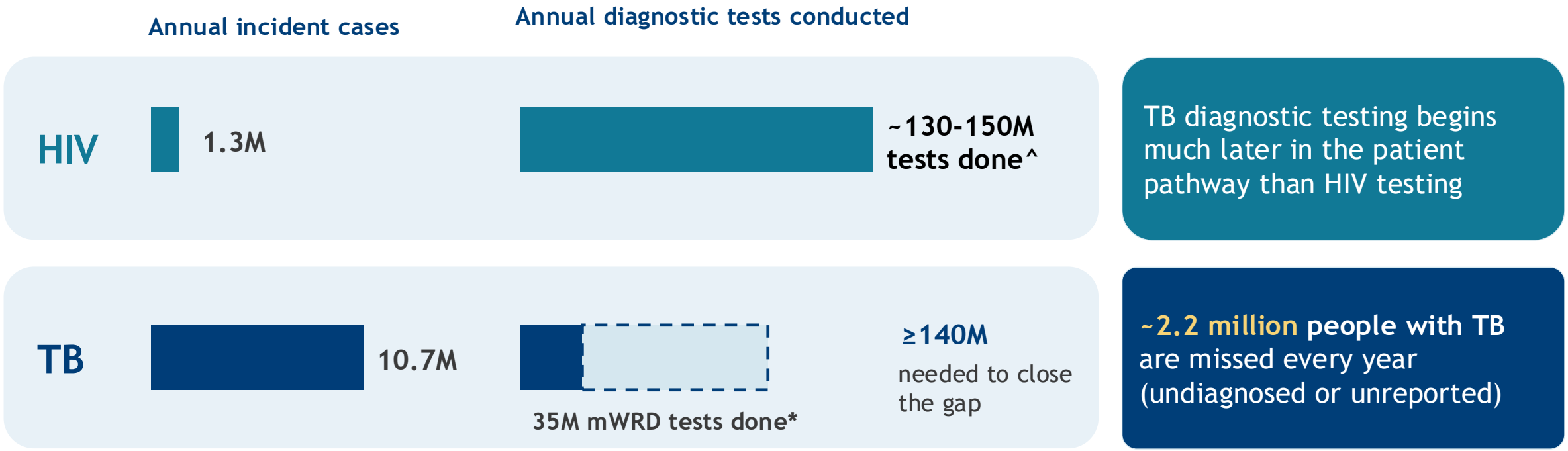
Near Point of Care (nPOC) TB diagnostics: from demand forecast to diagnostic system design

Demand outlook across 10 high-burden TB markets and early implementation evidence from Zimbabwe

Aug 2026

This work was supported by Unitaid. We thank the Ministries of Health and National TB Programs for their partnership and contributions to this assessment.

TB remains dramatically under-tested



TB diagnostic testing begins much later in the patient pathway than HIV testing

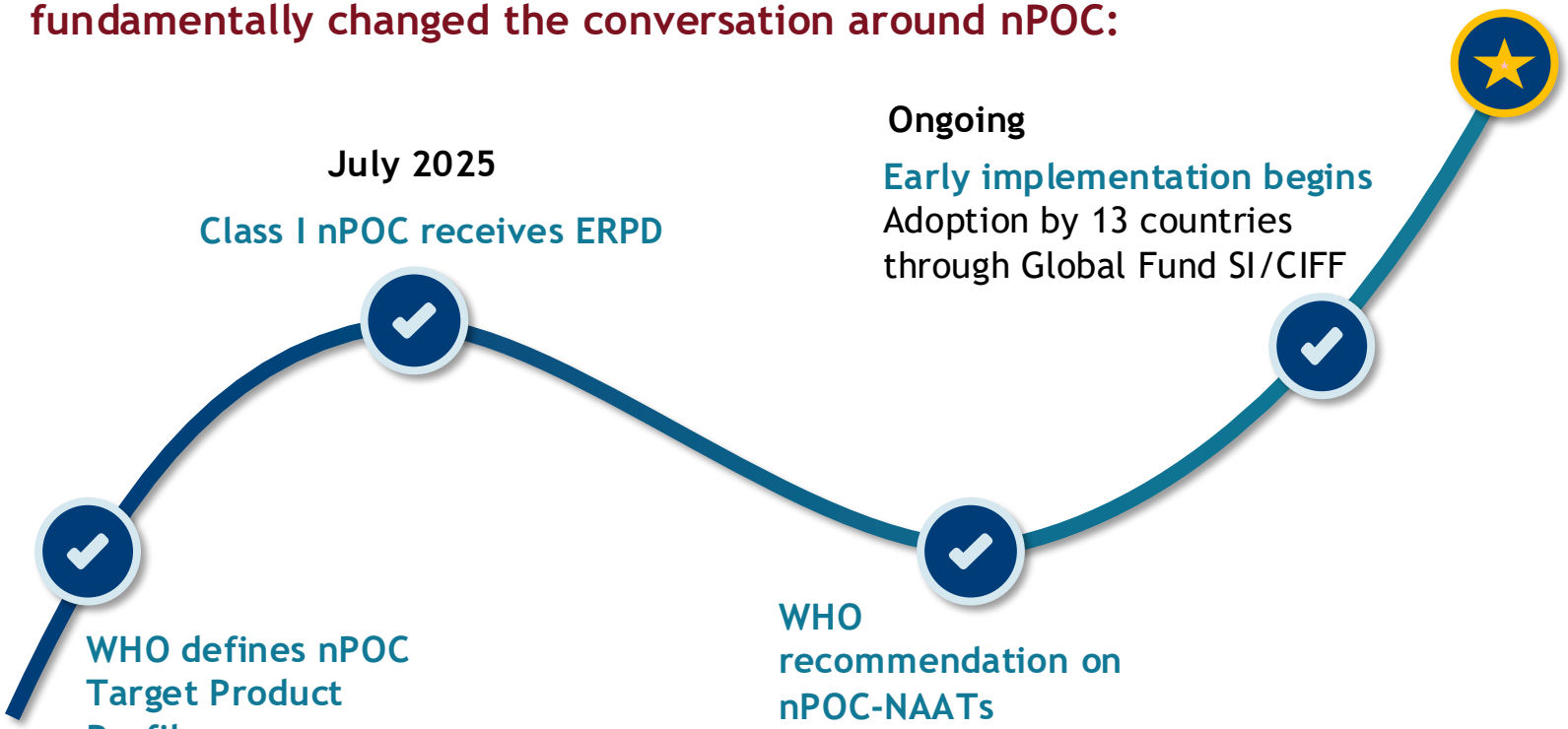
~2.2 million people with TB are missed every year (undiagnosed or unreported)

With WHO now recommending near-point-of-care (nPOC) testing for initial TB diagnosis, the key question is whether nPOC can dramatically expand access to molecular testing

**For TB, the 35M refers to molecular WHO-recommended rapid diagnostic (mWRD) tests only*
^ source: WHO/EIC Integrated HIV RDT Forecast, 2022 estimate

The conversation has shifted from validating nPOC technology to implementing it at scale

Over the past two years, several developments have fundamentally changed the conversation around nPOC:



This stage requires countries to answer new questions:

* Where should devices be placed?
* How do we make them work every day?
* How do we maximize their impact?

Today's session

01 Multi-country demand forecast for nPOC TB diagnostics

Findings from market assessment in 10 countries that combined quantitative modelling with stakeholder interviews across National TB programs, laboratories, and implementing partners

02 Early field results from Zimbabwe

Early implementation results from 29 activated sites across provincial, district, and rural microscopy levels, including field validation and impact on case finding

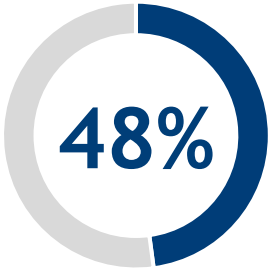
Multi-country Forecast and Learnings

10 markets representing half of global TB burden assessed to project nPOC demand

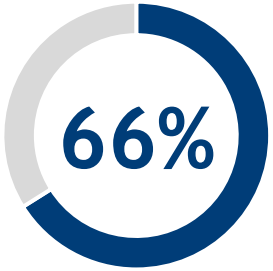
10 high-burden markets across Africa and Asia included in the forecast

India
Indonesia
Viet Nam
Nigeria
South Africa
Kenya
Uganda
Zimbabwe
Cameroon
Ivory Coast

Share of global TB burden



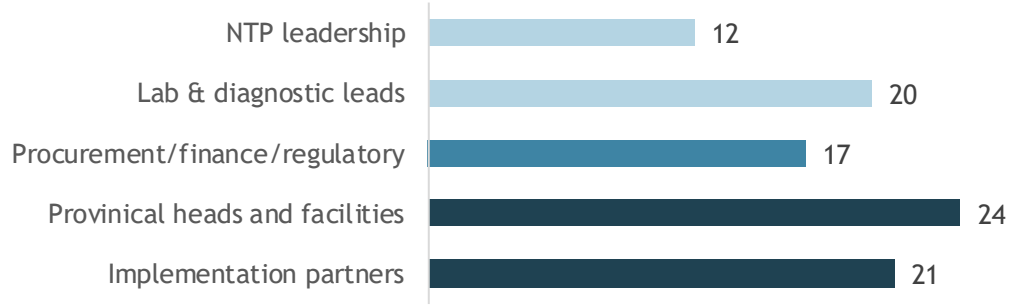
Share of molecular testing



How we build this outlook

94 **stakeholders engaged** across all 10 countries

Stakeholders interviewed



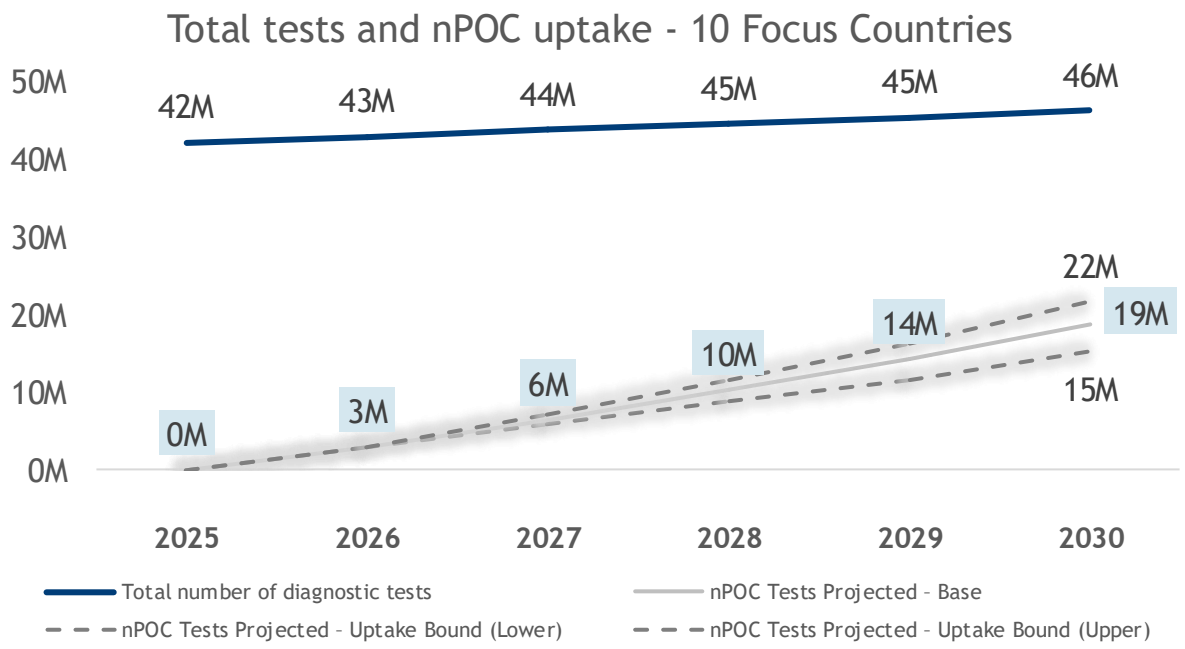
Topics covered in stakeholder consultations

- Current diagnostic landscape and testing priorities
- nPOC use cases, target deployment sites, and adoption pace
- Health system readiness and infrastructure
- Regulatory pathways and financing outlook

The qualitative inputs helped inform key model parameters on timing of nPOC introduction, pace of scale-up, and displacement pathway.

nPOC could reach 19M tests by 2030, representing 40% share of total testing volumes in these 10 markets

~19M nPOC tests by 2030 (range 15-22M) in 10 countries
Representing ~40% of projected TB diagnostic testing



Total diagnostic tests shown include molecular testing as well as smear used for diagnosis

- **Base case projects 19M tests by 2030 with upper bound of 22M**, range reflects uncertainty around constraints on HR, infra, financing
- **In this scenario, we are assuming nPOC demand is primarily substitutive -** nPOC assay volumes are displacing smear and LCNAAT rather than expanding overall market; though cost savings if reinvested can increase the total testing levels
- **India drives largest uncertainty in the forecast** with uptake contingent on domestically manufactured nPOC product becoming available
- **Near term momentum seen in several markets** Indonesia, Nigeria and Zimbabwe have confirmed procurement underway; South Africa, Kenya and Uganda are part of Global Fund Early Adopter program
- Assessment showed that uptake is likely to be **constrained by health system's ability to absorb volumes** and scale implementation**, not because of saturation of demand or lack of need**

Readiness and financing will determine whether countries can fully capitalize on nPOC's potential impact

Stakeholder engagement and modelling converged on three critical themes that will determine whether nPOC translates into impact

Placement

Where nPOC devices would be deployed

Activation

Whether placed devices are used

Reinvestment

Whether shift to nPOC would generate incremental testing

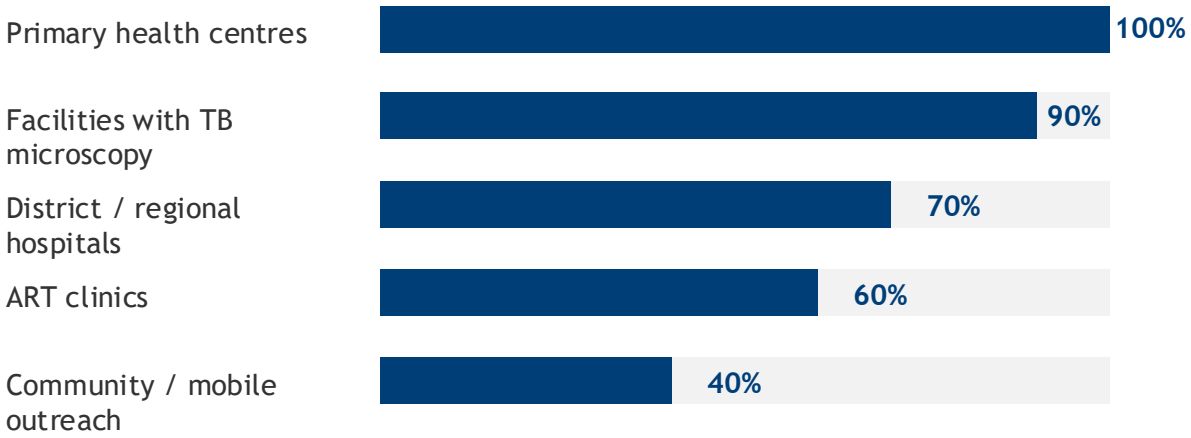
Diagnostic System Design

How countries translate technology into impact

Placement determines whether nPOC expands access; countries plan to decentralize testing by deploying nPOC at PHCs and microscopy sites

Priority sites for nPOC placement across countries

% of countries highlighting site as target for nPOC (N=10)



Use cases driving placement

Smear replacement: improves sensitivity and expands access at peripheral sites, but increases cost per test

LCNAAT substitution: generates immediate cost savings; impact depends on whether substitution occurs centrally or at peripheral sites

Hybrid pathway (most likely): substitution at higher-level sites frees resources; savings enable expansion into peripheral sites

Early evidence: placement drives impact

Kenya early implementation (N=12 sites)

Impact on testing depended entirely on where devices were placed:

Sites where placement expanded access

+82%

May-June 25 vs. May-June 26

increase at microscopy only sites

Sites where placement substituted existing capacity

-25%

May-June 25 vs. May-June 26

decline at existing GeneXpert sites

Kenya results are from work funded by Gates Foundation and GSK in partnership for lung health integration

CHAI has developed site prioritization and quantification tools for nPOC to help countries turn placement strategy into a phased rollout plan

Site prioritization framework

Step 1: Select priority site types

What role should nPOC play and at which sites?

Intended roles for nPOC

- Replace smear microscopy
- Decentralize molecular testing to peripheral sites
- Integrate TB testing with HIV care
- Reduce costs and offload higher-level platforms

Candidate site types

- TB microscopy sites
- Primary health centres
- ART and HIV clinics
- TB treatment / DOT centres
- Existing LCNAAT sites
- Community / ACF sites

Step 2: Prioritize by need and readiness

Which eligible sites should receive devices first?

NEED

- TB burden and notification gap
- High proportion of underserved / high risk population
- Large distance to nearest molecular testing

READINESS

- Access to reliable power supply (mains or external)
- Referral linkage for further testing (DST)
- Staff capacity and availability
- Supply chain reliability

Prioritization approach

- High need + high readiness sites first
- High need + low readiness: invest, then activate
- Lower need sites phased over later years
- **Readiness treated as investment based, not filter**

Quantification tool

Step 3: Phase and quantify

How many devices, tests, and resources?

- Estimate test volumes
- Determine device needed
- Estimate operating costs
- Inform investment planning and annual program forecasting

Designed to be iterative: select sites, quantify costs, adjust plan to match budget, re-run

CHAI Global TB Program has developed excel based tools to support the above process of site selection and commodity quantification. Please contact Prachi Singhvi (psinghvi@clintonhealthaccess.org) or Kuber Bathla (kbathla@clintonhealthaccess.org) for further details

Activation requires building functioning diagnostic service across five domains to realize uptake



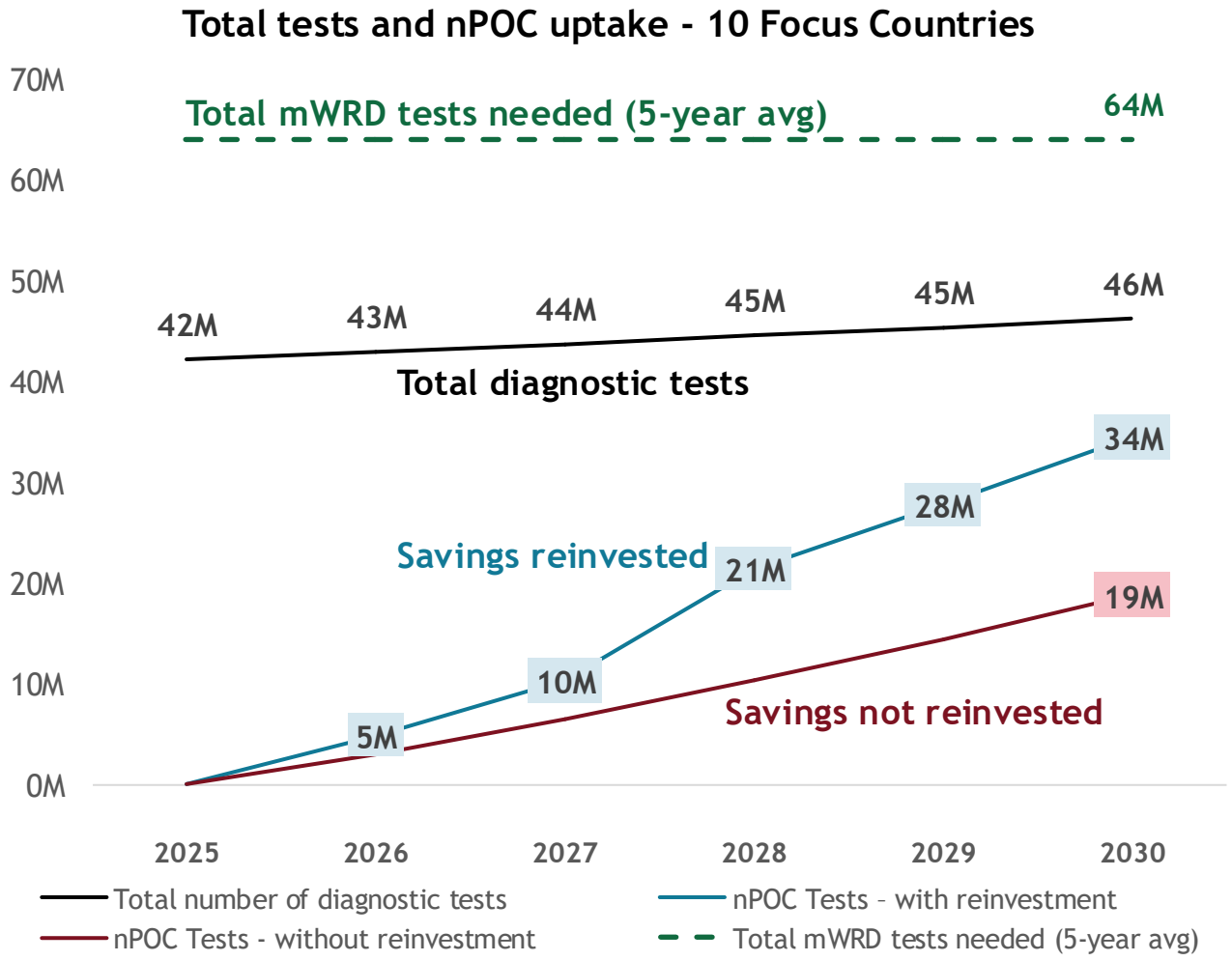


1. Clinical pathway	2. People	3. Operations	4. Data & Quality	5. Referral & Linkage
Can patients complete the diagnostic pathway? ✓ Testing algorithm & SOPs ✓ Patient flow ✓ Same-day treatment / reflex	**Can staff deliver the service?** ✓ Training & competency ✓ Mentorship & supervision	**Can the device run every day?** ✓ Power & maintenance ✓ Consumables & supply chain ✓ Inventory	**Can results be trusted?** ✓ Connectivity & reporting ✓ Quality assurance ✓ Performance monitoring	**Can patients complete care?** ✓ Sample referral ✓ Linkage to treatment ✓ Follow-up

Early implementation lessons (Kenya and Zimbabwe)

Device activation alone wasn't sufficient *Sites performed best when staff understood the new workflow and patient journey from screening to treatment*	*Staff competency was consistently high, hence training quality wasn't a limiting factor* *Yet, reliance on few trained operators increased the risk of service interruptions*	*Reliable consumables and supply systems are as critical as functional device for maintaining uninterrupted service*	*TB cases diagnosed through nPOC were not consistently captured in routine program reporting systems.* *In initial roll-out, training and tracking will be critical*	*nPOC reduced time result for initial confirmation. However, reliance on existing referral and specimen transport network for reflex testing led to unchanged downstream turnaround time*

Reinvesting savings generated with shift to nPOC would allow programs to double testing volumes by 2030



The same efficiency gains can produce two very different outcomes

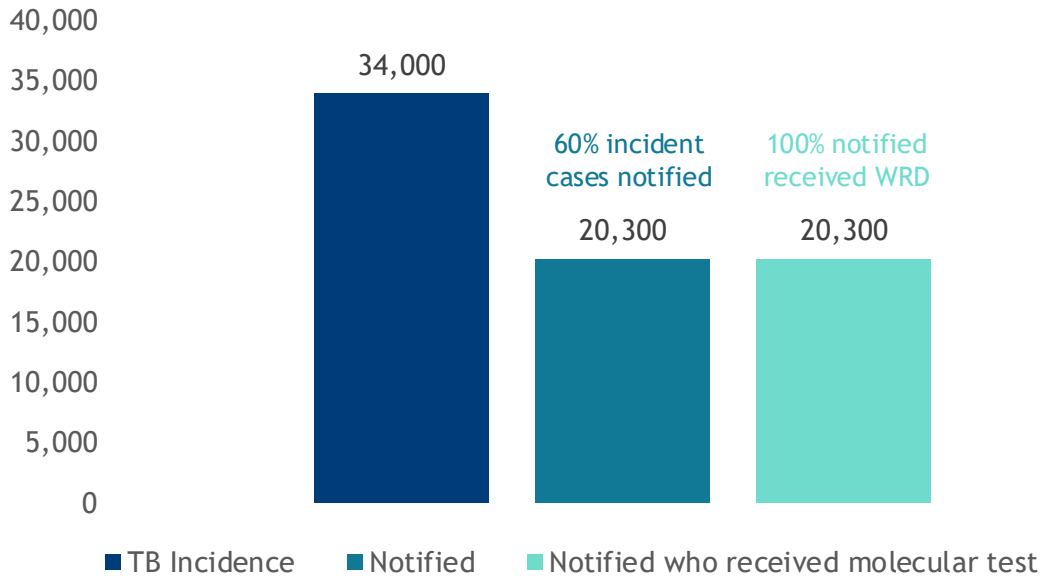
- **Retain savings**
  - nPOC testing reaches ~19M
  - Efficiency gains absorbed
  - Limited expansion of access
- **Reinvest savings**
  - nPOC testing reaches ~34M
  - Savings converted into additional testing
  - More patients reached and TB cases found

The measure of success is not dollars saved - it is additional patients diagnosed

Evidence from Implementation in Zimbabwe

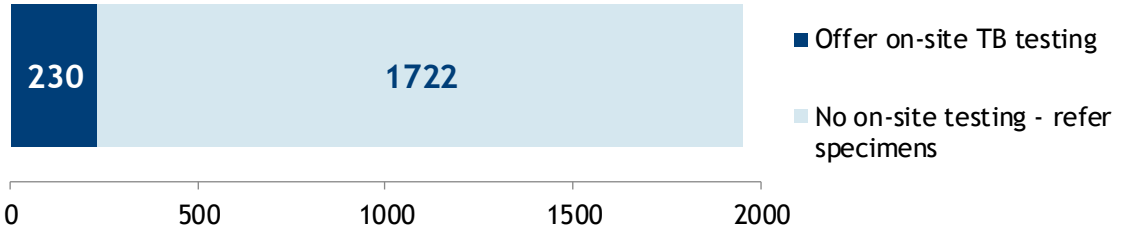
Zimbabwe currently notifies 60% of the 34,000 estimated TB cases; 88% of facilities lack on-site testing

TB burden and notification gap

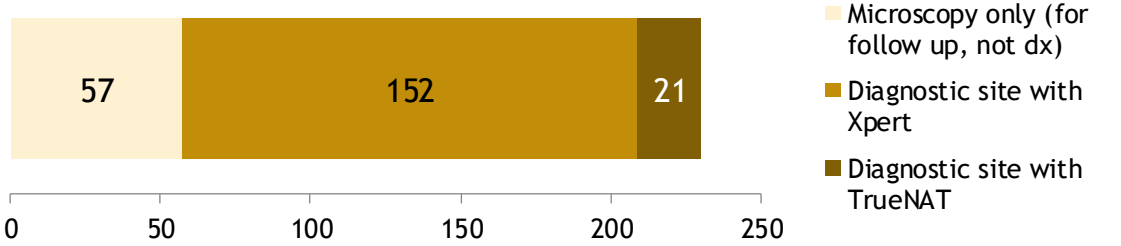


How TB Testing is structured in Diagnostic Network

Breakdown of facilities with on-site testing for TB v/s referral sites (N=1,952 sites)



Breakdown of 230 facilities with on-site testing



Closing the gap requires finding the missing 40%

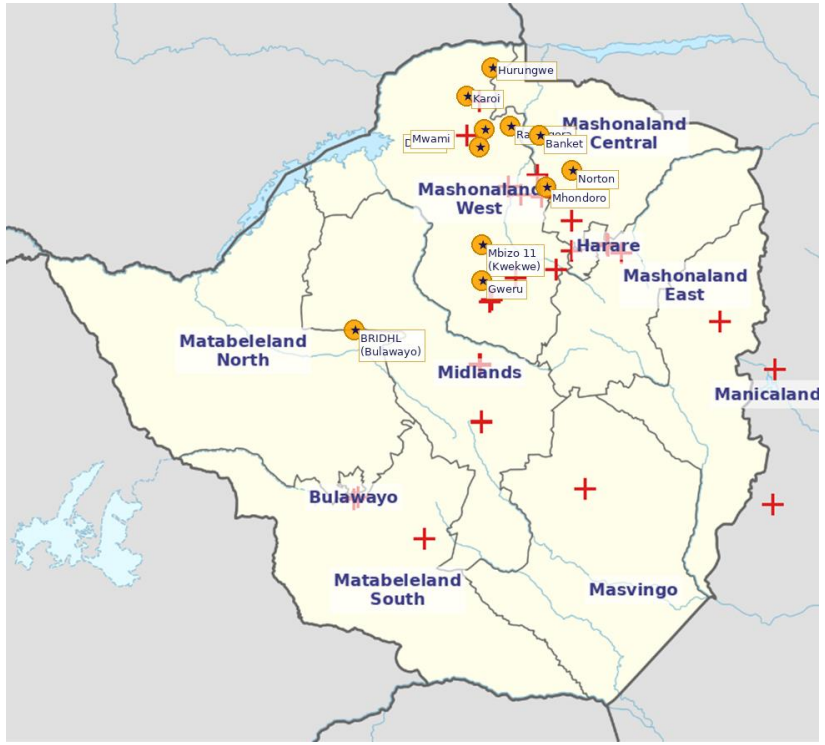
Zimbabwe already provides molecular testing to nearly all notified TB cases. The larger challenge is upstream: **~14,000 people with TB each year remain undiagnosed or unreported**, pointing to the need to expand access and case finding closer to where patients first seek care.

The plan: expand nPOC testing using sputum sample to 230 TB testing sites

- **At 173 existing mWRD sites:** substitute LCNAAT with PlusLife as the first-line diagnostic test but remain useful for reflex RR testing, HIV VL, HIV EID etc
- **At 57 microscopy only sites:** expand from microscopy to molecular diagnosis for the first time

MOHCC has activated 29 sites across service tiers to pilot nPOC and develop learnings for further near term nPOC scale up

Map of Health Facilities running nPOC Testing in Zimbabwe



★ Hospitals

\+ PHCs / clinics

Phase 1 combines national procurement, diverse service contexts, and routine performance learning

National commitment and reach

212 analysers and 118,000 tests procurement finalized, 29 activated sites, 300+ health workers trained. Costed plan, SOPs, supervision, and EQA are in place

Facility tiers and service model

Piloting across different site sites – high throughput hubs, peripheral clinics, ART services, and reference labs

Routine learning loop

Facilities report volumes, results, errors, stock, and linkage, feeding supervision, mentorship, and scale-up decisions.

Selection logic and scale-up value

Sites selected for pilot based on geographic spread, demand, reporting, and feasibility; each tier tests access, throughput, and capacity limits. (*The approach was test technology expansion vs geographic)*

Snapshots from the Sites Running nPOC Tests in Zimbabwe

Field validation confirms strong agreement with GeneXpert; microscopy sites show 2.2x increase in case finding

Sputum Validation : 26 Xpert MTB/RIF Ultra sites (N=2,813 paired tests)

86.7% Positive agreement

97.9% Negative agreement

98.5% Valid result yield

Agreement matrix

	Pluslife +	Pluslife −	Row total
Xpert Ultra +	260	40	300
Xpert Ultra −	53	2,417	2,470
Column total	313	2,457	2,770

TP 260 · TN 2,417 (concordant) FN 40 · FP 53 (discordant)

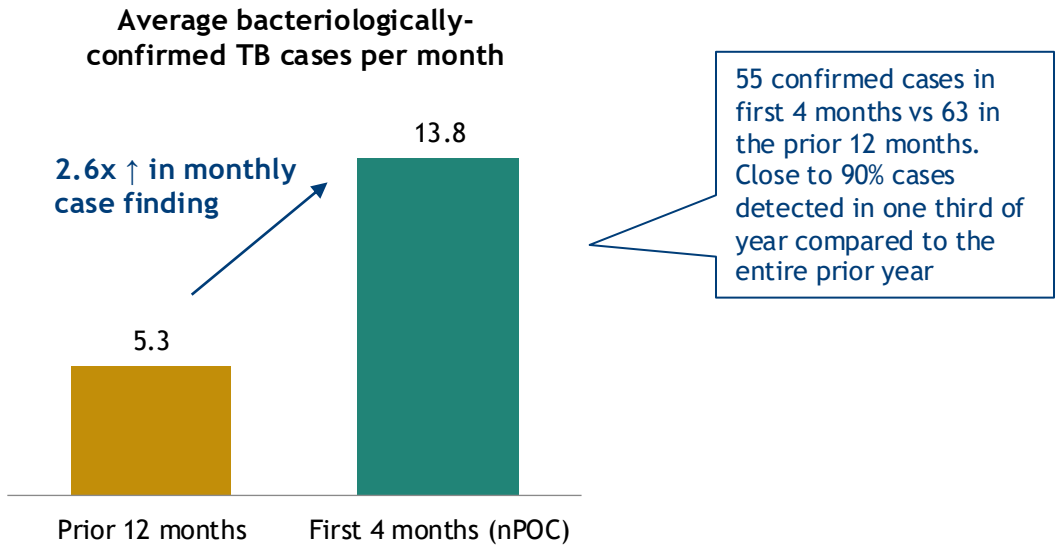
What the field data showed: Strong field agreement supports decentralized use. Of 2,813 paired tests, 2,770 produced valid paired results; positive and negative agreement were 86.7% and 97.9%, respectively.

Impact: microscopy sites (N=6, first 4 months)

525 TB tests performed

55 Confirmed TB cases

100% Treatment initiation



Strong field agreement over the first 3 months of implementation in high volume sites, supports decentralized use; placement at microscopy sites is validated and increasing case finding.

Almost every implementation challenge was a health system challenge, not a device challenge

1

LESSON 1

Train the whole facility

At some sites, screening, testing and treatment teams had not been oriented together, so eligible patients were not consistently routed for nPOC testing. Train the whole facility and reinforce the pathway during mentorship.

2

LESSON 2

Build an operating rhythm

Testing slowed when the only trained operator was off duty, while stock and utilization were not reviewed routinely. Cross-train operators and review tests, stock and downtime every week.

3

LESSON 3

Fix reporting and reflex pathways

Some results were entered incorrectly or not captured in registers and reports; discordant results did not always have a clear reflex pathway. Set up tools and algorithms before the first test.

4

LESSON 4

Secure ownership and support

Power (using mains), maintenance, referral or reporting issues sometimes lacked a named person to resolve them. Assign ministry and facility owners, escalation routes and funded follow-up support.

Zimbabwe has embedded nPOC in the National TB Strategic Plan and is planning full-scale procurement through GC8

1 Policy commitment

nPOC has been incorporated into the new National TB and Leprosy Strategic Plan (2027-2030).

This reflects MOHCC's commitment to transitioning nPOC from a pilot technology to a core component of the national diagnostic network.

2 GC8 procurement

Plans to procure additional devices in the Global Fund GC8 cycle to cover all targeted sites.

Procurement includes:

Additional nPOC devices and sample-processing units

Test cards for projected volumes

Warranty provision with service and maintenance plans

3 Scale-up targets

Share of presumptive TB clients to be tested using nPOC as the first-line diagnostic test:

50%	80%	83%
2027	2028	2029

Phased increase in nPOC coverage as additional sites are activated and supply capacity expands.

Phase 1 results are informing the GC8 application: Zimbabwe is scaling based on evidence, not assumption.

Forecast and field evidence converge that nPOC can expand access to molecular testing access, but realizing it depends on how countries plan placement, activation, and financing

WHAT THE FORECAST TELLS US

- Base case projects 15-22M nPOC tests annually by 2030, with upside to 35M if savings are reinvested
- Primary opportunity for nPOC is decentralization by integrating it into PHCS, ART clinics, and community
- Operational readiness (power, staffing, supply chain, reporting) could affect adoption despite high program interest
- LCNAAT platforms will not be fully replaced and need to be repositioned for reflex drug-susceptibility testing

WHAT ZIMBABWE SHOWS

- Decentralized molecular TB diagnosis through NPOC is validated and increasing case finding at microscopy sites (2.6x monthly cases)
- Placement at microscopy only sites or sites with access gaps is driving highest impact
- Site activation activities and program planning affect whether sites performed well
- Most challenges were health system challenges and not issues with technology itself

WHAT COMES NEXT

- Countries need to translate high level decisions in GC8 applications into structured plans using prioritization and quantification approaches
- Success of early pilot results from SI countries will drive the direction of market
- Introducing nPOC would generate savings in most countries which need to be used purposefully
- Countries will need to plan their financing and platform mix deliberately: which technology is used at which level, what is funded through Global Fund versus domestic resources, and how the overall diagnostic network is structured

Thank you!

This work was funded by Unitaid through the Multi-disease Diagnostics Grant

For questions or to access nPOC quantification tools: contact Prachi Singhvi at psinghvi@clintonhealthaccess.org

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Annexure

Forecast integrates country-level quantitative data and stakeholder intelligence across 10 priority markets

INPUTS

QUANTITATIVE

Epi and Program Baseline
- TB cases, notifications, bacteriological testing rates and NSP targets

Current Test Volumes and Mix
- Historical SSM, LCNAAT, LAMP and high-throughput NAAT volumes and growth trends

QUALITATIVE

Current Diagnostic Landscape
- Diagnostic priorities and molecular testing barriers

nPOC Use Case and Adoption Outlook
- Priority use cases, target sites and deployment approach

Implementation Consideration
- Health system readiness, infrastructure, regulatory pathways and funding outlook

MODEL PROCESS

1 Project future diagnostic testing volumes over 2026-30

- Total testing estimated assuming modest growth aligned to bacteriological trends and budget reality
- Smear volumes adjusted to exclude treatment follow-up testing

2 Estimate country-specific nPOC uptake curves

- Uptake curves anchored in country context and health system readiness
- Three scenarios captured:

Lower Bound: Constrained roll-out

Base Curve: Expected adoption trajectory

Upper Bound: accelerated adoption

3 Assess resulting test mix transition and commodity spend

- nPOC substitution allocated across SSM and LCNAAT based on country use cases
- Current and future commodity spend estimated from projected volumes and unit costs

OUTPUT

DIAGNOSTIC TESTING OUTLOOK

Platform and test mix evolution

nPOC test volumes over 2026-30

LCNAAT tests needed for reflex post nPOC

Change in test commodity spend

SENSITIVITY ANALYSIS

Total Tests under constant diagnostic commodity spend

- Cost savings from nPOC-driven test mix transition are reinvested into expanded testing volume, holding total diagnostic spend constant