

# Integrating and Optimising Laboratory Services: Innovations in Results Access and Programme Performance Monitoring

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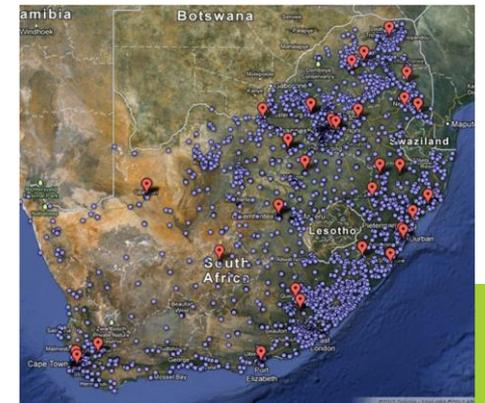
**Naseem Cassim**

*National Health Laboratory Service*

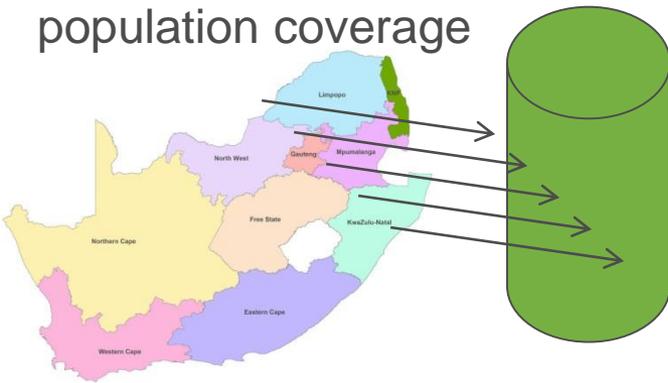
*and*

# Summary of NHLS laboratory landscape

- ~2million Xpert MTB/RIF tests in 207
- ~0.56million Liquid culture (16 labs)
- ~1.0million smear microscopy tests
- ~ 3.9 million CD4 tests in 60 laboratories
- ~ 4 million viral loads and 16 PCR laboratories
- ~360 000 EID tests in 16 PCR laboratories.



Big NHLS data: 90% population coverage



Analysis

Dashboards **for** program and patient management: patient, facility....national

Push result

Linkage to Care **for** LTFU

Service

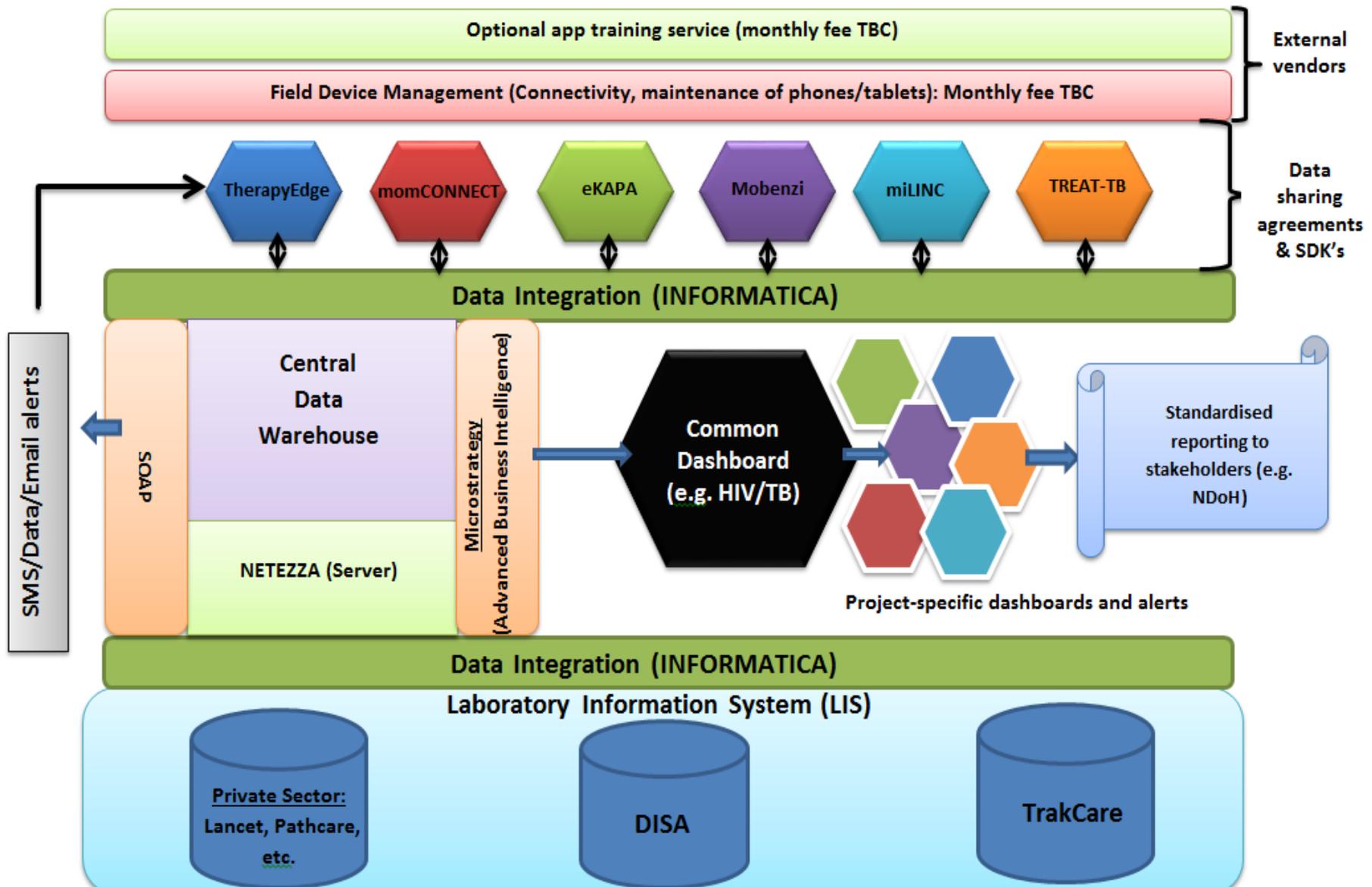
Coverage and implementation **for** service deliver

- **Significant Point 1:** Laboratory “BIG Data” analysis and subsequent dashboard data development facilitates program management, covers 90% of the national data; national to facility to patient level.
- **Significant Point 2:** Linkage to care can be approached more proactively from the laboratory: mHealth, push out rather than passive provision of results: push vs. retrieval.
- **Significant Point 3:** National Coverage of viral load can be attained by a tiered model (integrated service delivery model), includes high end automation, DBS VL to point-of-care options.

Leveraging on existing NHLS, CDW framework

# South African mHealth-HUB

With compliments: Lynsey Isherwood



# CCMT M&E Operational dashboard

- Track ART rollout and align with SDG
- Analyse key HIV indicators spatially (national, provincial, district, facility) and temporally (weekly month, year)
- Highlight “red flags” as areas of concern
- Report facility indicators by VL&CD4%, age, sex,
- Laboratory indicators: volumes, utility, TAT,

## 1. Geo Analysis

Calendar View | Fiscal View



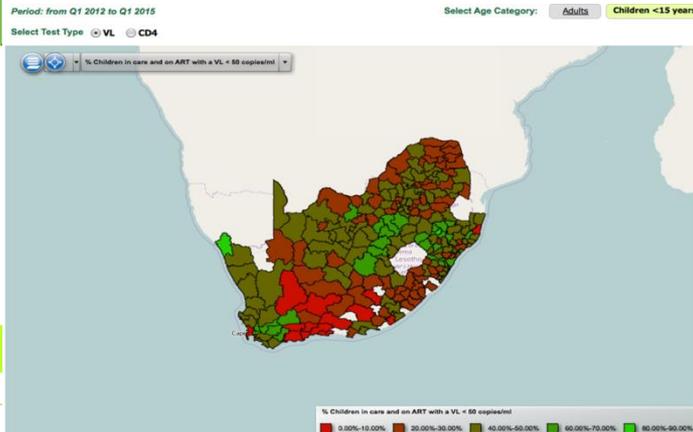
## 2. National & Provincial

Calendar View | Fiscal View



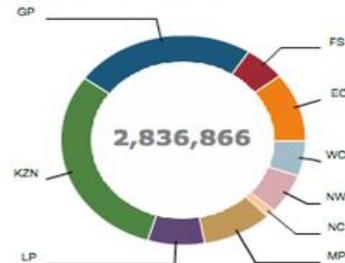
## 3. Indicators & Trends

Rolling 12 Months View

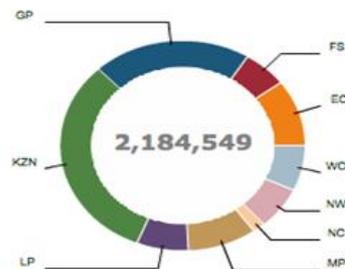


Period: from Q1 2012 to Q2 2015

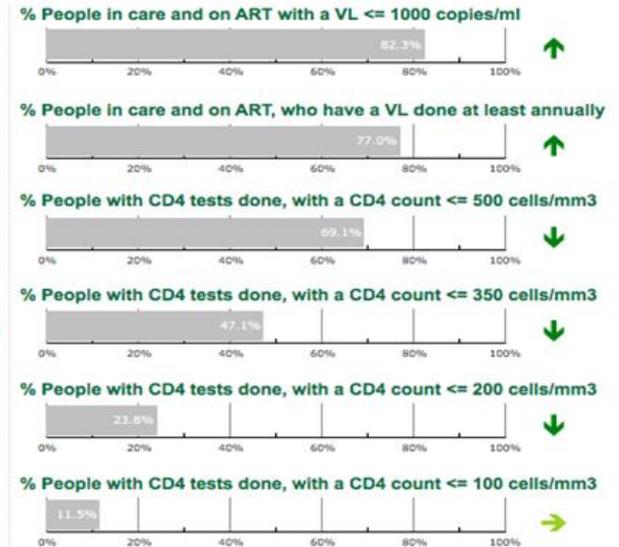
# People on treatment (DHIS)



# People with a VL test done in the last 12 months



Select Age Category:  Adults  Children <15 years



Output: National Summary Layout

Location: Folder

## National Summary of Dashboard

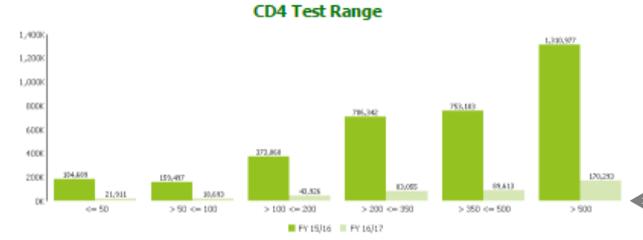
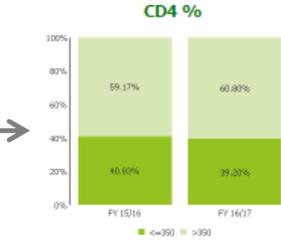
Step 1:

Select Test Type

NATIONAL HEALTH LABORATORY SERVICE **NPP CCMT Summary Report - CD4**

Test Type: **CD4**

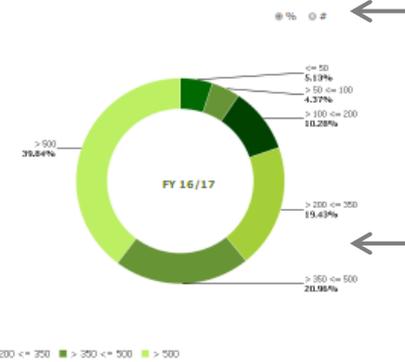
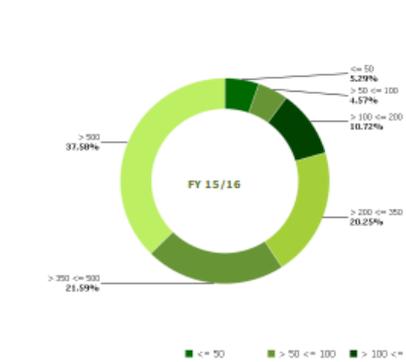
% and # (Values) of Summary Result Ranges for test types (based on selection): CD4, PCR, VL



Detailed Result Ranges yearly comparison

Year	<= 50	> 50 <= 100	> 100 <= 200	> 200 <= 350	> 350 <= 500	> 500	Total
FY 15/16	1,424,350	2,094,028	3,491,468	85,474	85,824	31,098	3,491,468
FY 16/17	187,985	259,908	427,491	70,539	11,788	59,352	427,491
Total	1,591,972	2,323,936	3,915,259	100,000	100,000	100,000	3,915,259

Year	<= 50	> 50 <= 100	> 100 <= 200	> 200 <= 350	> 350 <= 500	> 500	Total
FY 15/16	154,859	150,497	373,893	706,342	731,123	1,370,977	3,491,468
FY 16/17	21,911	76,663	43,928	83,025	89,813	170,253	427,491
Total	296,639	278,160	417,795	789,367	842,716	1,541,230	3,915,259



Option to view % or # (values)

Pie Chart displaying detailed result ranges for current and previous years.

### Additional Information

By selecting a test type, the user is able to view information for CD4, PCR and VL. All information is a year on year comparison. Information for current year is YTD (Year-to-date).

### Report Owner

User Name Division

### Report Developer

CDW Business Intelligence Team

# Viral Load exception Reports

## > 1000 cp/ml

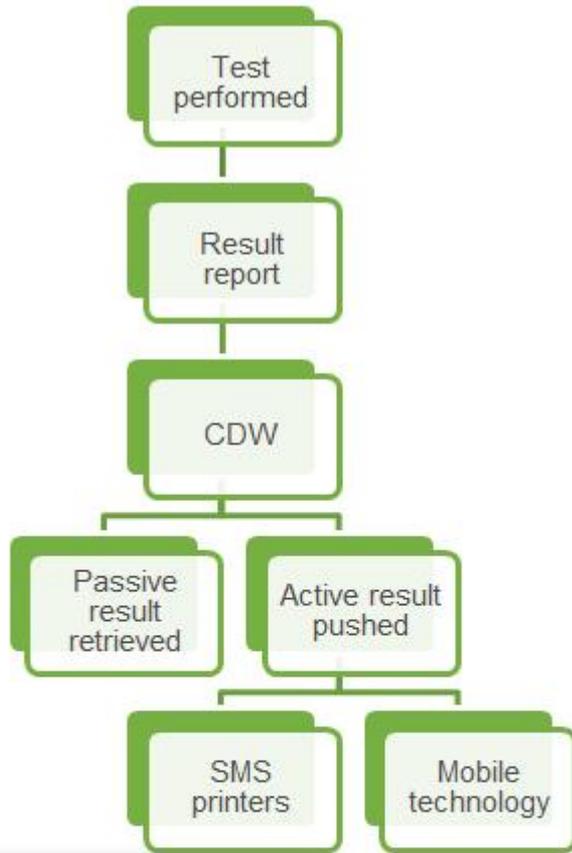
Ward	Folder Number	Patient Surname	Patient Name	Age	Episode No	Date Taken	Reviewed Date	Test Result VL >= 1000	log 10
Ward 58				54 years 7 months 12 days	HG03159335	29-FEB-2016	02-MAR-2016	315 000	5,50
Ward 58				27 years 2 days	HG03169787	03-MAR-2016	04-MAR-2016	12 500	4,10
Breast Clinic				38 years 11 months 14 days	HG03167411	02-MAR-2016	04-MAR-2016	35 300	4,55
Breast Clinic				Unknown	HG03166627	02-MAR-2016	04-MAR-2016	11 500	4,06
Ward G2				Unknown	HG03170604	03-MAR-2016	05-MAR-2016	9 340	3,97
Ward G2				45 years 1 day	HG03165836	02-MAR-2016	04-MAR-2016	41 700	4,62
Ward 38				Unknown	HG03151330	26-FEB-2016	29-FEB-2016	377 000	5,58
Ward 38				Unknown	HG03159061	29-FEB-2016	02-MAR-2016	2 920 000	6,47
Ward 38				30 years 5 months 20 days	HG03172733	03-MAR-2016	05-MAR-2016	3 450 000	6,54
Ward 36				2 years 19 days	HG03165555	02-MAR-2016	04-MAR-2016	3 038 849	6,48
Ward 36				1 year 10 days	HG03175736	04-MAR-2016	06-MAR-2016	2 130 940	6,33
Ward 35				Unknown	HG03154107	28-FEB-2016	01-MAR-2016	62 600	4,80

# Dashboard policy/program implications and Gaps

Improve access to VL testing through coverage, linkage and directed/targeted program interventions

- Sustainability and data maintenance of Central Data Warehouse
- Need for high level analytical and programming skills
- Unique identifier to eliminate probabilistic matching
- Continue streamlining dashboard outputs
- Train all levels of end users
- Improve exception reports for “call to action” functionality
- Do we conduct “impact studies” to measure dashboard and exception report tool uptake and action
- Integrate dashboard and reporting with TB
- Better integration with multiple clinic data platforms

# Linkage to care



**healthcare sector would be the most affected by Digital Disruption**

<http://www.cmo.com.au/article/564904/digital-disruption-isn-t-disruption-anymore-why-it-time-refocus-your-business/>

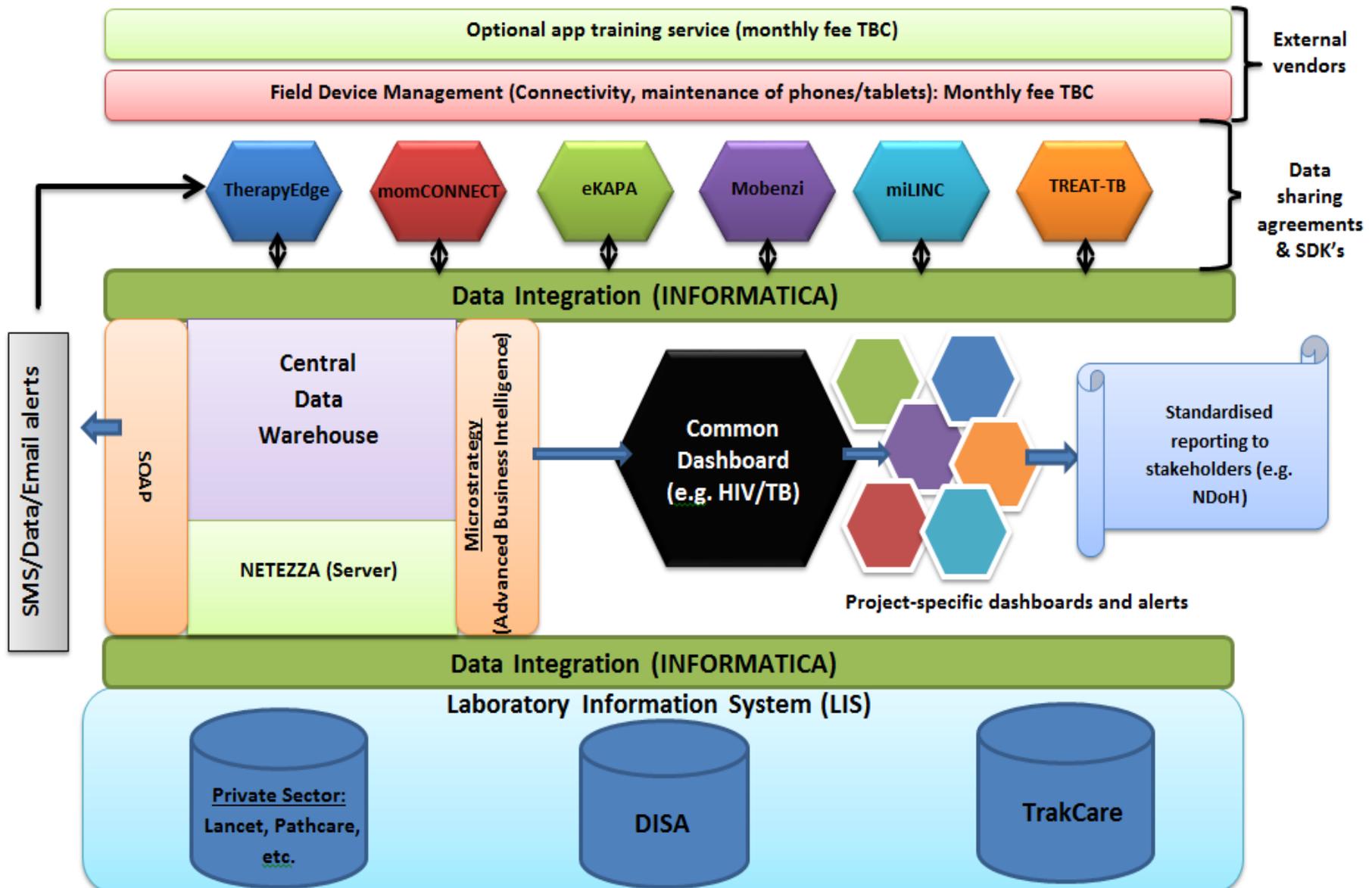


Source: <http://www.slideshare.net/wearesocialsg/2016-digital-yearbook/198>

Leveraging on existing NHLS, CDW framework

# South African mHealth-HUB

With compliments: Lynsey Isherwood



# mHealth projects and collaborations: NPP mHealth hub

1. Emocha



2. Treat-TB



3. M4JAM



4. WeChat

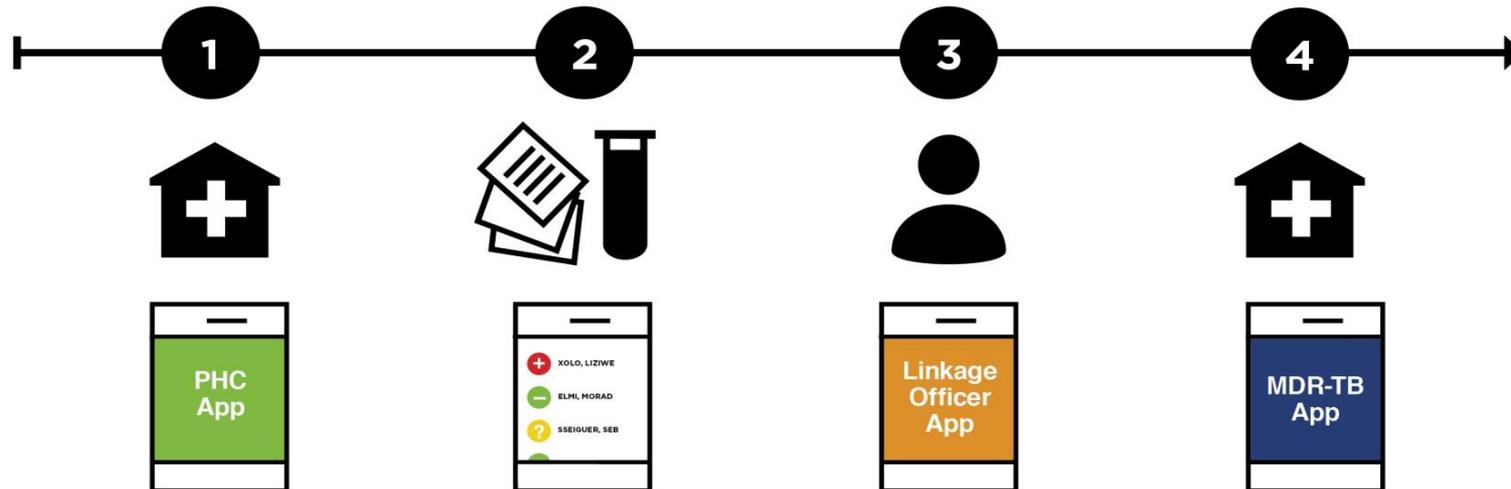


5. Other NPP mHealth projects

## LINKAGE TO CARE CASE STUDY

# Solution

1. Suspect tests for TB at PHC clinic and enrolls in emocha
2. Lab results appear on tablet in real time; Linkage status visualized
3. Linkage officer contacts suspects who are MDR-TB positive
4. Patient checks-in to MDR-TB clinic





# Pilot Locations

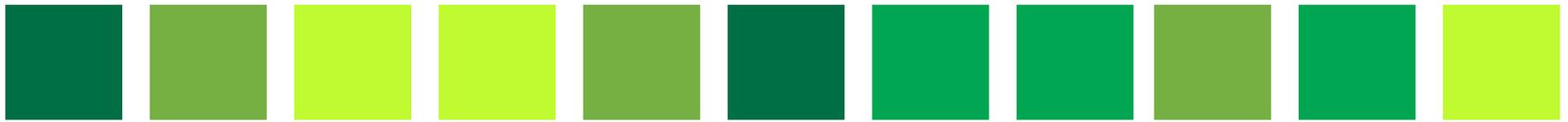
- Thembisa
- Pholosong
- Far East Rand
- Natalspruit
- Bertha Gxowa



## Ekurhuleni District (Gauteng)

Next District: COJ





## Calibre of expertise to manage HUB

- Program Manager
- Senior ETL Developer
- Specialist Health Systems Analyst
- Business Intelligence (BI) Architect
- Senior BI Developer
- Data Warehouse Architect
- BI Administrator
- Business (Operational) Reporting
- Monitoring & Evaluation Specialist
- Data Scientist

# m-Health Policy/program implications and Gaps

Laboratory data “in and out” is used appropriately, and include connectivity to clinical systems (bi-directional)

- Sustainability and maintenance of Central Data Warehouse hub
- Require application skills and include skills for device connectivity (phones, tablets etc)
- Investigate partners for field device management
- Funding for novel m-Health solutions and apps development
- Unique identifier to be implemented for bi-directional link to clinic data
- Requires policy development and implementation of Popi act
- Requires expansion to incorporate device management and “e-training”
- Do we conduct “impact studies” to measure uptake and action

# SA NHLS NPP HIV VL Laboratory footprint to perform ->2.8m VL.

## Relevant services will need expansion

1. Centralised high-throughput systems (constrained by specimen transport logistics and integrity)
  - Whole blood 6hrs @ 15° C - 37° C
  - Plasma (centrifugation) 24hrs @ 37° C to 5yrs @ -70° C (storage) < PPT tube
2. Decentralized lower-throughput testing platforms.
  - Extend service through sample integrity = DBS (1-2 weeks 37° C to 1 yr @ -70° C (storage).
  - Increases access to testing and reduce TAT = (POC).

### HIV viral load labs

#### 16 laboratories

3 sites with Abbott m2000 system

13 sites with Cobas 8800/6800 or CAP/CTM

Cobas 8800 current instrument capacity (8 hour shift)

**~ 1000 HIV VL / 8hrs**

Critical choices – available options (lab extension, lab replacement, lab multifunctional, clinic based service or combination)

## “Fit for purpose”

Laboratory based testing	Opportunity
1. Extend existing plasma services	<ul style="list-style-type: none"><li>• Ultra high throughput (e.g. Roche 8800 or equivalent)</li><li>• Decentralised (e.g. Cepheid)</li><li>• PPT</li></ul>
2. Replace/extend existing service through alternative matrices	<ul style="list-style-type: none"><li>• DBS on existing platforms using existing logistics</li></ul>
3. Multi-functional /polyvalency	<ul style="list-style-type: none"><li>• HIV/TB (Cepheid, Roche, Abbott etc)</li></ul>

### Clinic based testing using POC

Space, operators, connectivity!

Time to reportable result (35mins – 90mins)

Threshold change: on-site adherence vs clinic workflow disruption

Single or multiple assays

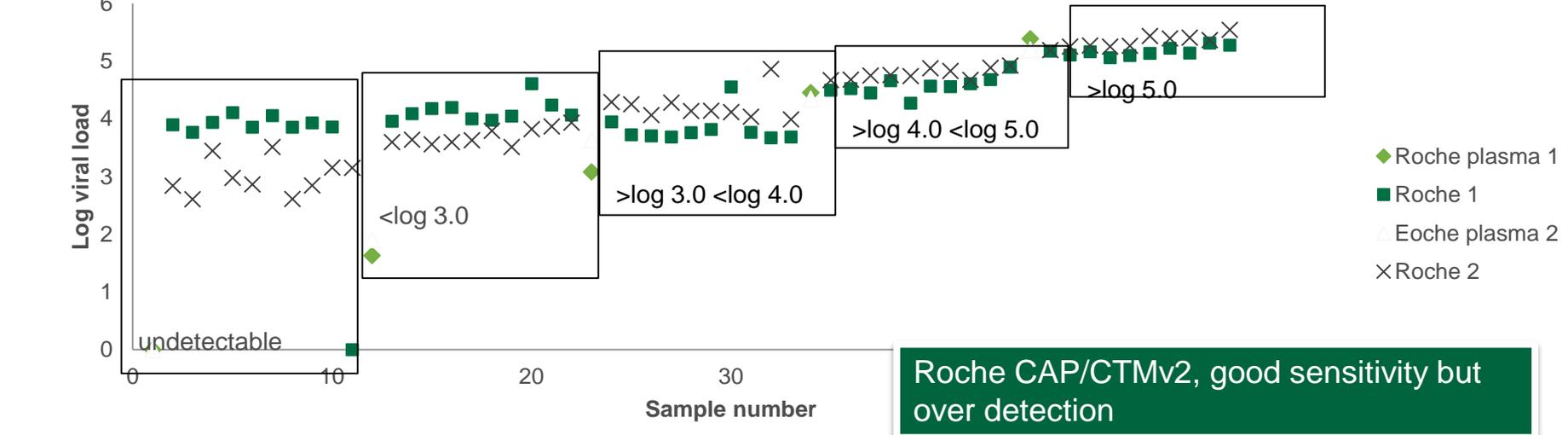
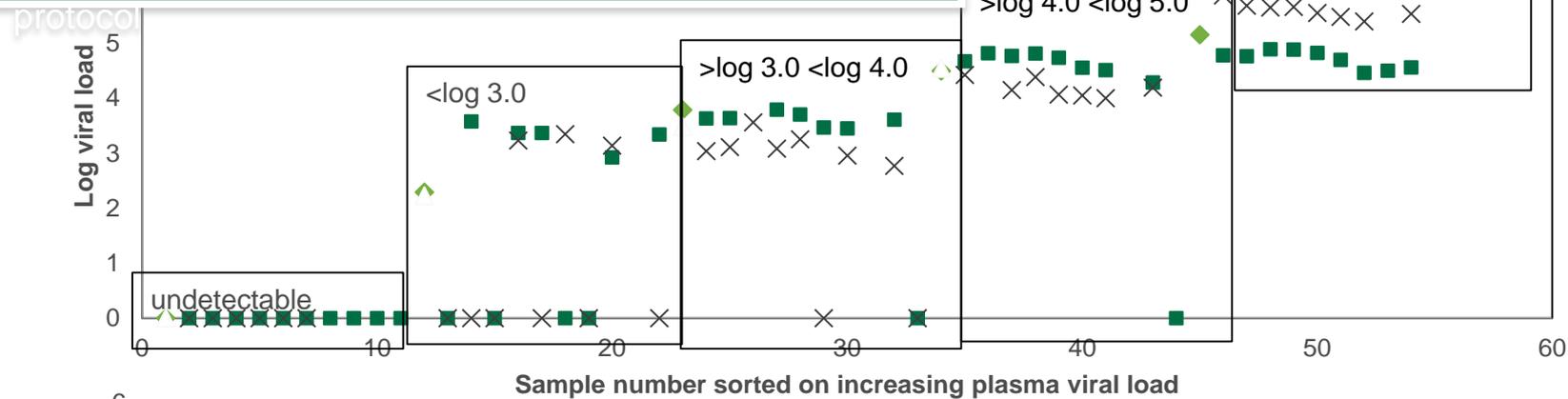
### Options

Diagnosis vs monitoring (whole blood/DBS): TNA selection vs RNA

Plasma vs whole blood with threshold change

# DBS precision on Abbott HIV-1 RT and Roche CAP/CTMv2 (10 DBS replicates): Different assays have different strengths

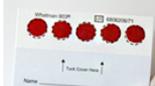
Abbott 2 spot vs 1 spot: greater variability, better sensitivity. Now being replaced by 1 spot new buffer



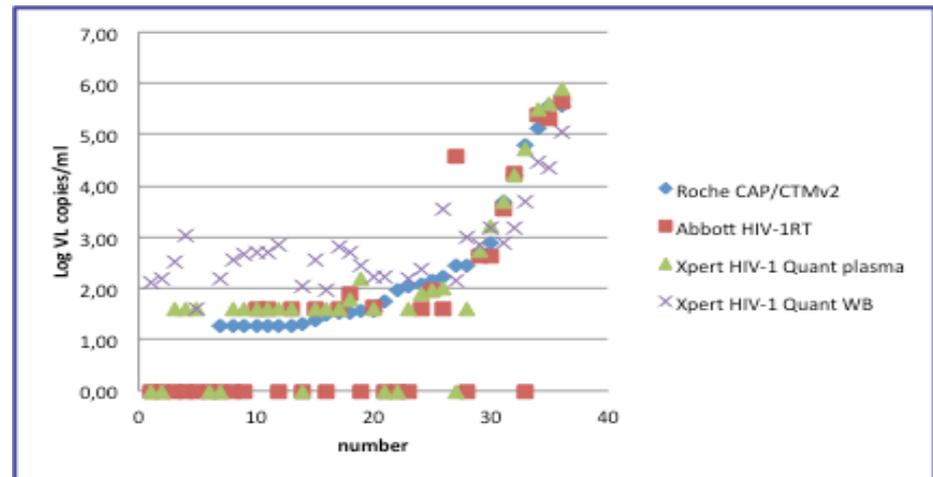
Roche CAP/CTMv2, good sensitivity but over detection

# GeneXpert HIV-1 Quant protocol

- Fully automated
- Real time molecular cartridge based
- Two internal quantification standards.
- Requiring 1ml plasma

1. WB	2. DBS	3. Plasma
<p>100ul WB + 1.2ml guanidinium-based Lysis Buffer, Invert</p>  <p>Add 1.2ml to cartridge</p> 	<p>Spot 70ul wb, allow to dry</p>  <p>Add 1 DBS + 1.3ml lysis buffer into 15ml nunc</p> <p>Place in thermomixer for 15minutes @ 56°C, 500rpm</p>  <p>Add 1.2ml to cartridge</p> 	<p>Centrifuge 15min</p>  <p>Add 1.2ml to cartridge</p> 
<p><b>Time to reportable result</b> <b>~109 minutes</b></p>	<p><b>~94 minutes</b></p>	<p><b>~107 minutes</b></p>

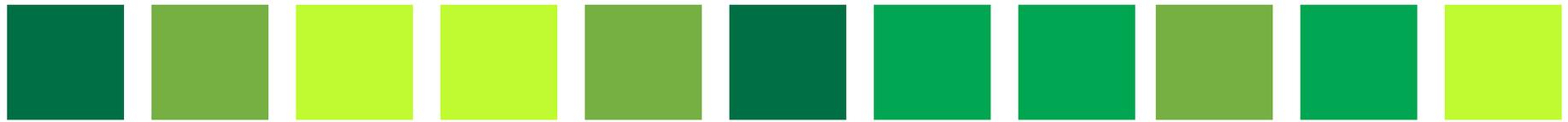
- LODetection ~20cp/ml
- LOQuantification 40cp/ml
- Linear range: 40 – 10million cp/ml
- Targets 3' end 5' LTR
- Detects HIV Group M,O,N and recombinants.
- TAT <95mins



# Considerations and options

- Xpert HIV/TB polyvalency for service integration
- Xpert VL assay as simple as the Xpert MTB/RIF testing
- Training minimal for users proficient in GeneXpert
- Xpert VL and Xpert MTB/RIF testing can be done concurrently, using the same instrument software with different assay definition files (ADF).
- Xpert MTB/RIF =120minutes/module, therefore 4 TB specimens/module/8hr
- Xpert VL =90minutes/module, therefore 5 HIV specimens/module/8hr
- 2 separate specimen preparation work areas for HIV and TB
  - cartridges are the same colour and visually look identical.
- Xpert VL plasma testing requires a centrifuge, on a separate bench to the GeneXpert to avoid increased vibration which may compromise analyser performance.
- True POC coming with Omni (4hr battery, mobile connectivity)





# Models for POCT implementation in SA

## **Appropriate, controlled placement is required**

**1.Total Coverage model:** where DBS and Point of Care added to ensure complete coverage of laboratory services in a tiered laboratory service, focussing on remote, low volume sites

Equipment selection: based on volumes, compatibility with larger systems

## **2. Point of Treatment (total decentralized)**

- Disease specific e.g. HIV treatment initiation, TB diagnosis, diagnosis of diarrhoea, non-communicable e.g. glucose, HbA1c
- Assay specific e.g. Hb, or GeneXpert, cryptococcal antigen or POC CD4 for wellness testing
- Not affordable

## **3. Product Niching**

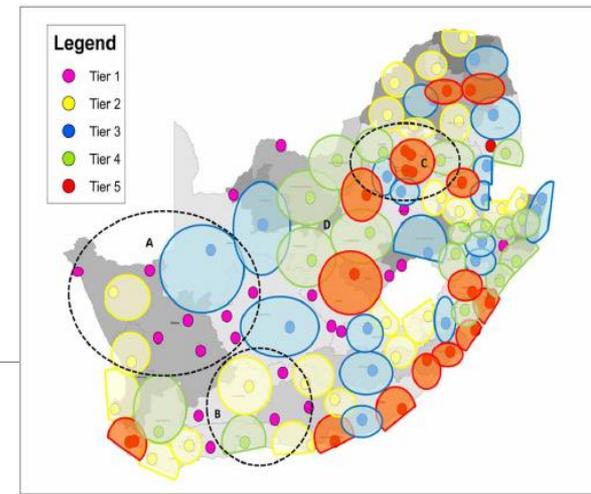
- Accreditation of sites: staff, quality and connectivity
- Product niching (Viral load)

*Stevens. W, Gous.N,Scott.L.E. Feasibility of HIV POCT for RLS: Challenges and solutions. BMC, 2014.*

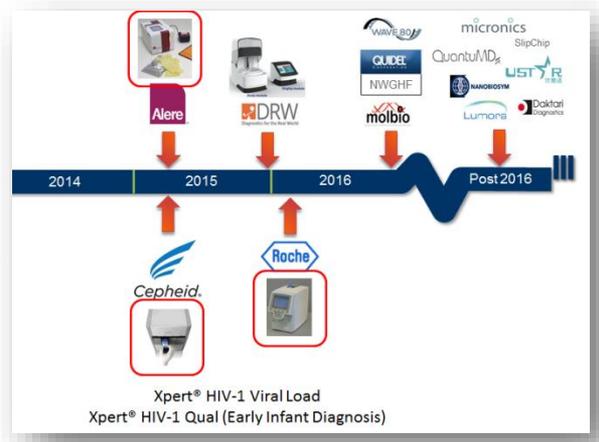
*Stevens.W, et al. POCT: Policy document for SA. NDoH, NHLS and partners collaborative forum. Pretoria, July 2013*

# Applying the ITSDM to achieve HIV Viral Load Coverage

- Match demand with the appropriate capacity
- Larger tiers 4 and 5 laboratories are in place
- Phase I: Introduce community laboratories and POC Hubs
- Phase II: Introduce POC sites



- Tier 1 (True POC)
- Tier 2 (POC hub)
- Tier 3 (Community labs)
- Tier 4 (Regional labs)
- Tier 5 (Centralised labs)



**Existing VL services scaled**

Red bubble (existing centralized VL labs) = 16 (m2000, COBAS up to 8800)

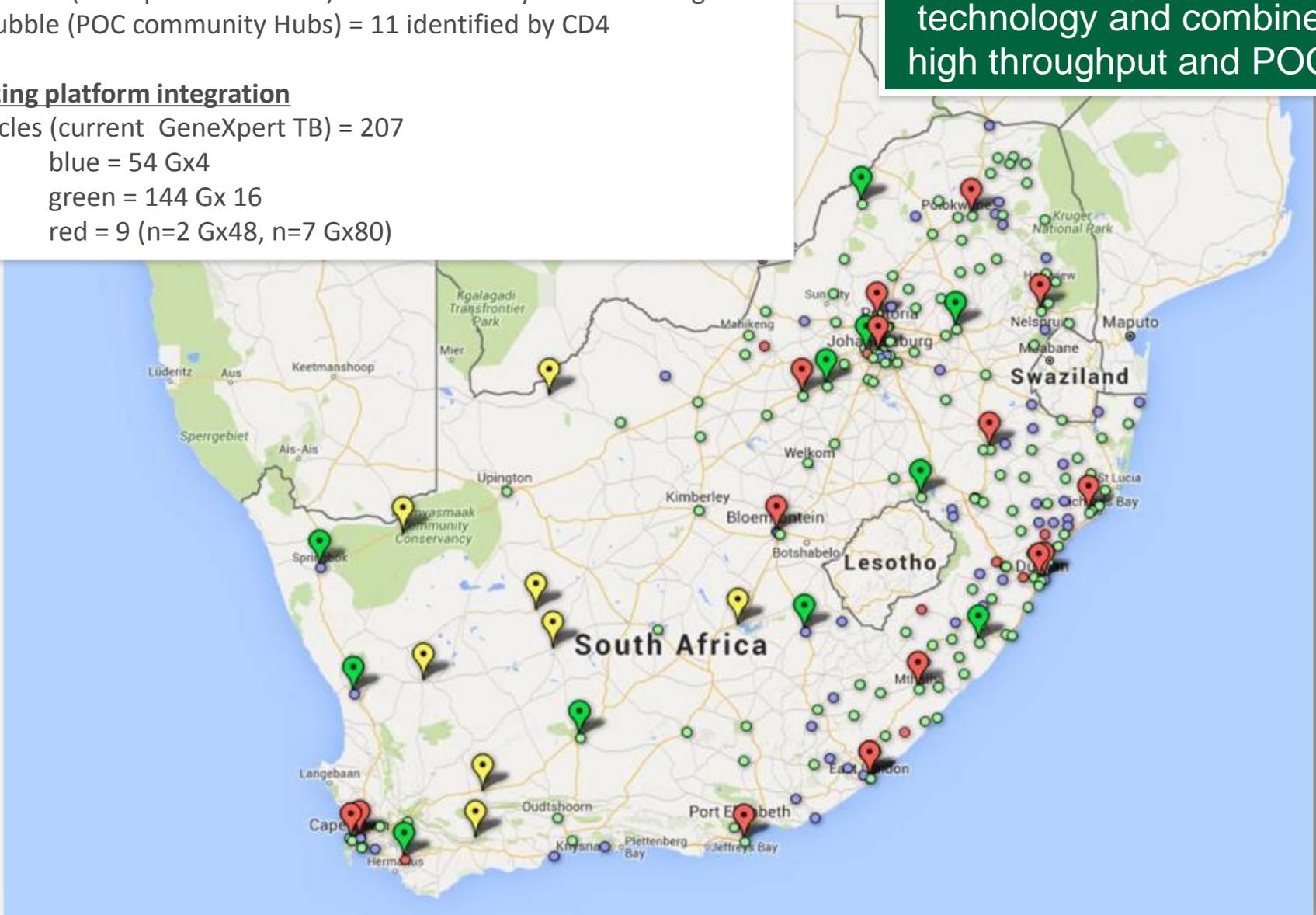
**Extending VL services through POC?**

Yellow bubble (anticipated true POC) = 9 identified by CD4 modeling  
Green bubble (POC community Hubs) = 11 identified by CD4

**Maximizing platform integration**

Small circles (current GeneXpert TB) = 207  
blue = 54 Gx4  
green = 144 Gx16  
red = 9 (n=2 Gx48, n=7 Gx80)

Optimizing VL services through a tiered VL model: maximize existing technology and combine high throughput and POC







# Innovative solutions to improve coverage

## Tier 3: Community Laboratory

- Expand testing to existing NHLS laboratories at district hospitals.
- Extend testing to include:
  - HIV Viral Load
  - Xpert MTB/RIF
  - CD4
- Routine clinical pathology services already in place

## Tier 2: laboratory hub

- One POC hub to service multiple health facilities within a given proximity
- Service to be provided by the NHLS will include:
  - HIV Viral Load
  - Xpert MTB/RIF
  - CD4
  - Basic Chemical pathology and Haematology tests to support ART services, i.e. Creatinine (eGFR), ALT and Hb/FBC
  - Improve courier logistics to hub

# Coverage policy/program implications and Gaps

Implementation Models can be used across multiple diseases/assays (CD4, Xpert, VL, EID, NCD)

- POCT national policy completion
- Costing of services required
- Opportunity for service integration (CD4, TB, VL) in testing hubs
- Support for funding for extension of services as per models
- POCT extension requires dashboard connectivity training



# Acknowledgments

