate closely to ensure all patients needing EID are able to be tested and all patient results are recorded properly.

How will the facility address these issues that may arise?

- There is a reagent stock out
- A device breaks down or is producing too many errors
- When an infant tests HIV+, how will the confirmatory test be conducted?
    - Who will collect a new sample? Will the test and result be fast-tracked? Will new lab forms be filled out? How will the confirmatory results be recorded?

SOPs should be put in place on how to address any issue that may arise that prevents samples from being tested or causes results to get lost between clinics and the lab/testing point

How could the facility address these additional challenges?

3

- Infants are being referred to the facility specifically for POC EID, however it is not clear where HIV-positive infants should be managed after the result is available. How could your facility manage referred infants?

- Poor documentation and weak linkages between the inpatient unit and ART clinic result in some HIV-positive infants being discharged or transferred out from clinic for children discharged/transferred out immediately after a test and before initiating treatment. How can the facility ensure all results are returned and infants and linked to care, not matter which entry point they present at?

- POC EID testing is interrupted due to a device breakdown. How can the facility ensure EID testing continues?

- The POC device is being used by HCWs who have not been certified. How can the facility ensure POC EID testing is only conduced by HCWs with the appropriate training?

Break into groups again and come up with solutions to the above challenges, then re-group to share conclusions

Agenda

1	Learning objectives
2	Changes required to maximize the impact of POC testing
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4	Summary

What is required in the clinic to maximize the effectiveness of POC EID?

4

1. Adjust clinic flow to accommodate same day testing, result return and clinical action
   - Start testing early in the day to maximize the number of patient that can be tested
   - Refer patients from triage to allow testing to begin earlier in the day

2. Review clinic and/or laboratory schedules to make sure testing is available as many hours per day and days per week as possible

3. Prioritize patients for testing to manage testing volumes

4. Manage data effectively to ensure all results reach patient records

5. Maintain open communication between the lab, mother-infant paird clinic and the ART clinic to address challenges that arise

Questions?

Thank You!

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