Integrated Diagnostic Network Optimization in Kenya

Improving accessibility of molecular diagnostics for TB, HIV and HPV

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LabCoP ECHO Session Webinar
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Project overview

- Integrated Diagnostic Network Optimization (DNO) for three diseases: HIV, TB, and HPV
- Scope: rapid molecular diagnostic tools for all three diseases and conventional platforms for HIV

Presentation outline

- Background
- Objectives
- Methodology & approach
- Results
- Implementation planning
- Tips & tricks

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BACKGROUND

The Kenyan context

Three disease programs within the Ministry of Health structure

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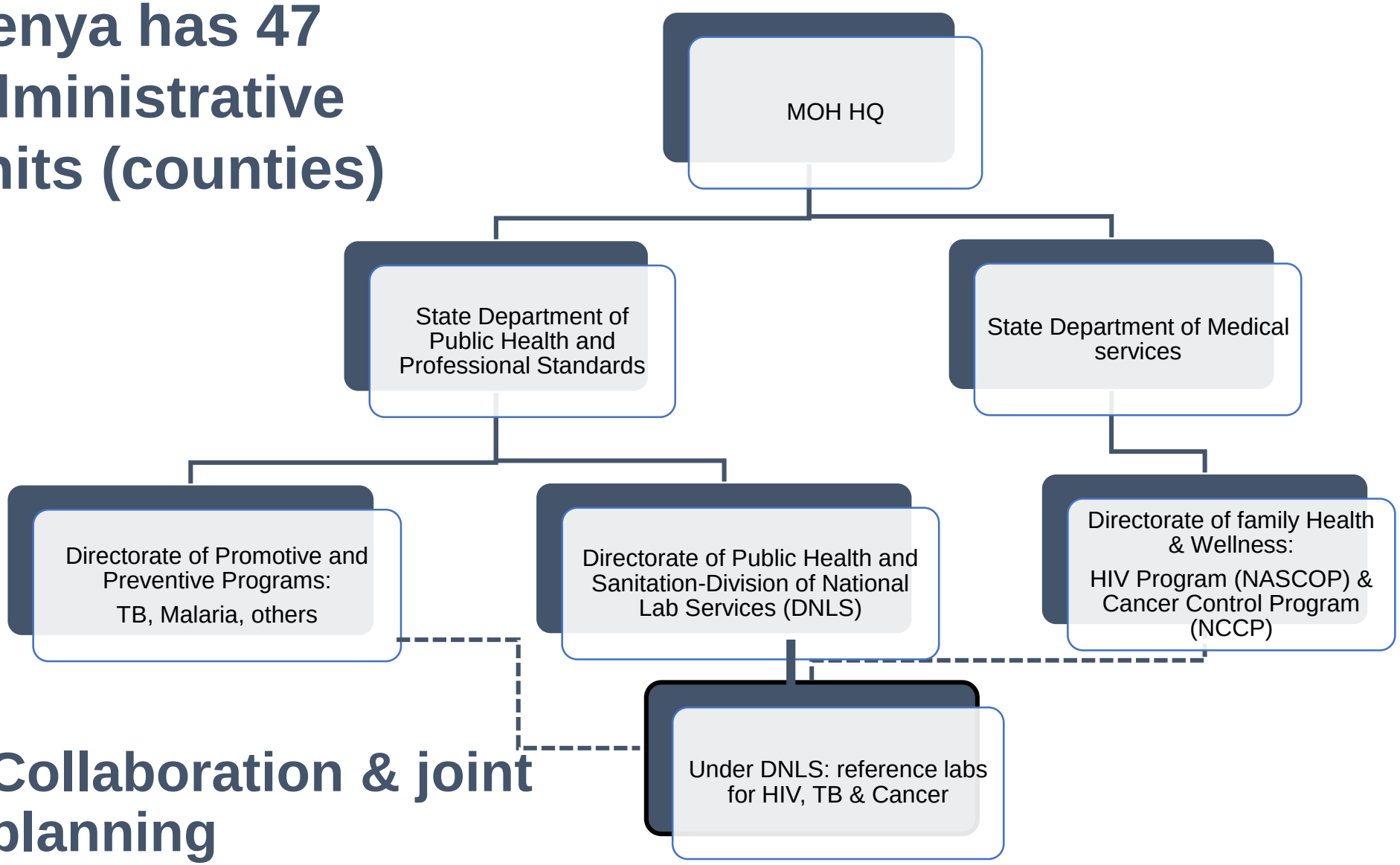
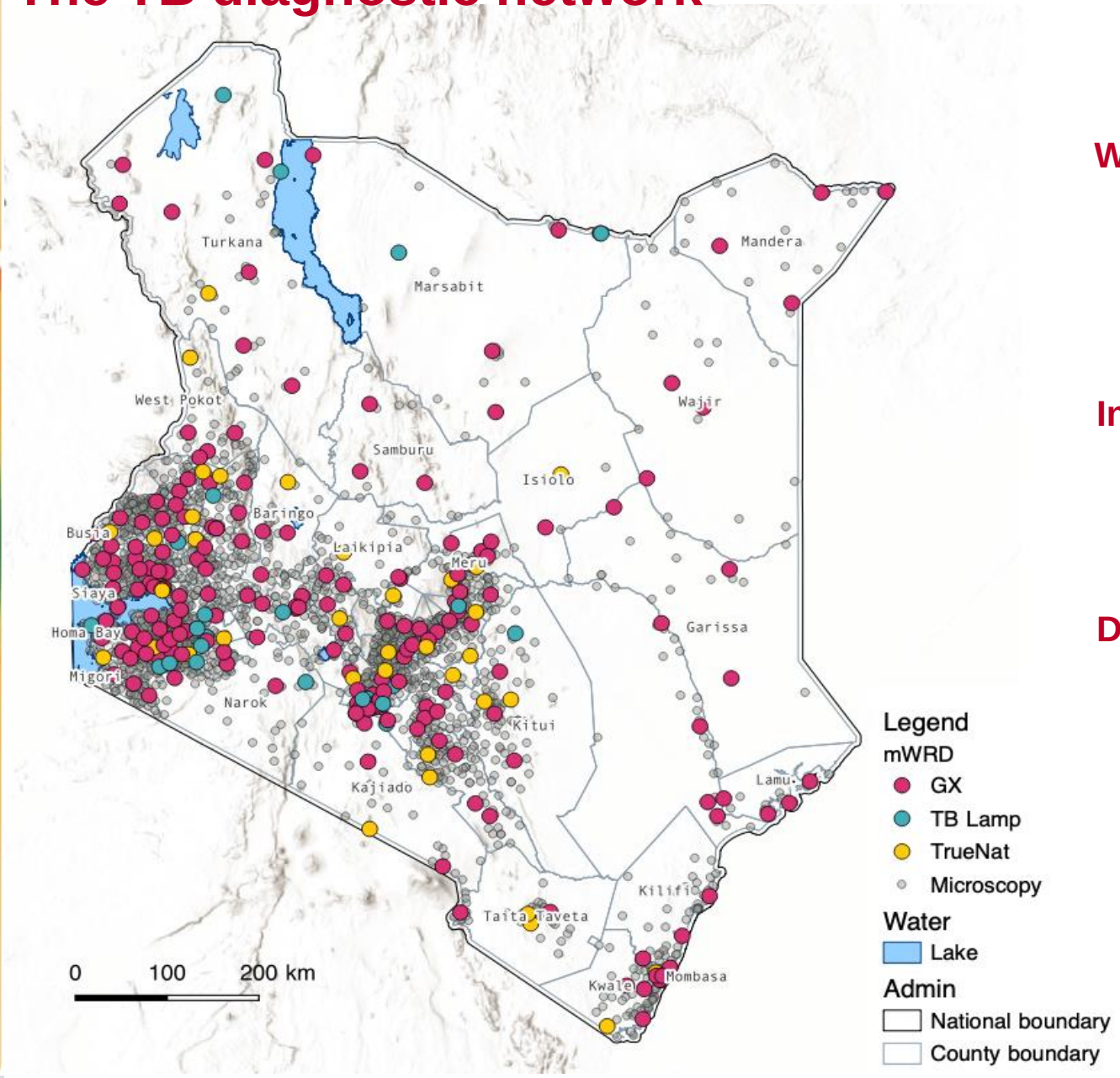
Kenya has 47 administrative units (counties)



Collaboration & joint planning

BACKGROUND

The TB diagnostic network



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WHO-recommended molecular diagnostics (mWRD)

- 278 instruments at 263 locations, which has been expanded in previous years, considering recommendations from previous DNO (2017/2018)

Instruments (at the end of 2022)

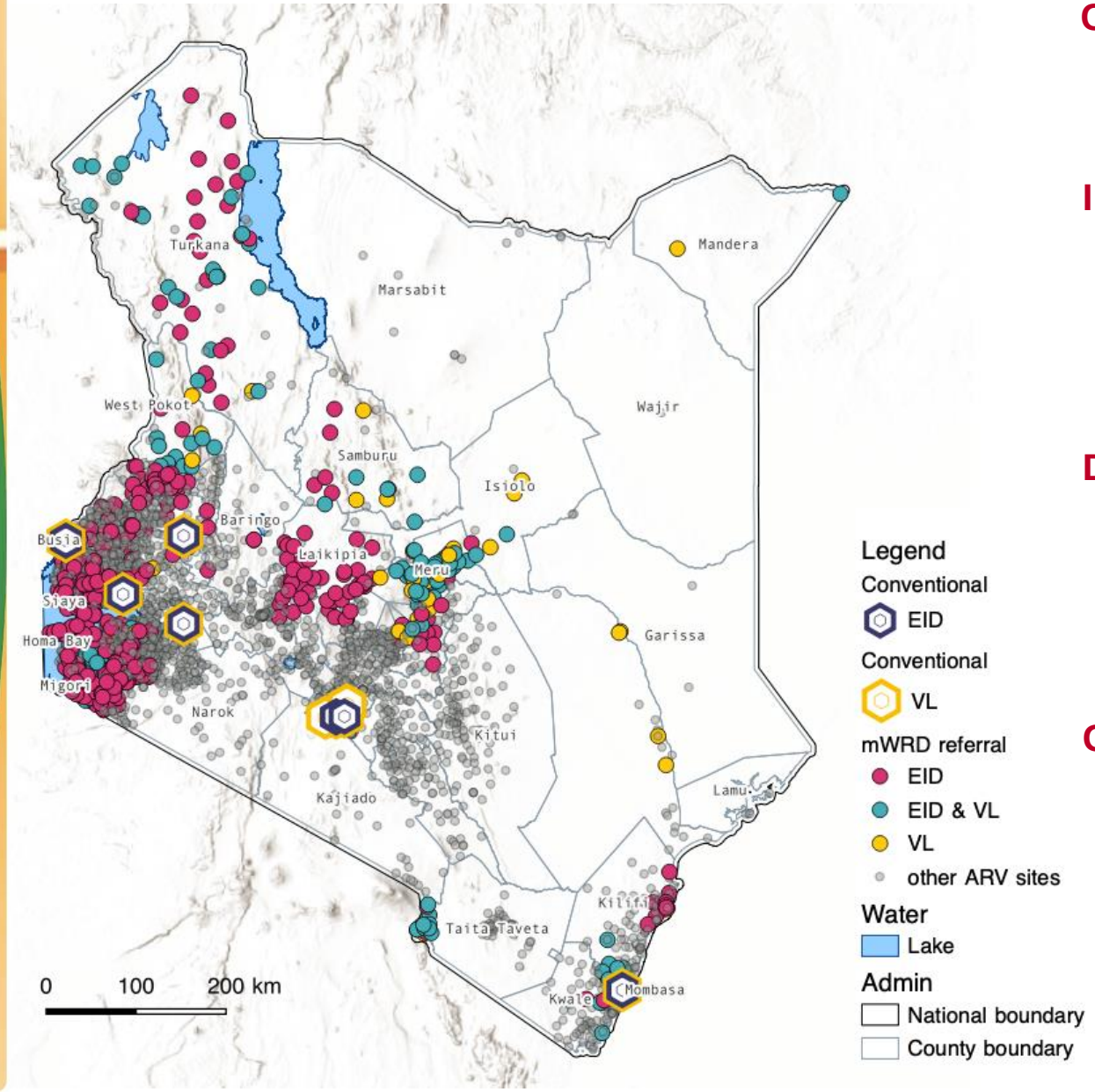
- GeneXpert: 215 instruments
- Truenat: 37 instruments
- TB LAMP: 26 instruments

Diagnostic use

- Diagnosis of TB and RIF-resistant TB (as per technology)
- Integrated use started already, shared with HIV- and Cancer Program

BACKGROUND

The HIV molecular diagnostic network



Conventional molecular platforms

- 52 instruments at 12 locations (HIV VL)
- and 9 locations (HIV EID)

Instruments (at the end of 2022)

- Roche c8800/c6800: 10
- Abbott M2000: 21
- Hologic Panther: 7
- Roche CAP/CTM: 14

Diagnostic use

- HIV VL for non-priority patients are tested on conventional platforms in 12 laboratories
- HIV EID testing on conventional platforms is offered at 9 laboratories.

GeneXpert platforms, shared use with other programs

- Xpert HIV-1 Viral Load for priority group patients (infants and pregnant/ breastfeeding women)
- Xpert HIV-1 Qual for early-infant diagnosis (EID)

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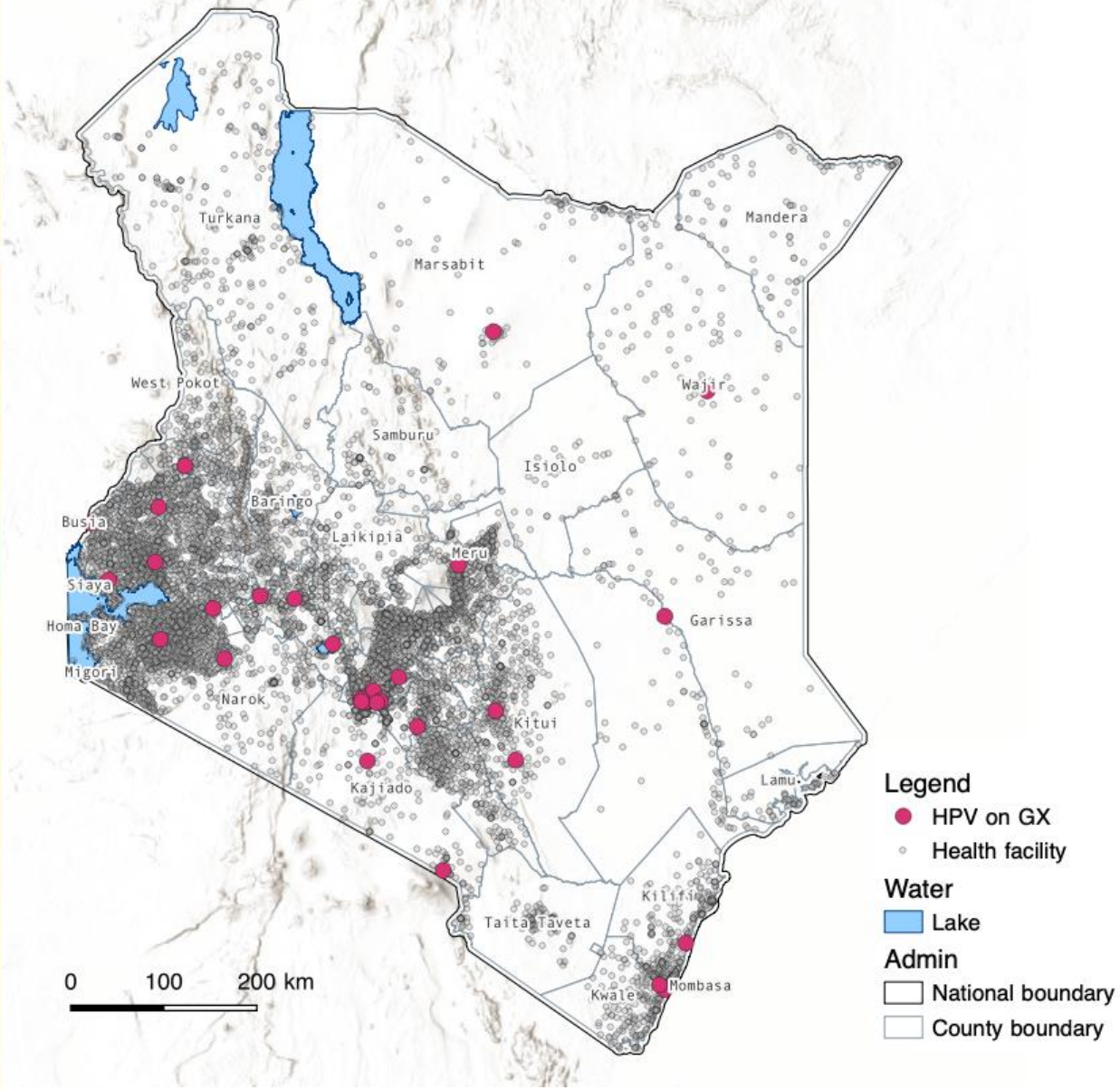
BACKGROUND

The HPV molecular diagnostic network



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GeneXpert platforms, shared use

- 31 GX sites tested for HPV at the end of 2022
- Ongoing: expand use is in the planning stage as part of the new strategic plan

Diagnostic use

- HPV testing (Xpert HPV) for women >24yrs

Conventional platforms

- Also available an in-use at National Reference Lab but not included as beyond the scope of this DNO

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Objectives

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Primary objective

To inform the optimal design of an integrated diagnostic network and sample referral system to enable equitable and timely access to TB, HIV and HPV testing, which allows each of the three National Disease Programs to reach their individual strategic goals and targets between 2024 and 2028.

! Integrated DNO that should still answer individual program questions

Scope

- **TB mWRD:** Xpert MTB/RIF, Xpert MTB/XDR, Truenat MTB-RIF, TB LAMP
- **HIV mWRD:** Xpert HIV-1 Viral Load, Xpert HIV-1 Qual
- **HIV conventional platforms**: Roche c8800 and c6800, Abbott M2000, Hologic Panther, Roche CAP/CTM
- **HPV mWRD:** Xpert HPV

OBJECTIVES

TB-specific objectives

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National strategic planning cycle

- Advanced: next National Strategic Plan had been already drafted
- Evidence was required from the DNO to support and fine-tune diagnostic strategies, as well as to inform budgeting

Developed DNO analysis questions & objectives

- How many mWRD instruments are required at which locations if the specimen referral system is expanded stepwise?
- How many mWRD instruments are required at which locations to implement INH/FLQ-testing on 10-colour-GX for all bacteriologically confirmed TB patients?
- How many mWRD instruments are required at which locations for equitable access to mWRD testing in remote areas?

INH/FLQ: isoniazid & fluoroquinolone susceptibility testing requires a 10-colour GeneXpert

OBJECTIVES

HIV-specific objectives

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National strategic planning cycle

- Advanced: next National Strategic Plan under development, targets reviewed
- Evidence was required from the DNO to finalize & budget diagnostic strategies

Developed DNO analysis questions & objectives

- How many GX instruments are required at which locations if more facilities would use the GeneXpert for HIV VL and HIV EID testing (stepwise expansion)
- What are optimal number & locations for new HIV VL conventional testing laboratories to ensure access and coverage?

HPV-specific objectives

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National strategic planning cycle

- Early: at the time of analysis, the National Cancer Program was in process of updating the national strategic plan, and targets had not been set yet
- Evidence was required from the DNO to support the drafting of possible new strategies

Developed DNO analysis questions & objectives

- How much spare GX instrument capacity would be available after the TB- and HIV-program had implemented their respective policies and plans?
- This information would be used by the program to design future HPV testing policies and inform the development of the national strategic plan.

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DESIGN

From individual programmatic questions to integrated DNO analysis design

DESIGN

From individual programmatic questions to integrated DNO analysis design

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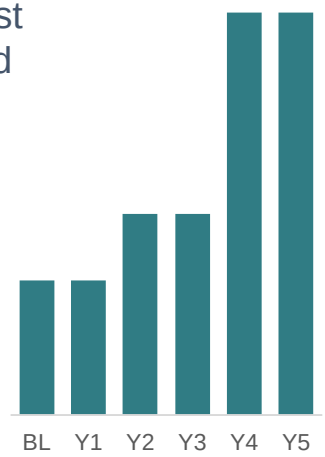
1) Start with preparation & design for each disease program individually

Determine demand locations

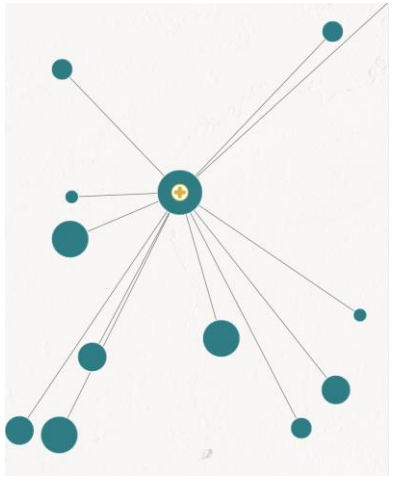
- Where a current services provided?
- What are the specimen referral facility linkages?
- Which facilities are planned do so in the future?

Forecast demand



- What are future policies and interventions that could influence demand?
- What are future coverage- or testing targets?

Geospatial modelling of lab locations to optimize coverage of demand



- How many testing locations are needed & where to ensure coverage of demand?
- Here for single test types:
  - new conventional HIV VL laboratories
  - new 10-colour GX locations for FLQ/INH testing

DESIGN

From individual programmatic questions to integrated DNO analysis design

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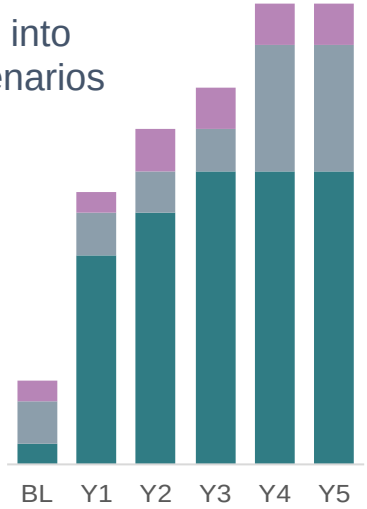
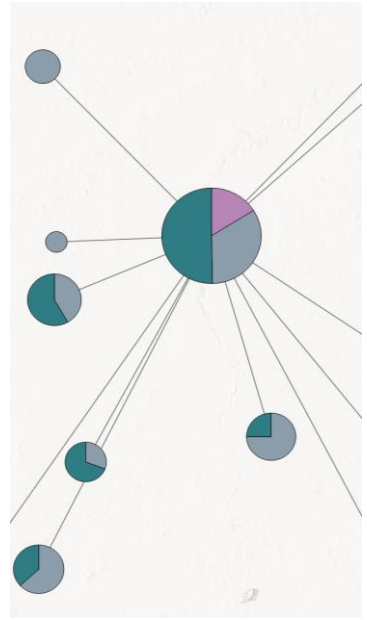
2) Combine interim, disease-specific results into multi-disease scenarios

Demand locations for 3 disease combined into future scenarios

Forecasted demand for 3 diseases, combined into future scenarios



Geospatial modelling of shared platform locations (mWRD) to optimize coverage of demand for all 3 diseases



- Optimized locations considering demand from all 3 diseases, with a special focus on remote area coverage

DESIGN

From individual programmatic questions to integrated DNO analysis design

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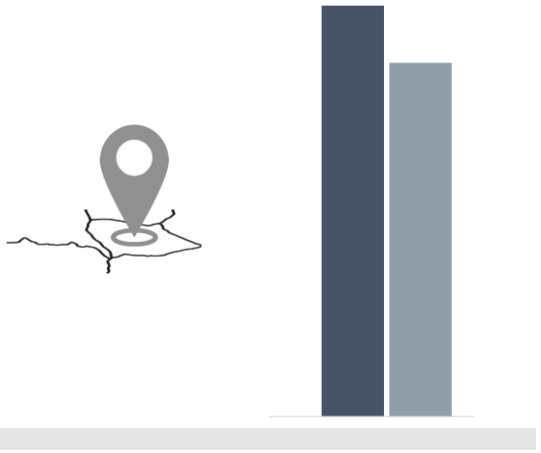
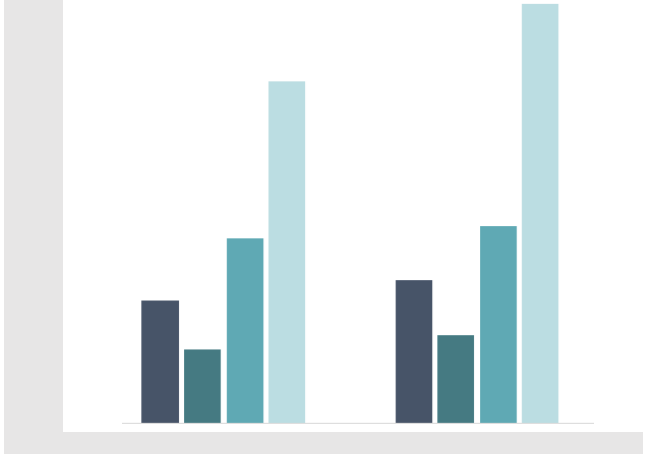
3) Integrated network analysis comparing the different scenarios

Optimization of instrument capacity vs. all-disease demand



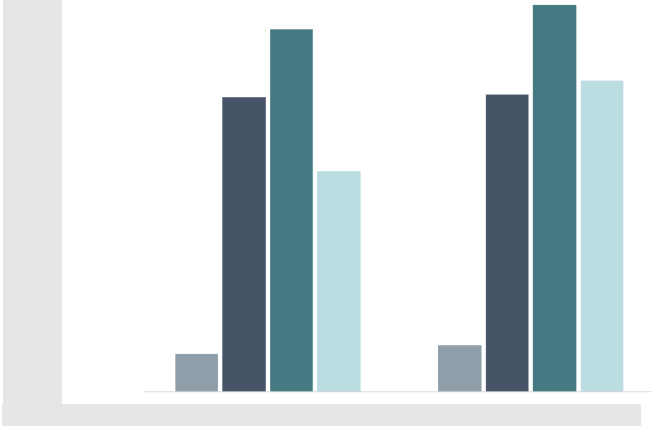
- With the newly modelled 3-disease demand, do all facilities have sufficient instrument capacity?

Analysis of service distances in the integrated network by disease- & test type



- Are the resulting referral distances adequate?

Analysis of instrument utilization in the integrated network and calculate spare capacity



- Are instruments in the final model optimally utilized or is there a need for adjusting the model?

From individual programmatic questions to integrated DNO analysis design

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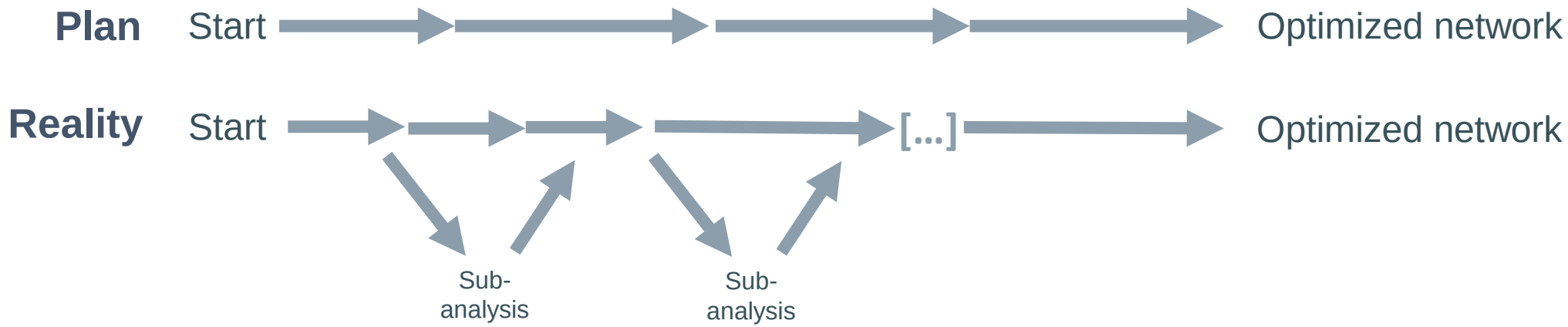

The typical DNO challenge

Future strategic plans ⇌ DNO

Example

HIV Strategic Plan

- Allow more facilities to refer their HIV VL and EID specimen to the nearest GX, based on their distance to existing conventional labs

Sub-analysis

- Baseline referral policy mapping and analysis
- Q: how many facilities would be newly referring if all facilities > 100km, 150km, 200km etc. would be allowed to do so
- Information were used by the HIV Program to make reasonable choices for stepwise expansion criteria that were used in the main DNO scenarios (here: 150km)

DESIGN

Future scenarios

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Modelled demand

Modelled policies & interventions

Scenario 1

- **TB:** Remaining microscopy & TB treatment facilities linked to specimen referral
- **HIV:** Additional facilities newly eligible for mWRD EID & VL referral if they are >150km from a conventional lab
- **HPV:** Generic demand increase

Scenario 2 (*deep dive during this webinar*)

- **TB:** Specimen referral is expanded to include all health facilities & mWRD testing efforts increase to achieve detection of 70% of estimated TB patients. INH/FLQ-testing implemented.
- **HIV:** All facilities eligible for mWRD EID & VL testing. Four new conventional labs are set-up.
- **HPV:** Generic demand increase.
- **All:** Newly mWRD locations to increase coverage of all demand, focus remote areas

METHODS

Tools

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Software

- Location optimization: ArcGIS Pro 3.1.0 Network Analyst Toolbox
- Supply-demand optimization & integrated network analysis: OptiDx

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RESULTS

The integrated & optimized diagnostic network

RESULTS

Optimizing access to mWRD testing

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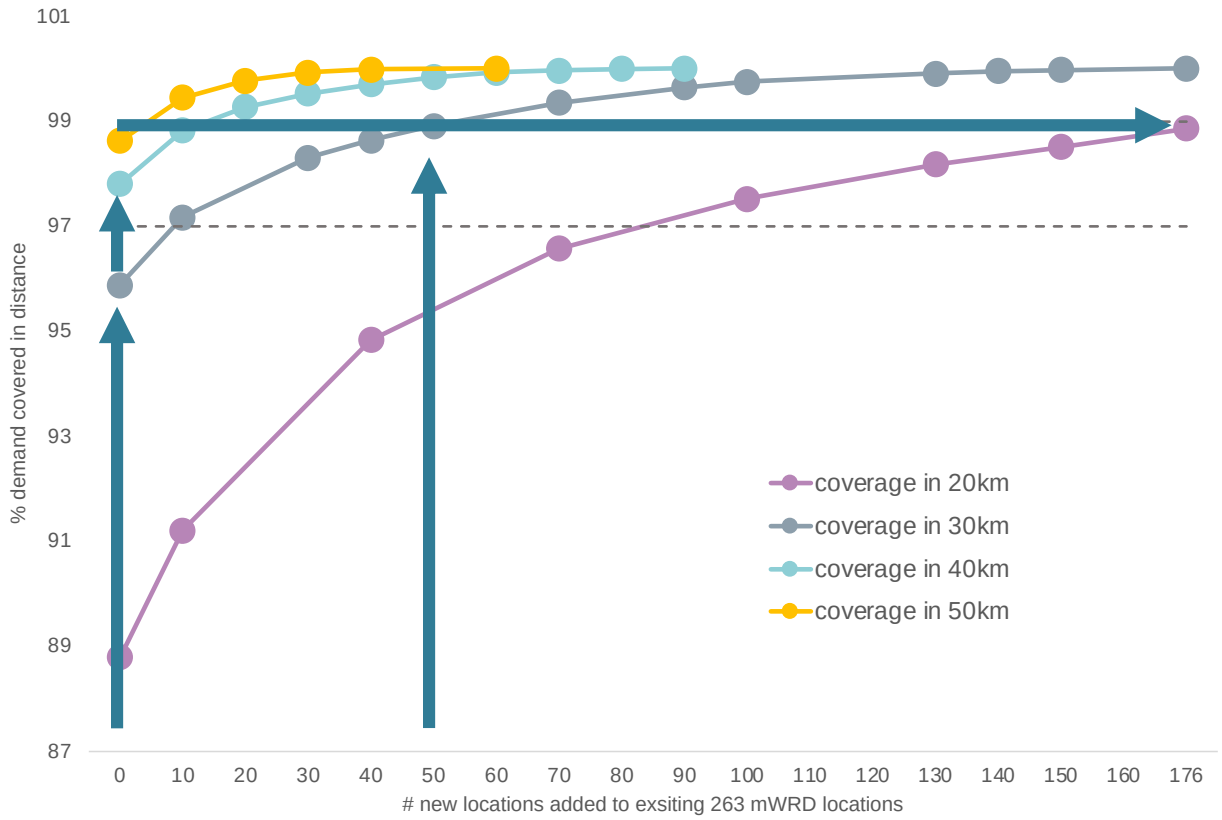
Exploring opportunities

- Which level of demand coverage can be achieved if we add new mWRD sites?

Used scenario 2: substantially expanded with high demand



- If no new testing locations are added, the existing 263 mWRD locations will cover for example approx. 96% of the total future demand in 30km distance
- If no testing locations are added, the existing 263 mWRD locations will cover approx. 98% in 40km distance
- If 50 mWRD locations are added, the resulting 313 mWRD locations will cover approx. 99% of total future demand in 30km distance
- If 99% of the demand should be covered in 20km, an additional 176 mWRD testing locations are needed

RESULTS

Optimizing access to mWRD testing

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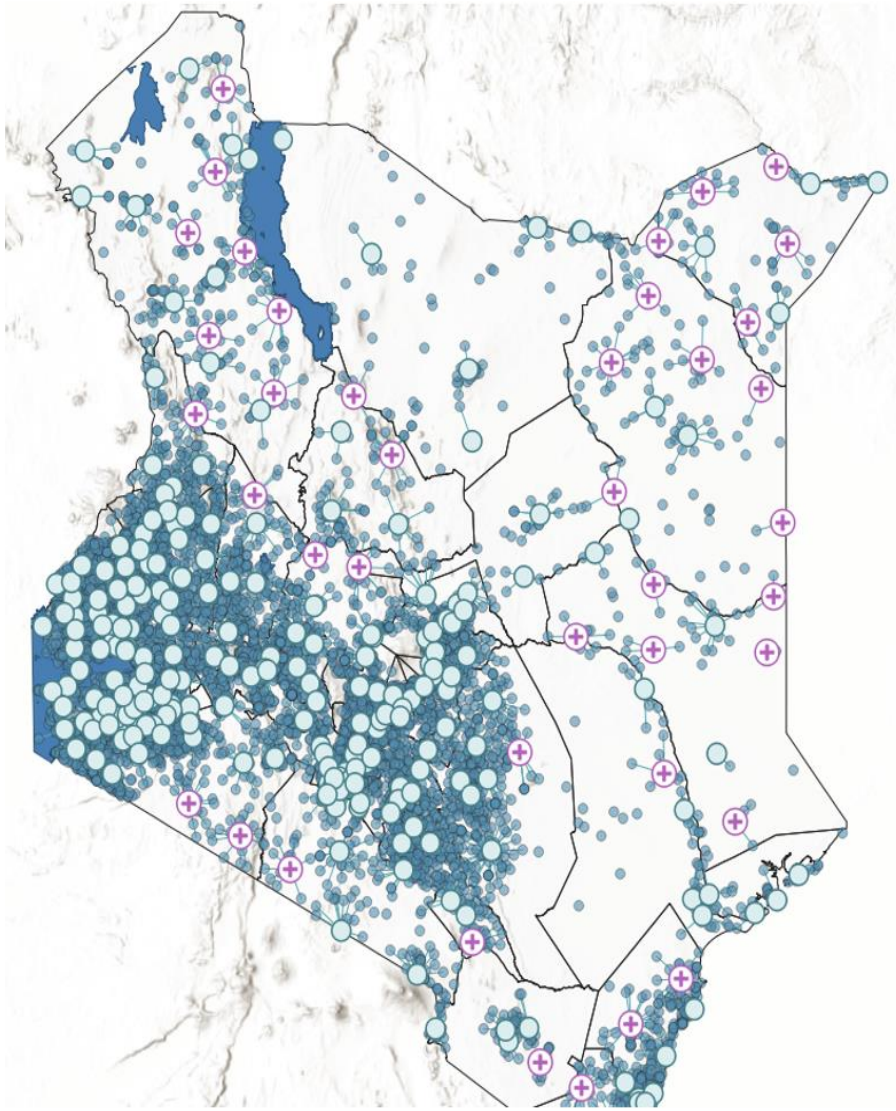
Final model choice

- Modelled and compared various placement options to achieve coverage, balancing efficiency vs investments
- Final model was chosen which requires 40 new mWRD locations, total (263+40) 303 locations

Model performance

- Coverage of all future demand
  - small increase from approx. 98% to >99% in 40km distance (national level average), but:
  - Important! Increase in Northern, remote areas is very large from approx. 77% to >96%
  - This addresses the National Strategic Plan target of providing equitable access to mWRD testing in remote areas

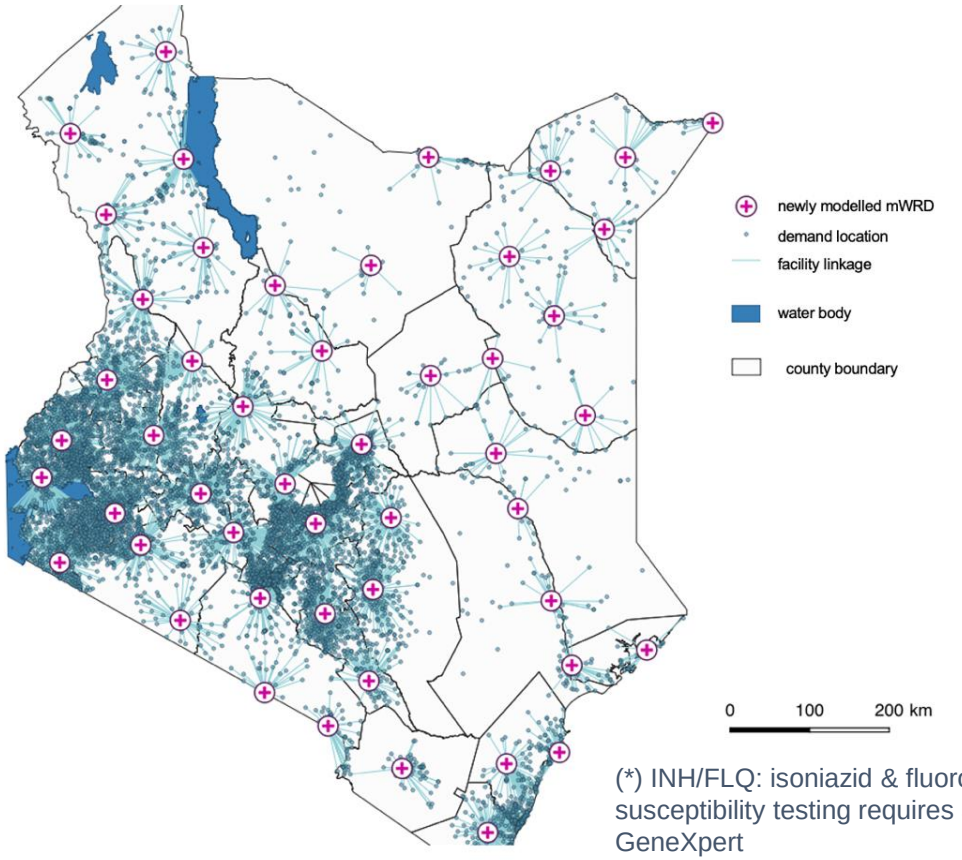


RESULTS

Optimizing access to INH/FLQ*-susceptibility testing on (10colour)-GX

Applied the same concept & methods as for mWRD location optimization

Final model: Chosen from existing & newly modelled mWRD: 50 new 10colour GX locations to achieve 98% coverage of future INH/FLQ demand in 60km

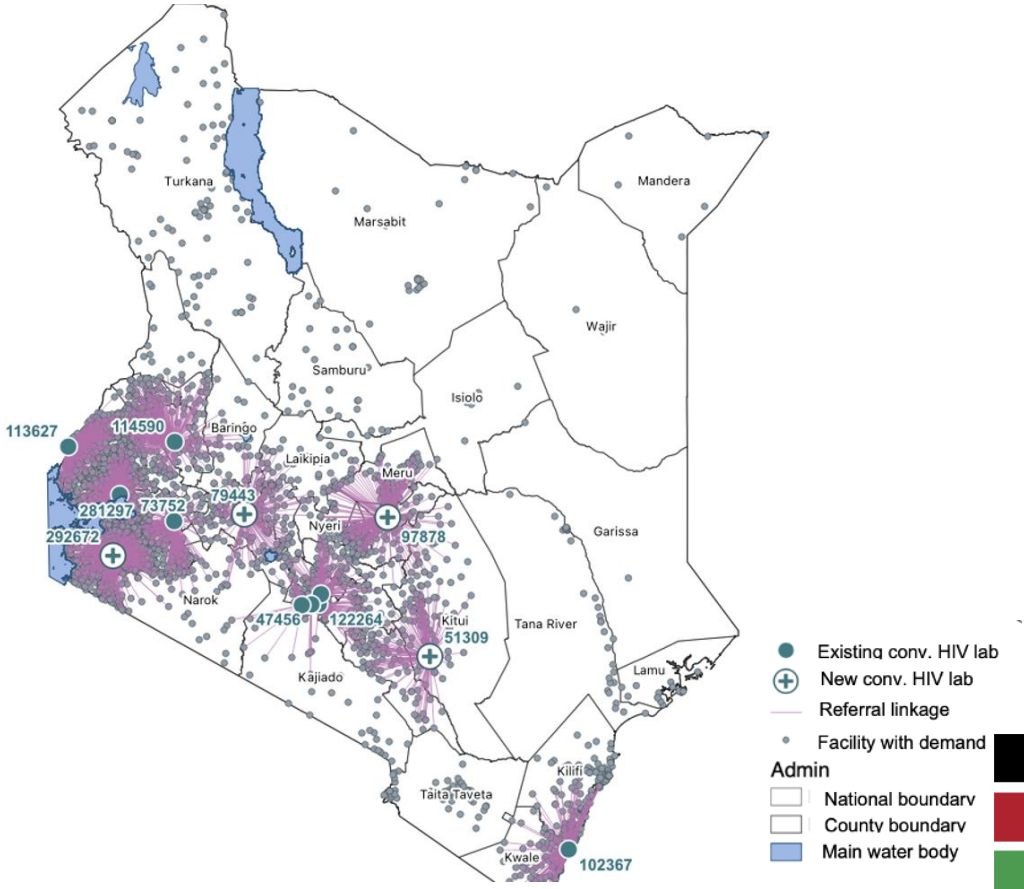


(*) INH/FLQ: isoniazid & fluoroquinolone susceptibility testing requires a 10-colour GeneXpert

Optimizing access to conventional HIV VL

Applied the same concept & methods as for mWRD location optimization

Final model: Confirmed initial plans to add 4 new labs (total 16) & selected optimal locations, which will increase the future demand coverage from 83% to 96% in 100km



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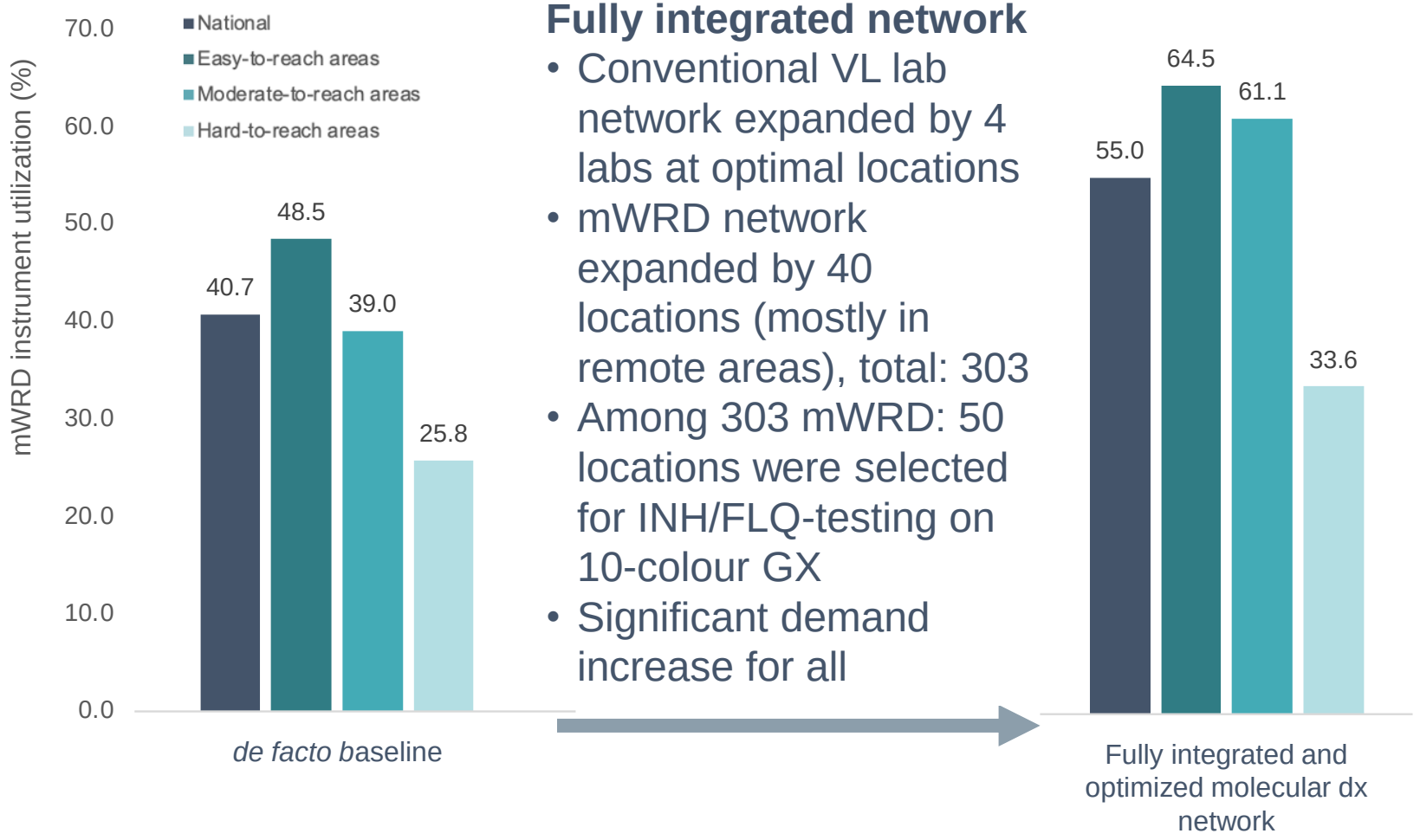
RESULTS

Final analysis of the fully integrated mWRD diagnostic network

Analysis of mWRD instrument utilization in the final network



Fully integrated network

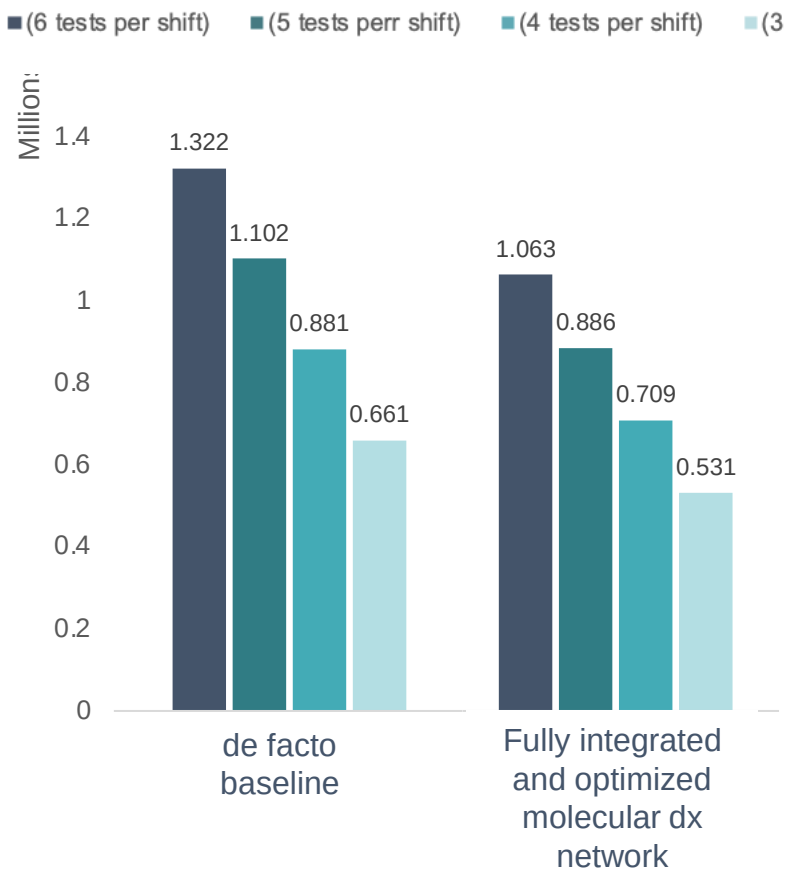
- Conventional VL lab network expanded by 4 labs at optimal locations
- mWRD network expanded by 40 locations (mostly in remote areas), total: 303
- Among 303 mWRD: 50 locations were selected for INH/FLQ-testing on 10-colour GX
- Significant demand increase for all

- Utilization improved notably in all areas but still substantial spare capacity
- In hard-to-reach areas, utilization is still much lower due to low population and demand and new instruments were added
- **Of note!** The primary aim to expand the mWRD network in remote areas was to ensure coverage and accessibility, whereby the disease programs accepted the downside of lower instrument utilization in those areas.

RESULTS

Spare GX capacity for HPV testing

Analysis of spare capacity in No. of tests for HPV Xpert per year



- At baseline: the existing instrument capacity of 215 GX instruments are already sufficient to meet demand for all future policies and plans for all three disease programs.
- Integrated/optimized network: if TB and HIV program implement all their plans (including expansion of mWRD network and substantially increasing demand), the resulting new GX fleet would have substantial spare capacity
- This provides ample opportunity for the cancer program to substantially increase HPV testing in the future,
- Or, for the TB- and/or HIV Program to even further increase their testing demand, above and beyond the modelled scenarios

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NEXT STEPS

Recommendations chosen for implementation

NEXT STEPS

Selection process

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- Throughout the entire process, multiple meetings and discussions were held incl. interim result presentation and further fine-tuning of analysis according to program needs

- **A workshop** was held with representatives from all disease programs & respective partners to review and discuss all final findings and pre-select network scenarios for future adoption.

- **Selection criteria** were:
  - Availability of funds and future funding opportunities
  - Priority interventions as identified by the strategic plans
  - Common priority areas of interest
  - Highly impactful and realistically achievable by the disease programs
  - Data availability to support evidence based implementation (beyond DNO data)
  - Capacity to implement & deliver identified activity

- **A technical working group (TWG)** with representatives from all programs & partners was set-up to further develop detailed implementation plans

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Recommendations chosen for implementation

- Set-up four new conventional HIV VL laboratories in modelled areas
- Increase referral of GX for HIV EID and HIV VL, final selection criteria are currently under review
- Set-up 50 newly modelled 10colour-GX for INH/FLQ-testing
- Implement 40 new GX locations to improve access in remote areas.

Integrated implementation planning

- Strengthen the integrated specimen referral system (ISRS)
- Considerations for full pooled procurement system
- Identify additional DNO focal points (previous FIND training on OptiDx): will monitor & possibly update DNO
- Sustaining collaboration & communication between all disease programs, including already set-up Technical Working Group
- Implementation plans were used for GC7 Global Fund grant writing

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LESSONS LEARNT

Tips & tricks for conducting an integrated DNO

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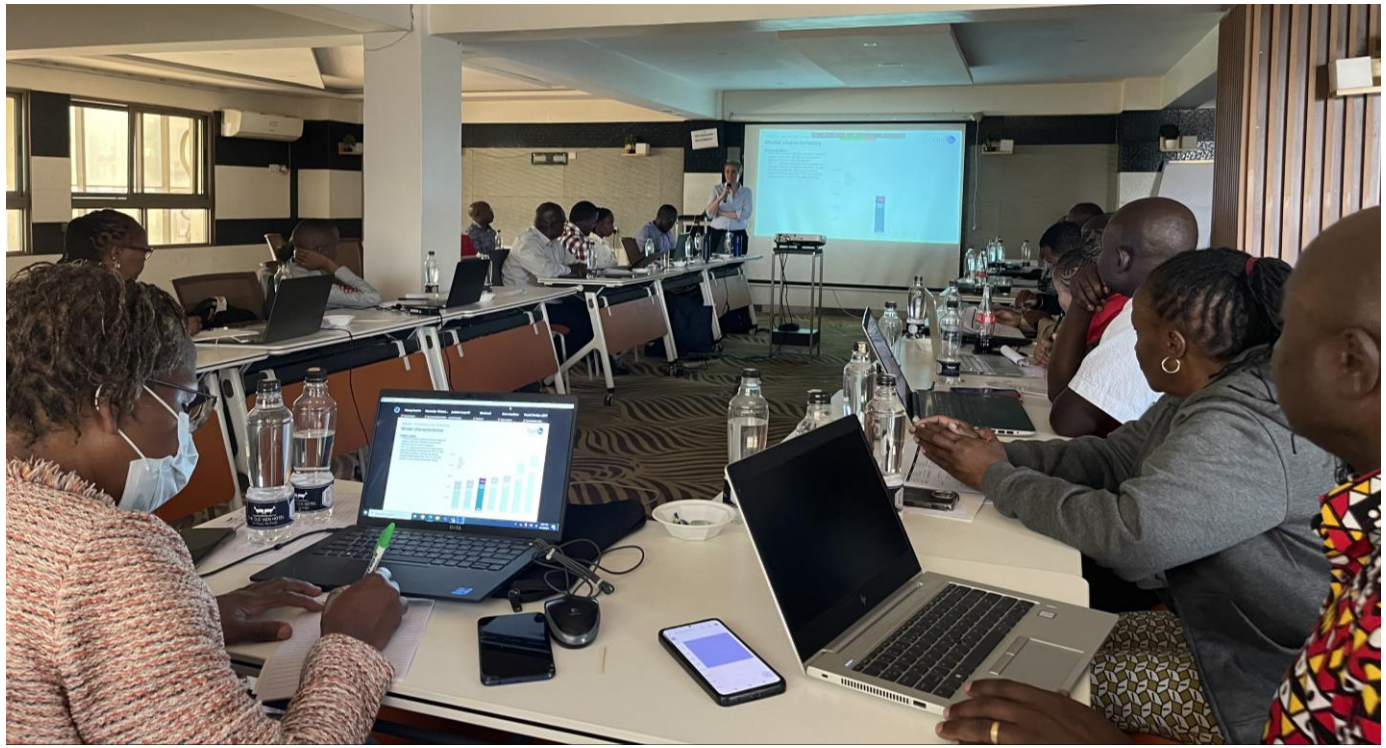
Tips & tricks for conducting an integrated DNO

- **Establish sub-committees for each disease program**, whereby one should be chosen as the DNO lead. This will simplify and steer coordination and communication for an integrated DNO.
- **Agree on key questions and objectives first**, before starting the DNO work and analysis. That is especially critical for aspects that affect all disease programs, such as here, the mWRD network.
- **Start early!** Conducting an integrated DNO takes much longer than a single-disease DNO. Especially if a deadline is ahead.
- **Consistency in participation of experts in all discussions is key.** Otherwise, the analysis may be planned and conducted with implications for the experts' own disease programs, without their input.
- **Different planning stages are possible:** an integrated DNO can still be done even if different disease programs are at different stages of their respective planning cycles.

Thank you!



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Kenya county representatives as well as clinical and laboratory specialists

Kenya Centre for Disease Control and Prevention

World Health Organization (WHO)

Global Fund to Fight Aids, Tuberculosis and Malaria

Clinton Health Access Initiative (CHAI)