Optimizing TB diagnostic networks to improve patient access to quality TB diagnosis and treatment

KENYA: FINAL REPORT

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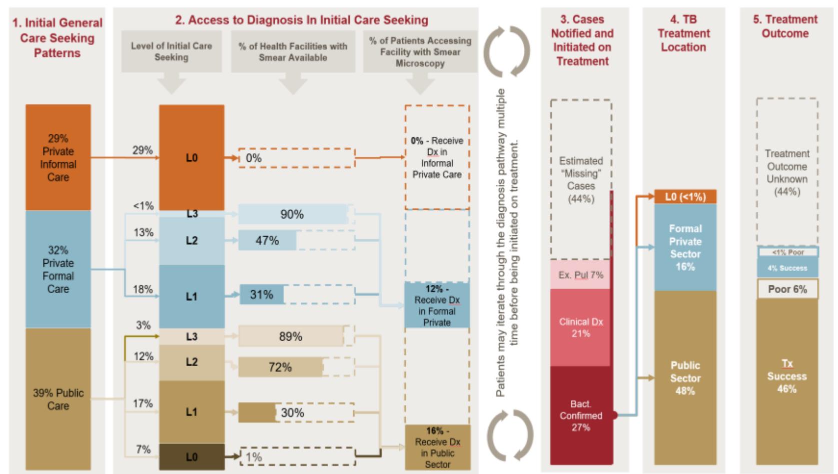
01 December 2018

Contents

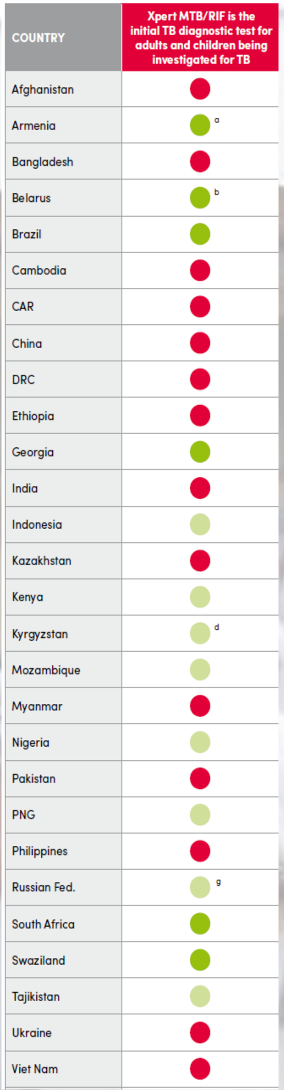
Mismatch between care-seeking path & TB diagnostics availability

Innovations only matter when they reach the people who need them.

- Sue Desmond-Hellmann, CEO, Bill & Melinda Gates Foundation



Low access to TB dx services, e.g. patient pathway analysis BMGF



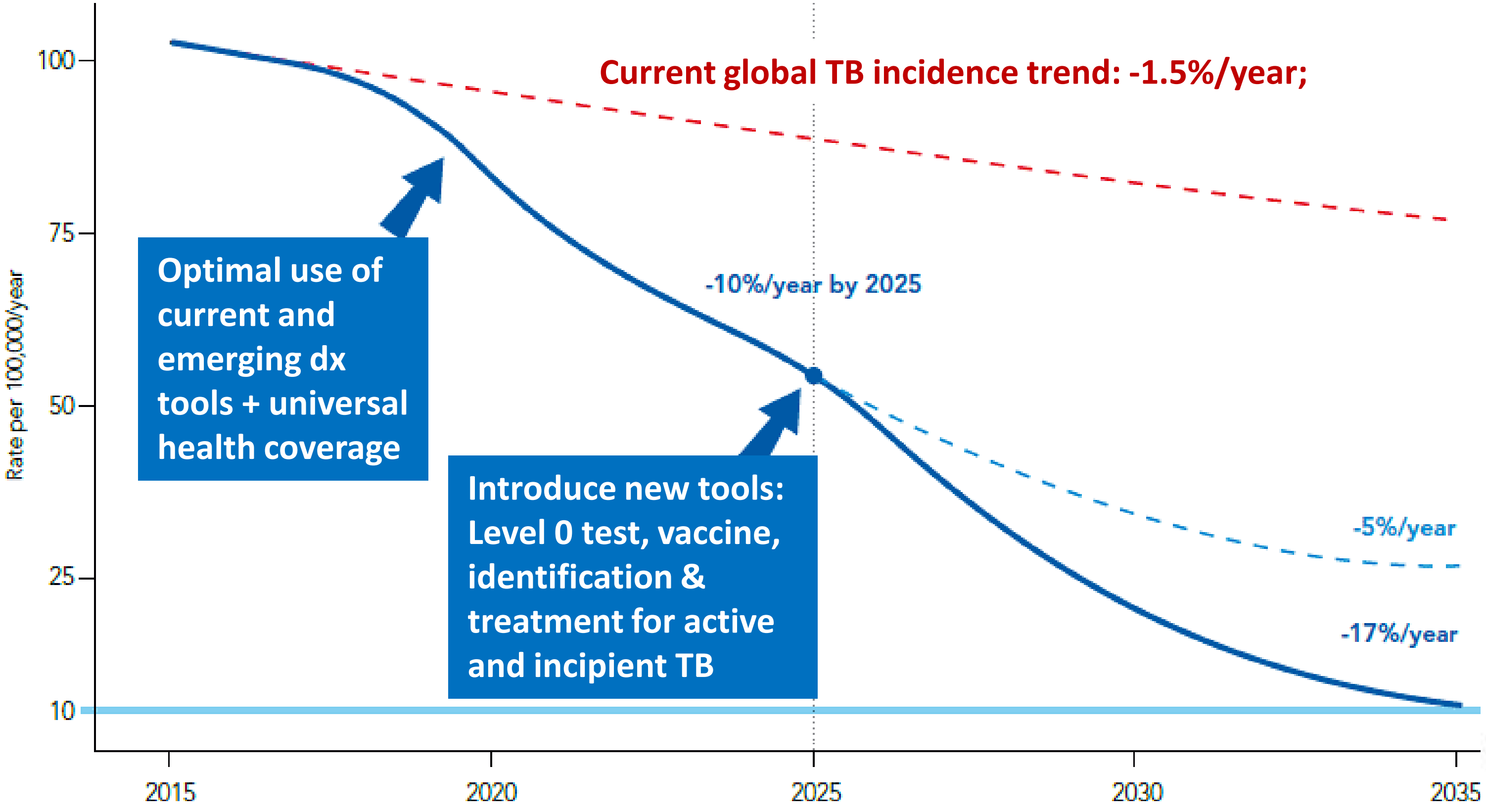
COUNTRY	Xpert MTB/RIF is the initial TB diagnostic test for adults and children being investigated for TB
Afghanistan	●
Armenia	● [a]
Bangladesh	●
Belarus	● [b]
Brazil	●
Cambodia	●
CAR	●
China	●
DRC	●
Ethiopia	●
Georgia	●
India	●
Indonesia	●
Kazakhstan	●
Kenya	●
Kyrgyzstan	● [d]
Mozambique	●
Myanmar	●
Nigeria	●
Pakistan	●
PNG	●
Philippines	●
Russian Fed.	● [g]
South Africa	●
Swaziland	●
Tajikistan	●
Ukraine	●
Viet Nam	●

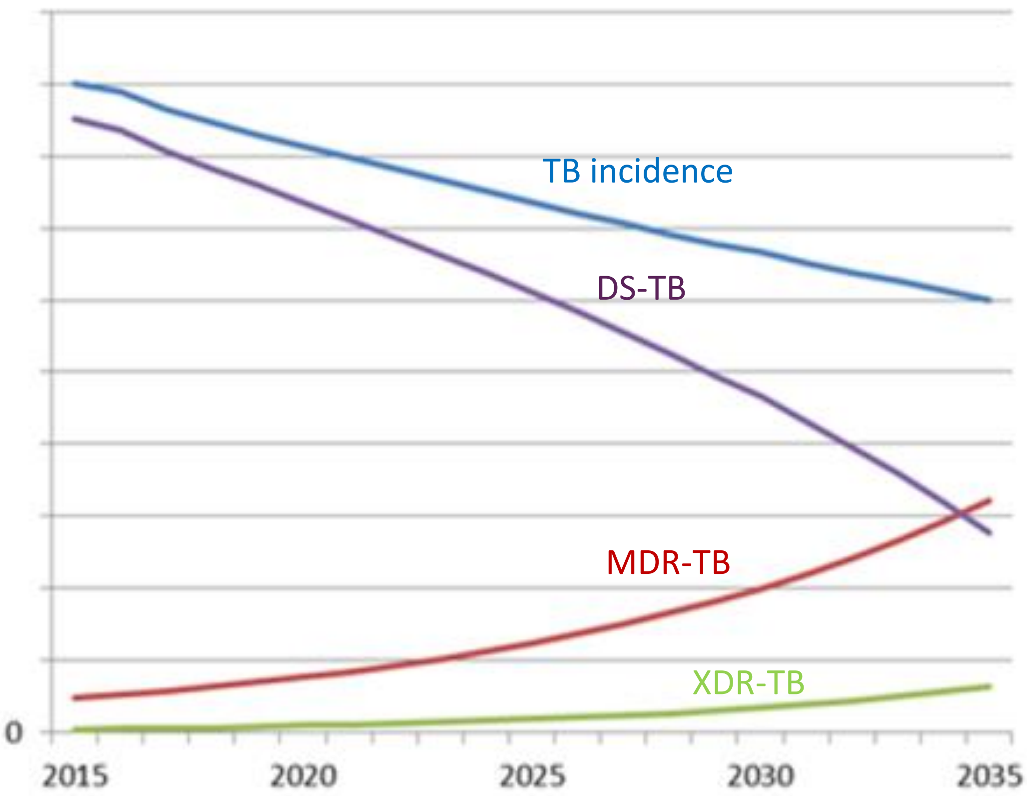
Incomplete uptake of new tools, *Out of Step Report (2017)*

Without finding the missing TB and MDR-TB cases, we will not bend the curve(s) and achieve End TB targets

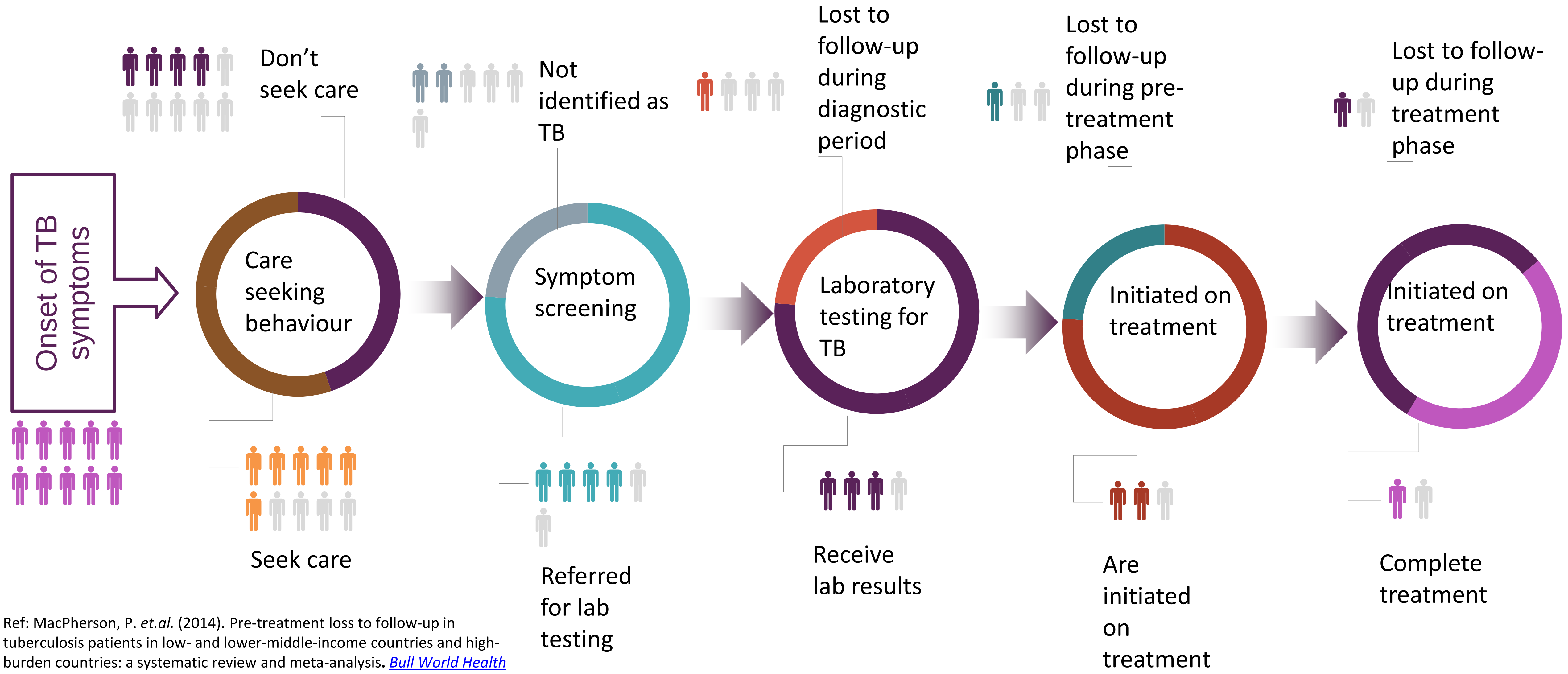
Only 60% of TB cases detected and notified: 4.3 of 10.4 million TB cases missed

Only 20% MDR cases diagnosed or treated: 448,000 of 580,000 MDR cases missed





TB diagnostic cascade



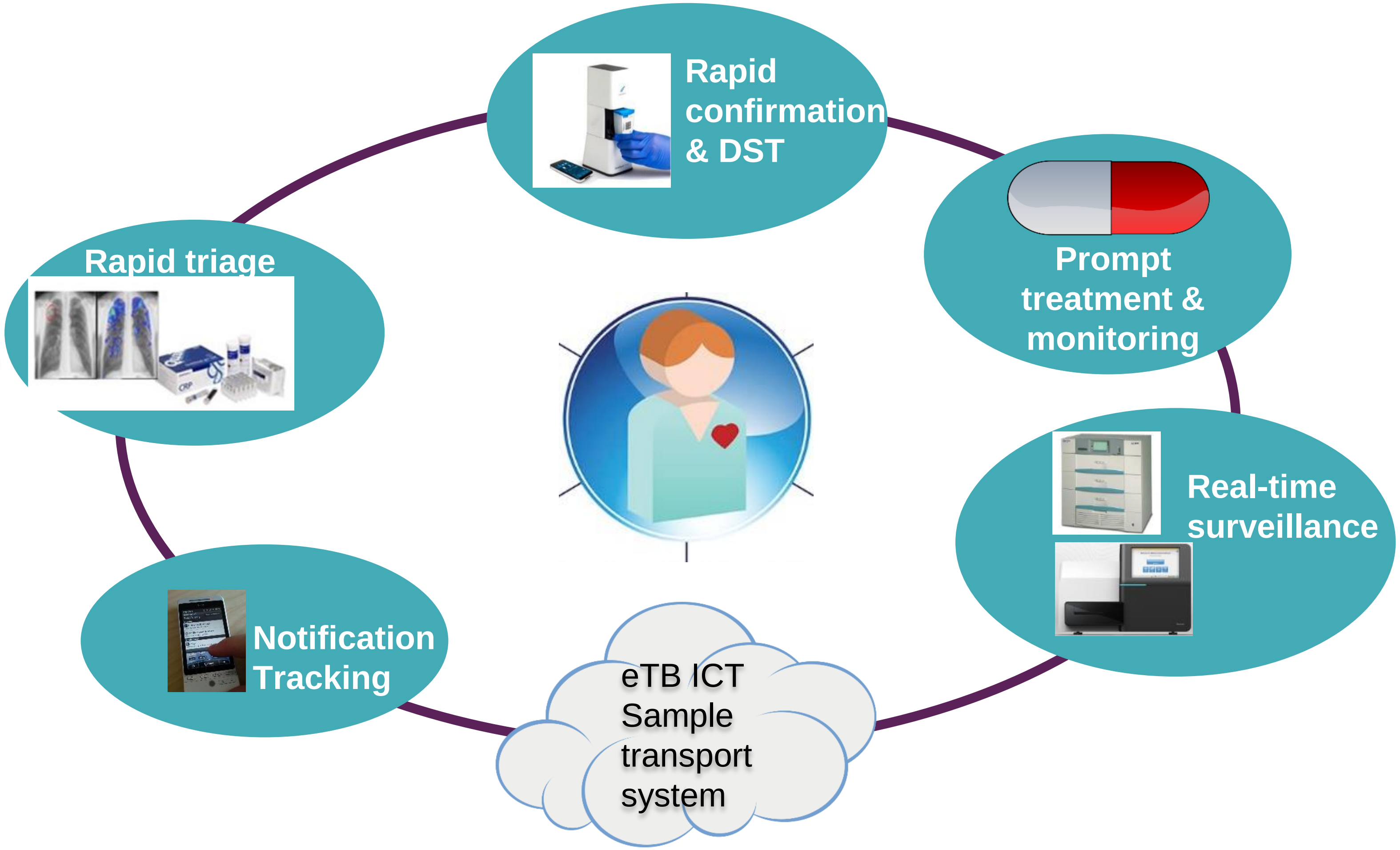
Ref: MacPherson, P. *et.al.* (2014). Pre-treatment loss to follow-up in tuberculosis patients in low- and lower-middle-income countries and high-burden countries: a systematic review and meta-analysis. *Bull World Health Organ.* 2014 Feb 1;92(2):126-38

A patient-centered diagnostic network is central to ending TB

What we have

- Integrate testing & treatment
- Strategically expand testing capacity
- Optimize product use

What we need



Contents

Towards data-driven diagnostic network planning

TODAY	VISION
Geographic spread – e.g. 1 instrument per district or region, not based on where patients seek care	Diagnostic services made available where patients seek care • Either on-site or via efficient referral mechanism
Based on current case notification data not demand for testing	Location of diagnostic capacity determined by demand for testing • Current and estimated future demand to find the "missing cases"
Siloed approach to planning focusing on TB laboratories • Laboratory testing only (not screening, CXR) • Not integrated with other TB planning impacting on diagnostic capacity, e.g. ACF • No or limited integration across diseases	Integrated planning across the whole diagnostic network • From screening to treatment • Across the whole TB diagnostic algorithm • Integration of testing and sample transport across diseases

Key objectives

Current status

Low Xpert utilization

Limited access to Dx services

Sample referral lacking

NSP process

Using available evidence to inform a prioritized and patient-centred National Strategic Plan

Diagnostic network optimization embedded within NSP process and aligned with NTP priorities

Diagnostic Network Optimization

How to improve access with current network footprint? - relocation, longer working hours etc.?

Can future testing demand be met without the need for capital outlay?

How to build an efficient sample referral network to improve patient access to services?

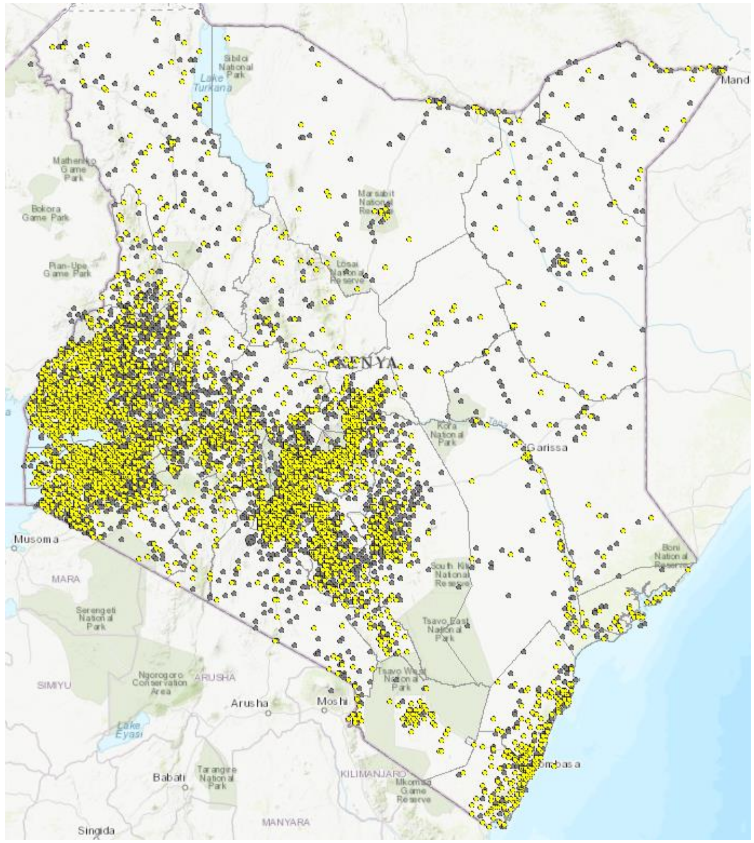
Are more instruments needed and if so, where to place them?

How to best integrate HIV EID and TB testing and sample referral?

Building a data-driven plan for TB diagnostic network strengthening to deliver on NSP 2018-2023 targets

Diagnostics network design and optimization

Aim of network optimization is to inform: instrument placement, sample transportation and referral mechanisms, staffing, geographical prioritization, quality assurance and integration of testing to meet the priority needs of the TB programme.



Objectives in Kenya in 2018:

- Map TB burden and current demand for TB diagnostic services
- Map current TB diagnostic network structure
- Identify the extent and distribution of gaps in existing services according to burden of disease
- Develop a set of diagnostic network designs defined by NTP and partners that better and more efficiently reach "missing" TB cases (unmet demand) using existing infrastructure
- Model a set of new network paradigms defined by NTP and partners, including new product and/or services investment, to advise government strategic planning and budgeting processes

Use of private sector software adapted to support diagnostic network optimization

- Adapting use of LLamasoft's **Supply Chain Guru ®**, supply chain modeling software and Data Guru software
- Used by major companies such as PepsiCo, Unilever, and Heineken to optimize supply chain management
- Global health applications, e.g. supply chain network design for vaccine delivery

Methodology

- Using data compiled for patient pathway analysis (PPA)* where possible
- Compiling additional laboratory services data where needed (from existing NTP and other sources)
- Map health facilities and TB diagnostic testing sites, workload and epidemiological data, to overlay with diagnostic component of PPA.
- Map current specimen referral patterns and test methodologies used based on existing referrals as well as potential demand based on full actualization of current diagnostic algorithms
- Conduct a network optimisation analysis where instrument/laboratory locations will be established based on a centre of gravity analysis using total patient demand.
    - Answers the question: **Given a set of clients, what are the "best" geographic locations for potential facilities and design of associated referral systems?** The candidate locations will be established *de novo* as well as layered onto the existing network.
- Run a series of optimisation scenarios to determine the optimal number and location of laboratories, technology placement, and improvements in referral mechanisms to increase access to services and efficiency

* Masini, Hanson, Ogoro, *et al*. Using patient pathway analysis to inform a differentiated program response to tuberculosis: the case of Kenya. J Inf. Dis. 2017.

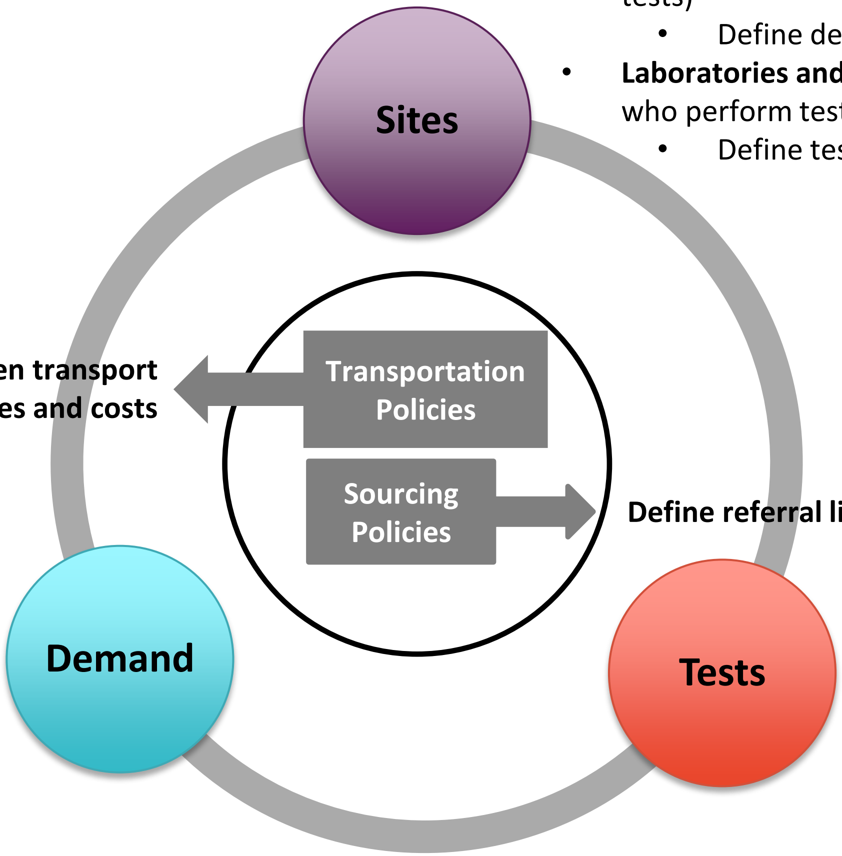
Diagnostic network optimization overview

1. Define scope	2. Collect data	3. Build baseline and validate	4. Analyze scenarios	5. Select and implement change	6. Monitor impact
Identify problem and set objectives	Collate routine programmatic and survey data in multiple formats	Validate baseline model and document validation criteria	Comparison of access and cost by scenario	Assess feasibility of preferred options for implementation	Knowledge transfer
High level scenario setting	Document assumptions and methodology to fill any data gaps	Check assumptions and outputs with country experts	Diagnostic capacity utilization	Implementation roadmap	Post-optimization benefit audit
Detailed project plan and timelines	Data include tests, facilities, patients, costs, referral patterns		Detailed maps for technology placement and network referral flows	Relocation of existing diagnostics, invest in new technologies, optimize sample referral flows	Establish impact indicators and monitoring system and conduct regular review

Constructing a network model: data inputs

- **Define number, location and level/type of sites**
- **Health facilities** (customers who order tests)
  - Define demand for testing
- **Laboratories and testing sites** (suppliers who perform tests)
  - Define test menu and capacity

Define specimen transport modalities, routes and costs



Define referral linkage between sites

- **Define number and type** of tests orders per facility

- **Define inputs**
- **Estimate costs**

Inputs: Fixed Costs, Per-Test Costs, and Site Opening Costs

- We add fixed and per-test costs for each site
- Fixed Cost:
    - HR costs: Technician annual salary 300,000 KSh (25,000 KSh per month)
    - Training, QA, maintenance, calibration: annually 80,000 KSh
- Per-test Cost:
    - Cartridge and results printing: 1159 KSh per test
- New-site opening cost (if new site to be opened)
    - Equipment depreciation: KSh 360,000 (USD 18,032 machine cost over 5 year life)
    - Site set-up and initial training costs: KSh 80,000

These costs can be revised as needed – results are not extremely sensitive to specific costs

Inputs: Transport costs – important driver for overall network design and cost efficiency

- Data obtained from ongoing sample transport using motorcycles in Siaya and Mombasa.
    - Transport costs were Siaya: 28.5 KSh per km and Mombasa: 22 KSh per km
- We used costs of 25 KSh per km throughout (and considered round-trips).
    - In line with available data on motorcycles and benchmarks from other countries.
    - In follow-on work: will refine by county (e.g. accounting for terrain, cost per sample instead of per km etc.)
    - In follow-on work: will account for multi-stop routes for sample transport, and not only point-to-point transport lanes
- Overall transport costs are heavily dependent on **frequency** of transport.
- NTP and partners defined the following **county level** stratifications for sample transport :
    - Easy-to-reach counties: every working day (240 times a year) – TAT 2 days
    - Moderate-to-reach counties: every-other-working-day (120 times a year) – TAT 4 days
    - Hard-to-reach counties: once-per-week (50 times a year) – TAT 7 days
- Further need to stratify **referral sites** depending on demand
    - Sites with a low number of samples infrequently - if samples are available for referral at less than the county-level frequency of transport, then the facilities are served on-request only

Transport costs can be updated for specific counties or even specific lanes as needed.
Sensitivity tests indicate that overall model outputs are not very sensitive to small transport cost changes.

Inputs: Xpert site capacity

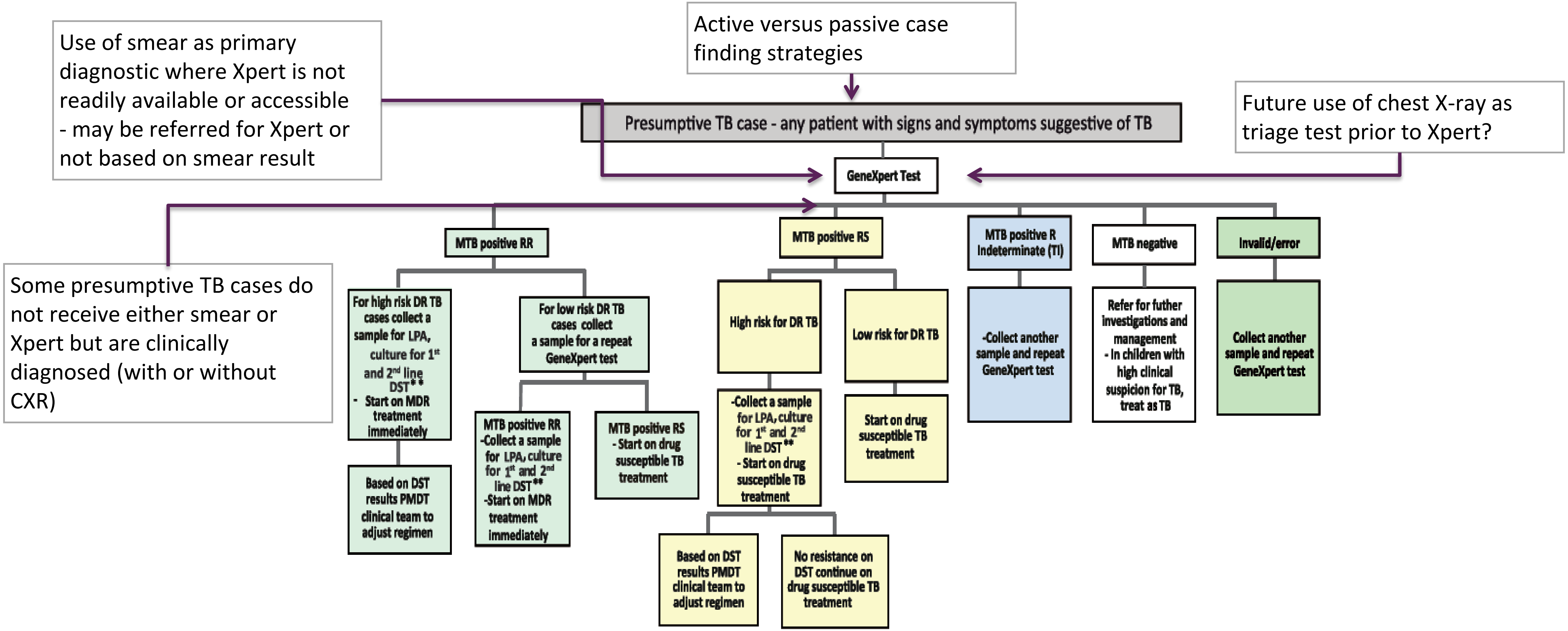
- For a GX4 machine, we considered the following annual capacity:
  - 12 tests/day for an 8-hr working day shift
  - 240 working days/year
  - 2880 tests per year
- For larger machine GX16, we considered:
  - 48 tests/day for an 8-hr working day shift
  - 240 working days/year
  - 11520 tests per year
- Some sites operate 24 hr/day – for all those sites we considered site capacity to be 2.5x the site capacity for a single shift (up to 3 shifts possible)
- For each testing level beyond the regular 8-hr working day, the cost of another technician was included in the analysis

Contents

How do we estimate demand for testing?

- **Current demand** is equivalent to the current supply of TB diagnostic testing throughout the network (how many tests were done in 2017?)
  - based on actual testing data for all TB diagnostics (LM, LED FM, Xpert, solid & MGIT culture, FL & SL MGIT DST, FL & SL LPA)
- **Total future demand** is based on full actualization of the national diagnostic algorithm
  - How many tests would be conducted if the national algorithm was followed completely for all presumptive TB cases, in all locations?
- *e.g.* Kenya's algorithm calls for Xpert MTB/RIF as the initial diagnostic test for all presumptive TB patients, but this algorithm is not fully implemented in all locations yet and smear remains in widespread use
  - future demand for Xpert MTB/RIF will be greater than the current demand
  - future demand for smear will decrease compared with current demand as Xpert MTB/RIF is increasingly used as the initial diagnostic test
- Need to define a level of **Intermediate future demand** to use in model, in line with NSP targets
  - e.g. if Xpert-based algorithm were rolled out fully in all high burden counties

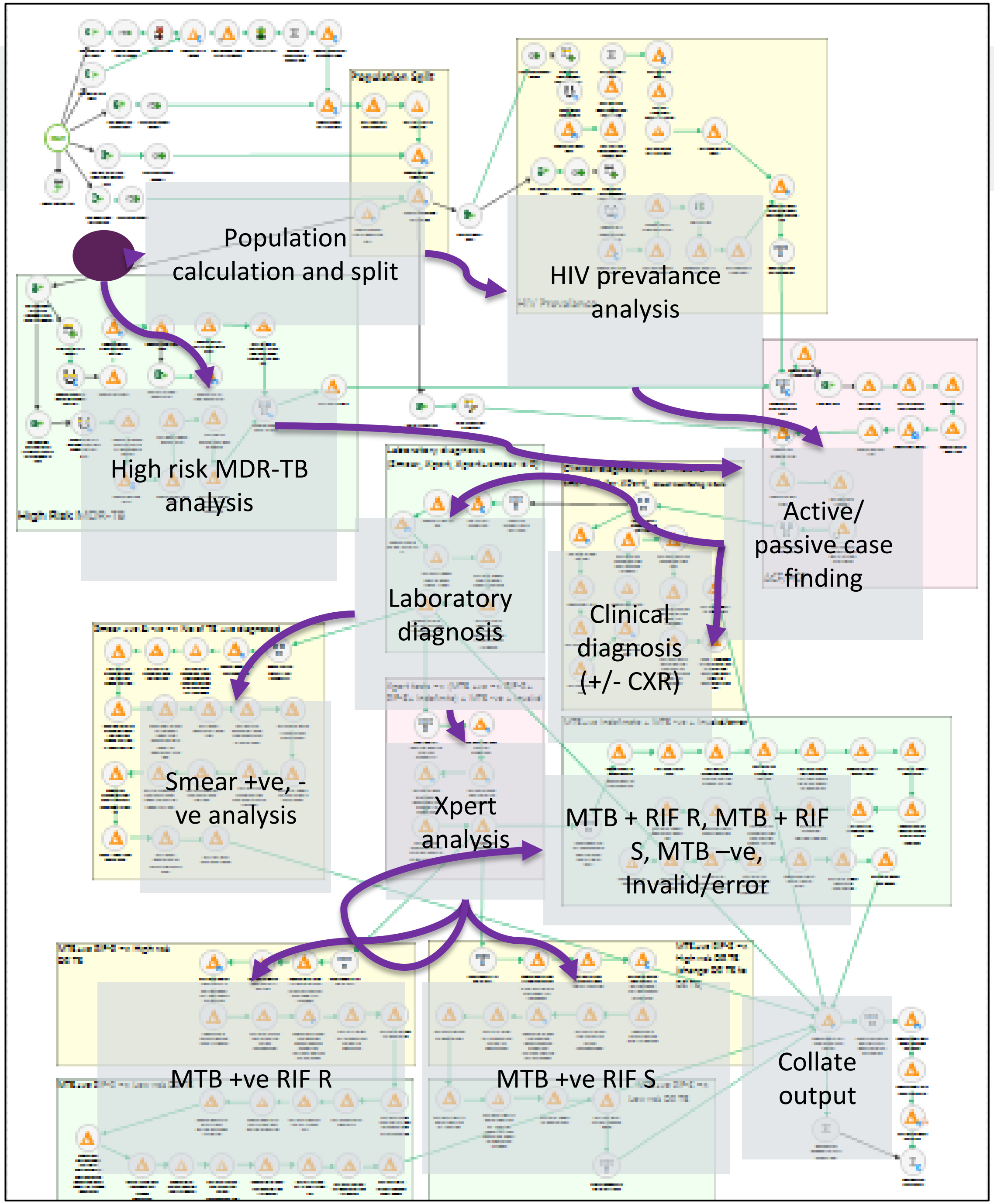
Using composite diagnostic algorithm framework to estimate testing demand

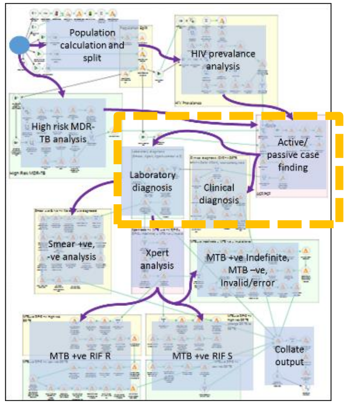


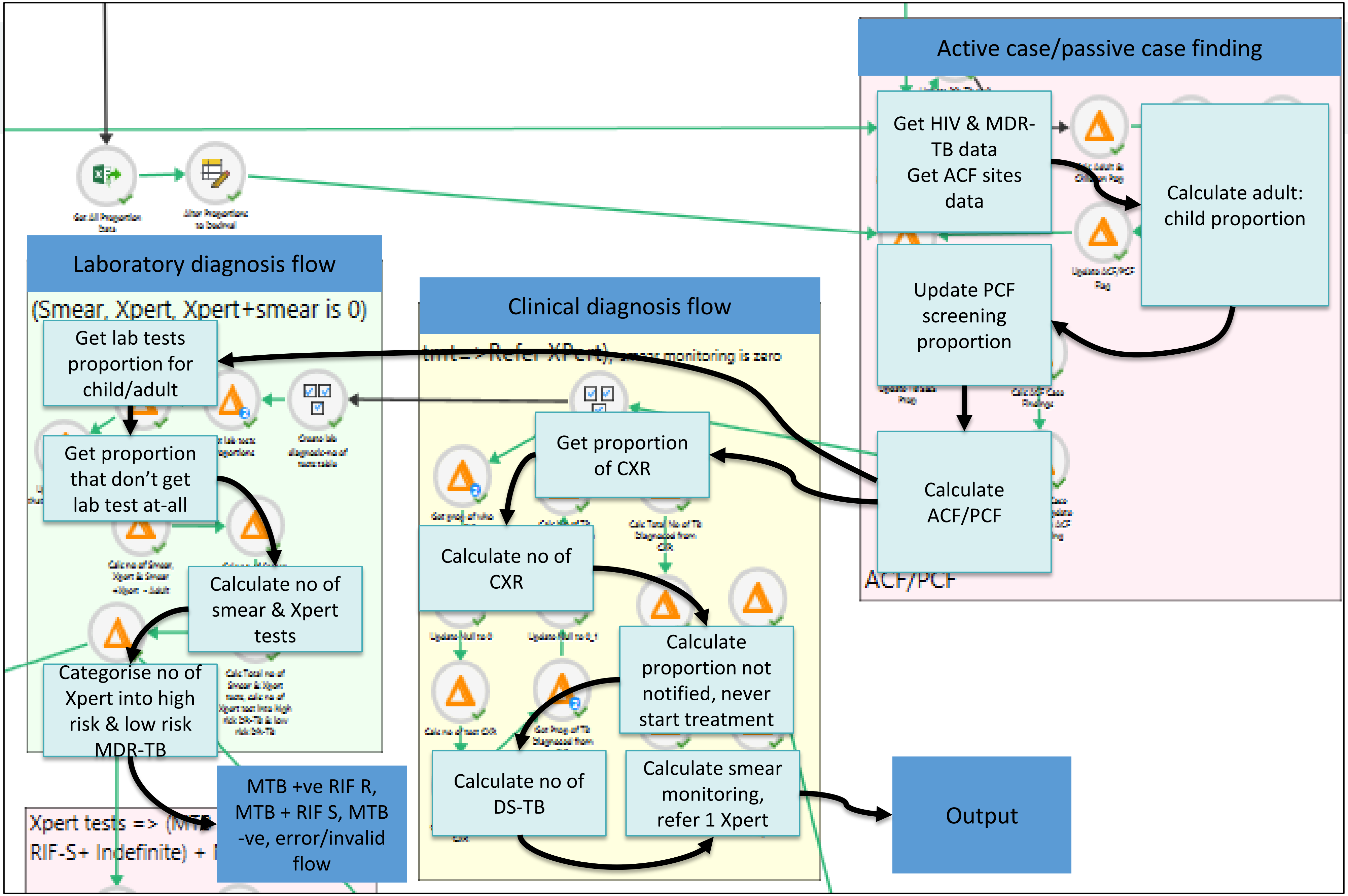
Kenya's National TB diagnostic algorithm

Demand estimation approach

- Representation of full algorithm from Population -> Screened -> Tested -> Diagnosed -> Notified -> Treatment -> Monitored in *Data Guru* workflow (Llamasoft tool)
- Population disaggregated by age, gender, poverty, HIV prevalence, MDR risk (prevalence of previous tmt)
- Calculation of variables at the level of the individual health facility
- Validated various parameters to match available Kenya data
- **Output >> Facility level demand for each diagnostic test**




Population calculation and split
HIV prevalance analysis
High risk MDR-TB analysis
Active/ passive case finding
Laboratory diagnosis
Clinical diagnosis
Smear +ve, -ve analysis
Xpert analysis
MTB +ve Indefinite, MTB –ve, Invalid/error
MTB +ve RIF R
MTB +ve RIF S
Collate output


Active case/passive case finding
Get HIV & MDR-TB data
Get ACF sites data
Calculate adult: child proportion
Update PCF screening proportion
Calculate ACF/PCF
ACF/PCF
Laboratory diagnosis flow
(Smear, Xpert, Xpert+smear is 0)
Get lab tests proportion for child/adult
Get proportion that don't get lab test at-all
Calculate no of smear & Xpert tests
Categorise no of Xpert into high risk & low risk MDR-TB
MTB +ve RIF R, MTB + RIF S, MTB -ve, error/invalid flow
Clinical diagnosis flow
Get proportion of CXR
Calculate no of CXR
Calculate proportion not notified, never start treatment
Calculate no of DS-TB
Calculate smear monitoring, refer 1 Xpert
Output

2017 testing demand validated against current data, used NSP targets to obtain 2021 and 2023 demand estimates

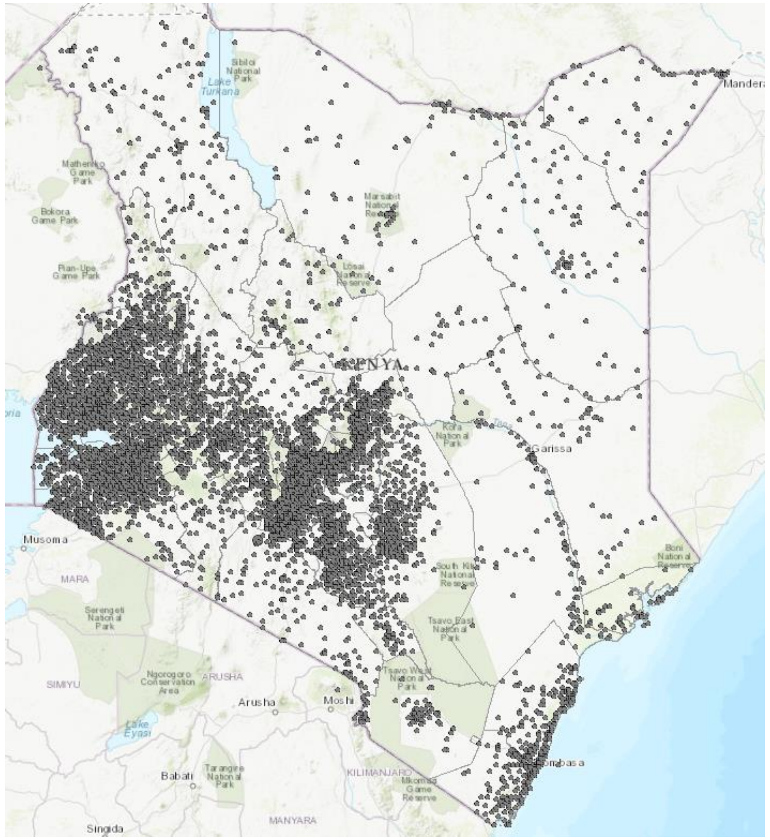
- Future demand calculated from NSP targets - focusing on targets for testing of presumptive TB patients and number of Xpert tests needed, for case detection and % notified cases who receive Xpert (95% by 2023)
- **Projected number of Xpert tests for TB increases by factor of 2.5 from 2017 to 2021, and by another factor of 2.1 from 2021 to 2023**

Element	2017	2021	2023	Notes
Population Estimate	49,521,246	55,073,900	57,974,973	Population projects available also from NSP targets
Number Eligible for screening	21,888,391	24,342,664	25,624,938	Available indications from DHS - 3.4 visits per person, 13% for respiratory
% of those eligiible for screening actually screened	34%	62%	90%	Available indications from discussion 40%-60%, should be higher for PLHIV, should be lower for children
% of total pop Screened	15%	27%	40%	
Number Screened	7,377,963	15,133,824	23,079,861	
% Passing Screen	12%	8.7%	8.4%	As screen is broadened the pass-rate keeps dropping
Number Passing Screen	864,006	1,317,931	1,945,458	
% of those passing screen that get Xpert	32%	58%	73%	
Number of Xperts	**275,139**	**682,511**	**1,424,874**	
Xpert Positivity Rate	13.5%	11.2%	9.7%	Xpert positivity on tested presumptive TB patients drops as the number of patients tested keeps increasing
Postive Xperts	37,043	76,650	138,259	
Notified Cases with any Xpert	44,552	84,278	105,915	
Total Notified Cases	85,188	112,371	111,490	From current data and NSP 2021, 2023 Target setting
Expected Total Incident Cases	166,038	149,829	139,362	From current data and NSP 2021, 2023 Target setting
Incidence Rate	334	272	240	From current data (2016 incidence) and NSP 2021, 2023 Target setting
Case Detection Rate	51%	75%	80%	From NSP 2023 Target setting and an intermediate target for 2021
% Notified Cases with any Xpert	52%	75%	95%	95% is the 2023 target and an intermediate target is taken for 2021

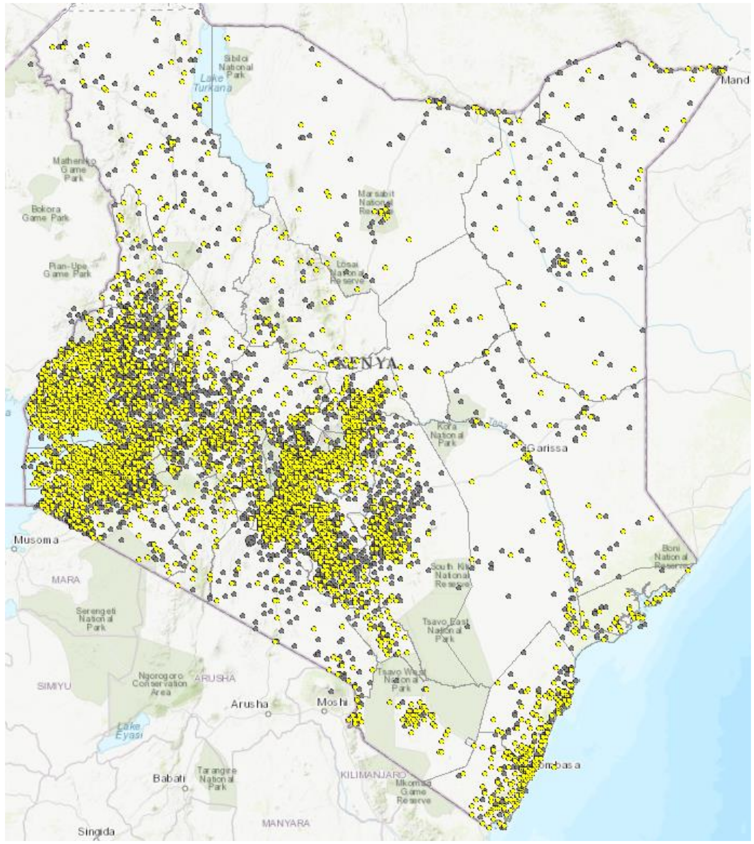
Contents

2017: baseline

Distribution of health facilities in Kenya

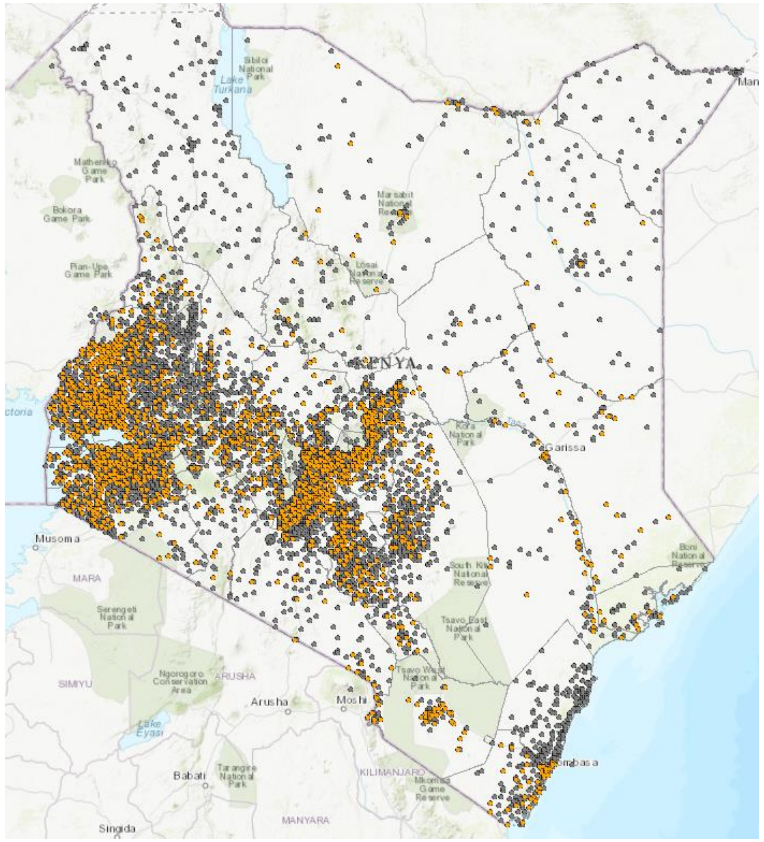


Over 12,000 HFs in Kenya



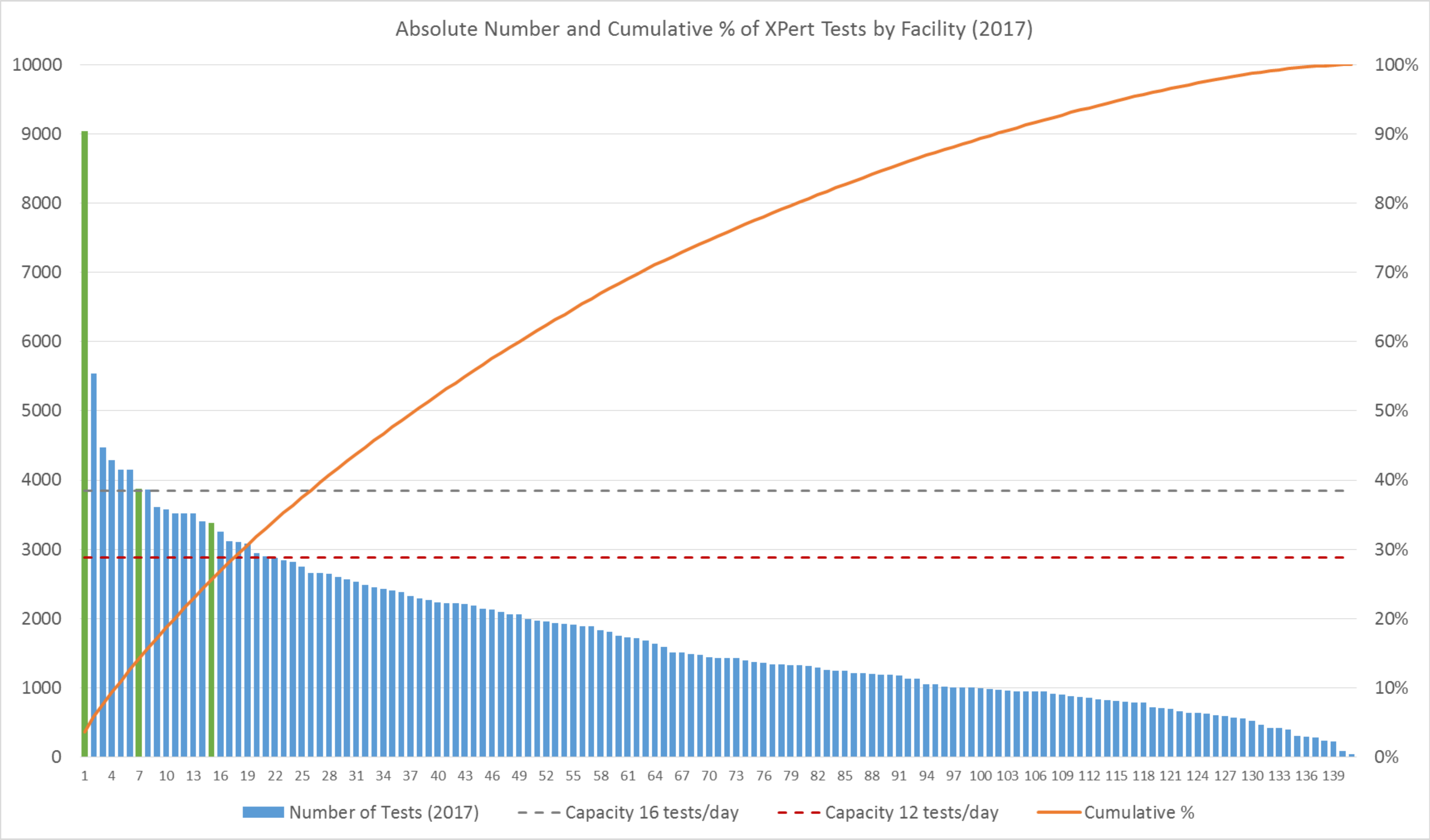
~3500 sites estimated to refer for any Xpert tests currently (yellow).

TB treatment sites that have a non-zero patient care-seeking proportion according to PPA. Xpert testing data for 2017 was provided per county. We used PPA data to allocate testing within a county

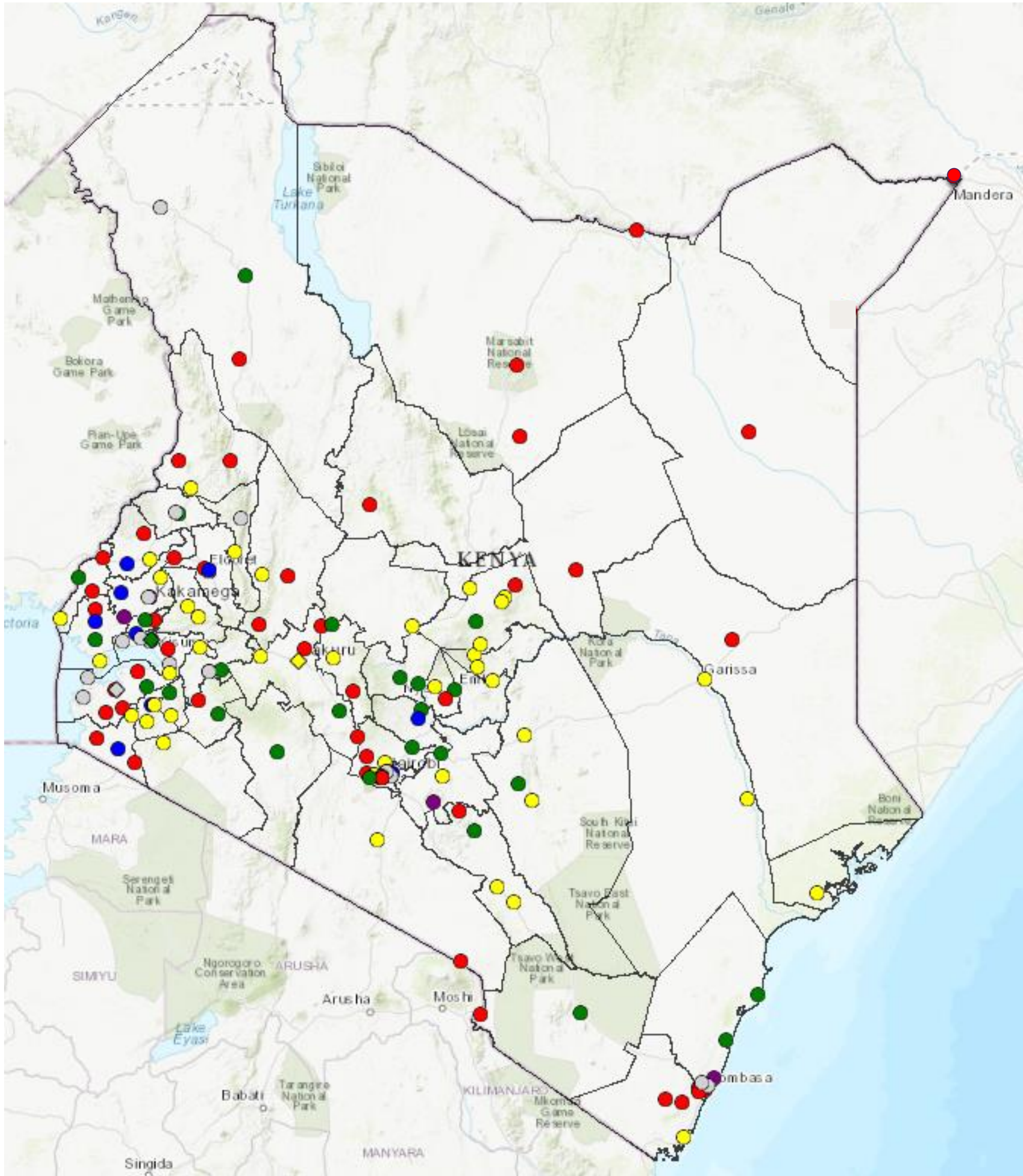


~2000 smear microscopy sites (orange)

Xpert sites, Kenya – 2017 TB tests (data from 141/162 NTLP Xpert sites)



- **Majority of sites (90 of 141 reporting) have utilization of <8 tests/day**
- 5 GX4 sites are over utilized even with 16 tests/day capacity
- 21 of 162 sites have no demand data for 2017
- Bars in green are GX XVI
- The top 25% (~35) sites account for 50% of total tests and the top 50% account for about 80%



Distribution and capacity of NTLP Xpert testing sites - 2017

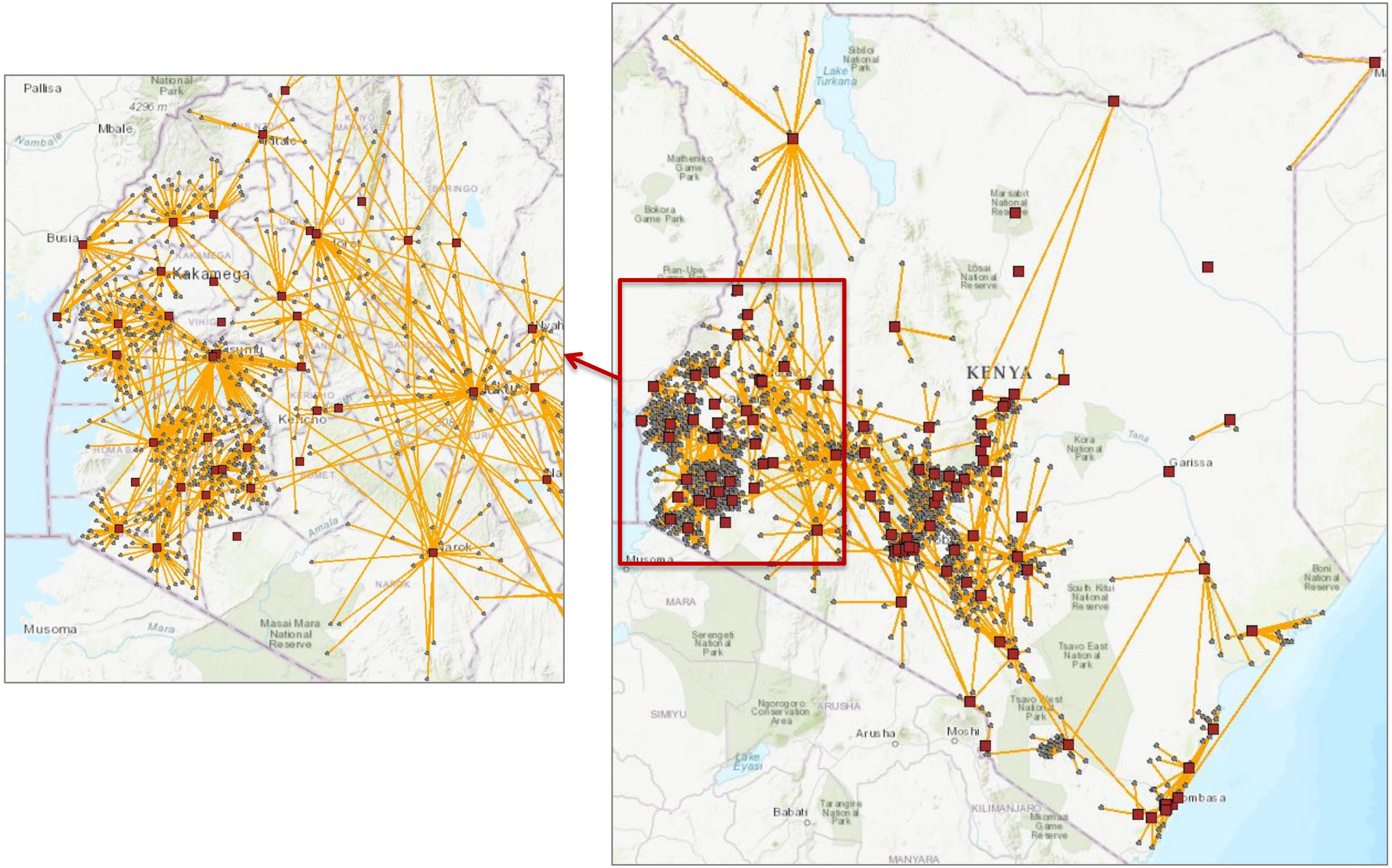
- Map shows 162 NTLP Xpert sites, of which 141 reported data in 2017
- Over-capacity (Purple > 16 tests/day for GX4 or Blue 12-16 tests/day for GX4) and heavily under-utilized (Red < 4 tests/day) sites are often right next to each other
- Part of broader pattern of different levels of utilization in same geographic cluster
- Largest number of sites fall into low utilization categories (Red < 4 tests/day and Yellow 4-8 tests/day)

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 (over single shift capacity limit)
Purple:	over 16 tests/day for GX4
Light Gray:	No data available

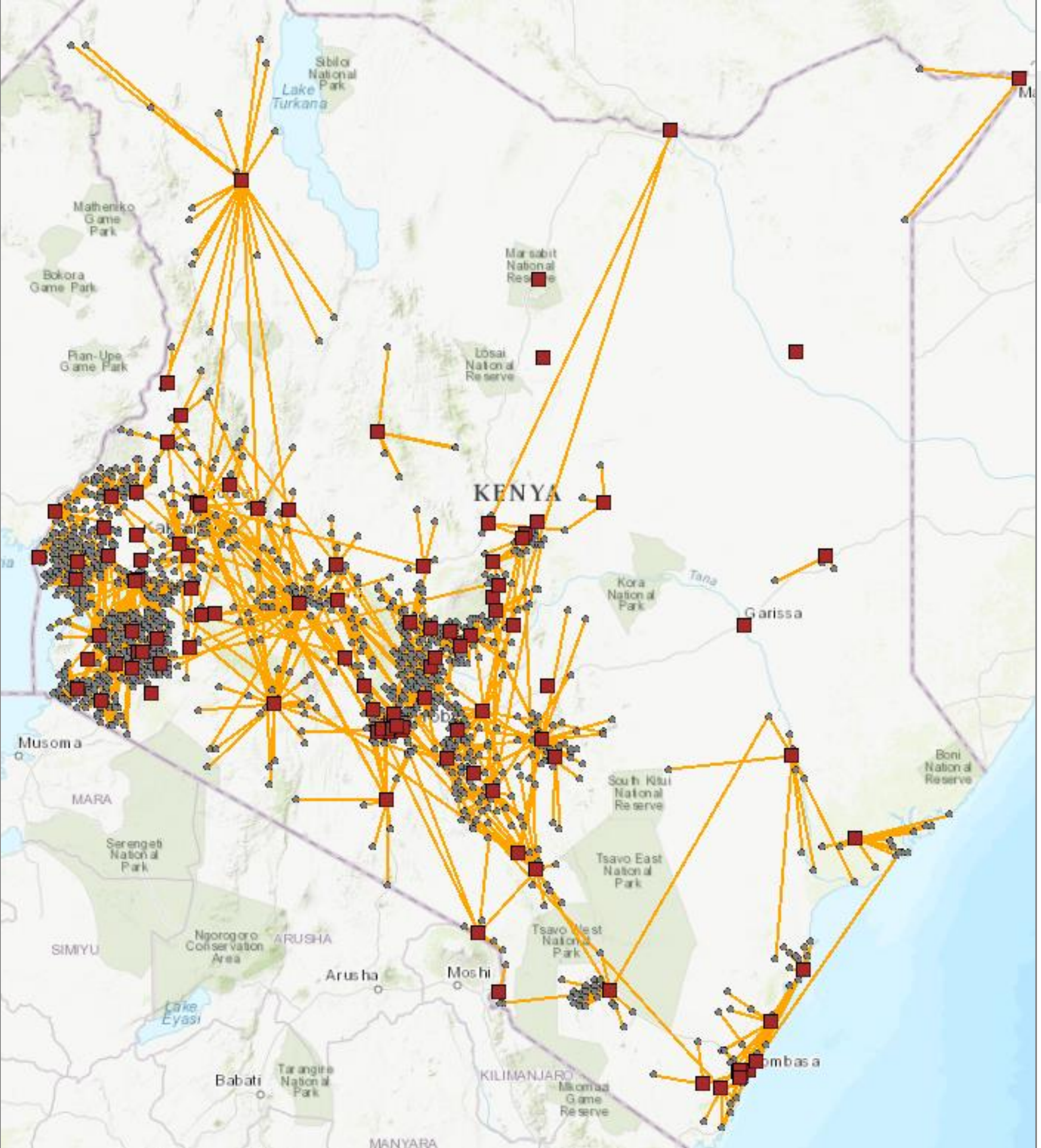
All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.

Current sample referral flows – partial snapshot



- Incomplete data on the current sample referral flows
- What we know from the available data:
  - ❑ Health facilities often refer to multiple testing sites
  - ❑ Utilization of testing facilities in the same geographic area varies widely
  - ❑ Most referrals are within county boundaries although not always to the closest site
  - ❑ Some cross-county border referrals do occur

Partial snapshot of current flows



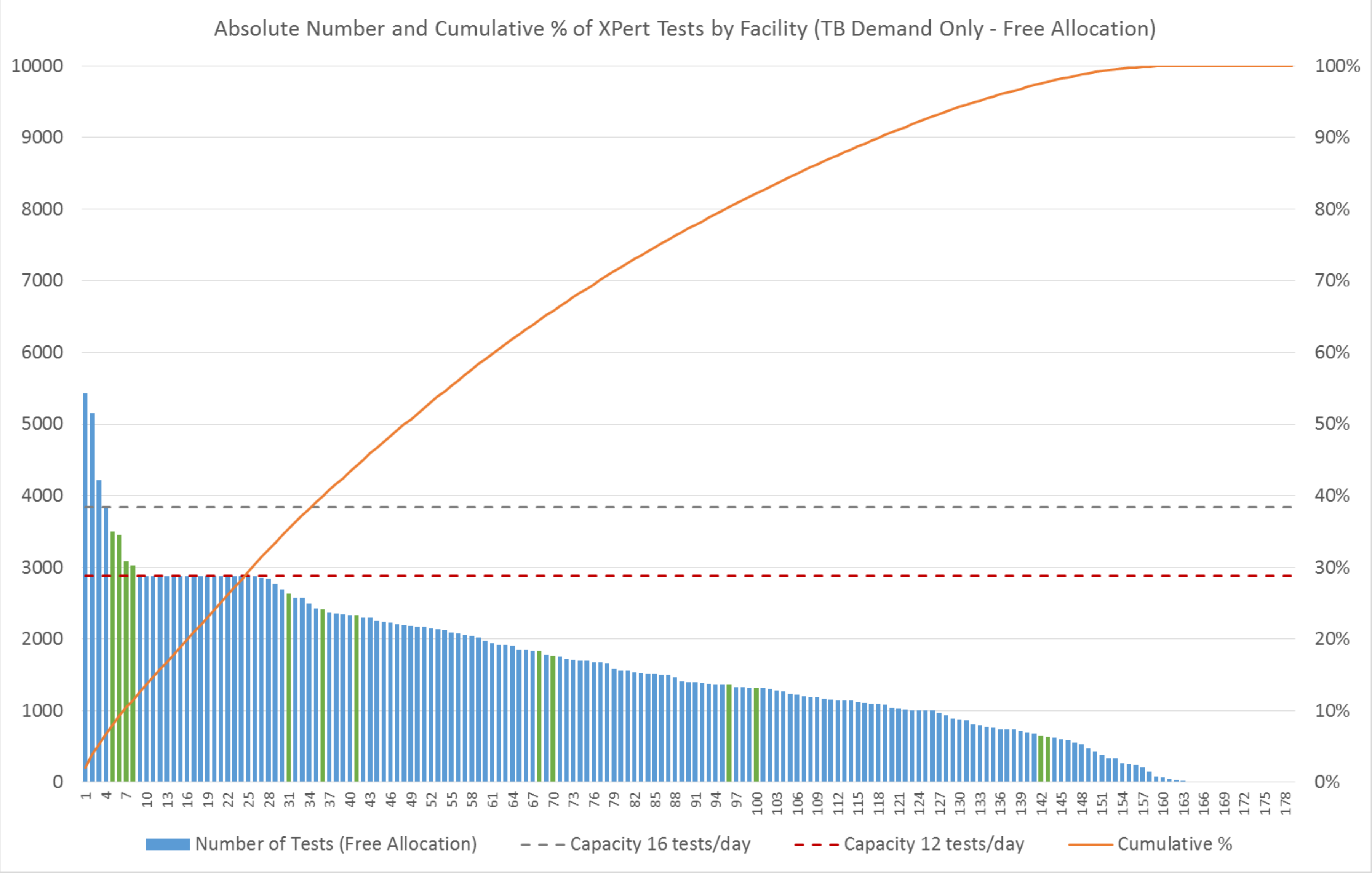
2017: optimized

Current state actual capacity is higher than first assumed

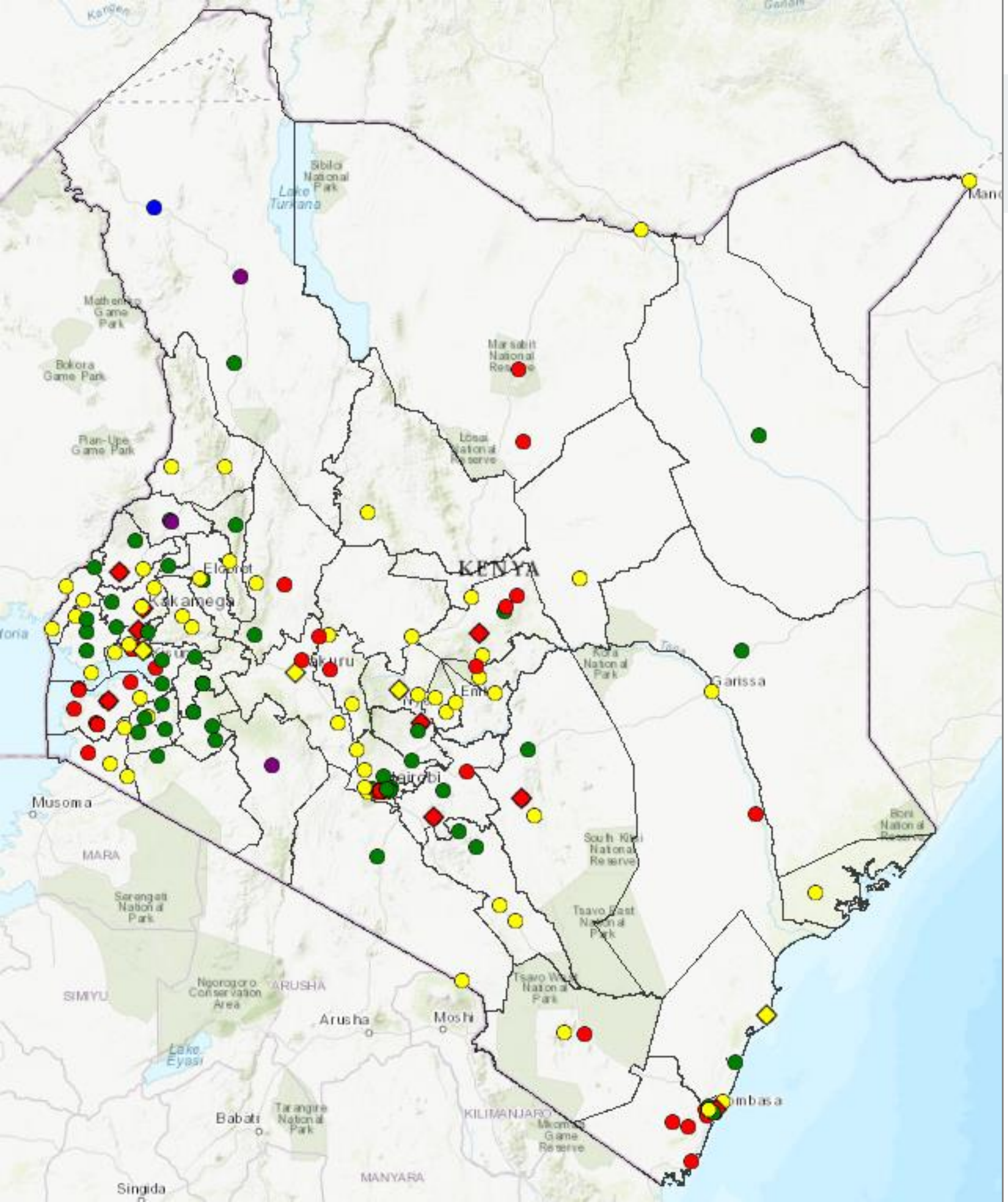
- In the current network:
  - 37 NTLP GX4 & 4 GX 16 sites operate 24 hrs
  - Beyond the 162 NTLP Xpert sites, 10 private sector sites also allow referrals from the public sector and are included in the current network capacity
  - 9 new GX16s have been procured, and can be thought of as existing network capacity. These are allocated to facilities that are expected to operate 24 hrs
- So the current network capacity is already **much higher** than one would calculate from 162 NTLP machines operating at a single shift
- If one considered only the 162 NTLP machines for a single shift, the network has capacity for ~500K tests. However, with all the additions mentioned above a further 72% capacity is available (total 860K tests)

	Number of Sites	Capacity in 8 hr day (12 tests/day)	Total Capacity
GX4 Sites	157	2,880	452,160
GX16 Sites	4	11,520	46,080
GX2 Sites	1	1,440	1,440
New GX16	9	11,520	103,680
Additional Capacity 24 hrs - GX4 (assuming capacity is 2.5x)	37	4,320	159,840
Additional Capacity 24 hrs - GX16 (assuming capacity is 2.5x)	4	17,280	69,120
Private Sector Sites - sharing	10	2,880	28,800
Total Current			861,120

Optimizing current network capacity, free allocation of 2017 TB test demand



- **Optimized model uses only 164/180 sites (including new GX16 and private sector)**
- **Existing network capacity is very large and more than sufficient for 2017 demand**
- Demand is spread more evenly by the optimized model, but 100+ sites are still used below 8 tests/day
- Model does not choose to use 16 sites at all (these are excess capacity if only TB demand is considered)
- 8 sites perform over 2880 tests (12 tests/day) in the free allocation – of which 4 are GX XVI sites and others are GX4 sites operating 24 hrs
- Bars in green are GX XVI



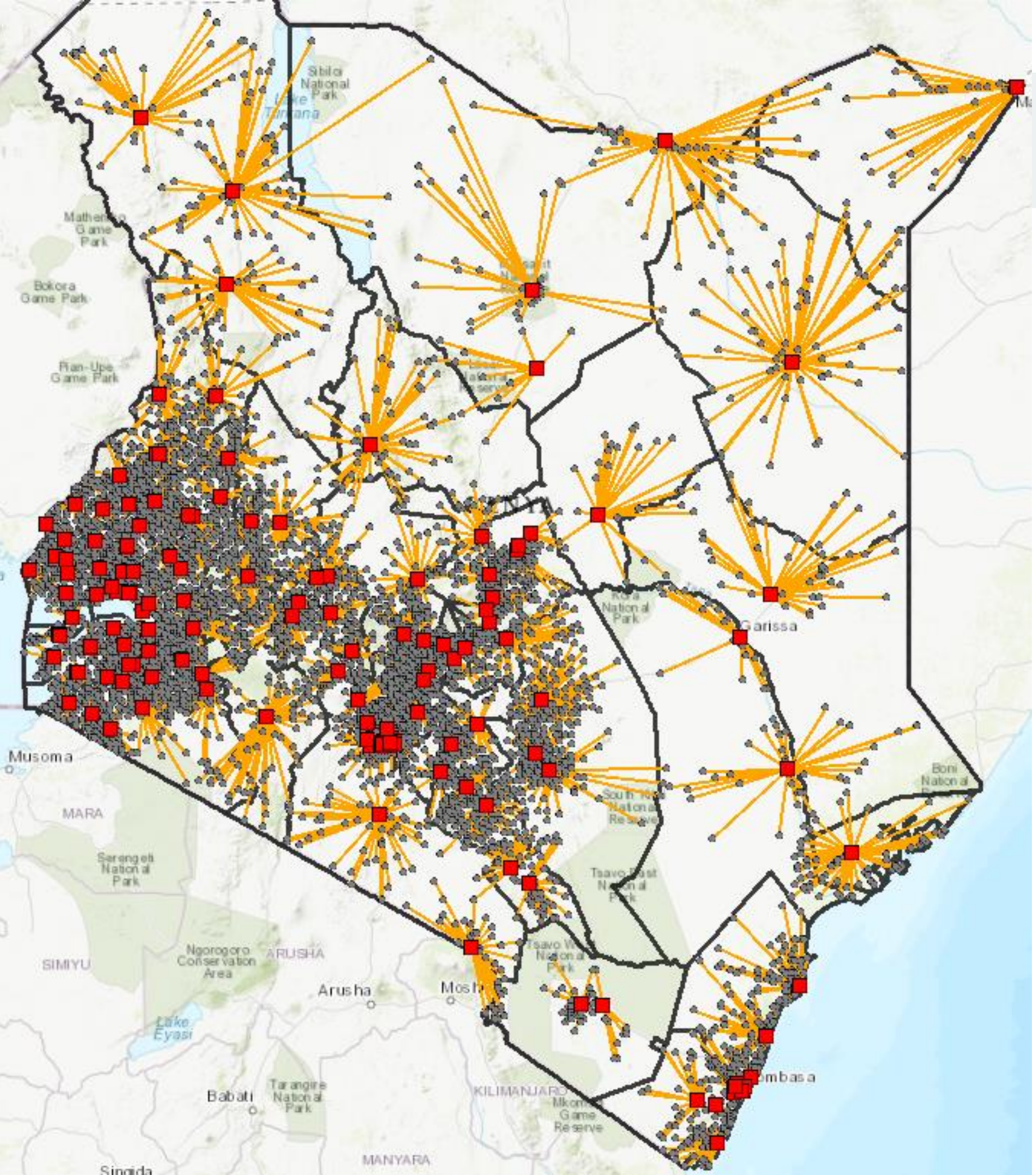
Utilization of available machines with model allocation of demand

- Map shows 180 sites available for current use
- Sites were kept in the same location as baseline in the analysis
- Largest number of sites still fall into low utilization categories (Red < 4 tests/day and Yellow 4-8 tests/day for GX4)
- Hard-to-reach counties in the north don't only have low-utilization sites – some green, blue, and purple is present.
- The GX16 sites are very underutilized (all are yellow or red) if only 2017 TB demand is considered (as model prefers to use GX4 sites). Due to cost of 1 technician per GX 4 and 2 technicians for GX 16 sites.

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 (over single shift capacity limit)
Purple:	over 16 tests/day for GX4
Light Gray:	Not used

All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.

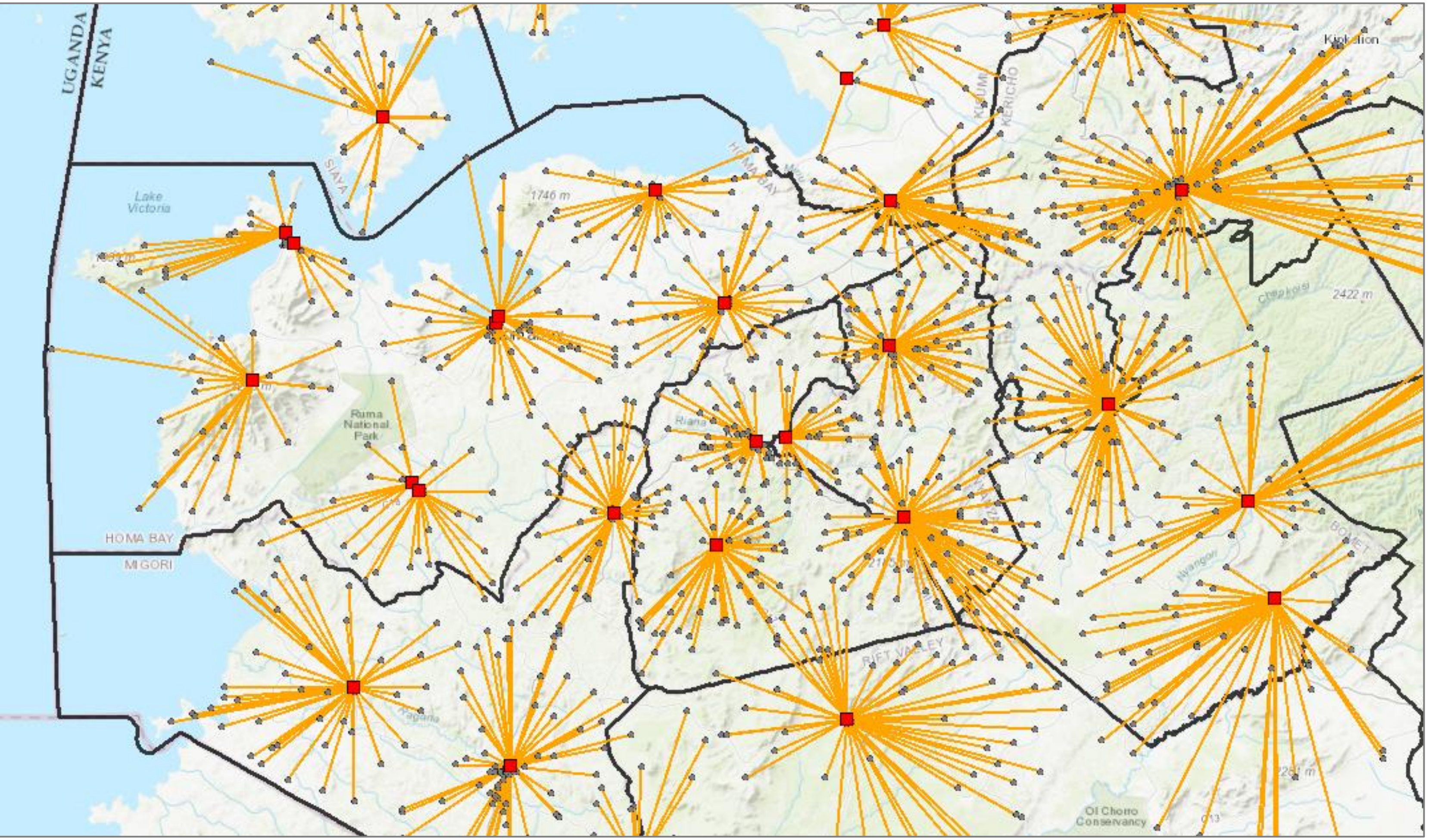


Designing demand-driven TB sample referral network - 2017

- Geographic clusters of referral instead of ad-hoc referral patterns
- Placement of GeneXpert is reasonable based on current demand
- However, in the north, there are long travel legs for samples to be transported to nearest Xpert which may hinder access to services
- While, currently in practice sites referring for Xpert are only the ~3500 TB treatment sites, the network optimization model considers demand from all HFs in Kenya (12000+) and considers them all as referral sites. The goal is to improve access to Dx services

Referral pattern with free allocation – minimizing sample transport distance

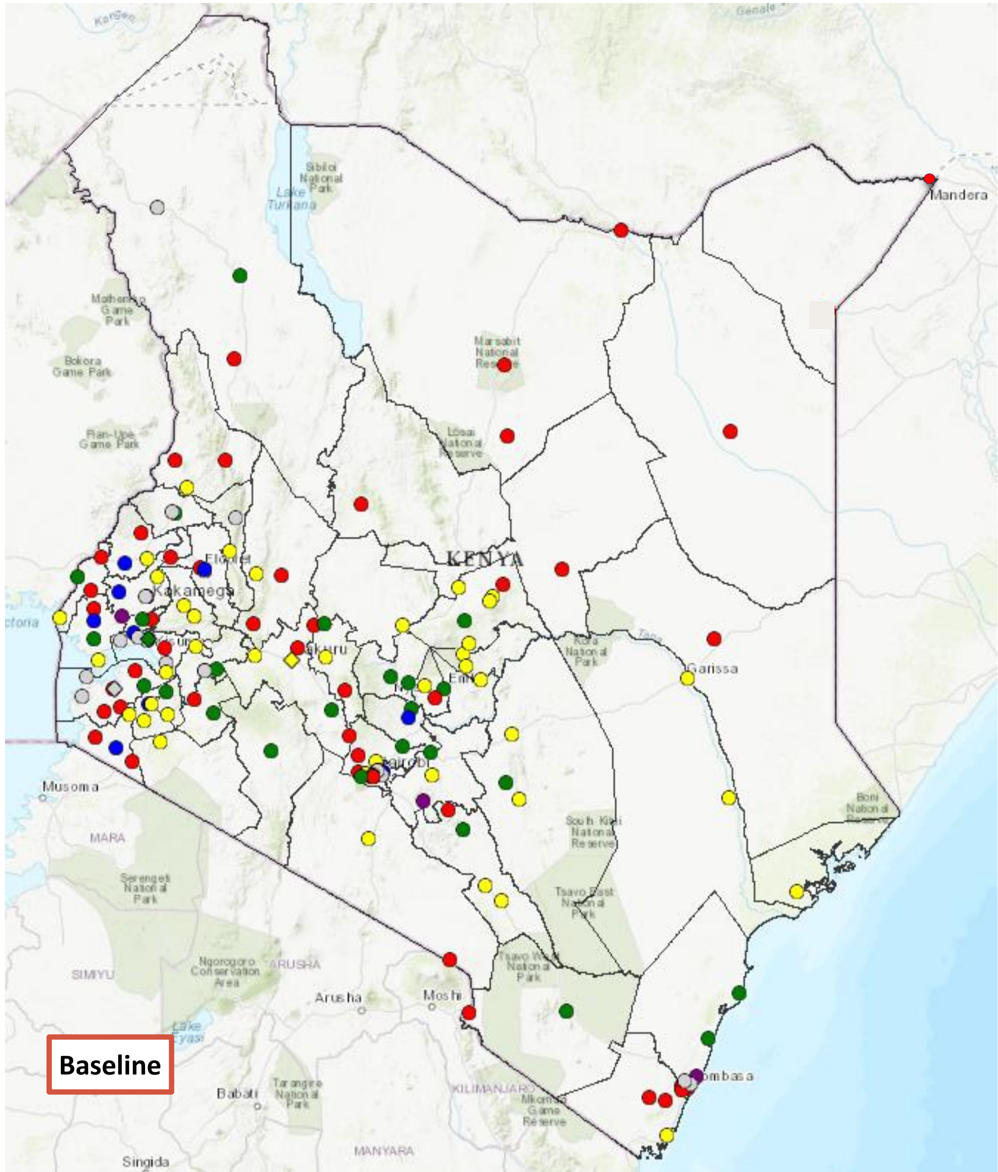
Designing demand-driven TB sample referral networks

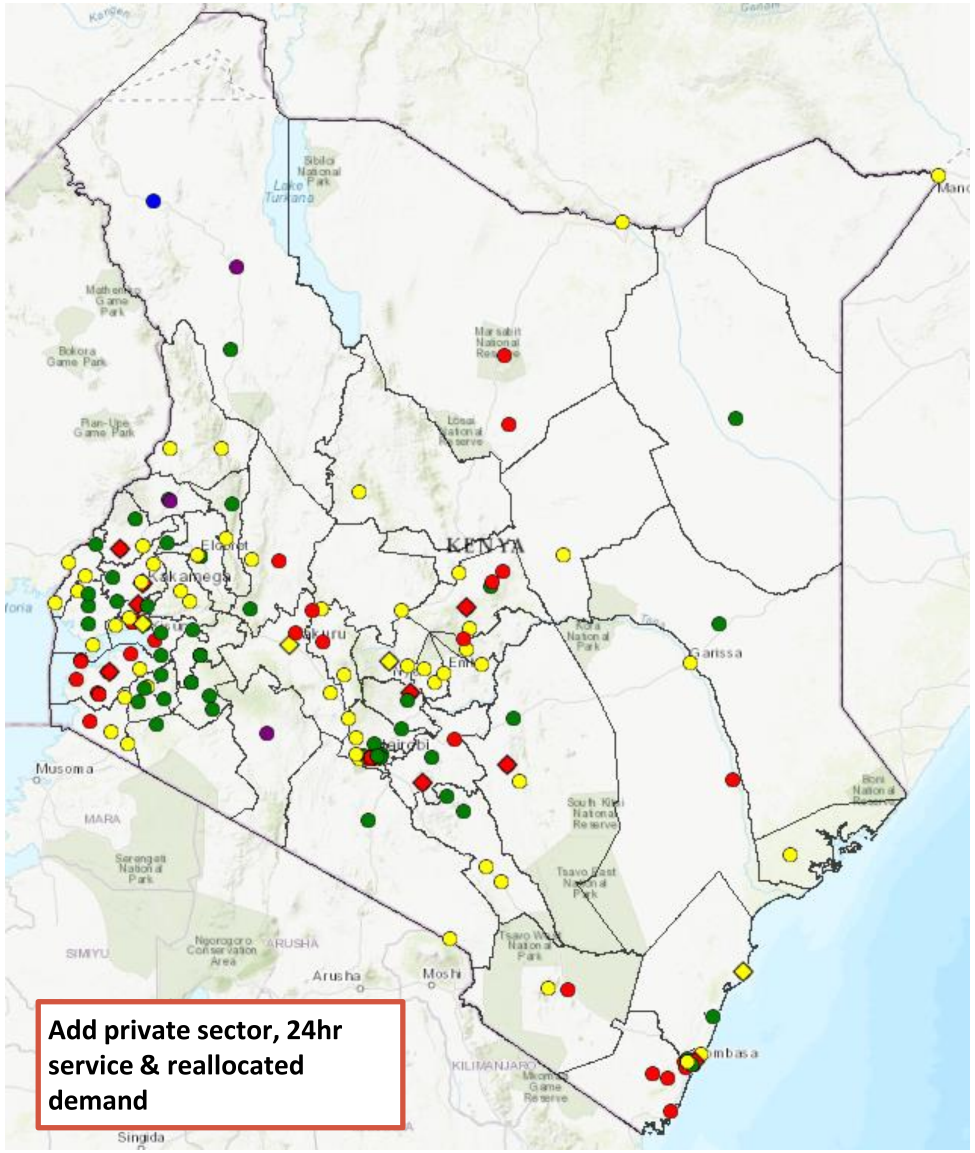


Zoom in on Homa Bay area

Referral pattern with free allocation – minimizing overall sample transport distance

Comparing Xpert utilization at baseline with reallocated TB demand





Summary: 2017

- Existing network capacity for Xpert testing is large and more than sufficient for current TB demand
- Utilization of instrument capacity varies widely within the same geographic area, with over-utilised and under-utilised equipment located close together
- Available data suggest that facilities often refer samples to multiple testing sites, mostly within county boundaries although not always to the closest site
- Xpert testing sites are well placed to respond to referrals from TB treatment sites and there is no pressing imperative to consider relocating instruments. However there are long travel distances in northern counties even in the optimized network design which may hinder access to services (further analysis presented for 2021)
- Recommended sample referral system designs seek enable better utilization of available capacity and enable referral from all health facilities to Xpert testing sites.
  - More in-depth referral system planning will be conducted in a follow-on analysis in selected counties.

Contents

2021

Looking forward to 2021

- What strategies can we consider to improve access to diagnostic services as demand increases?

1. **Extend current network capacity without procurement of new instruments**
   - Strengthen referral networks and enable increased and more efficient utilization of existing capacity
   - Enhance existing capacity by extending working hours in more facilities
   - Engage more private sector facilities in the network

2. Allow procurement of more instruments to decentralize service delivery

- A differentiated approach to network strengthening will take into account operational considerations that may vary across the country:
  - longer working hours are already implemented in some locations and may be expanded in selected facilities only (e.g. larger hospitals, certain counties) but may not be feasible elsewhere
  - where private sector facilities are present and provide quality services, engaging them may be an efficient means to expand capacity
  - higher number of instruments in the network requires more resources for set-up, personnel, supervision and monitoring to ensure high quality services can be maintained; supply chain may be challenging to enable uninterrupted services
  - it may be feasible to establish and maintain good referral networks in some counties but may be difficult in hard to reach counties where road infrastructure and insecurity are challenging

2021: Two approaches to projecting future demand

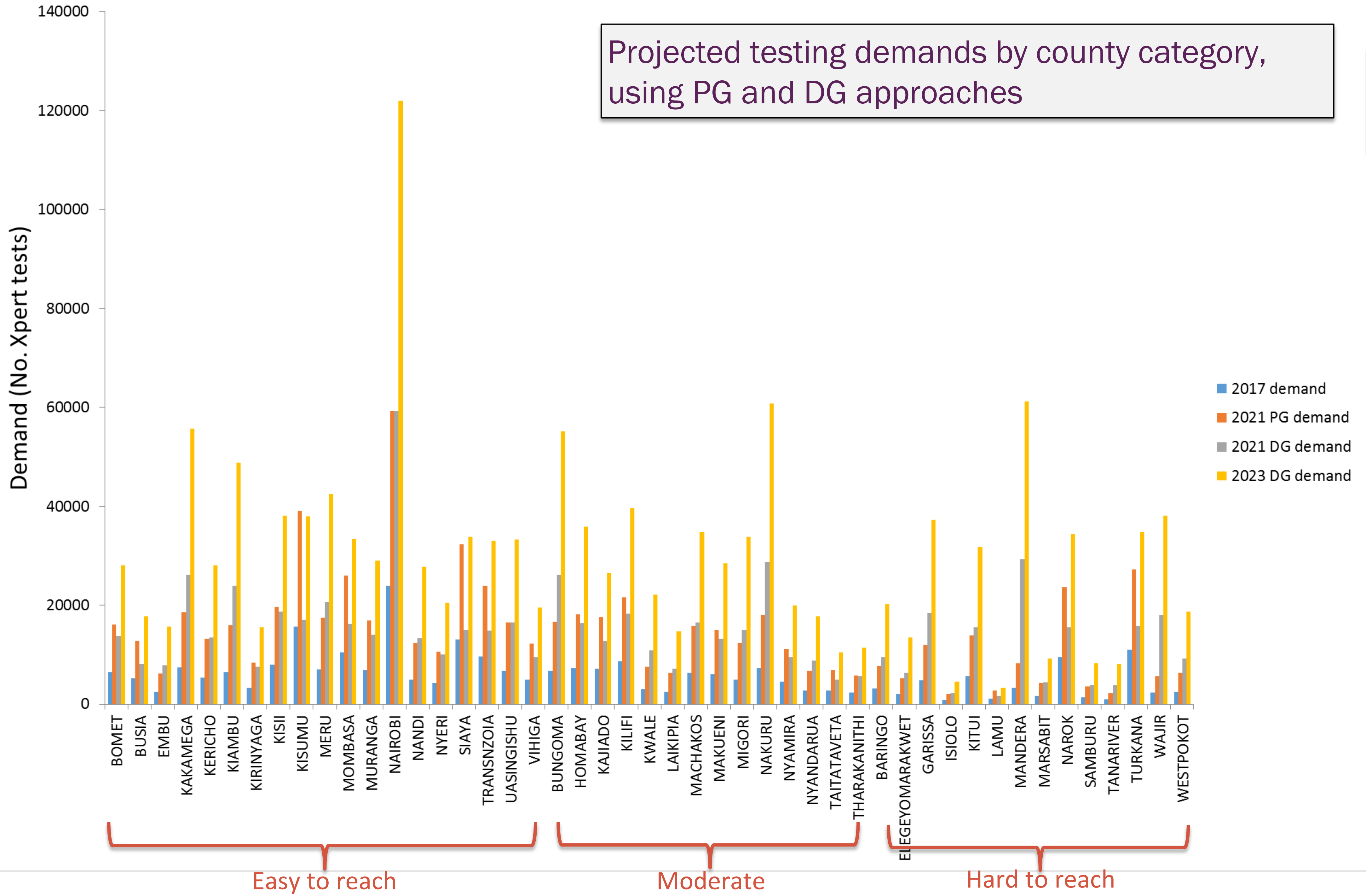
- For 2021, we have a total of ~680K Xpert tests as our approximate total demand projection based on NSP targets for 2021 (see details on Slide 23)

- To reach this overall national total, we have taken two approaches:
  - **Proportional growth (PG) demand**: What if the 2021 demand followed the same pattern in terms of distribution across counties as 2017? What if the counties maintain the proportions of demand they contribute in 2017, but scaled up to 680K tests in 2021? This means that each county has the same rate of growth in tests (the national growth rate) from 2017 to 2021.

  - **Differential growth (DG) demand:** What if we start with the national proportions of people screened, yields etc. from NSP targets? County populations are disaggregated by age, gender, HIV, MDR risk, poverty and testing demand is calculated using algorithmic workflow (see Slides 21-22). For each county we use a differential growth rate of testing demand based on outputs from workflow. This means that each county will have different rates of growth in tests from 2017 to 2021, and the proportion of demand the counties each contribute will be slightly different from 2017.

  - As a general guiding statement, the DG approach tends to give a higher testing demand estimate in hard to reach (lower burden) counties compared with PG approach. High burden counties tend to have a higher demand estimate using the PG approach.

Projected testing demands by county category, using PG and DG approaches



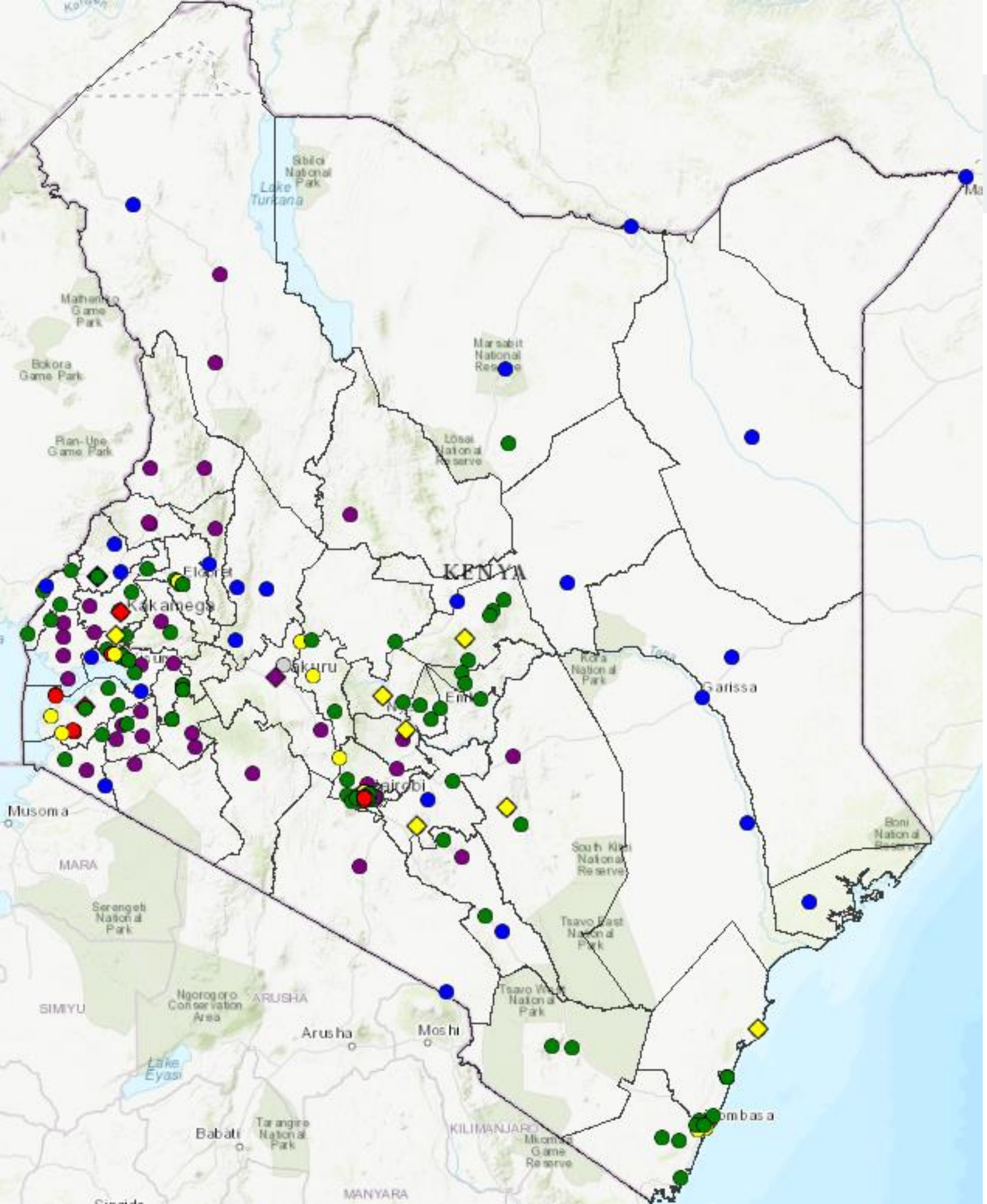
2021: Two types of demand projections – comparing demand numbers by county

Demand
ummaries by Coun

Looking forward to 2021: extending current capacity without adding new instruments

- Testing is expected to increase by a factor of 2.5 (to ~680K) tests if NSP screening targets are met
- Capacity of the network can be extended by:
  - Increasing working hours for more sites (e.g. 30 more in table below)
  - Integration of private sector labs (to all existing private sector Xpert facilities – an additional 19 GX4 sites and 4 GX16 sites)
- With these changes, there is total capacity in the network for up to 1.2M+ tests
- Number of sites = **208**

	Number of Sites	Capacity in 8 hr day (12 tests/day)	Total Capacity
GX4 Sites	**157**	**2,880**	**452,160**
GX16 Sites	**4**	**11,520**	**46,080**
GX2 Sites	**1**	**1,440**	**1,440**
New GX16	**9**	**11,520**	**103,680**
Additional Capacity 24 hrs - GX4 (assuming capacity is 2.5x)	**37**	**4,320**	**159,840**
Additional Capacity 24 hrs - GX16 (assuming capacity is 2.5x)	**4**	**17,280**	**69,120**
Private Sector Sites - sharing	**10**	**2,880**	**28,800**
Total Current			**861,120**
Potential Additional Capacity 24 hrs - 9 new GX 16 (assuming capacity is 2.5 x)	9	17,280	155,520
Convert more GX4 sites to 24 hrs (assuming capacity is 2.5 x)	**30**	**4,320**	129,600
Additional private sector sites - GX4	19	2,880	54,720
Additional private sector sites - GX16	4	11,520	46,080
Total Potential with no new equipment			**385,920**



Distribution and utilization of Xpert testing sites 2021 PG demand allowing only existing sites

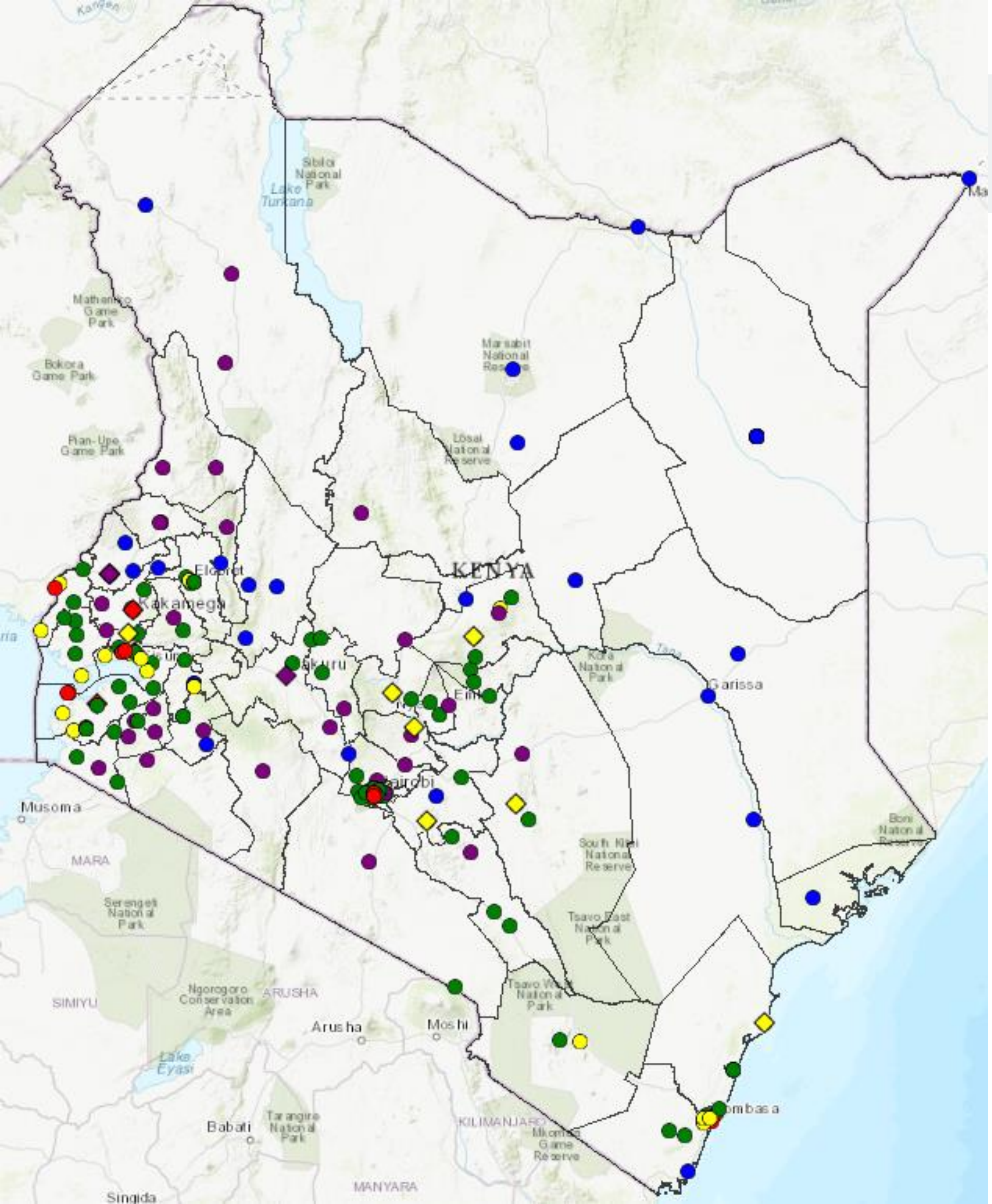
- 208 sites used
- There is a high proportion of highly utilized (green) and over-utilized (blue and purple) sites
- Highly utilized sites are spread across the country, including hard to reach areas
- Some GX-XVI sites are under-utilized in this analysis (yellow/red), due to model preference for GX IV (due to lower HR cost)

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 and 36-48 tests/day for GX16
Purple:	over 16 tests/day for GX4 and 48 tests/day for GX1
Light Gray:	Not used

All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.

Distribution and utilization of Xpert testing sites 2021 DG demand allowing only existing sites



- 208 sites
- Only very minor differences in utilization patterns compared with PG demand projection (previous slide)

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 and 36-48 tests/day for GX16
Purple:	over 16 tests/day for GX4 and 48 tests/day for GX1
Light Gray:	Not used

All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.

Allowing procurement of new instruments:

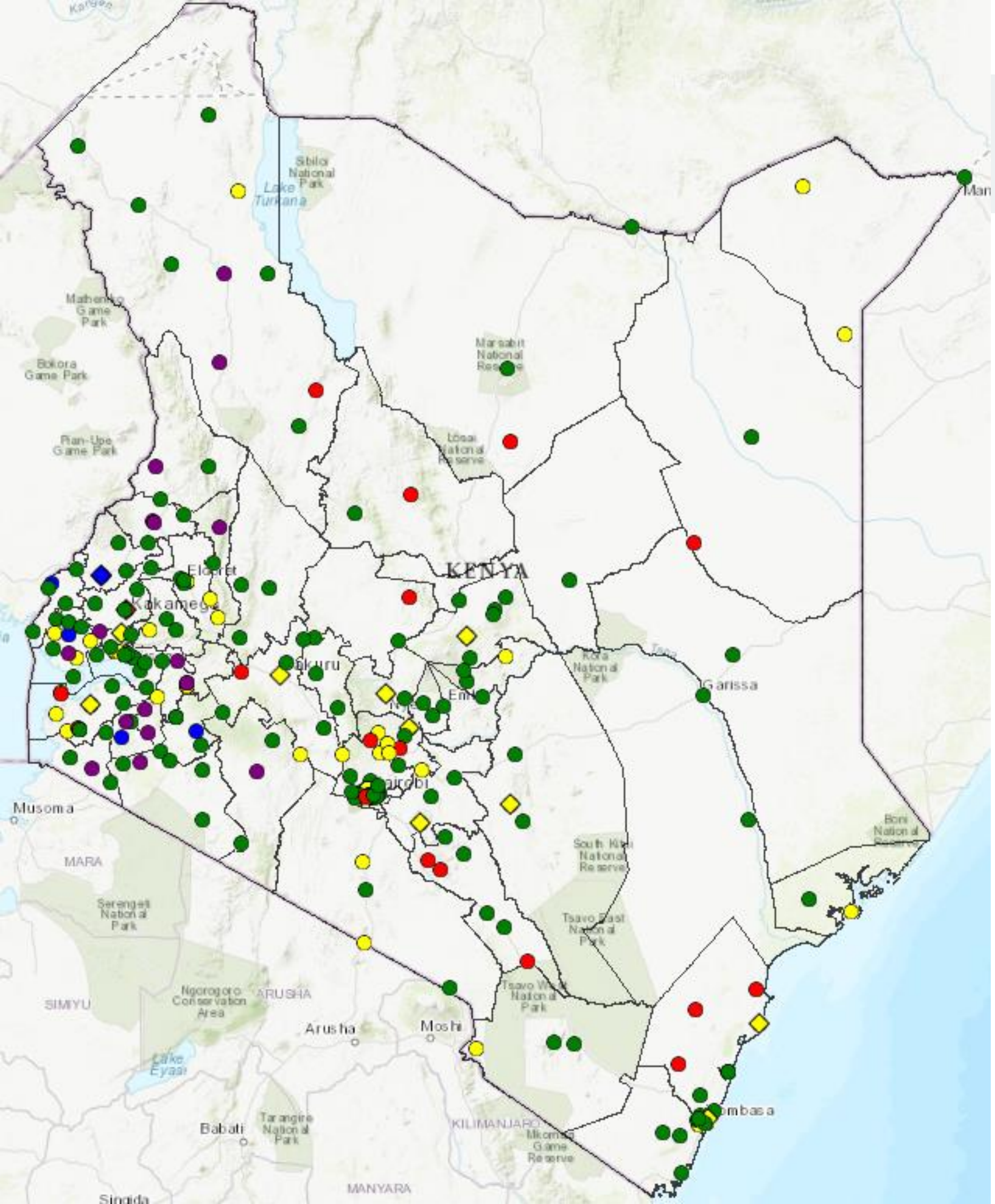
How many sites and what placement does the model recommend for 2021?

- For 2021, if we allow the model free choice of placing an Xpert at any current TB treatment site, how many sites does the model choose as optimal?

- How does the model recommendation of number of sites compare to if we only used existing sites with the private sector and working hour increases?

- If we only allow the model to use existing sites (with private sector and extended hours) then we have **208 sites**

- If we allow the model to choose freely – then it selects to use a total of between **262-297 sites** as optimal (depending on the demand projection approach)



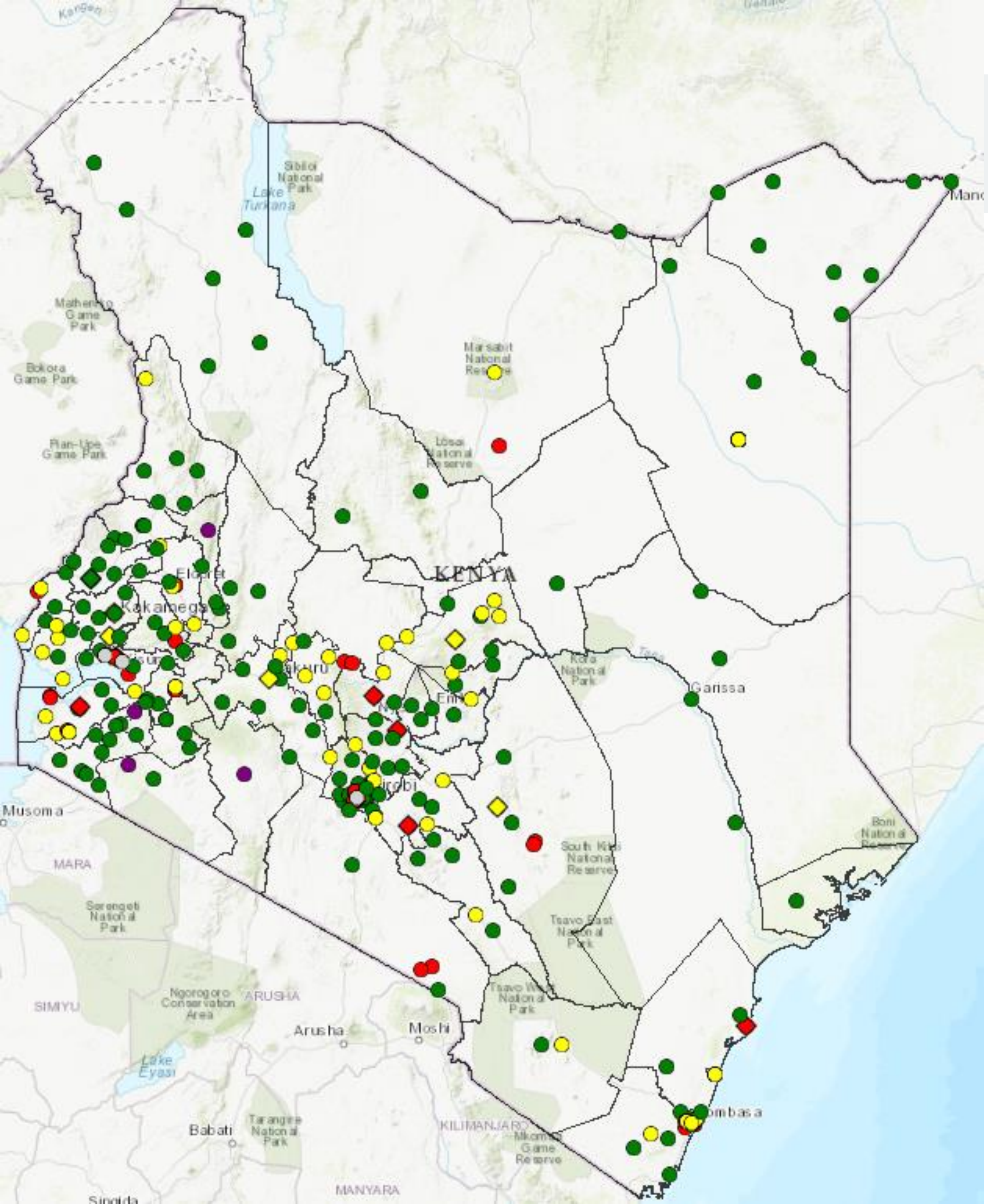
Distribution and utilization of Xpert testing sites 2021 PG demand, existing sites + potential new sites

- 262 sites used
- Significant proportion of new potential sites in hard to reach counties, but also added in high burden, easy to reach counties
- Majority of sites have good utilization (green, 8-12 tests per day), but there remain some that are over-utilized (blue, purple) and under-utilized (yellow/red)

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 and 36-48 tests/day for GX16
Purple:	over 16 tests/day for GX4 and 48 tests/day for GX1
Light Gray:	Not used

All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.



Distribution and utilization of Xpert testing sites 2021 DG demand, existing and potential new sites

- 297 sites used
- Higher number of new potential sites in hard to reach counties compared with PG demand, and the new sites are well utilized (green).
- More sites also added in high burden, easy to reach counties compared with PG demand.
- Majority of sites have good utilization (green, 8-12 tests per day), but there remain some that are over-utilized (blue, purple) and under-utilized (yellow/red)

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 and 36-48 tests/day for GX16
Purple:	over 16 tests/day for GX4 and 48 tests/day for GX1
Light Gray:	Not used

All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.

What is the size/utilization profile for 2021 DG demand comparing use of existing sites only vs allowing the model free choice?

Existing Sites only

	Annual Number of Tests	Tests per day	Implied Machine Size or Extra Shifts	Number of Sites	Notes
Existing	Less than 1440	Less than 6 tests/day	GX2 or smaller	40	Not in hard-to-reach areas, but rather counties with lots of capacity (e.g. Nairobi, Homa Bay, Kisumu)
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	95	58 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or using existing GX16s	73	
	Total			208	

Model free choice

	Annual Number of Tests	Tests per day	Implied Machine Size or Extra Shifts	Number of Sites	Notes
Existing	Less than 1440	Less than 6 tests/day	GX2 or smaller	54	
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	138	78 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or using existing GX16s	13	
	Total			**205**	
Potential New Sites	Less than 1440	Less than 6 tests/day	GX2 or smaller	12	These are in mid-size counties e.g. Nyeri, Nandi
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	80	48 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or adding GX16s	0	No large new sites or extra shifts added
	Total			**92**	

What is the size/utilization profile for 2021 PG demand comparing use of existing sites only vs allowing the model free choice?

Existing Sites only

	Annual Number of Tests	Tests per day	Implied Machine Size or Extra Shifts	Number of Sites	Notes
Existing	Less than 1440	Less than 6 tests/day	GX2 or smaller	24	Not in hard-to-reach areas, but rather counties with lots of capacity (e.g. Nairobi, HomaBay, Kisumu)
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	105	72 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or using existing GX16s	71	
	Total			200	

Model free choice

	Annual Number of Tests	Tests per day	Implied Machine Size or Extra Shifts	Number of Sites	Notes
Existing	Less than 1440	Less than 6 tests/day	GX2 or smaller	24	
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	148	91 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or using existing GX16s	35	
	Total			**207**	
Potential New Sites	Less than 1440	Less than 6 tests/day	GX2 or smaller	26	These are in remote counties e.g. Turkana, Wajir
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	29	9 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or adding GX16s	0	No large new sites or extra shifts added
	Total			**55**	

2021 – where do we add new sites?

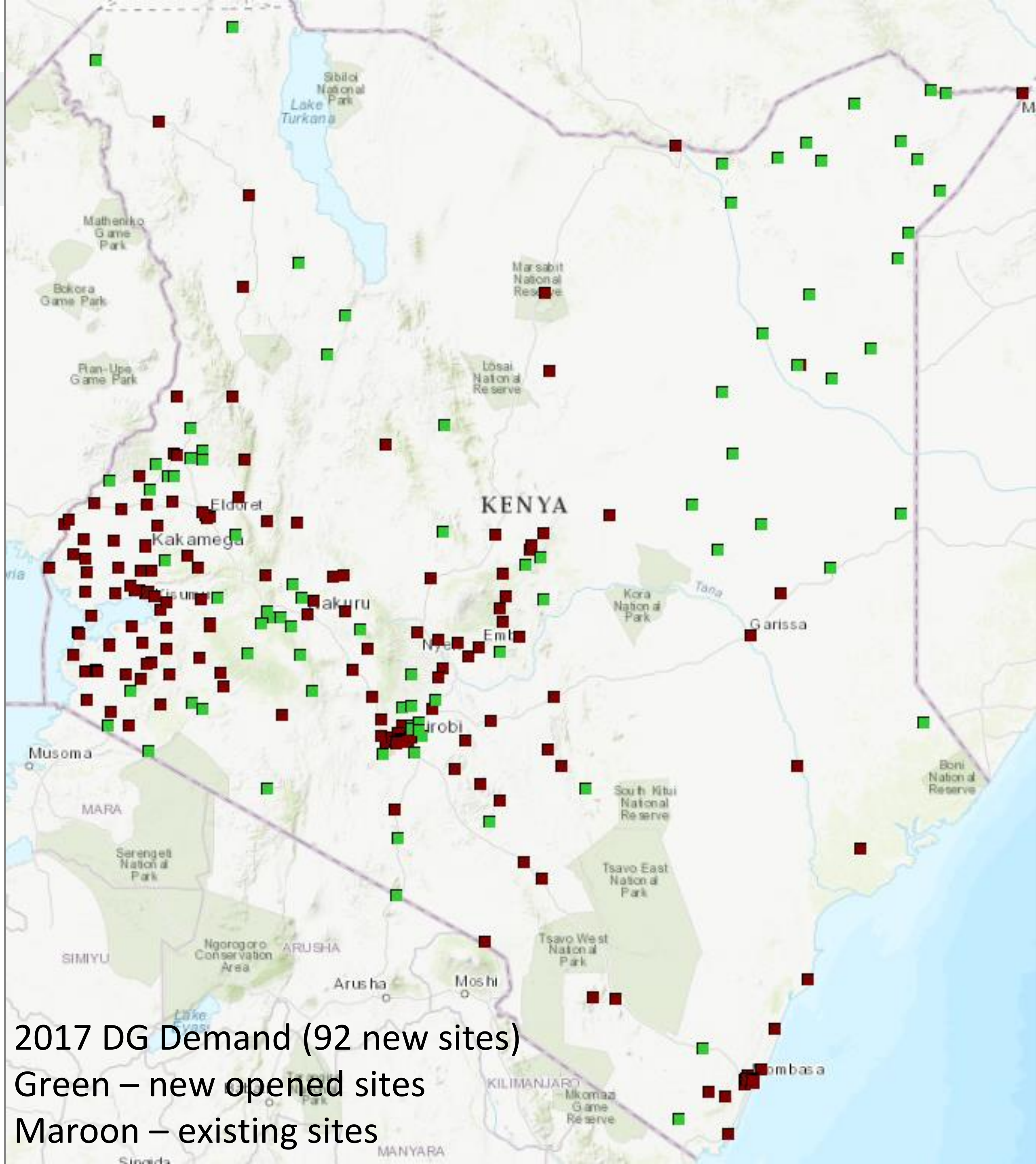
County	# new sites	County Type
WAJIR	10	Hard
MANDERA	8	Hard
NAKURU	6	Moderate
KIAMBU	5	Easy
MACHAKOS	5	Moderate
WESTPOKOT	4	Hard
MURANGA	4	Easy

With **DG demand**, 92 new sites, listing all counties with more than 3 machines added
34 of 92 new machines added to hard-to-reach
(all recommended GX-4)

County	# new sites	County Type
NAROK	9	Hard
TURKANA	7	Hard
SIAYA	5	Easy
MURANGA	5	Easy
KILIFI	4	Moderate

With **PG demand**, 55 new sites, listing all counties with more than 3 machines added
25 of 55 new machines added to hard-to-reach

Full listing of 2021 recommended sites – see slide 54



2021 – where do we add new sites? – full list

Existing and
ntial Sites by Coun

What is distance from health facilities to Xpert sites in 2021?

- Allowing addition of new instruments leads to a reduction in average service distance compared with use of existing sites only, esp. in moderate and hard to reach counties
- However, in 2021, if we add the recommended number of machines (55 in PG and 92 in DG demand), we still have long service distances in hard to reach counties, double the national average
- As expected, easy to reach counties have lower average service distance (4.5 km from an Xpert site in 2021) than hard to reach counties (16-20 km away from an Xpert site)
- Table shows Average Service Distance (in km) from health facility to allocated Xpert site
- Refer to attached Excel for individual county data

Average Service Distance by County

	Average service distance (km)		
County Category	**2021 Using Existing* sites only**	**2021 PG demand**	**2021 DG Demand**
Easy	5.3	4.5	4.5
Moderate	11.0	8.6	8.3
Hard	28.5	21.7	16.1
National	13.1	9.3	8.0

How do we define access?

- Do we only consider turnaround time (TAT) with sample transport (1 week in hard to reach counties) or should we also consider the proximity of health facilities to nearest Xpert site when determining criteria for access?
- If we combine these elements we can set a **maximum service distance band**.
- Incorporating a maximum service delivery band will support the higher-end estimation for the number of sites recommended in hard to reach counties as it seeks to reduce the distance between health facilities and diagnostic services
- Incorporating the element of maximum service distance may also push towards placing smaller machines in some sites

How strong is the case for adding new instruments?

Considering operating costs and capacity utilization

- While the model chooses to add instruments (between 262-297 sites) as optimal, how strong is the case for adding machines?

- Overall annual operating costs are very similar for the optimal network (new instruments) and the extended current capacity network

- Estimated cost reduction of using the optimal number of sites is 2.5% - 6.4% of annual operating costs (approx. 1% of total network costs)
  - In absolute value that is 9M - 22M KSh
  - This may be an over-estimation as actual transport costs likely to lower when using multi-stop routes
  - Total network costs are mainly driven by costs that are not impacted by design-related factors (per test costs such as reagents and supplies)

- But adding new instruments requires significant capital outlay, can this be justified by improved service efficiency and access?

  - A high proportion of sites in the existing sites only model are running at very high capacity (12 tests or more)
  - Where addition of new sites is allowed, the added sites are well-utilized (6-12 tests per day)
  - Addition of new sites to hard to reach areas significantly reduces the average distance to an Xpert site (see later for data on Average Service Distance)

How strong is the case for adding new instruments?

Considering demand projection approaches

- Which demand projection approach do we consider most likely to give us the best estimate of demand for 2021?
  - PG assumes growth in demand for testing follows the national average county contribution to cases in 2017, whereas DG assumes a differential growth in testing across counties
  - As noted previously, as a general guiding principle, DG tends to give a higher future demand estimate in hard to reach (lower burden) counties while high burden counties tend to have a lower future demand estimate using DG.
  - Use of DG projections (or an intermediate between PG and DG) provides stronger justification for additional instruments

Summary: 2021

- The model recommends up to approximately 300 sites for the 2021 optimized network
- Operationalizing the findings of the diagnostic network optimization analysis for 2021 will rely on balancing trade-offs associated with different options
- Various considerations are required in weighing up options for operationalization including, capital costs for new devices and resources needed for management of a larger device fleet balanced against the operational feasibility of establishing and maintaining efficient sample referral systems needed to deliver targeted turnaround times (esp. in hard to reach counties) and the feasibility of operating extra shifts at many more sites than currently.
- Incorporating maximum service distance and using the differential growth projections for 2021 demand would tend to favour the higher end recommendation for number of Xpert sites
- Consideration of the detailed county level analytical outputs provided is strongly recommended for inform operationalization of the findings
- Furthermore, the above analysis is only considering demand for TB testing only. Since plans for integration with EID testing are already underway we should also consider EID demand when decision-making. (Initial work on integrating EID demand on the GeneXpert platform is reported later in presentation)

2023

How many sites and what placement does the model recommend for 2023?

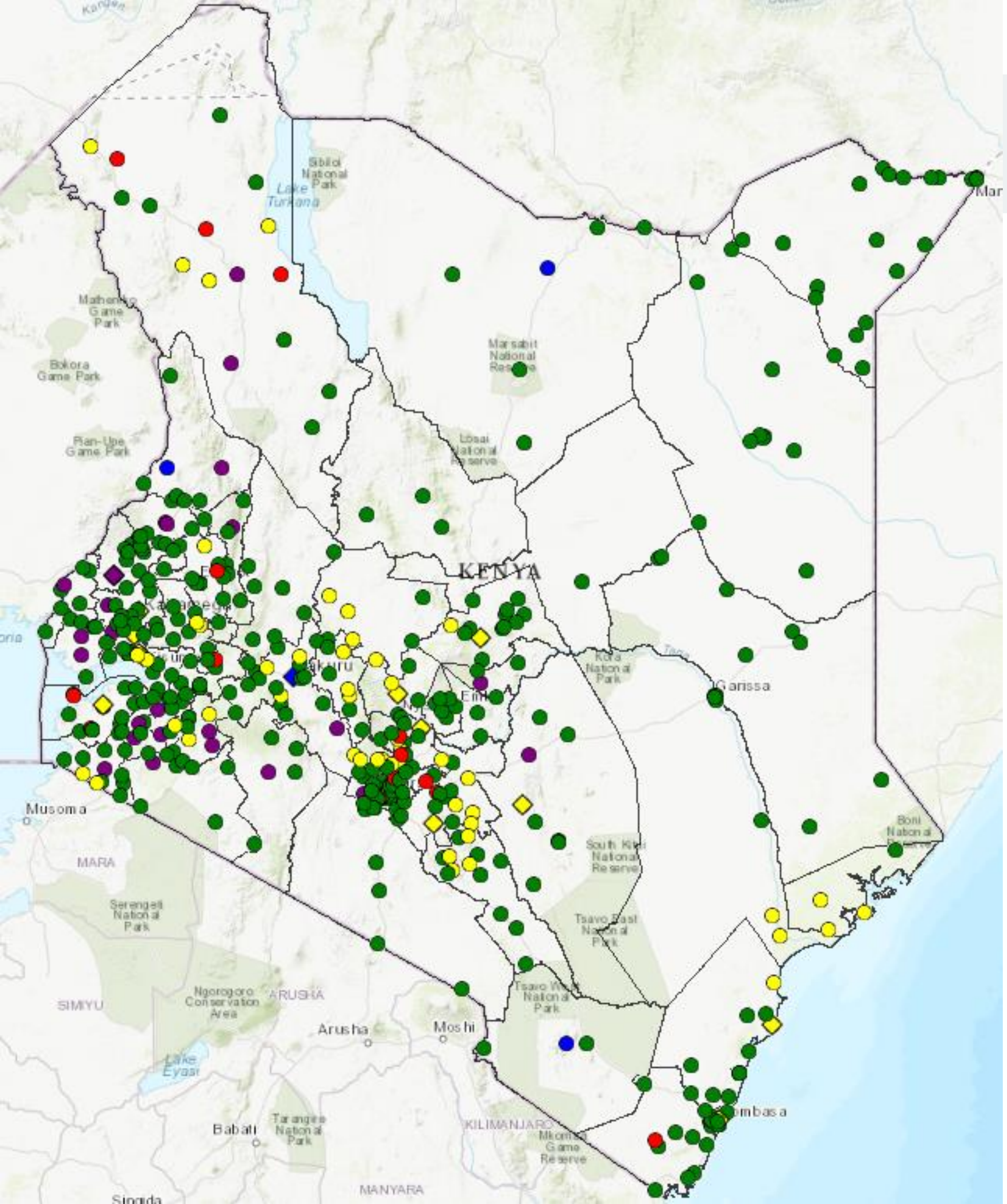
- For 2023, we allow the model free choice of placing an Xpert at any current TB treatment site. How many sites does the model choose as optimal?

  -The model chooses just under 500 sites (497 sites) as optimal for 2023

- How big is the benefit from having the optimal number of Xpert sites, vs. less sites?

  -For 2023, there starts to be a steep increase in costs below 450 sites, suggesting between 450 and 500 sites should be considered

- We have also run sensitivity tests with transport costs. Multi-stop routes are expected to reduce costs to a factor of one-half in easy-to-reach counties and a factor of one-fourth in hard-to-reach counties.
- Even with transport cost sensitivity tests, the model still recommends over 450 sites.



Distribution and utilization of Xpert testing sites 2023 DG demand, existing and new potential sites

- 497 sites used
- Majority of sites perform 6-12 tests per day
- Utilization of capacity is generally well distributed across the country

Key: (Color: Utilization) – Circles (GX4) and Diamonds (GX16)

Red:	<4 tests/day for GX4 and <12 tests/day for GX16
Yellow:	4-8 tests/day for GX4 and 12-24 tests/day for GX16
Green:	8-12 tests/day for GX4 and 24-36 tests/day for GX16
Blue:	12-16 tests/day for GX4 and 36-48 tests/day for GX16
Purple:	over 16 tests/day for GX4 and 48 tests/day for GX1
Light Gray:	Not used

All utilization calculations consider 12 tests/day capacity per GX IV and 240 working days. 48 tests/day for GX XVI.

What is the size/utilization profile for 2023 DG demand?

	Annual Number of Tests	Tests per day	Implied Machine Size or Extra Shifts	Number of Sites	Notes
Existing	Less than 1440	Less than 6 tests/day	GX2 or smaller	15	Not in hard-to-reach areas, but rather counties with lots of capacity (e.g. Nairobi, Kisumu)
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	148	117 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or using existing GX16s	42	3 of the GX16 used to 11520 tests, full single shift capacity
	Total			**205**	
Potential New Sites	Less than 1440	Less than 6 tests/day	GX2 or smaller	26	These are in a mix of hard to reach counties (Turkana) and moderate counties (Laikipia, Machakos)
	Between 1440 and 2880	6-12 tests/day	GX4 single shift	265	193 of these used to full capacity of 2880 tests/year or 12 tests/day
	More than 2880	More than 12 tests/day	Extra shifts at GX4 or adding GX16s	1	1 single larger site added used to 3840 tests
	Total			**292**	

What is distance from health facilities to Xpert sites in 2023?

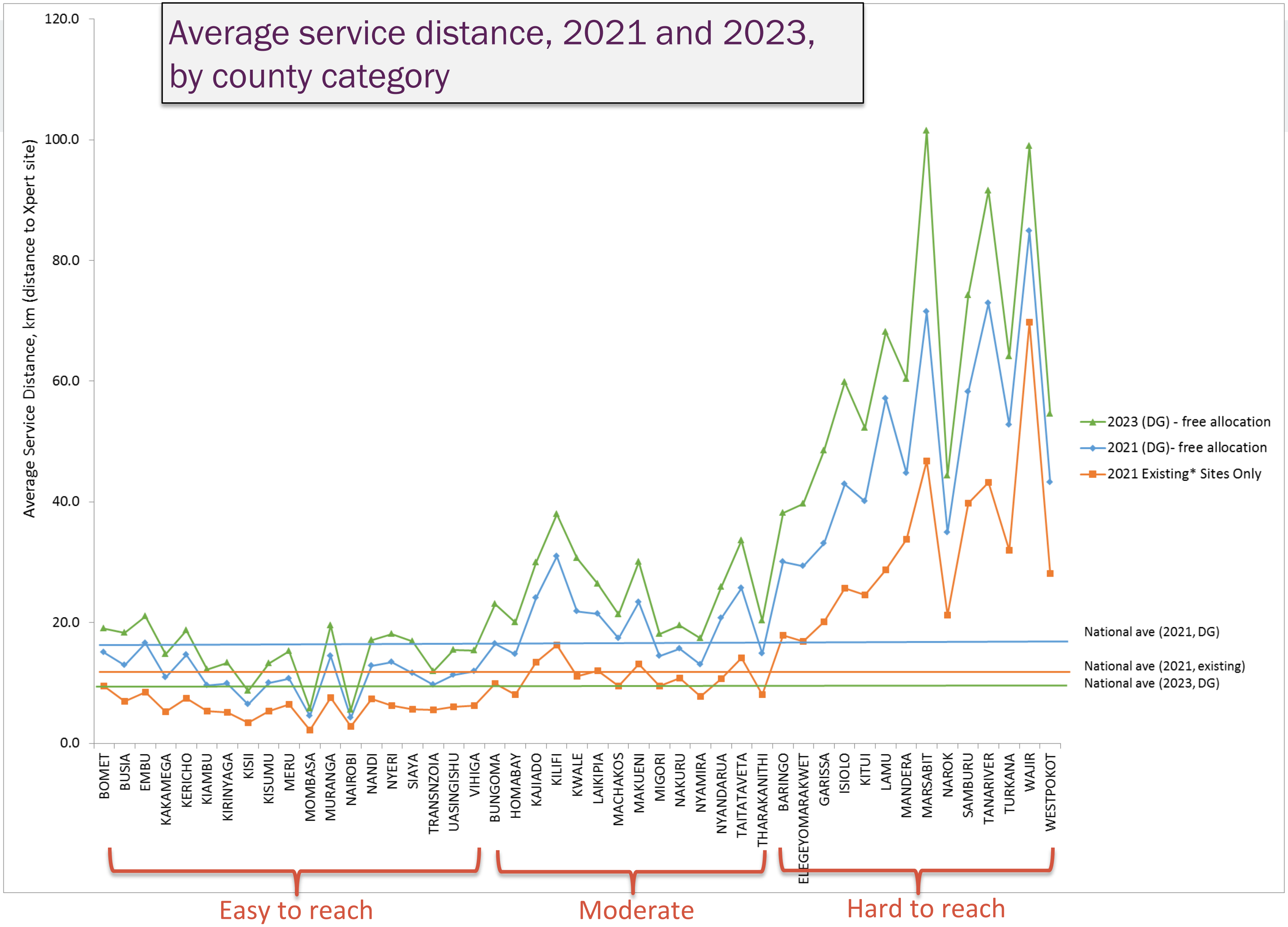
- In 2023, if we add the recommended number of machines the average distance to an Xpert site is further reduced compared with 2021 (less than half the distance compared with 2021 existing sites model nationally and for moderate and hard to reach counties)

- Table shows Average Service Distance (in km) from health facility to allocated Xpert site
- Refer to attached Excel for individual county data

Average Service Distance by County

	Average service distance (km)			
County Category	2021 Using Existing* sites only	2021 PG demand	2021 DG Demand	2023
Easy	5.3	4.5	4.5	3.3
Moderate	11.0	8.6	8.3	5.4
Hard	28.5	21.7	16.1	12.8
National	13.1	9.3	8.0	6.0

Average service distance, 2021 and 2023, by county category



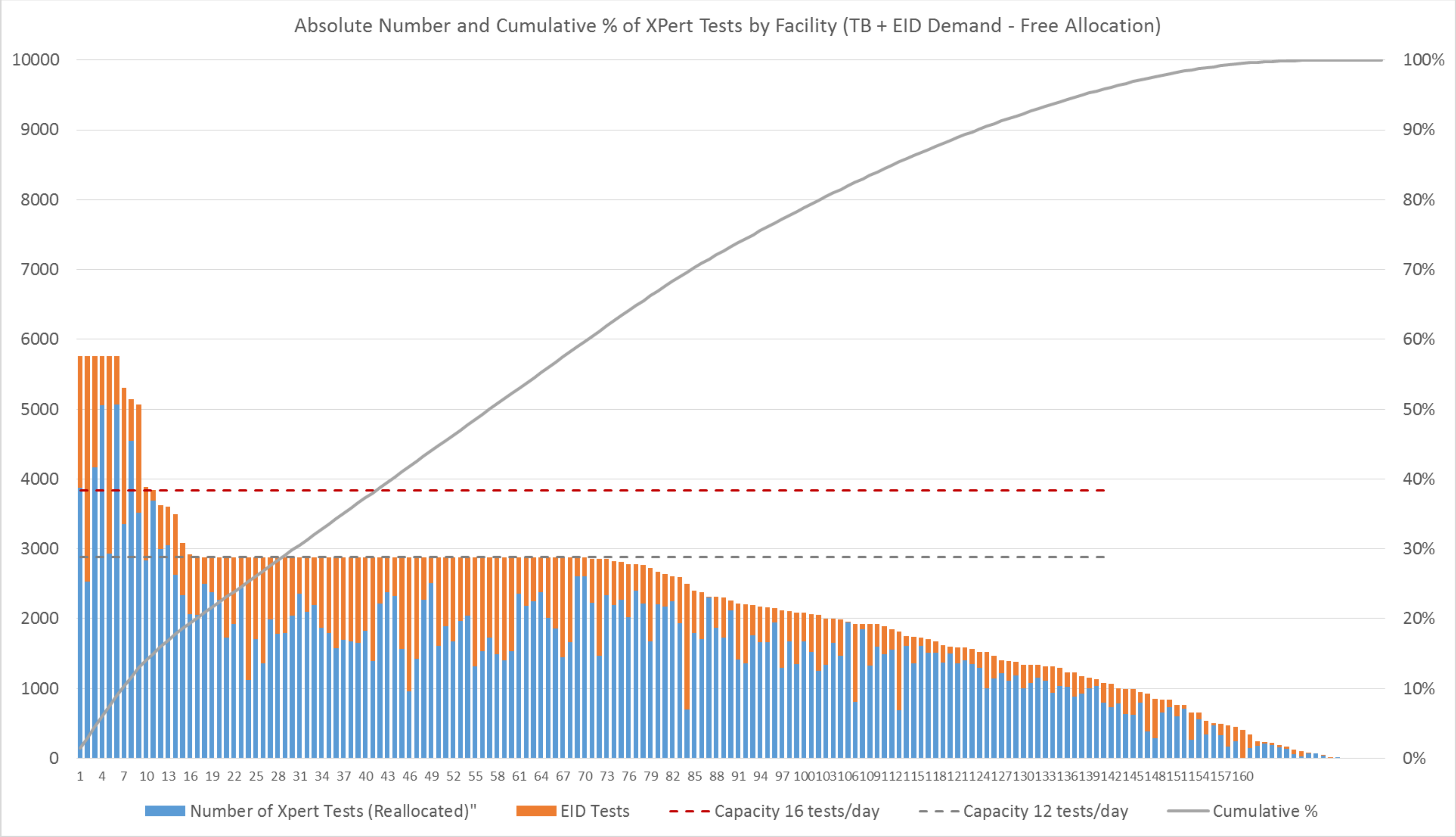
Summary: 2023

- There is strong justification for increasing the number of sites to 450-500 for 2023, even when considering TB demand only

- Depending on the plans and trajectory for EID testing, a higher number of instruments, or larger instruments may need to be considered (full analysis of future EID demand should be conducted in future)

Contents

Adding 2017 EID demand to 2017 TB demand at existing GeneXpert sites



- EID tests from 2017 (Initial PCR + 2nd and 3rd PCR) across all counties in Kenya totaled 110,202 tests*
- This scenario considered allocation of TB & EID demand in parallel and allowed referral across counties
- 6 sites are still not used. Only 16 sites are used at levels above 2880 tests. 53 sites below 1440 tests.
- With the addition of EID, utilization of the network capacity increases substantially, but there is still capacity to allow substantial testing growth

* https://eid.nascop.org

Significant county variation in EID demand

County	No of Xpert Tests (actual)	No of Xpert Tests (Data Guru Estimate)	EID No of Tests **– Initial PCR only**	% Increase in Xpert Test (actual + EID test)	% Increase in Xpert Test (DG Estimate + EID test)
MIGORI	6,427	6,924	5,554	86%	80%
HOMABAY	8,446	8,334	6,616	78%	79%
SIAYA	14,545	14,467	7,313	50%	51%
KISUMU	19,901	19,668	7,033	35%	36%
KAKAMEGA	9,556	9,825	2,698	28%	27%
TURKANA	2,751	2,990	747	27%	25%
BUSIA	5,746	5,652	1,415	25%	25%
VIHIGA	3,548	3,904	862	24%	22%
BUNGOMA	6,291	6,678	1,370	22%	21%
MERU	8,060	8,352	1,369	17%	16%
NYAMIRA	5,335	5,196	633	12%	12%
WAJIR	969	1,011	14	1%	1%

Orange: Hard to Reach Counties

- Nationally, the EID Initial PCR demand of ~110,000 tests, represents about a 40% increase over existing Xpert test volumes (~275,000 tests).
- This masks important variation across counties. Looking at the 12 initial priority counties, the addition of EID test volumes represent widely varying increases on existing Xpert volumes

Enabling integrated planning for TB & HIV referral systems

Zoom in on Homa Bay county area

TB flows in purple, EID flows in orange

Shows an example of how TB and EID flows would operate together (EID referrals coming only from EID and PMTCT sites)

EID integration : looking forward to 2021

- Using available information to project the volume of EID tests for 2021 (Initial PCR + 2nd and 3rd PCR)
  - 2017 across all counties in Kenya totaled 110,202 tests
  - If we apply an annual growth of 30%, we will have 314K EID tests in 2021
  - If we apply an annual growth of 10%, we will have 161K EID tests in 2021
- Follow-up work can consider refined look into EID demand
- For now, we have run scenarios with both of the above demand projections to see the effect
- With an annual 30% increase, so an additional 314K EID tests on the Xpert network, the model recommends 298 sites (each used to a higher utilization). With this assumption and full-transport costs, there is a big gain from adding sites. The difference between using 2021 existing sites only and the optimal number of sites is 15%-20% of annual operating costs (that can be affected by the network design). This is about 100M KeSh or 1M USD. On the basis of this, there seems to be a case to consider adding extra machines for 2021
- However, when we consider the lower EID demand (a 10% annual increase) the case becomes much weaker. The model still chooses the same number of sites as optimal, but now the benefit is reduced to 11% or ~50M KeSh or ~500K USD
- When we consider lower transport costs, as would be realized by multi-stop routes (e.g 1/3 of current point-to-point costs) the benefit of adding additional sites reduces greatly to 8% (of a lowered total cost) or only 25M KeSh or ~250K USD.
- When you consider that the test costs (cartridge and results printing) alone in 2021 will be over 10M USD, these differences are seen to be small

Contents

Additional Culture/DST/LPA facilities - inputs

- Current capacity for culture/DST/LPA is at 2 sites, namely NTRL, Nairobi and CDC KEMRI laboratory, Kisumu
- Seven additional sites are being considered for future implementation (Machakos, Kitale, Homabay, Malindi (Kilifi), Wajir, Walter Reed and MTRH)
- Estimated demand for culture, DST and LPA testing:

Type of test	Yr 2017	Yr 2021	Yr 2023
Culture (Dx+monitoring)	**9,175**	**10,128**	**11,275**
No of FL DST	782	841	1,202
No of FL LPA	782	841	1,202
No of SL DST	-	84	120
No of SL LPA	-	84	120

- Total DST demand = FL DST + SL DST, total LPA demand = FL LPA + SL LPA
- Assumptions in calculating demand

  NSP targets for number of DR-TB patients used; all Xpert RIF R patients referred for culture, DST and LPA, FL DST for all Xpert RIF R and SL DST & LPA for all RIF R on FL DST; Xpert RIF S patients at high risk of DR-TB also referred for culture, DST/LPA

  2017 – average 12 cultures per year for treatment monitoring for DR-TB patients

  2021 & 2023 – average 6 cultures per year for treatment monitoring for DR-TB, based on expected scale up of shorter regimens

  Assume 75% of MGIT capacity is utilized for culture, 25% for DST

Additional Culture/DST/LPA facilities – model outputs

- If all planned culture facilities are established, average utilization of testing capacity will be only 10-15% per site (<1000 samples per year)
  - This is close to the recommended minimum threshold stipulated by GLI that is required to maintain proficiency in culture/DST (minimum 20 specimens per week)
  - Furthermore it is challenging to maintain infrastructure requirements and equipment service & maintenance costs for a larger number of labs
- If we allow the model to consider whether or not to use the proposed additional sites, it choses to open only 2 additional sites (Wajir and Kilifi) for culture
- If adopted, the following % utilization of culture facilities would apply:

Facility	2021	2023
NTRL	846	984
CDC KEMRI	4453	5041
Wajir	3944	4243
Kilifi	1056	1112

For DST and LPA, no additional sites are recommended based on the demand, but it may be practical to maintain the same referral patterns for all tests and therefore they can be added at the locations of the two proposed culture sites (Kilifi and Wajir).

Contents

Summary & Recommendations

- There is sufficient network capacity to meet current TB demand; capacity is largely well placed. Establishing a sample referral network based on the recommended model will enable scale up of testing to find the missing cases
- Transport legs remain long in hard to reach counties even with an optimized network design, therefore procurement of additional devices appears warranted

- 2021 findings show that two alternative approaches to network strengthening are suggested that have similar overall annual operating costs.
  - The optimal model involves a total of approximately 300 sites, but requires procurement of 50-90 new instruments.
  - The alternative (near-optimal) model utilizes existing capacity but relies on the ability to scale up shift work at a significant number of new facilities, to partner extensively with private sector, and importantly to be able to operationalize efficient sample referral systems in some challenging environments.
  - Hard to reach countries are prioritized for placement of new instruments, in addition to some high burden countries (easy to reach)
  - If integration of EID testing is included, the additional instruments will be necessary

- Contextual factors and reducing maximum service distances in hard to reach areas would tend to favour procurement of new instruments. The number of instruments required and prioritization of sites for placement should be informed by review of the detailed county level model outputs by country experts

Summary & Recommendations

- For 2023 there is a strong justification for additional sites, between 450 and 500 Xpert sites in total are recommended, even when only TB demand is considered

- Integration of EID testing and significant scale up in testing volumes may require additional capacity

- However, uncertainty exists around future testing volumes calculated on the basis of NSP targets – the need for expanded lab capacity is highly dependent on generating demand for testing, i.e. by successfully scaling up screening and active case findings interventions
- Based on existing data, assumptions and targets for DR-TB, the model recommends a total of four culture/DST/LPA facilities would be adequate to meet demand up to 2023. Operational considerations linked with implementing this recommendation should be reviewed by local experts, together with other proposed network redesign options

- An interim re-analysis of the network model in mid-late 2020 is strongly recommended, using 2018-2020 data, to enable updated recommendations to inform future procurement and placement decisions

- The proposed network optimizations contribute towards enabling a more patient-centric and efficient diagnostic network with greater and better-placed capacity to diagnose missing cases and improved access to services by reducing the distance from health facilities to Xpert testing sites

Contents

Next steps

- Expanded analysis on HIV/TB testing integration:
  - Support the establishment of policy for integrated sites (e.g. prioritization of TB or EID testing)
  - Recommend sites that will require expanded testing capacity & sample referral design
- Updated demand estimation analysis using 2018 data based on roll out of ACF and other interventions since 2017
- Include additional diagnostic scenarios (e.g. use of CXR prior to Xpert)
- Overlaying network optimization with work from other groups, e.g. transmission modelling, sub-national incidence estimation, MATCH
- Detailed sample referral system design at county level
- Building capacity of local team to use outputs for decision-making
- Impact evaluation of changes made to the network based on diagnostic network optimization outputs

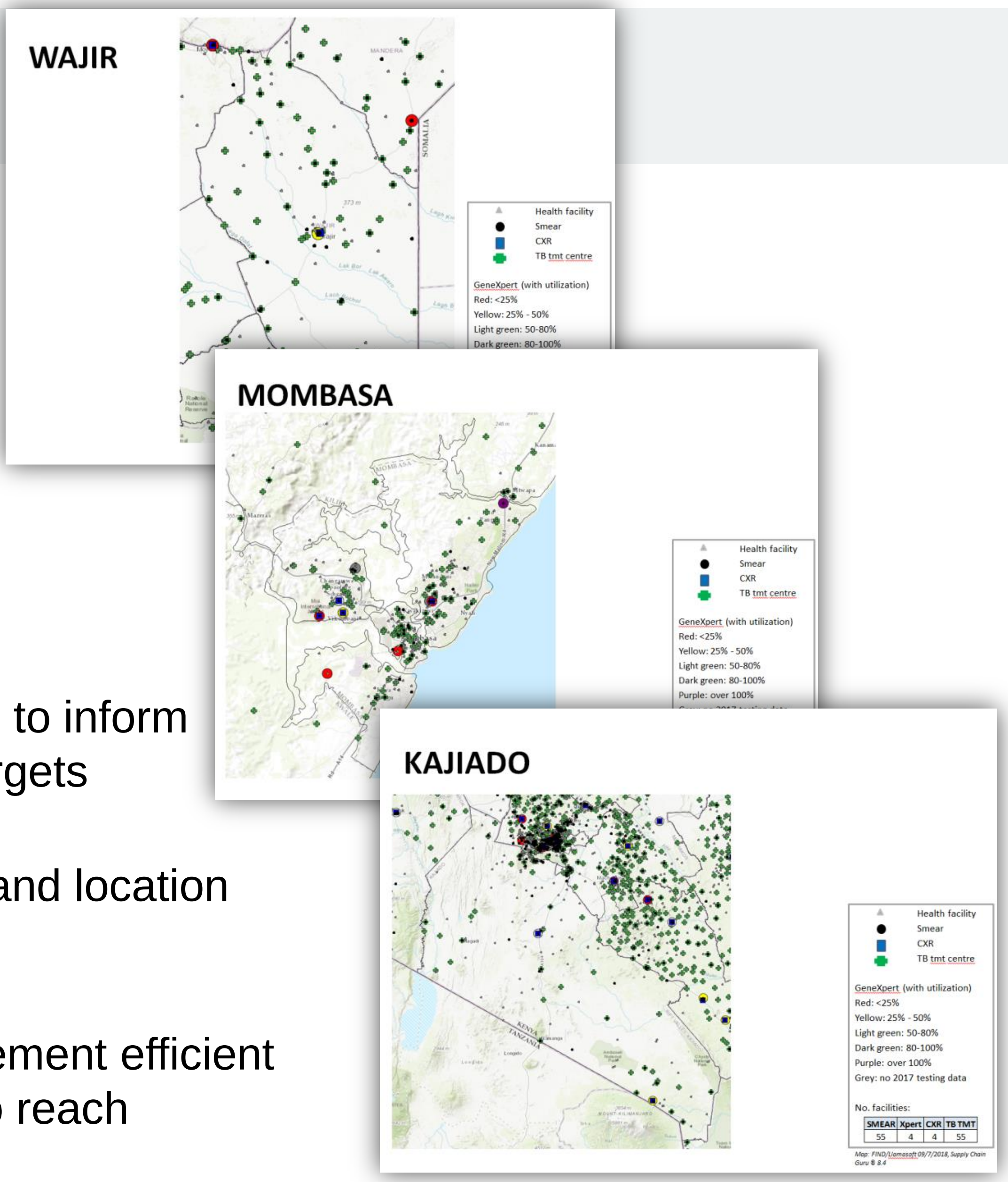
Programmatic impact

- Supporting key NSP strategies:
  - Continued expansion of Xpert MTB/RIF as the initial diagnostic test
  - Building an efficient sample transport system (SRS) to increase access to DX services
  - Exploring TB/HIV integration for sample referral and testing on GX platform

- Network optimization is embedded in NSP development process to inform development of the diagnostic strategy towards meeting NSP targets

- Developed county level maps with baseline diagnostic capacity and location which will be used for county operational planning

- Working with NTP & partners to refine the SRS design and implement efficient sample referral in selected counties (easy, moderate and hard to reach regions)



Conclusions

- Diagnostic network optimization is a novel analytical approach which enables use of available country data to inform rational evidence-based decision-making on optimizing access to TB diagnostic services in support of finding the missing TB cases

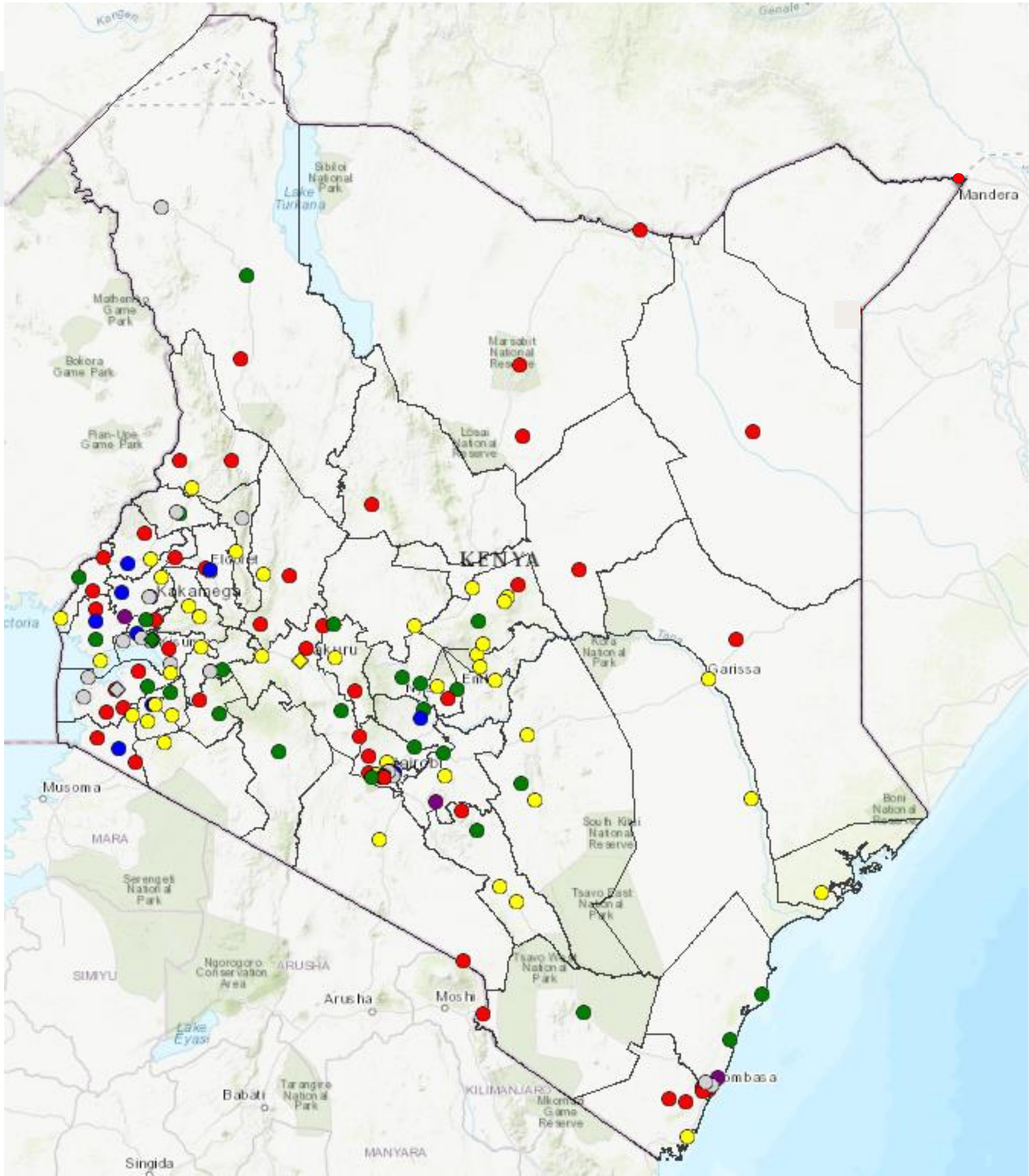
- Diagnostic network optimization allows a differentiated approach to be used to account for sub-national differences and preferences, enabling pragmatic and action-oriented recommendations to be developed

- As with any analytical approach, the findings should be reviewed to determine the feasibility for operationalization, and accounting for the impact of uncertainties in some data sources and sensitivity analysis around key inputs

- Tracking the uptake of diagnostic network optimization recommendations and their impact on the overall network “health” in terms of access, quality and coverage, will be critical to demonstrate the value of the approach to building patient-centred and efficient diagnostic networks

2017

baseline

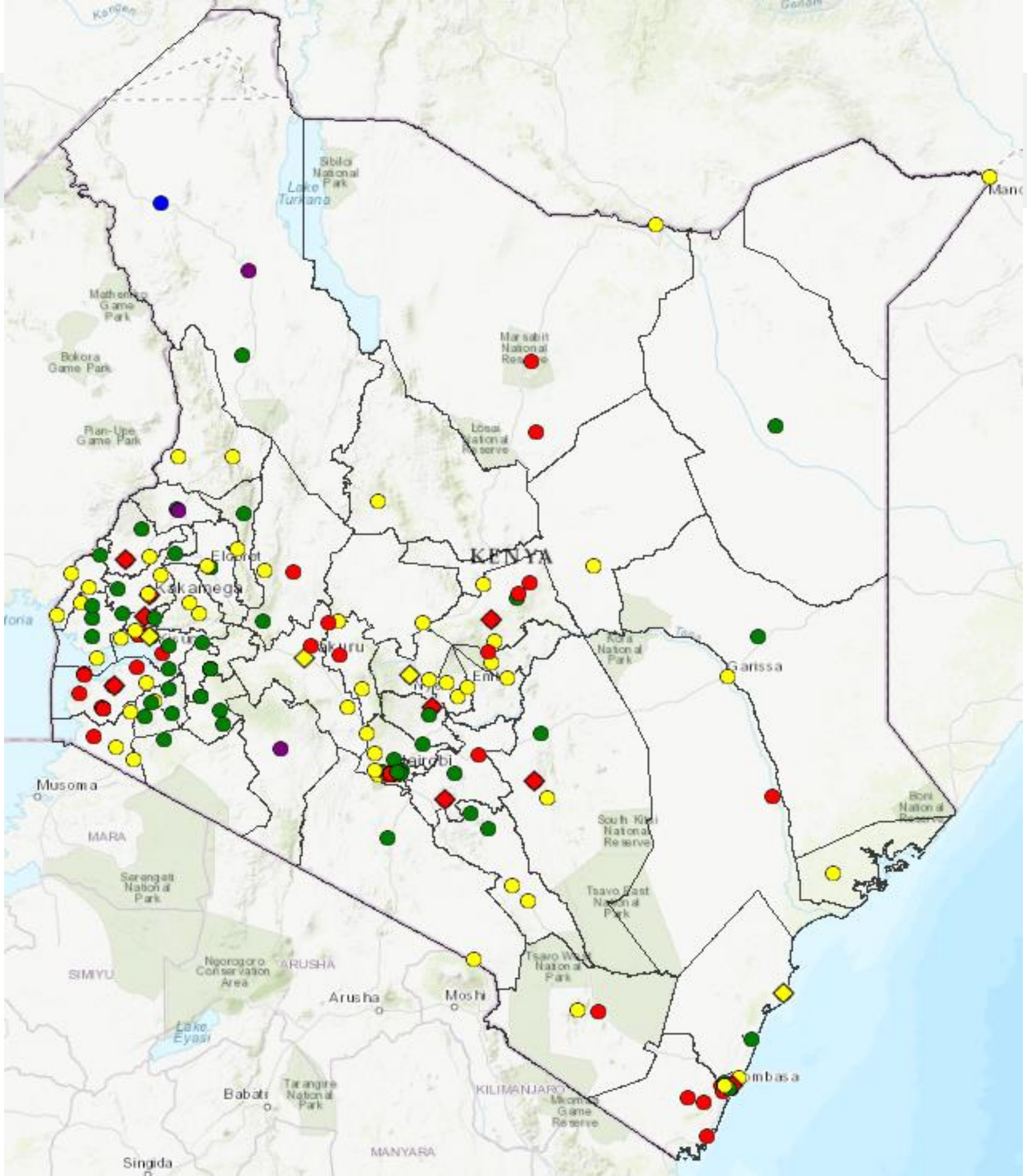


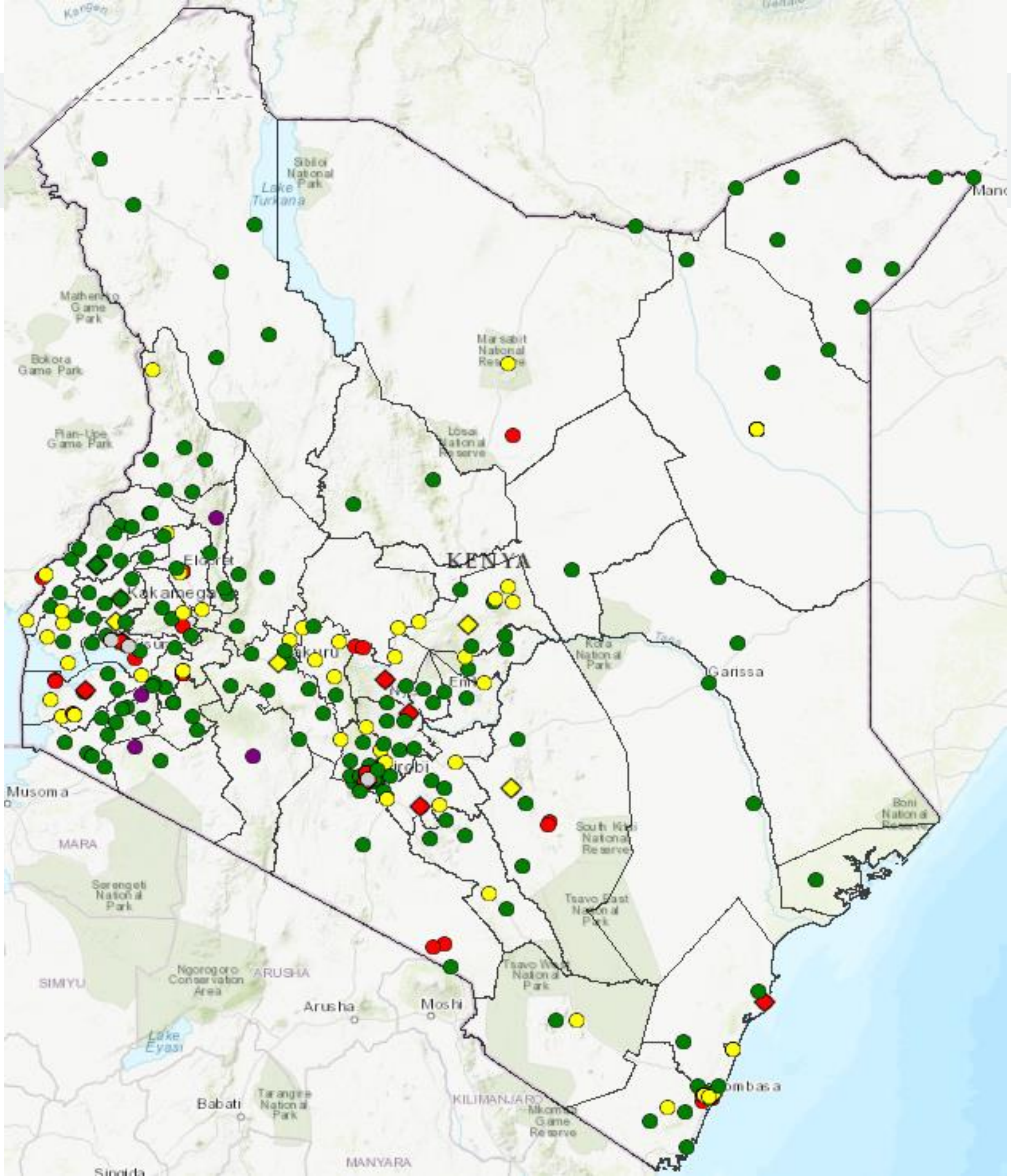
Visualizing recommended TB diagnostic network evolution, 2017-2023

Visualizing recommended TB diagnostic network evolution, 2017-2023

2017

optimized



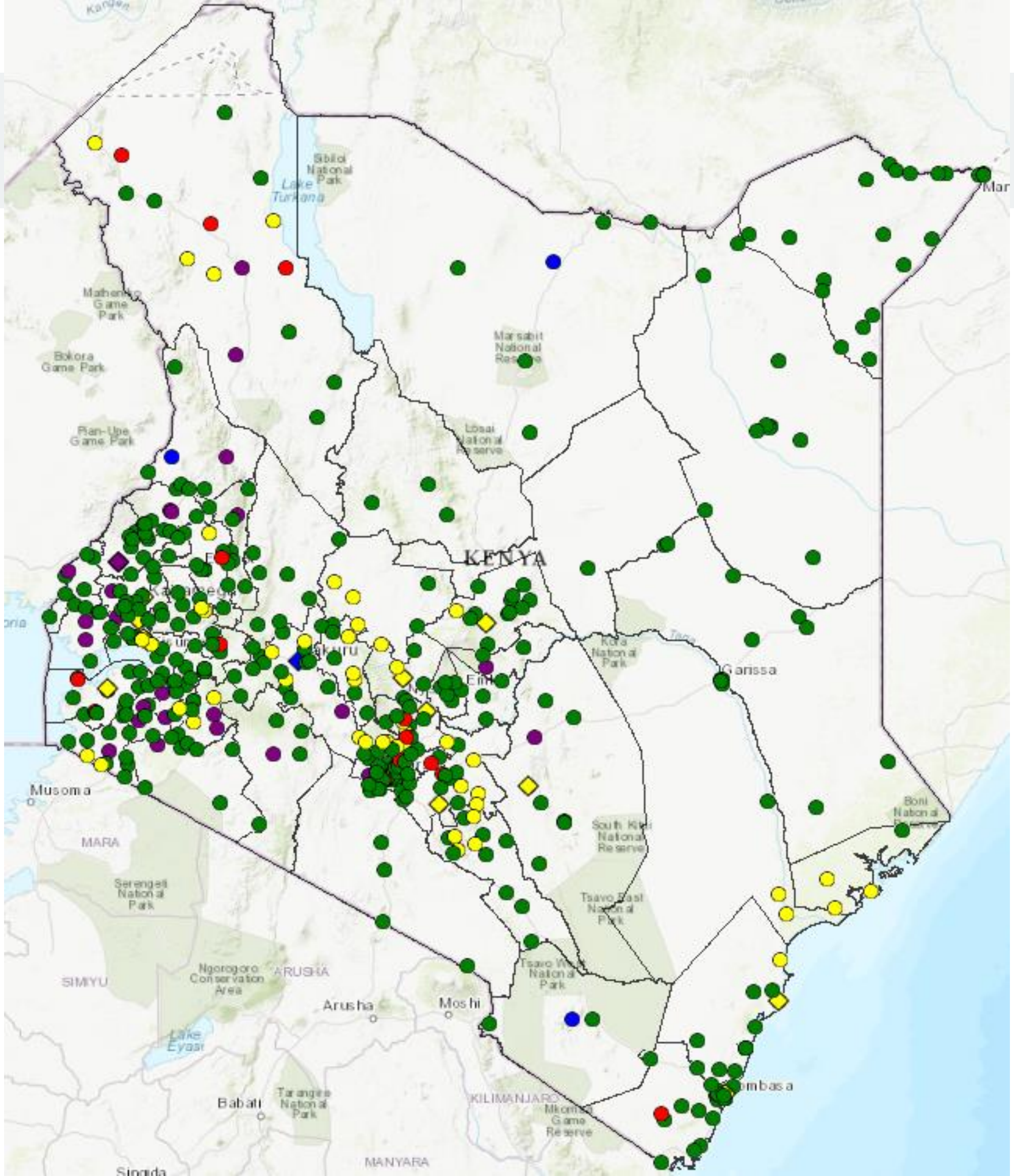


Visualizing recommended TB diagnostic network evolution, 2017-2023

2021

DG

Visualizing recommended TB diagnostic network evolution, 2017-2023



2023

DG

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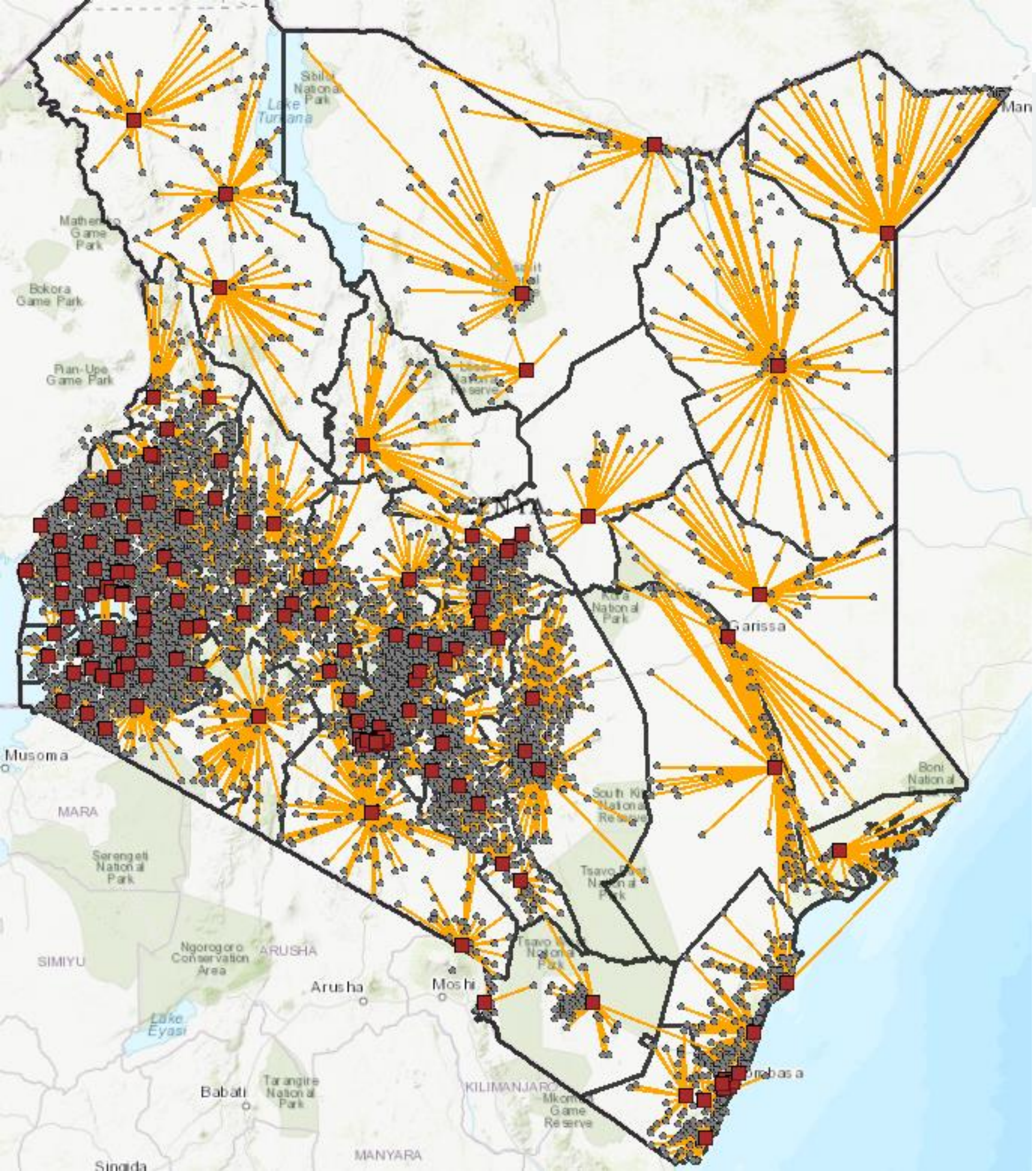
Supplementary information



What if TB demand could only be referred within same county?

- Transport costs increase by 21%
- This is because instead of referring to nearest site, we now have to go to site within the same county. For many HFs, there is an increase in distance.
- See example of Garissa and Tana River with Xpert sites right on the border and many HFs having distance increases because of county restriction

Consensus priority scenarios for Kenya network optimization (1)

DEMAND LEVEL					
		Baseline (2017)	Mid-point (2021)	Total (2023)	Policy-relevant questions
SAMPLE REFERRAL	Capacity	▪ Current equipment & placement ▪ Free allocation of current equipment to any TB tmt centre (at least 1 instrument per county)	▪ Free allocation of current equipment to any TB tmt centre (at least 1 instrument per county) ▪ Free choice of any equipment type & placement to any TB tmt centre (at least 1 instrument per county) ▪ Iterations of scenarios based on findings	▪ Best option from 2021	• What is the current capacity of the network and to what extent can it meet future demand? • What is the best device placement and referral network design for current equipment and an "ideal" device footprint to meet current and 2021 demand? • Where the model suggests benefit of reallocation, consider operational feasibility
	Turnaround time	▪ 2 day (easy to reach) ▪ 4 day (moderate) ▪ 7 days (hard to reach)	▪ 2 day (easy to reach) ▪ 4 day (moderate) ▪ 7 days (hard to reach)	▪ 2 day (easy to reach) ▪ 4 day (moderate) ▪ 7 days (hard to reach)	• Can recommended approaches to sample referral network and device placement enable target TATs to be reached?
	Cross county referrals	▪ Within county referral ▪ Cross county referral allowed ▪ Cross county referral in South, within county in North	▪ Within county referral ▪ Cross county referral allowed ▪ Cross county referral in South, within county in North	▪ Best option from 2021	▪ What impact on DX access and network efficiency does considering cross-country referrals bring? ▪ Where the model suggests high potential impact, consider operational feasibility

Consensus priority scenarios for Kenya network optimization (2)

DEMAND LEVEL				
	Baseline (2017)	Mid-point (2021)	Total (2023)	Policy-relevant questions
EID INTEGRATION	▪ National EID demand (all EID testing) ▪ Optimal location of 9 GX-16 & 9 displaced GX-4 ▪ Allocation for EID & TB demand in parallel	▪ National EID demand (projection to 2021, all EID testing) ▪ Optimal location of 9 GX-16 & all GX-4 ▪ Allocation for EID & TB demand in parallel	-	• Where should Xpert devices be placed to optimally meet needs of TB and EID testing demand? • What is the best design for an integrated sample referral system for TB and EID? • Considering future demand for TB (based on scale up of facility ACF), how much and where is spare capacity than can be leveraged for EID testing?
CHEST X-RAY	-	▪ Best sample referral design & CXR versus no CXR (on-site CXR at public sector sites only)	-	• Can utilization of existing CXR services as a triage test prior to Xpert improve impact and efficiency of the diagnostic algorithm? • How does inclusion of CXR impact the optimal network design for Xpert?
ADDITIONAL CULTURE/LPA/DST LABS	-	▪ Compare current & planned referral with model county-wise allocation	-	• Do the NTP plans for new culture labs meet the expected future demand for testing? • Are the planned referral patterns optimal?

Developed and approved at NTP Stakeholder's workshop, Nairobi, August 2018

Scenarios considered but not included

- **Full analysis of EID integration**
  - using comprehensive demand estimation method, costing of Xpert and traditional EID to examine cost-benefit of integration
- **Full analysis of public-private referral mechanisms**
  - consider when more data available on private sector capacity and location
- **Full analysis of chest X-ray integration into algorithm**
  - consider following CXR modelling work and when more data available, esp. private sector X-ray location
- **VL integration**
  - consider as follow on project

2021 Output Xpert Site Utilizations – by county category

DG Demand

Type	Total Number of Xpert sites	% of total demand	Tests/Day per Site on Average
Easy	152	44%	8
Hard	62	26%	12
Moderate	83	30%	10
Total	**297**	**100%**	

PG Demand

Type	Total Number of Xpert sites	% of total demand	Tests/Day per Site on Average
Easy	139	52%	11
Hard	53	21%	11
Moderate	70	26%	11
Total	**262**	**100%**	