



Achieving Integrated Hepatitis Testing through Decentralization: A Nasarawa Case Study

Chukwuemeka Agwuocha

ASLM December 2022 LabCop ECHO Session

Agenda



| | | |
|------|-------------------------------------------------------------------------|----|
| I. | Introduction: Viral Hepatitis Overview | 3 |
| II. | Challenges: Major barriers to Hepatitis C diagnostics range of Hep B-BD | 6 |
| III. | Intervention: Pilot on Use of GeneXpert for Hepatitis C Testing | 9 |
| IV. | Impact: Benefits of the integration model | 19 |

Viral hepatitis affects over 354 million persons and causes 1.1 million deaths annually



WHO HBV AND HCV DISEASE ESTIMATES: DISEASE ESTIMATES: BURDEN, INCIDENCE AND MORTALITY (2019)

HBV: 296M people living with chronic HBV
1.5M new infections; **820K** deaths

HCV: 58M people living with chronic HCV
1.5M new infections; **290K** deaths

Americas

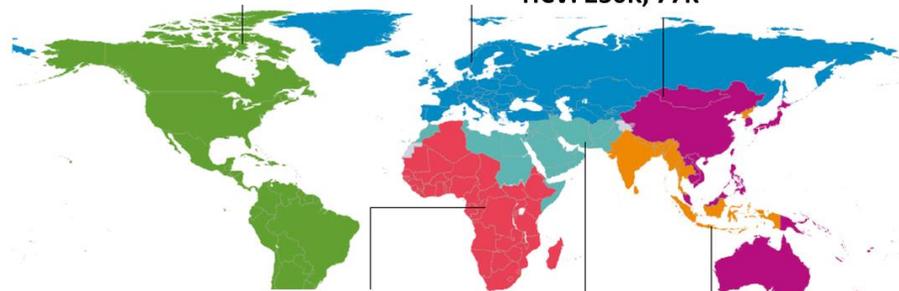
HBV: 10K; 15K
HCV: 67K; 31K

Europe

HBV: 19K; 43K
HCV: 300K; 64K

Western Pacific

HBV: **140K** new infections; **470K** deaths
HCV: **230K**, **77K**



Africa

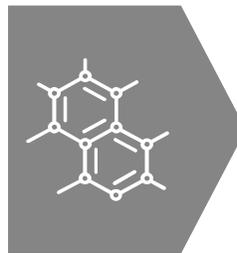
HBV: **990K**; **80K**
HCV: **210K**; **45K**

Eastern Mediterranean

HBV: 100K; 33K
HCV: 470K; 31K

Southeast Asia

HBV: **260K**; **180K**
HCV: **230K**; **38K**



- Hepatitis is a viral infection of the liver
- HBV and HCV are spread through contact with blood/body fluids from an infected person
- Infection can lead to **significant liver damage, cancer, and death**



- **354 million** chronically infected people worldwide
- More than **80%** live in **low- and middle-income countries**
- Annually, **1.5 million** new HBV and HCV infections and **1.1 million deaths**



- **Africa region** contributes **66%** and **16%** of global HBV and HCV infections respectively
- Only **17%** of newborns in the Africa region receive HepB-BD
- Opportunity exists to integrate HBV into the ANC platform and move towards triple elimination



- A safe, effective treatment is available at a **cost of less than \$80 / person for HCV**
- CHAI is working in **7 high HCV burden in low- and middle-income countries in Africa and Asia**, including Nigeria, to scale-up HCV diagnosis, treatment and prevention programs

Nigeria has one of the largest viral hepatitis burdens in the world, with an estimated 2M HCV cases and 16M HBV cases



National Viral Hepatitis Burden

- With a prevalence of 8.1% and 1.1%, over 16 million and 2 million Nigerians are estimated to be infected with HBV and HCV respectively.¹
- An estimated 90% of individuals affected are unaware of their disease status

HCV Burden Landscape in Focal States



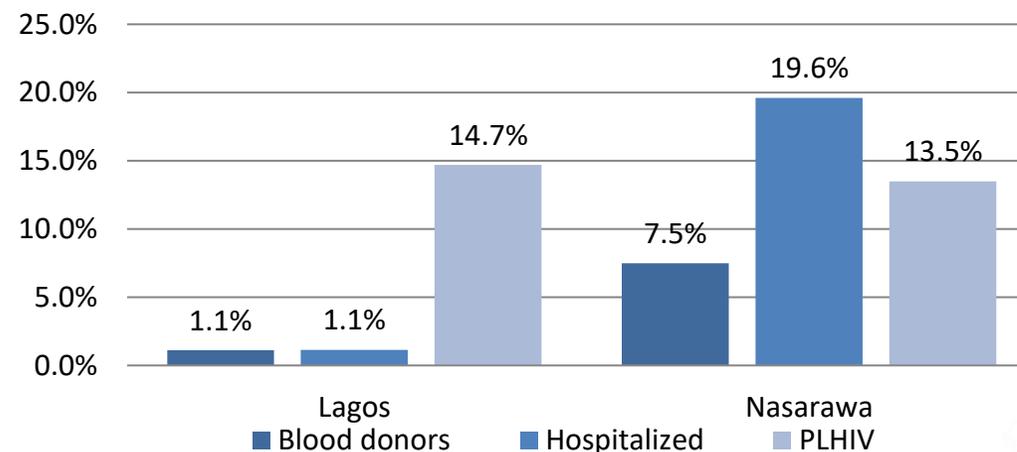
NASARAWA STATE HCV BURDEN

- Positivity rates: 19.6% and 7.5% among hospitalized patients and healthy blood donors
- Over 200k are chronically infected
- 95% unaware of their status
- **High state-wide burden**

LAGOS STATE HCV BURDEN

- Positivity rates: 1.1% hospitalized and healthy blood donors
- Positivity rates amongst HIV positive clients: 14.7%
- **Absence of HCV VL reagents to facilitate diagnostic testing**
- **Robust State DRF**

Cross sectional prevalence data 2016



¹National AIDS Indicator and Impact Survey, 2018

Agenda



| | | |
|------|-------------------------------------------------------------------------|----|
| I. | Introduction: Viral Hepatitis Overview | 3 |
| II. | Challenges: Major barriers to Hepatitis C diagnostics range of Hep B-BD | 6 |
| III. | Intervention: Pilot on Use of GeneXpert for Hepatitis C Testing | 9 |
| IV. | Impact: Benefits of the integration model | 19 |

CHAI worked with Lagos and Nasarawa State Governments to address the barriers to testing and treatment access



Challenges



- **High cost:** HCV VL offered for over \$140 in the private sector, out-of-pocket (OOP) payment
- **Limited Access:** In certain states, patients traveled up to 350km and 850km to access testing in the private and public sector respectively
- **Long results Turnaround time (TAT):** An average of 90 days TAT from sample collection to result dispatch
- **Low HCV case detection:** 461 HCV seropositive patients identified over 54 months and only 21 initiated on treatment



Objectives



- **Decentralization:** Support decentralization of diagnostic and treatment access through decentralized testing and treatment
- **Leverage lab infrastructure:** Introduce models that leverage existing HIV and TB lab infrastructure for HCV diagnostics
 - Nasarawa: 13 GeneXpert used for TB
 - Lagos: 3 Roche Taqman platforms
- **Sustainable commodity supply & funding**

Integration Approach



Pre-Selection of Sites:

- Conducted site **readiness assessment** by determining **capacity utilization**
- Proposed **increase in lab work hours**

Stakeholder Engagement:

- Obtained **buy-in from stakeholders** on policy shift towards integrated testing
- **Defined roles and responsibilities**

Operationalization:

- **Trained clinicians and lab workers** to drive case detection and testing
- Identified lab technicians to run lab shifts
- **Upgraded GX software** and set-up supply chain

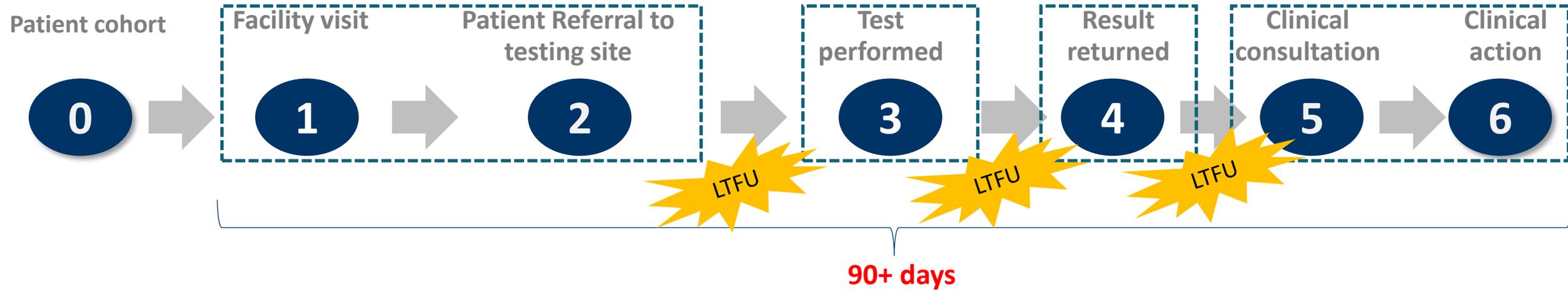
Secured Commodity Supply:

- Advocated for **state funding** for seed stock of HCV VL testing
- Obtained **Pharma support** for seed stock for pilot testing through a PPP model

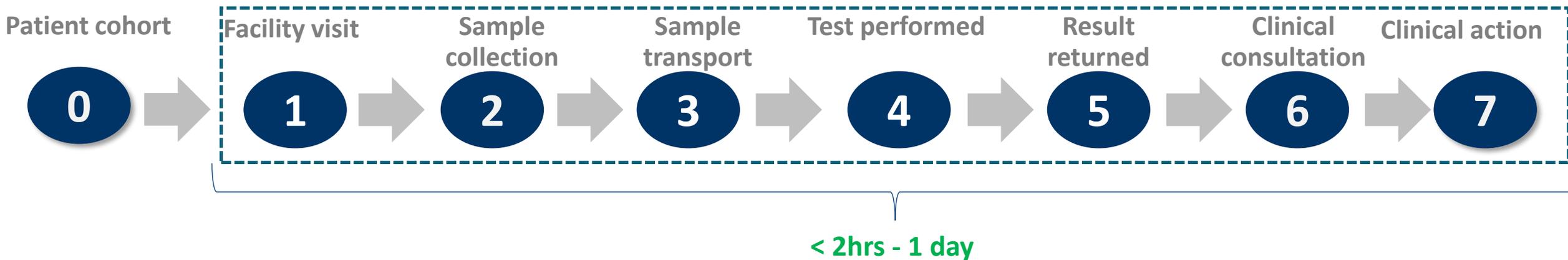
Point-of-care testing can enable same day HCV VL test results, reduce patient loss and early clinical action



Conventional HCV Testing



Point-of-care HCV Testing



Agenda

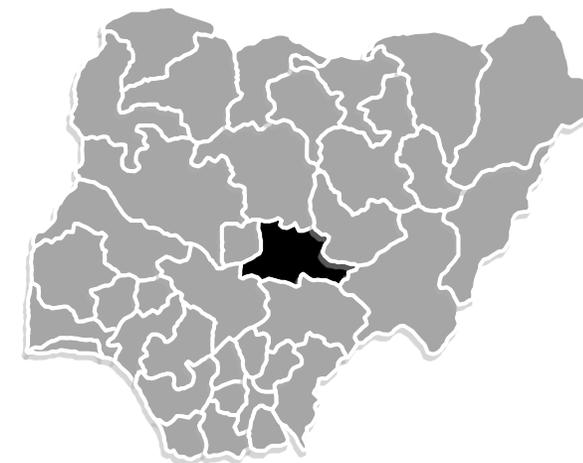


| | | |
|------|-------------------------------------------------------------------------|----------|
| I. | Introduction: Viral Hepatitis Overview | 3 |
| II. | Challenges: Major barriers to Hepatitis C diagnostics range of Hep B-BD | 6 |
| III. | Intervention: Pilot on Use of GeneXpert for Hepatitis C Testing | 9 |
| IV. | Impact: Benefits of the integration model | 19 |



An observational pilot was conducted in Nasarawa State to understand the feasibility, acceptability, and impact of integrated TB/HIV testing on the GeneXpert

| | |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Number of Sites | 1 Tertiary Hospital: Dalhatu Araf Specialist Hospital (DASH) |
| Baseline Period | 54 months (January 2013 – June 2017) |
| Pilot Duration | 13 months (July 2017 – August 2018) |
| Tests | TB, HCV VL |
| Key Objectives | <ul style="list-style-type: none"> ▪ Evaluate the uptake of diagnostic services with integration of HCV confirmatory testing on the GeneXpert platform ▪ Determine the uptake of DAAs for viraemic patients following HCV VL testing on the GeneXpert platform |
| Indicators | <ul style="list-style-type: none"> ▪ Testing volumes ▪ Device utilization ▪ Laboratory processing times ▪ Cost of testing ▪ Rates of HCV treatment initiation at Gastroenterology unit |



GeneXpert IV

A critical component was to ascertain the feasibility of integration based on the unused / spare capacity under each scenario



- 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)

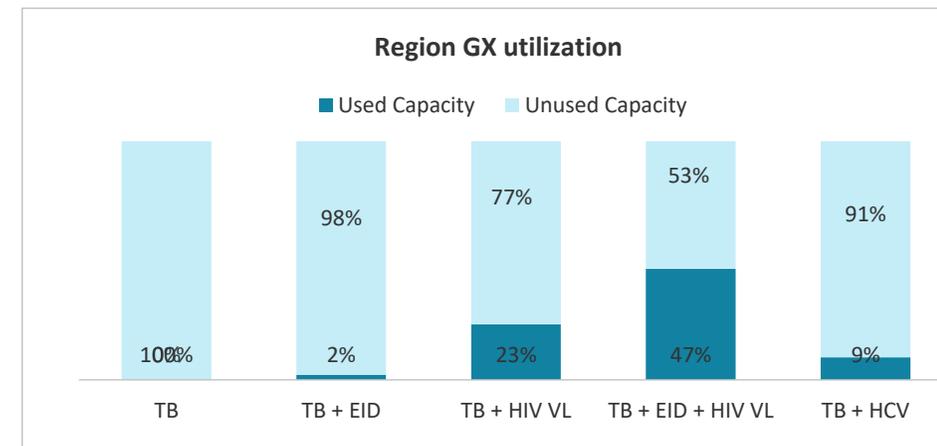
1 Set thresholds

| 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 |

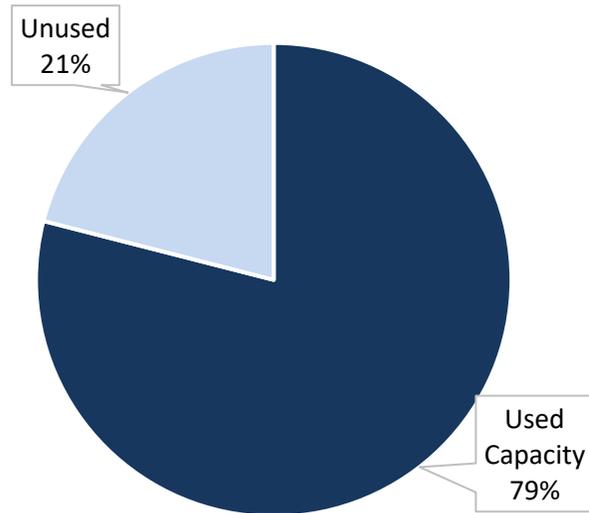
Additional aggregate outputs: National/Regional/provincial-level analysis on machine availability, spare capacity, testing needs, and utilization



Pre-selection of Sites: Device Capacity Analysis

1. Pre-Integration Scenario

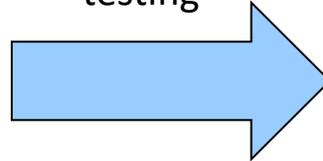
GeneXpert Capacity Utilization



Key highlights

- Device used only for TB testing
- 8 hours laboratory work time, 240 days
- Less than 25% unused capacity
- Annual capacity = 3840 TB tests

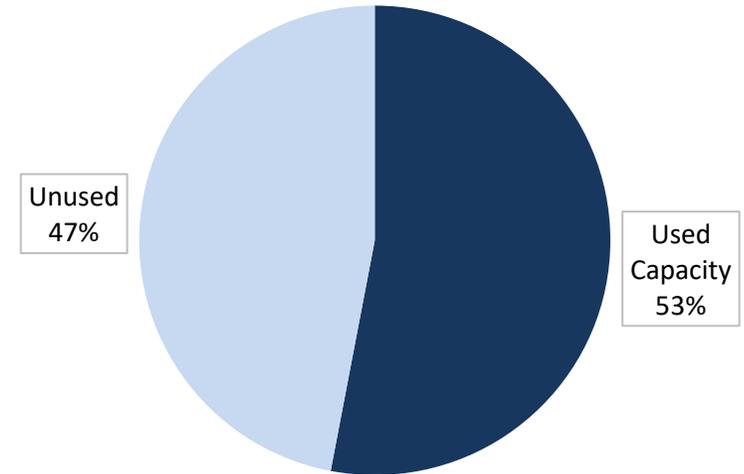
Adjustments made to lab work hours to accommodate HCV VL testing



Increase in laboratory work hours from 8 to 12 hours

2. Proposed Integration Scenario

GeneXpert Capacity Utilization



Key highlights

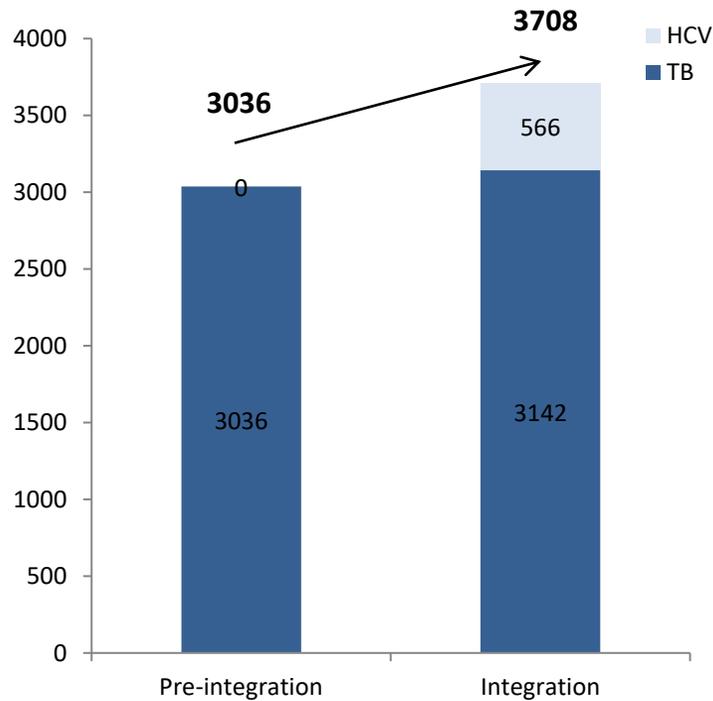
- Device used for TB and HCV testing
- 12-hour laboratory work time, 240 days
- Additional 26% unused capacity
- Annual capacity = 5760 TB tests
- Projected HCV VL demand = 1418 tests

Pilot results for 6 months indicate that near POC testing enabled access to on-site HCV testing with quicker TAT, while maintaining TB testing service delivery



10% of additional TB tests were accommodated with modified lab workflow

Total test volume

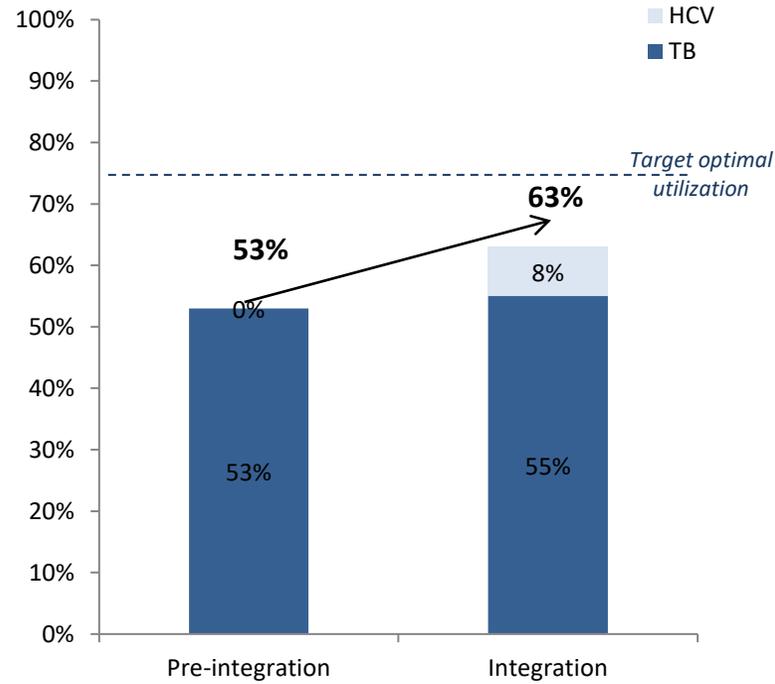


During the pilot, despite the addition of HCV VL, 90% of all GX testing was for TB samples

Integration pilot results captured from July-Dec 2017

GX Capacity utilization remained under optimal levels after adding HCV VL volumes

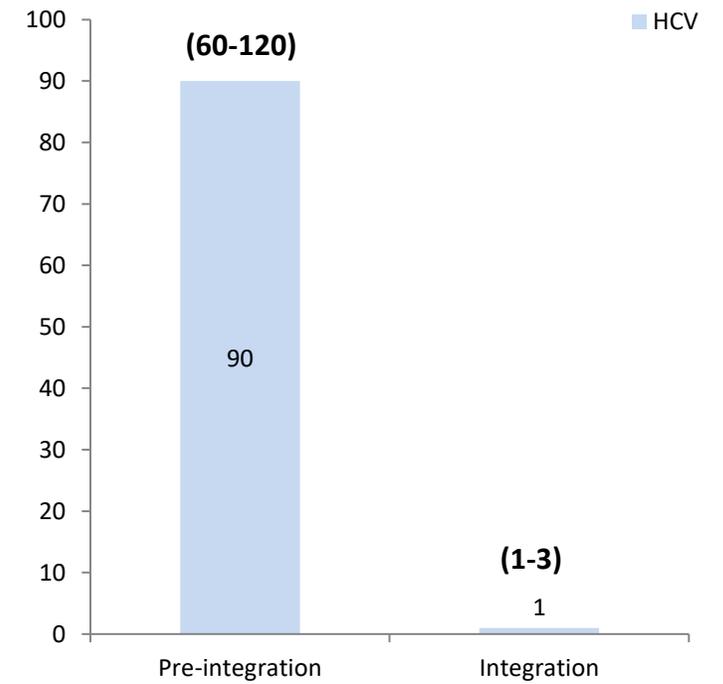
Percent Device Utilization



HCV VL test volumes occupied only 8% of GX capacity

Near-POC testing decreased time between sample collection and result return for HCV VL

In-Lab Median Turnaround time (TAT)

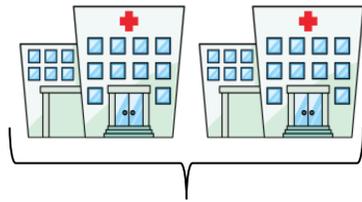


On GX: HCV VL lab processing times were an average of 24 hours, TB test processing times had a negligible increase (mean: 24 hours pre-integration vs. 26 hours post-integration)

Successful integration at pilot facility catalyzed expansion to 6 Secondary Healthcare Facilities across the 3 geographical regions in Nasarawa State

Phase 1 Scale-Up (Nov 2017)

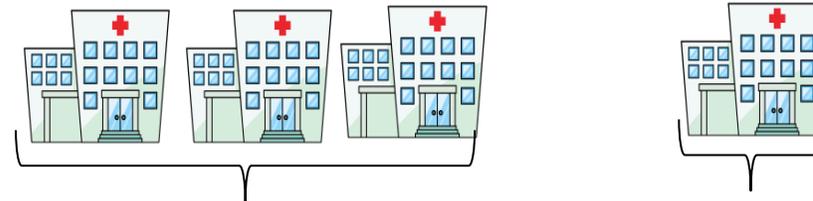
Expansion to 2 district hospitals
(low volume sites)



- Low TB volume site
- Significant unused capacity
- 8 hours lab work hours
- Eligible for referral testing

Phase 2 Scale-Up (March 2018)

Expansion to 4 district hospitals
(mix of high and low volume sites)



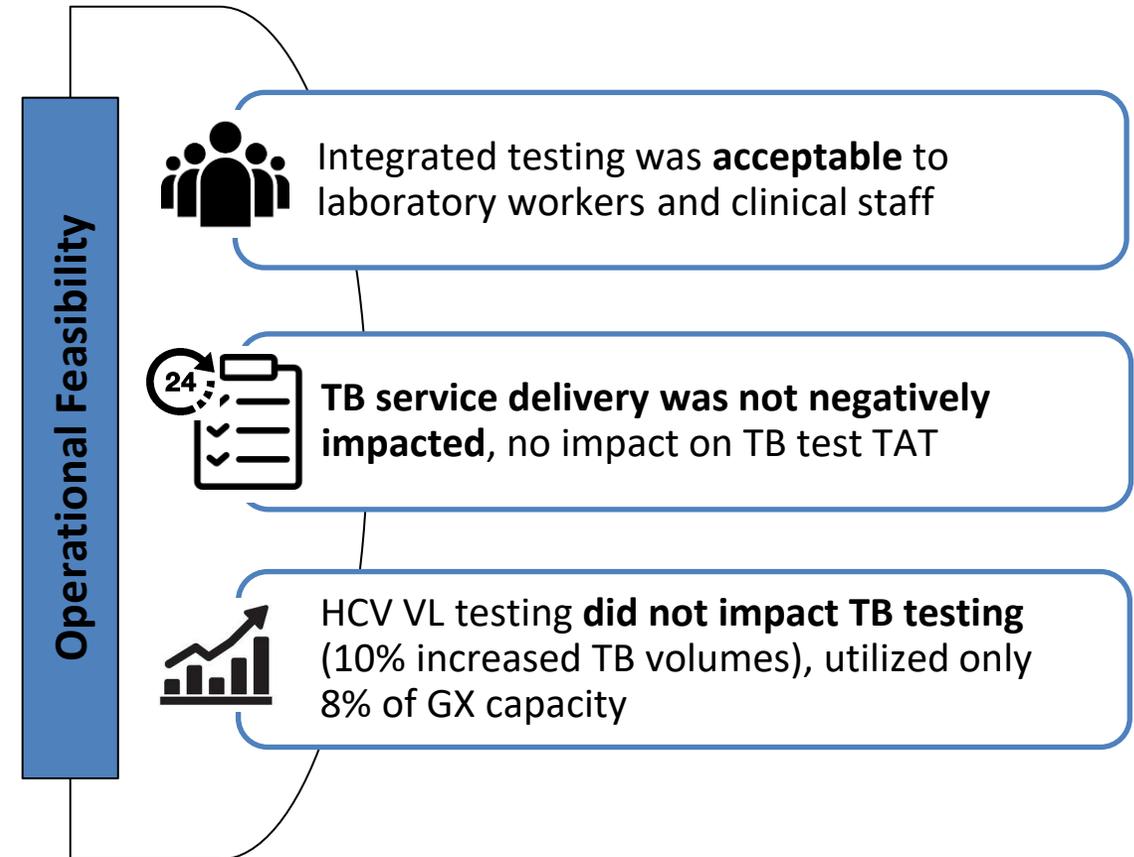
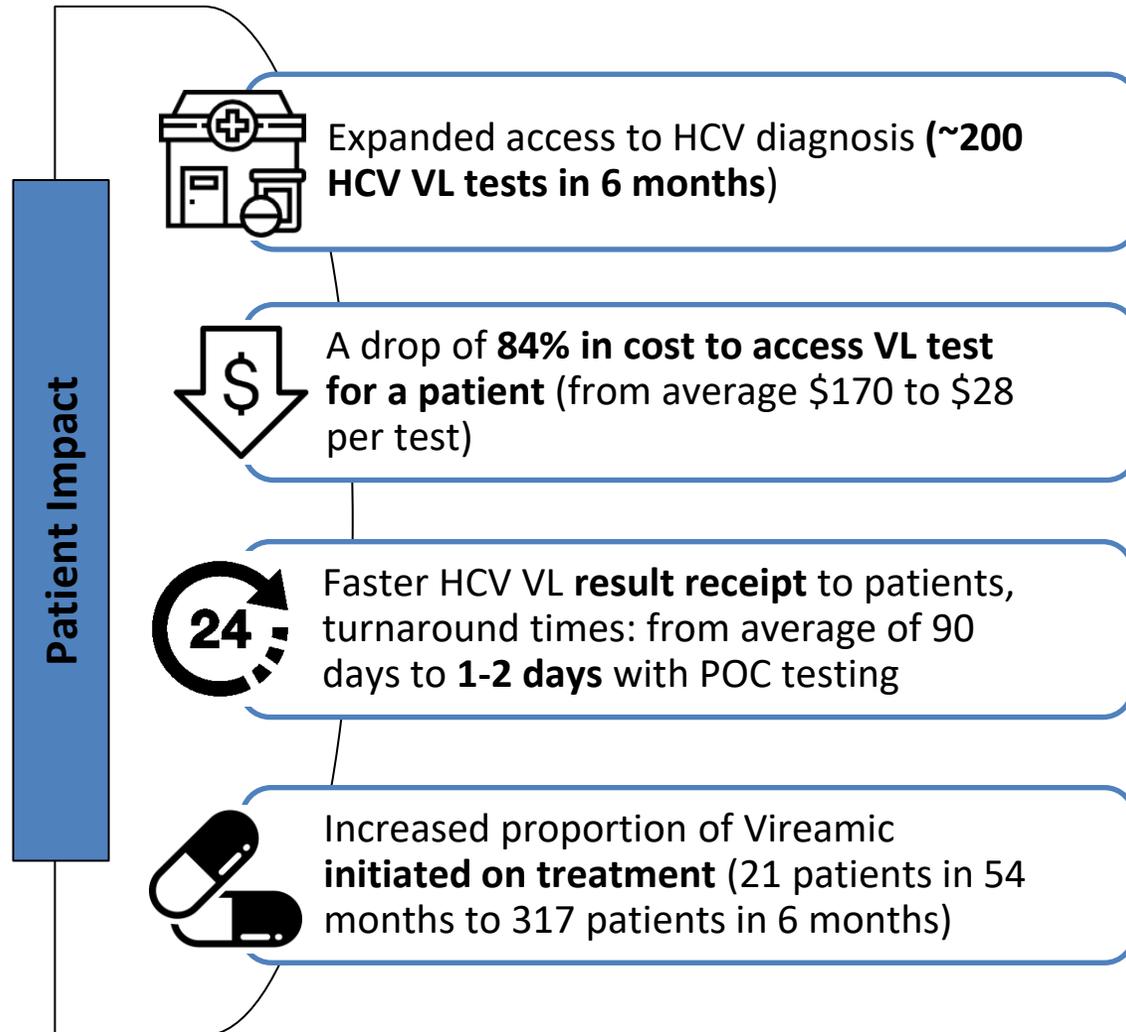
- Low TB volume site
- 54% unused capacity
- 8 hours lab work hours
- Eligible for referral testing

- High TB volume site
- 22% unused capacity
- Advocate for increased lab work hours to 12 hours
- Eligible for onsite testing

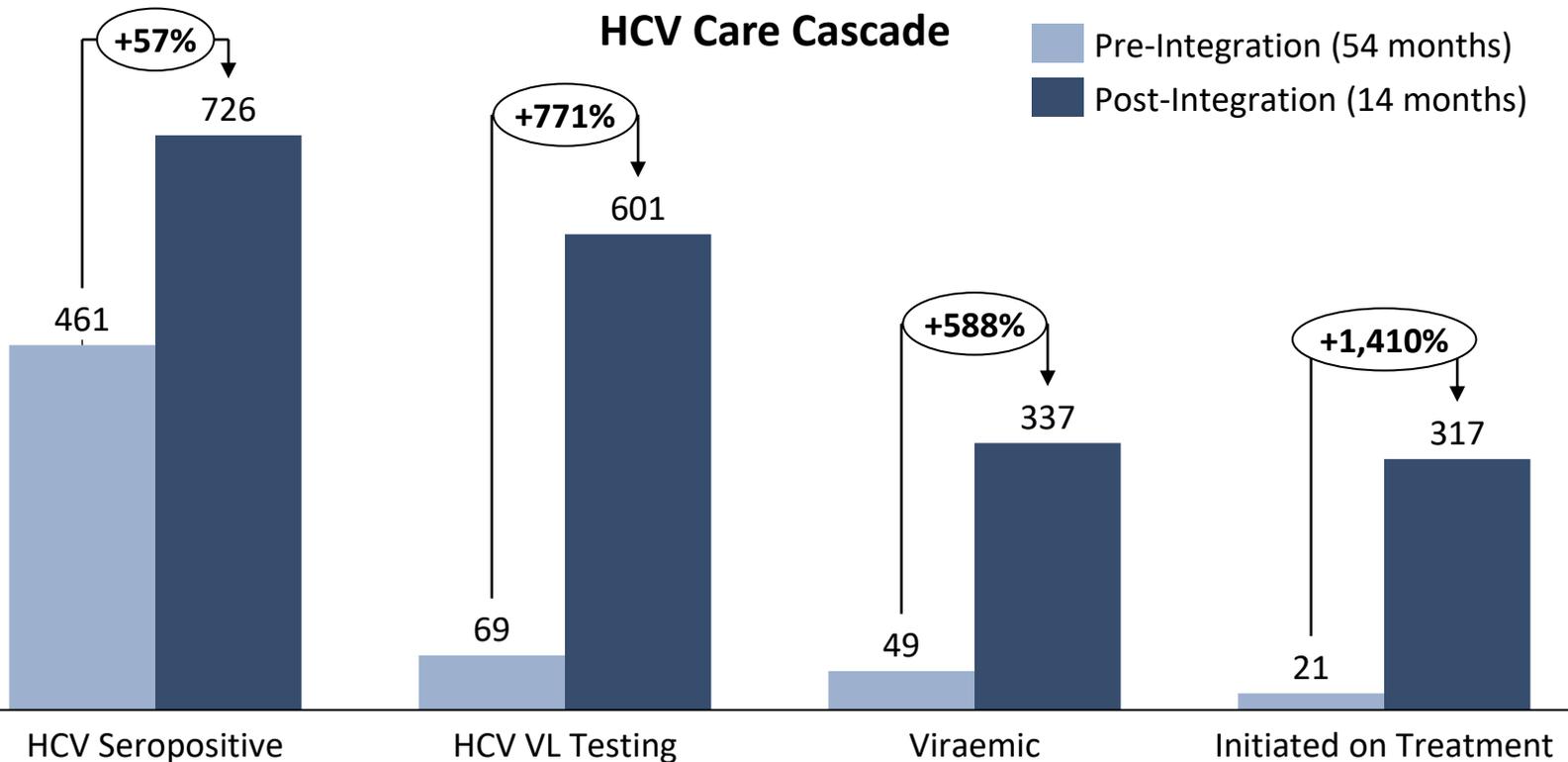
Preliminary Outcomes

- **146% increase** in number of patients accessing HCV VL testing from March to December 2018
- Set-up **external sample referral systems**
- **Improved visibility** of certain facilities due to high volume of referred samples

HCV-TB Integration pilot successfully demonstrated the operation feasibility and positive impact of integrated testing on the GeneXpert



The pilot demonstrated that the addition of HCV VL testing on available GeneXpert platforms is feasible



- Availability of on-site HCV VL on the GeneXpert was associated with a **dramatically increased number of patients accessing confirmatory testing (5.5-fold increase in the monthly VL volumes) and initiated on treatment (58-fold increase in the monthly DAA enrollments).**

Way forward

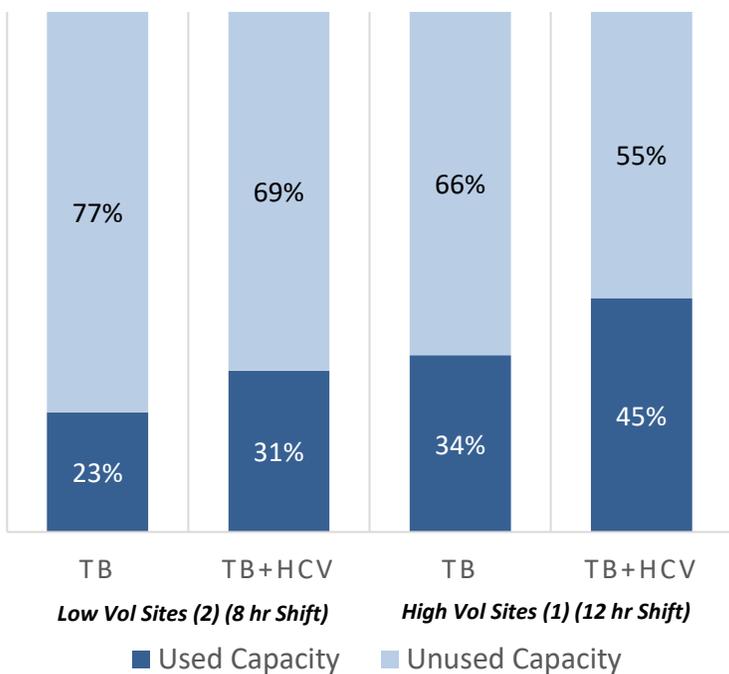
- ✓ System strengthening mechanisms by leveraging and integrating with other programs: linkage to care, ST, data management, M&E
- ✓ Connectivity solutions for monitoring of decentralized testing
- ✓ Advocate for placement of GX 16 as required
- ✓ Explore financing options to accelerate diagnostics and treatment uptake

Analysis of the TB and HCV Testing volumes from 2019 to 2021 demonstrated significant capacity with the State

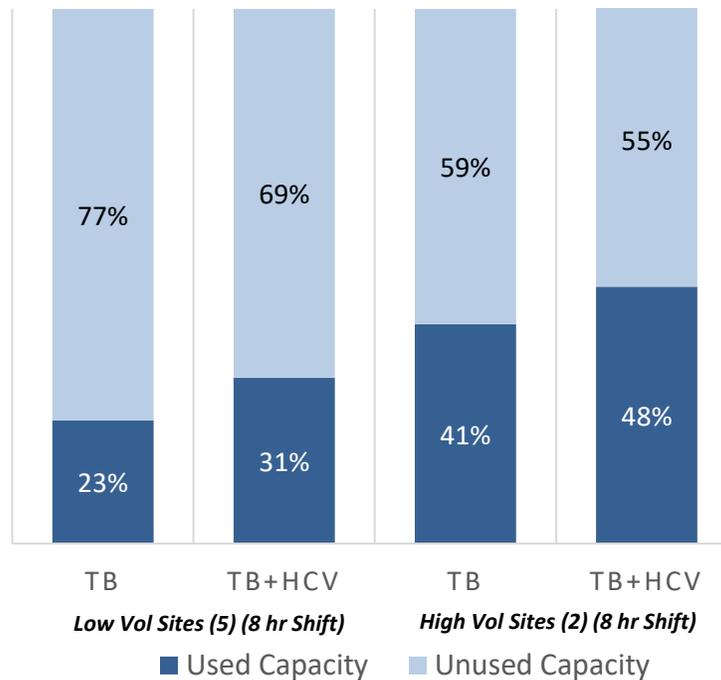


Annual review of the capacity utilization across the low and high Volumes sites in the state

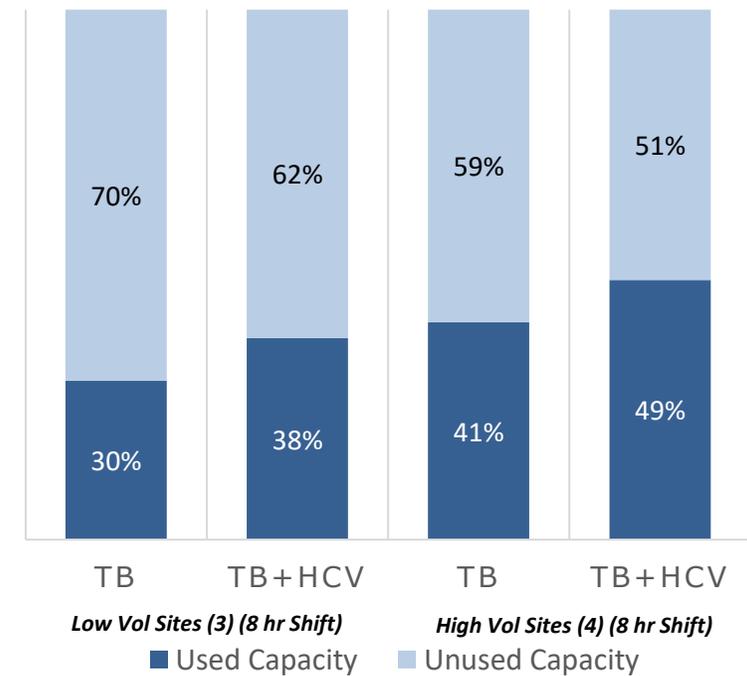
2019



2020



2021



Average Error Rates: TB= 4%, HCV=7%

Average Error Rates: TB= 7%, HCV=3%

Average Error Rates: TB= 3%, HCV=3%

Stakeholder share experience on the HCV/TB integration model



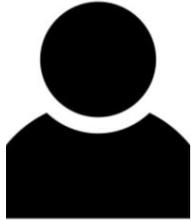
“Patients are being **managed within the hospital**, can access HCV VL tests within the same vicinity and **obtain results in less than 24hours**”

- HOD Lab, DASH



“Increased access to HCV VL tests to patients from far and wide at a **cost-effective price**, integration **enhances GeneXpert platform optimization**”

- TB GX Focal Person, DASH



“The Quick Start program has ben a **huge success, facilitating diagnostic and treatment access for patients who ordinarily could not afford the treatment**. With increased awareness, more patients have presented at the facilities, **mortality due to HCV reduced and high cure rates recorded** as evidenced by the sustained virological response achieved 12 weeks post treatment. Honestly, the CHAI Quick Start program has been a good program and I wish it can continue”

- Dr. Ruth Bello, Gastroenterologist, DASH



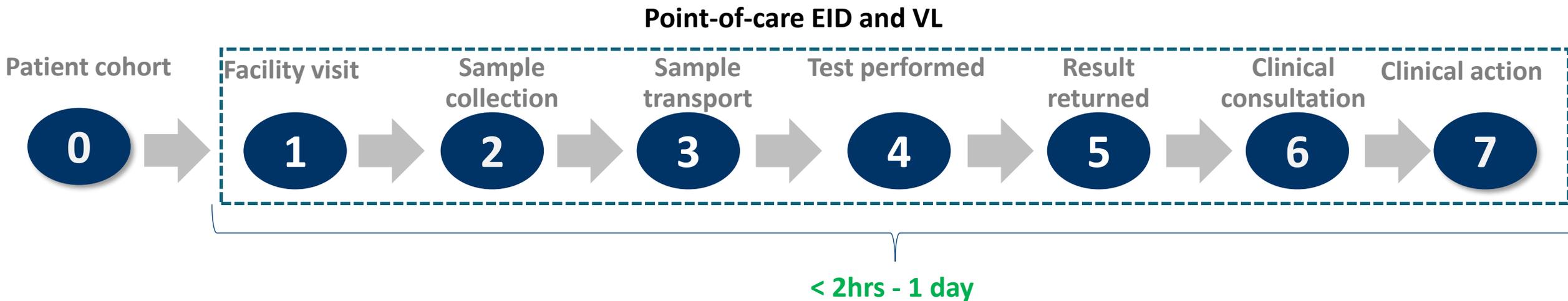
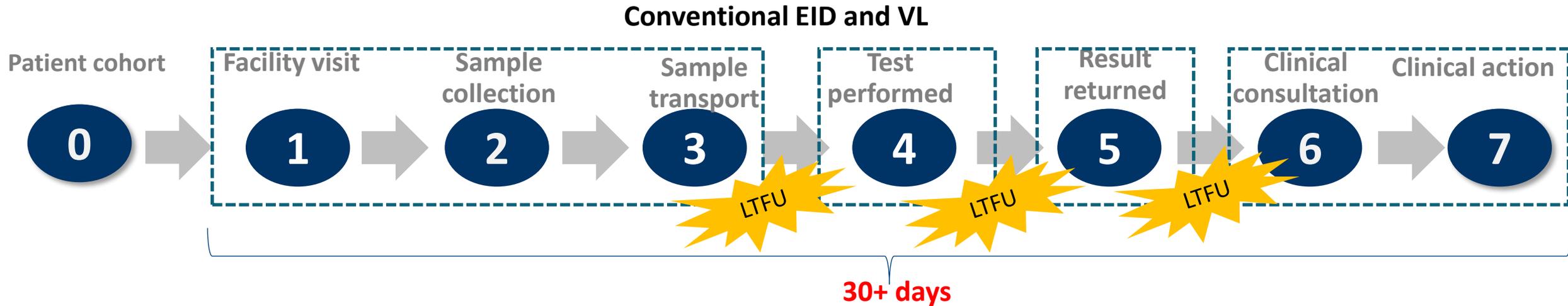
HCV/TB Integration was large a success through teamwork across all cadres of care/stakeholders

Agenda



| | | |
|------|-------------------------------------------------------------------------|----|
| I. | Introduction: Viral Hepatitis Overview | 3 |
| II. | Challenges: Major barriers to Hepatitis C diagnostics range of Hep B-BD | 6 |
| III. | Intervention: Pilot on Use of GeneXpert for Hepatitis C Testing | 13 |
| IV. | Impact: Benefits of the integration model | 19 |

Point-of-care testing can enable same day EID and VL tests results, reduce patient loss, and enhance early clinical decision

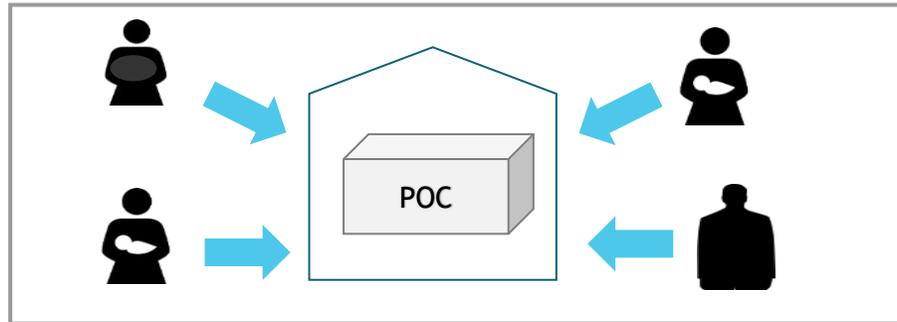


A combination of POC testing strategies can be used to: increase access to testing; expand case finding; decrease TAT; optimize platform utilization

A

Onsite Testing

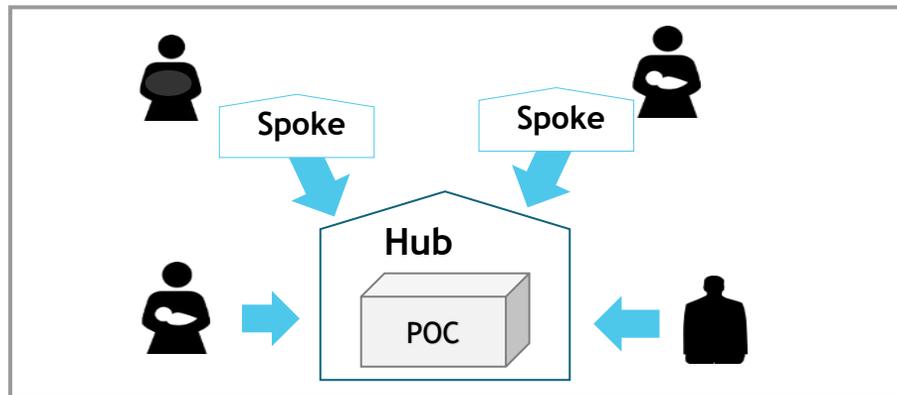
Receive samples directly from clients and perform POC EID tests on site



B

Hub-and-Spoke Networks

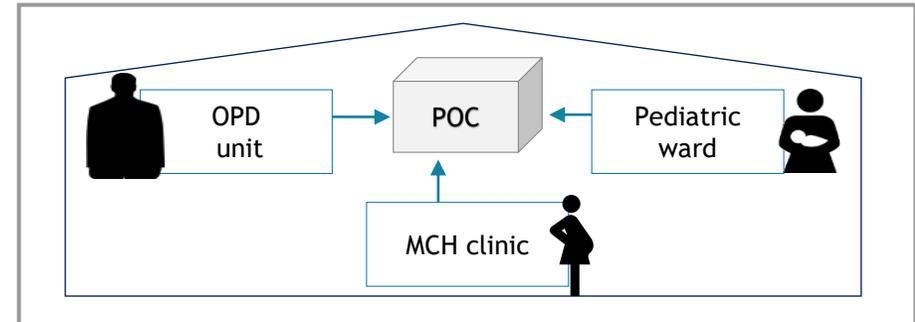
Hub sites provide testing for patients at that site and for spoke sites. Nearby spoke sites send samples to the hub sites for testing



C

Multiple Entry Point Testing

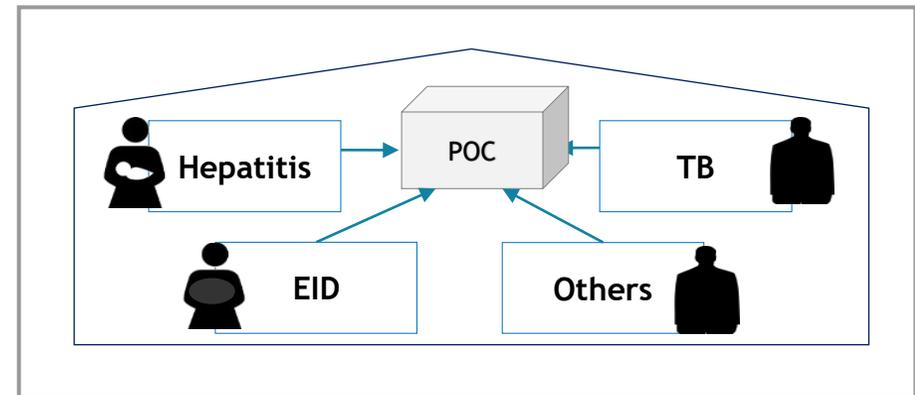
Stand-alone or hub testing sites receive samples from different units or wards within the same health facility



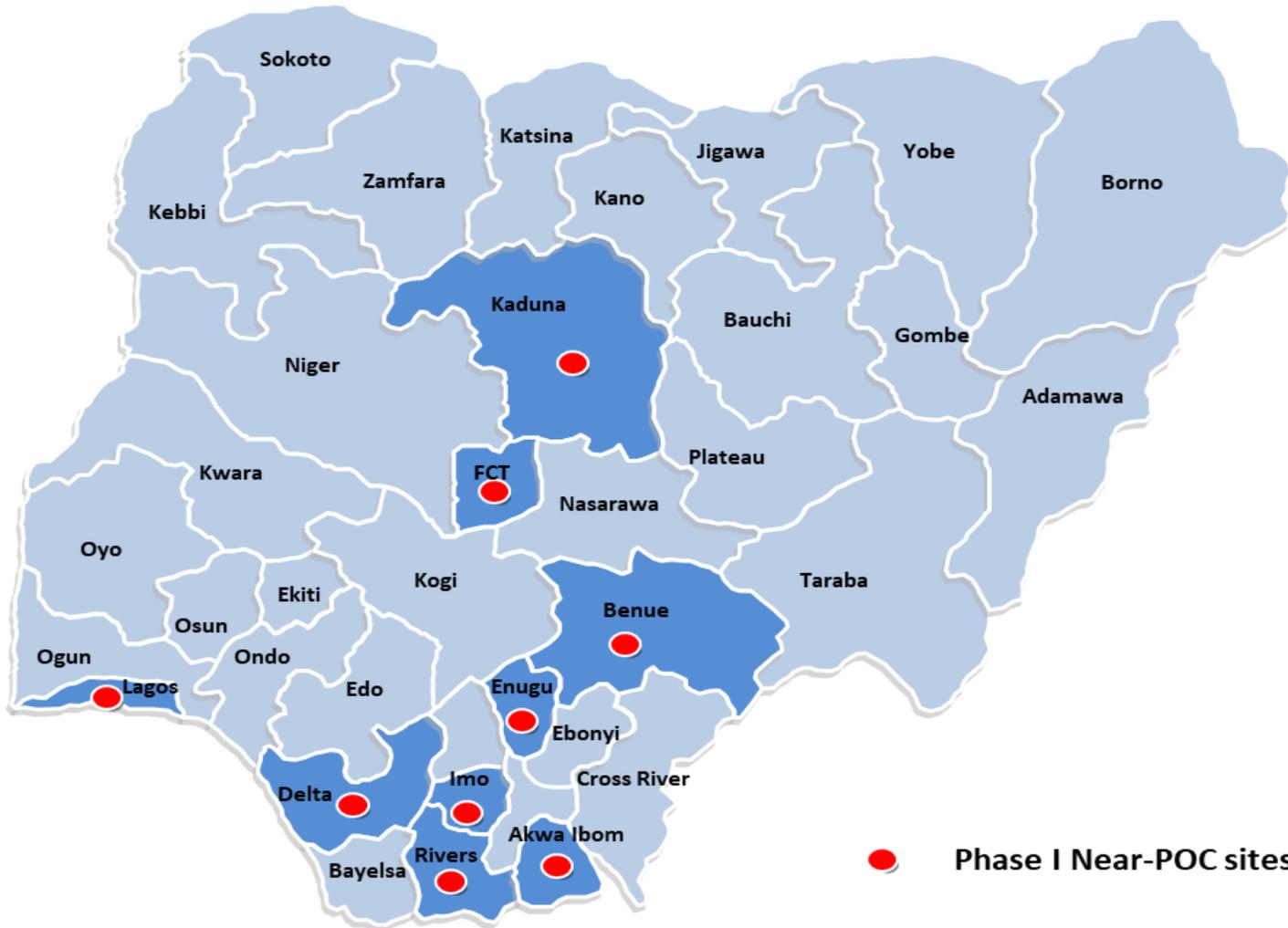
D

Multi-Disease Testing

Process different types of POC tests (e.g. EID, TB, other)



States Implementing near-POC testing (Phase I) for HIV EID Testing



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

TB samples take priority over other samples:

TB > EID > HPV > HIV VL

GeneXpert Integration focused on **EID, HPV and HIV VL**

Approximately 2000 EID tests were run on the GeneXpert platforms in a one-year period



Key Takeaways

- Integrated testing is feasible on the GeneXpert
- The availability of significant unused capacity remains a key site/platform selection criteria
- The reduction in testing observed in September is associated with the stock out of EID
- The national HIV program with support from PEPFAR commenced supply of cartridges to these sites in May 2022

Nasarawa State has leveraged lessons learned from VL integration to build momentum towards HCV Elimination



Nasarawa State HCV Elimination Strategies



- Policy guidelines in-place
- One of the first states to launch a VH public program



Effective screening and diagnostic tools at community level: near Point-of-care VL testing (**7 sites**) and Provider initiated testing and counselling (**217HCW**)



- Direct Acting Antivirals (DAA) treatment, >95% cure rates
- 8-12 week treatment period
- Pan-genotypic, oral drugs, no side affects



Cost of quality-assured generic drugs has reduced by **67%** to **USD 60** and **diagnostics by 28%** to **USD 23**.



Outcomes

- 1. Demonstrated State government commitment** to HCV elimination
- 2. Leveraged funding for viral hepatitis** through state budget lines to accelerate viral hepatitis services roll-out and reduce the high OOPE
- 3. Negotiated further price reductions for diagnostics and drugs** for Nasarawa in line with global prices
- 4. Strengthened service delivery**
 - Increased awareness amongst the general population to improve case detection
 - Supported routine capacity building for HCWs to effectively identify and manage cases of the disease

WHO and other countries are increasingly recognizing the benefits of diagnostic integration towards building more resilient health systems



Policy Generation

- Adoption of integrated testing to drive provision routine testing
- New WHO HIV recommendations are **increasingly supporting VL testing integration** across TB/HIV programs

Improve Case Finding and Reduce TAT

- Drastic reduction in TAT from weeks/months to approximately 24hrs
- **Increase case finding** by expanding screening through PoCs and reach more people at the community level

Device Optimization

- Expansion to other program areas such as HIV, HPV, others
- Covid-19 has reinforced the **need for wider availability of PCR testing**

Market Shaping

- Integration of HCV VL testing on the GeneXpert led to an 84% reduction in the cost per test
- Expansion of testing, leading to increased volumes resulted in an additional 23% price reductions

Improved Reporting and SCM

- Strengthening reporting and identifying opportunities for interoperability
- Increased visibility of testing on the GeneXpert

QUESTIONS

