



GeneXpert Integration

POC EID implementation in Nigeria using Xpert HIV-1 Qual XC



What was the need?

Background



- National burden is 1.8 million PLHIV
- National prevalence: 1.4% (0 - 14 years = 0.2%)
- There are 6 states with the prevalence of 2.0% or above, 13 states + FCT have a prevalence between 1.0% and 1.9%, and 17 states have a prevalence below 1.0%
- 12% of the burden are children (0 - 14 years)
- Adolescents account for 8% of the total burden
- EID Coverage (\leq 2 months) remains low at 28% (2020 FMOH data)
- Female incidence is significantly higher than male, both in adolescents and young adults (15 - 29 years).

Background: Existing laboratory-based testing is complex and faces numerous challenges



Challenges



Low EID coverage: In 2020, only **28%** HEI received EID test within 2 months of birth

12% of the HIV burden is among children (0 - 14 years), and adolescents account for 8% of the total burden; case finding remains low

Long EID results turnaround times (median: **3 to 5 months**) due to batching at different stages from sample collection through testing and results delivery

High rate of **lost results**

Delayed communication of results to patients without proper tracking mechanisms leads to high rates of **LTFU**

Low ART initiation for HIV+ infants, adolescents and young adults

Approach



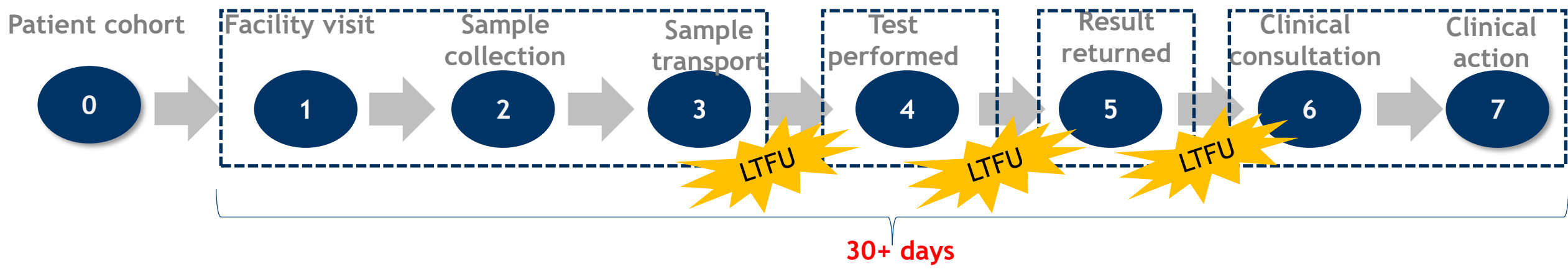
- POC EID and VL testing along with electronic results delivery models can support in
 - ✓ Increase testing coverage
 - ✓ Ensure same day testing and results receipt
 - ✓ Ensure early ART initiation for HIV positive infants
 - ✓ Reduced loss to follow-up
 - ✓ Improve client management
- Use of sub-optimally utilized but widely available GeneXpert platforms can enable access to POC testing

Point-of-care testing can enable same day EID and VL test results, reduce patient loss and waste due to lost results

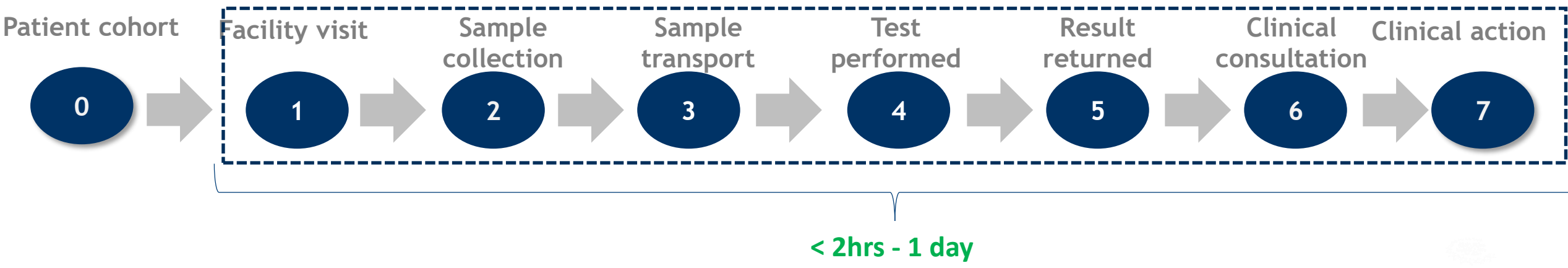


Continuum of Care

Conventional EID and VL



Point-of-care EID and VL



How was the implementation done-which level of care, the cadre used, what does the testing algorithm say, any trainings done and stakeholders involved?

TB/HIV Integration on GeneXpert Platforms in Nigeria



Aim:

- Demonstrate the feasibility and impact of integrated testing on TB and HIV programs
- Describe the service delivery approaches that enable access to integrated testing and document the linkage systems necessary to ensure access to treatment and care.
- Define how to effectively offer multi-disease testing to maximize the impact of molecular testing networks and inform scale-up.

Expected Outcome:

Inform policy decision making for the adoption of integrated testing and demonstrate the impact of integrated testing on routine provision of diagnostic testing services to optimize use of GeneXpert machines

Optimized case finding for both the TB and HIV programs

Showcase successful model of integration and thus catalyze national level scale-up across the existing multiplexing platforms

Inform programming for higher throughput platform placements like the GX-16 and GX Infinity.

A large existing fleet of GeneXpert devices established through the National TB Program has multiplexing capability to run different disease assays

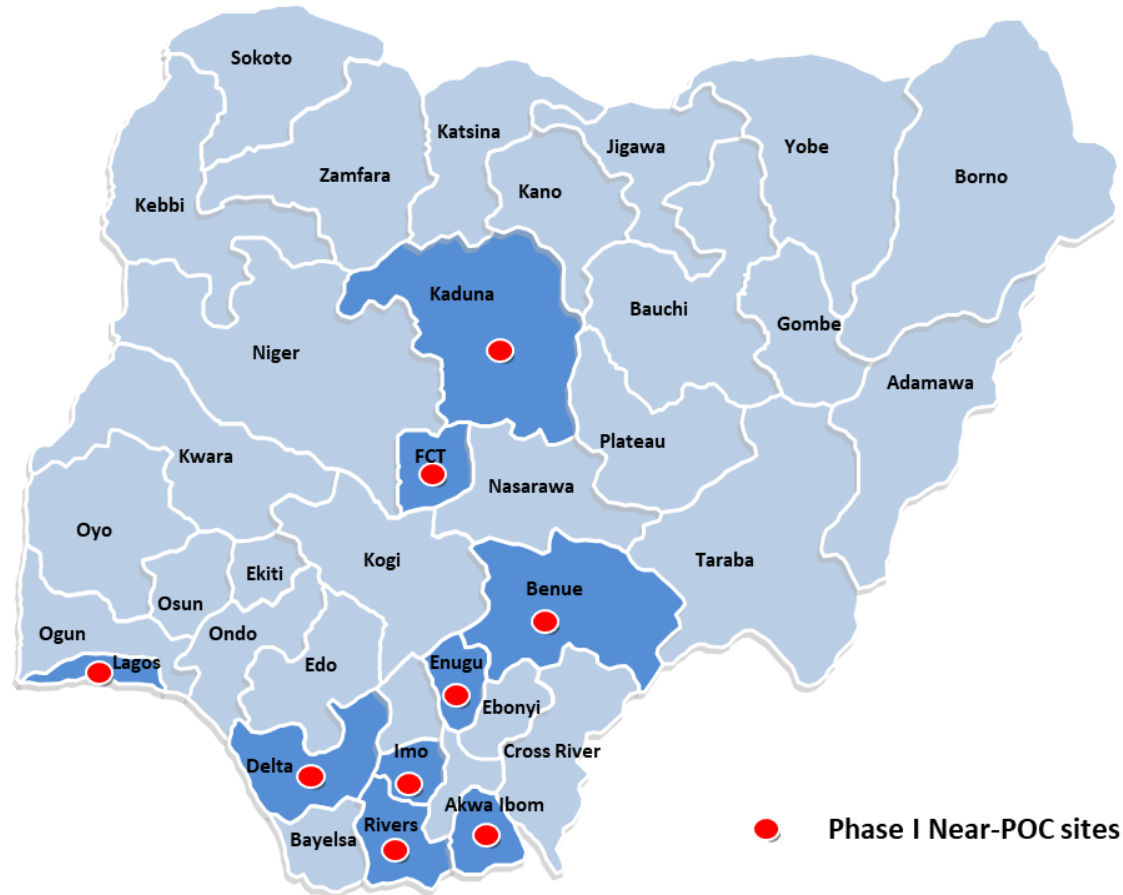


TB samples take priority over other samples: **TB > EID > HPV > HIV VL**

GeneXpert Integration will focus on **EID, HPV and HIV VL**

Assay	HIV 1 QUAL (EID)	HIV 1 QUAL XC(EID)	HIV-1 VL	HPV
Regulatory	WHO PQ CE-IVD	CE-IVD**	WHO PQ CE-IVD	WHO PQ CE-IVD
Sample	1 DBS 100ul WB	1 DBS ≤100ul WB	1ml plasma	Cervical Swab
Time to Result	1H55min (DBS) 90min (WB)	91 Mins (DBS) 79 mins (WB)	90 mins	60 mins

Methodology



- Stakeholder buy-in (National TB and HIV programs)
- State Selection
- Capacity utilization assessment
- Site selection
- Site optimization
- Commodity procurement
- HCWs capacity building
- Testing! Testing! Testing!
- Monitoring and Evaluation

Methodology



Q4 2020

- Engaged NTBLCP, NASCP and stakeholders (TWG and partners) to advocate for a phased implementation of integration on GX platform (TB and HIV)
- Conducted site assessments and identified challenges at sites

Q1 2021

- Meetings to finalize development of training materials, tools, SOPs and data collection tools
- Addressed challenges at GeneXpert sites for integration
- Engaged Cepheid on equipment calibration, software upgrades and trainings
- Commenced trainings and sensitization (use of GeneXpert platforms for multi-disease testing, demand generation)

Q2 2021

- Completed trainings and sensitization (use of GeneXpert platforms for multi-disease testing, demand generation)
- Implementation for multi-disease testing on the POC platforms commenced
- Commenced routine M&E, supportive supervision

Q3 2021- Q1 2022

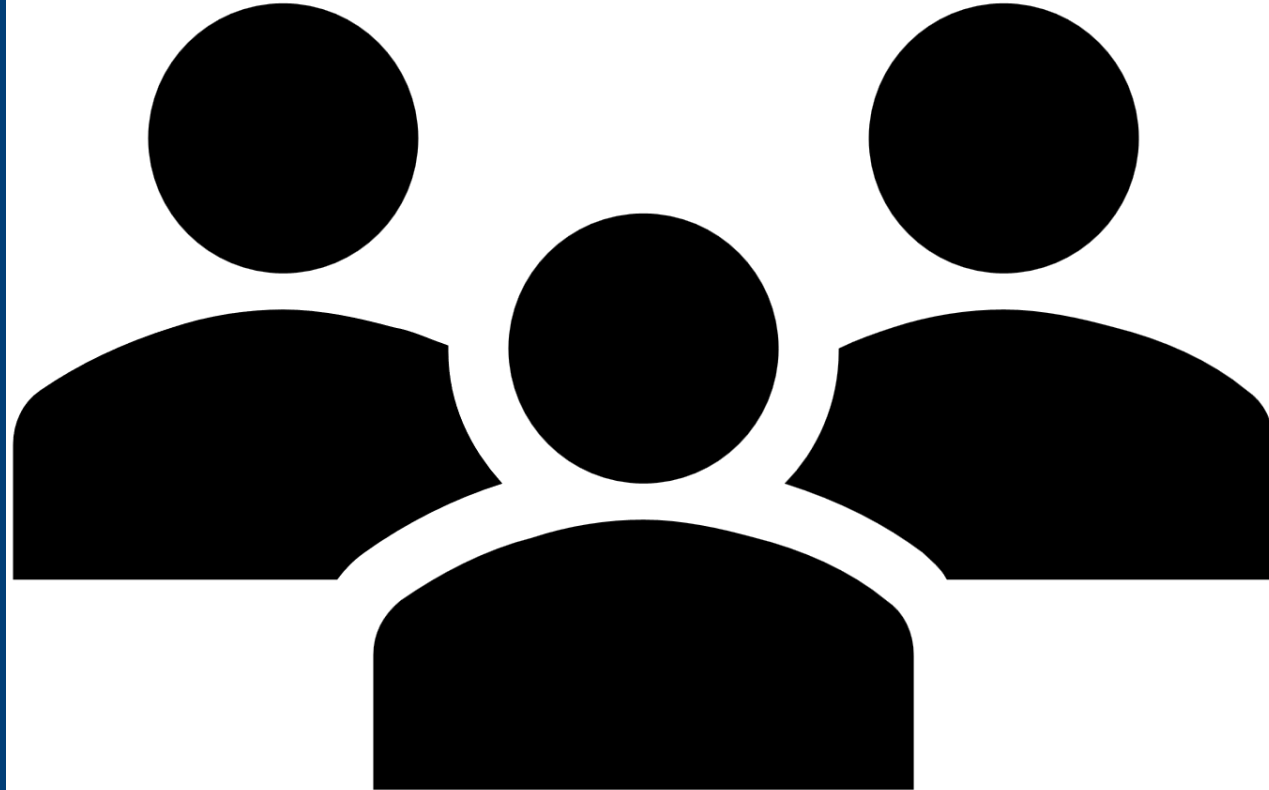
- Implementation for multi-disease testing on the POC platforms continued
- Routine M&E, supportive supervision

Q2 2022

- Dissemination of preliminary results from Phase I implementation to stakeholders (meeting)

Who Are the Stakeholders?

- National Tuberculosis, Buruli Ulcer and Leprosy Control Programme (NTBLCP)
- National AIDs, Viral Hepatitis and STIs Control Programme (NASCP)
- National PMTCT Task Team
- PEPFAR (CDC, USAID and DoD)
- KNCV Nigeria
- State HIV and TB programs
- Implementing Partners (IPs)
- Cepheid
- NAFDAC (regulatory approval for GXpert XC)



Phase I implementation Site selection process

1

State selection criteria

- High TB or HIV prevalence , High TB/ HIV co-infection rate,
- Low/Medium overall GeneXpert utilization,
- Partner supported sites

Site selection criteria

- | | |
|---|---|
| <ul style="list-style-type: none"> • Co-location of HIV and TB testing services, Existing sites (TB GX, EID, ART) • Functional GeneXpert machines • Human Resources –staff dedicated to GX platforms • Additional costs | <ul style="list-style-type: none"> • High/moderate volume TB suspect • High ART patients (>1500 patients on ART) • High/moderate volume HEI • Far distance from regional molecular labs • Long TAT >4 weeks for EID, HPV and VL, LTFU challenges |
|---|---|

2

GeneXpert Testing Capacity	HIV Testing Need at the Facility
Annual TB testing volume	# Adults on ART (proxy for adult VL testing need)
Annual TB testing need	# Women on ART (proxy for women HPV testing need)
Spare annual testing capacity which could be used for HIV testing	# Exposed infants (proxy for EID testing need)
Device throughput and downtime in hours per day or days per month	Annual EID testing volume and VL testing volume

3

Other factors to consider for site selection:

- Willingness of the facility to support phased implementation and sustain integration post-implementation
- Sites assessment outcome to confirm phase I implementation sites
- S&M cost vs. sample transport cost, also considerations of costs to optimize sites
- Connectivity solutions (GxAlert functionality)

* Utilization information and site evaluation to confirm testing volumes

Capacity Utilization

- The tool compares GX utilization per facility when used for only TB testing vs integrated testing.
- The output is an indicative list of GX sites feasible for integration (according to capacity), which should be assessed for actual suitability for integrated testing (site-level assessments)

1 Set thresholds

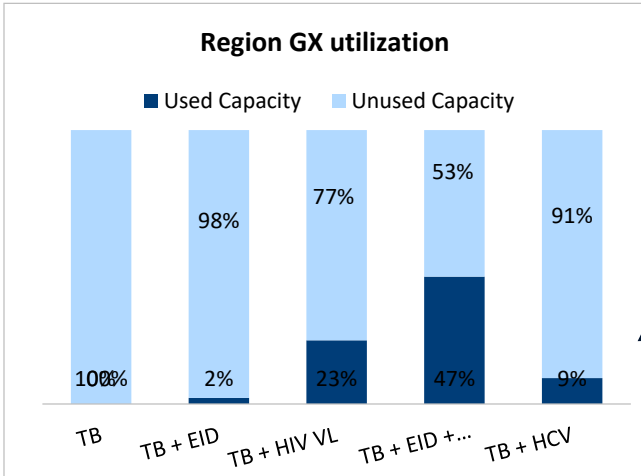
Unused / spare capacity thresholds		Integrate?
Low	10%	No
Medium	25%	Maybe
High	50%	Yes

2 Is it feasible to integrate based on unused/spare capacity by facility and scenario?

#	Region	District	Facility Name	Integration scenario				
				TB + EID	TB + HIV VL	TB + EID + HIV VL	TB + HCV	TB + EID + HIV VL + HCV
1	Region 1	District 1	Facility 0	No	No	No	No	No
2	Region 1	District 1	Facility 1	Maybe	No	No	No	No
3	Region 1	District 2	Facility 2	Yes	No	No	Yes	No
4	Region 2	District 3	Facility 3	Yes	Yes	Yes	Yes	Yes
5	Region 2	District 4	Facility 4	Yes	Yes	Yes	Yes	Yes

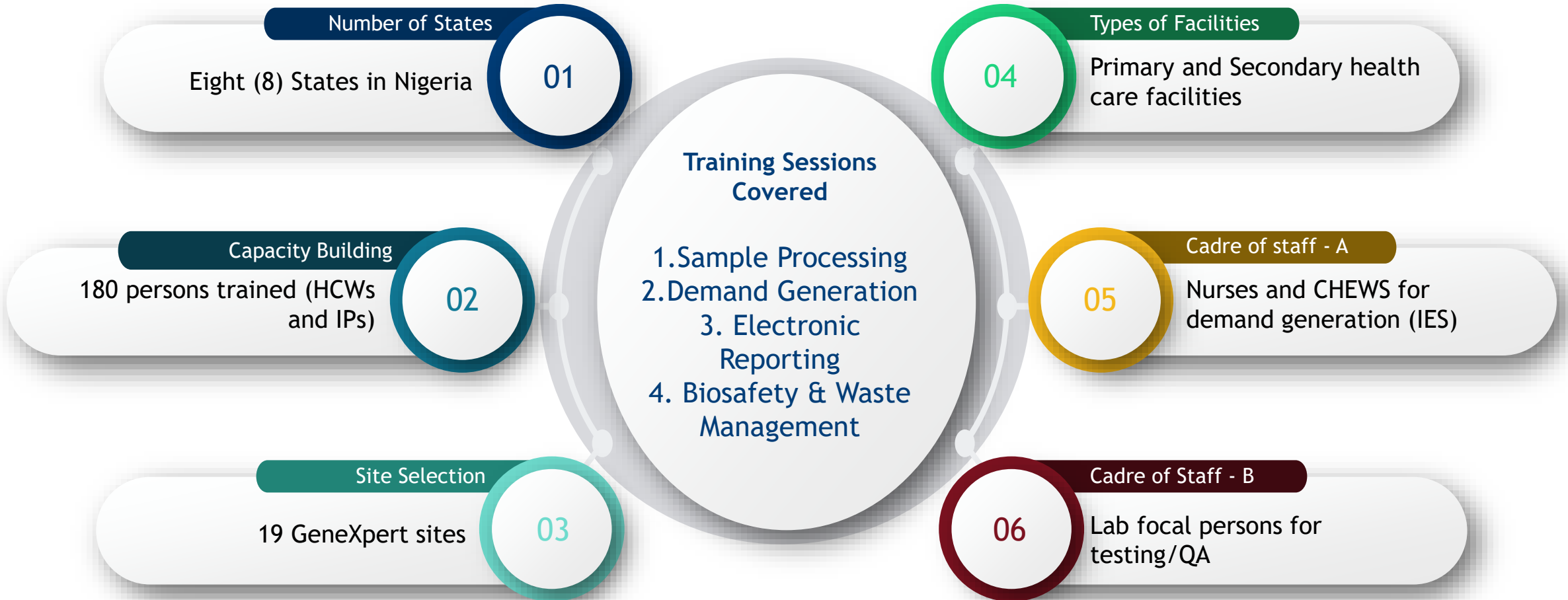
Additional aggregate outputs: National/Regional/provincial-level analysis on machine availability, spare capacity, testing needs, and utilization

Demonstration States for near-POC testing (Phase I): Akwa Ibom, Benue, Delta, Enugu, Imo, Lagos, Rivers states and the FCT



The key output is a list of GX sites where integration is feasible based on unused/spare capacity under each scenario

Capacity Building



Key Thematic Areas



- **Consumables:** All required consumables for integration of EID, HPV, and VL were provided to the GeneXpert Sites by CHAI and PEPFAR.
- **Waste Management:** Arrangements were made for the incineration of the GeneXpert cartridges either on-site or off site depending on the availability of incinerators at the site. In August/September 2021, Cepheid released an updated GeneXpert cartridge for EID (XC) that does not require thermomixers or incineration.
- **Human Resources (HR):** FMOH and CHAI conducted advocacy to the hospital management boards and focal persons at the health facilities hosting the GeneXpert platforms, to address potential HR Challenges with integration.
- **Biosafety:** The Biosafety requirements are the same as that for TB. Refresher trainings were conducted in March 2021.
- **Sample referral:** Clients are tested on-site. If needed, sample referral/hub-and-spoke mechanisms are managed by PEPFAR and PEPFAR IPs.
- **Testing Volumes:** Sites selected are those with spare capacity to ensure TB testing is not affected. The training also included a section on how TB tests should be prioritized.

What test kit did we use?

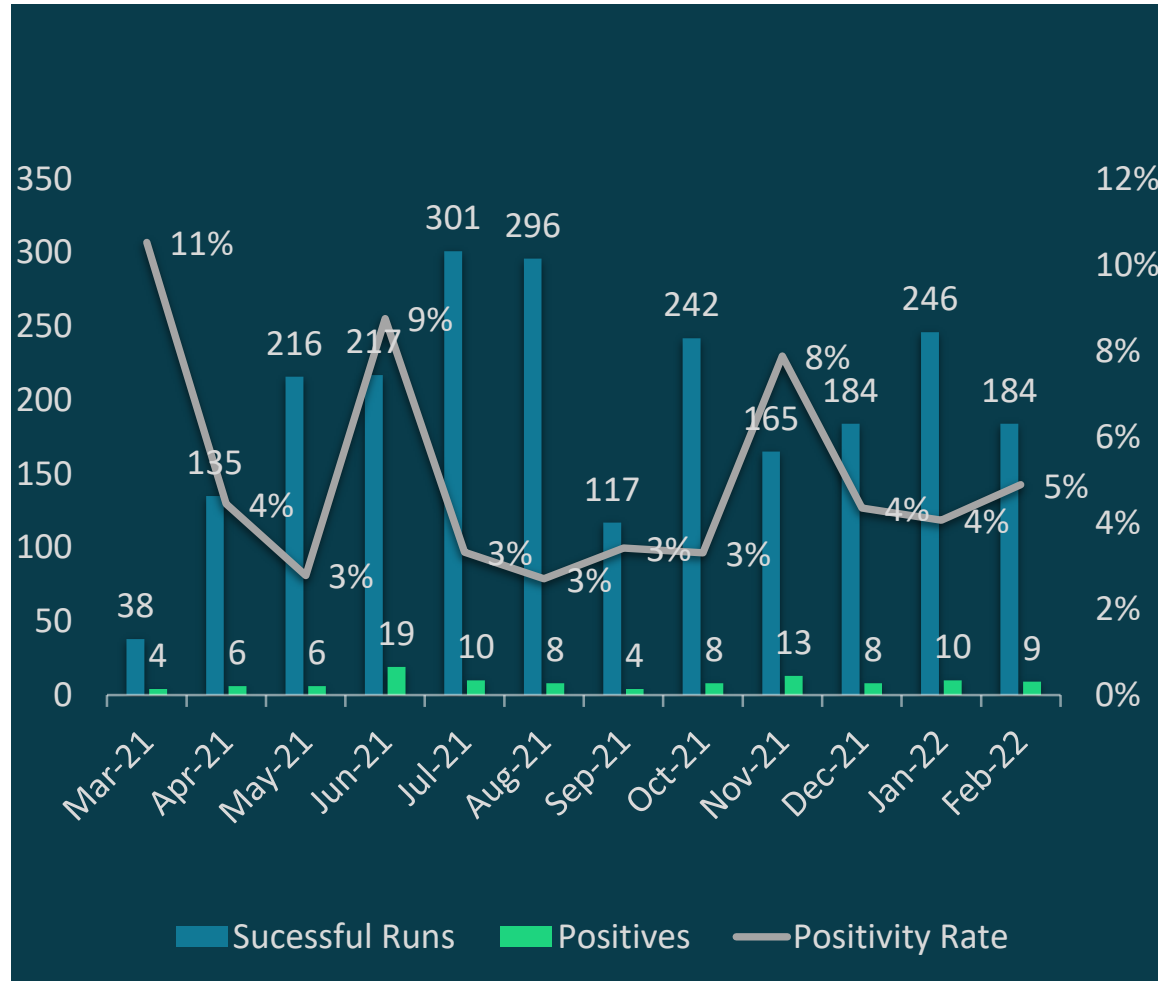


Xpert HIV-1 Qual	Xpert HIV-1 Qual XC
Started implementation with test kit	Commenced use mid-project when product was launched
Required auxiliary equipment like thermomixers for sample processing	Simplified sample collection and processing <ul style="list-style-type: none">• Capillary, venous or DBS• Load WB or DBS directly to cartridge
Contained GTC which required incinerators of >1000 deg Celsius for waste disposal	GTC free which allowed for environment friendly disposal and cost savings
Approved in-country	Pending in-country approval



What was the impact?

Results



- The average TAT for the POC EID testing was **24-72 hours**, compared to **8-12 weeks** experienced on conventional PCR equipment
- All the identified positive infants were linked to care within **24-72 hours** of sample collection, indicating a **100%** linkage rate to ART
- GeneXpert POC-EID testing utilized an average of **2%** of device capacity; there was no equipment downtime, reagent stockouts, or increased TAT for TB during the implementation period.
- POC-EID made up **6%** of the national EID testing volume in during the implementation period



What is the sustainability plan-resource mobilization?



Sustainability Plan

- Inclusion of POC-EID commodities on the national supply plan
- GeneXpert POC-EID included in PEPFAR's COP
- In 2023, FMOH scaled up POC EID and procured POC-EID commodities through GF funding (GxPert and m-Pima)
- EID testing on the GeneXpert platform scaled to over 143 sites (with potential for expansion)
- Development of SOPs for continuous capacity strengthening and training of healthcare workers

Resource Mobilization:

- Exploring partnerships with the private sector to leverage private sector resources and expertise.
- Advocacy to the Nigerian government for increased funding for HIV/AIDS programs, including early infant diagnosis.

Acknowledgements



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Thank you!
Questions



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