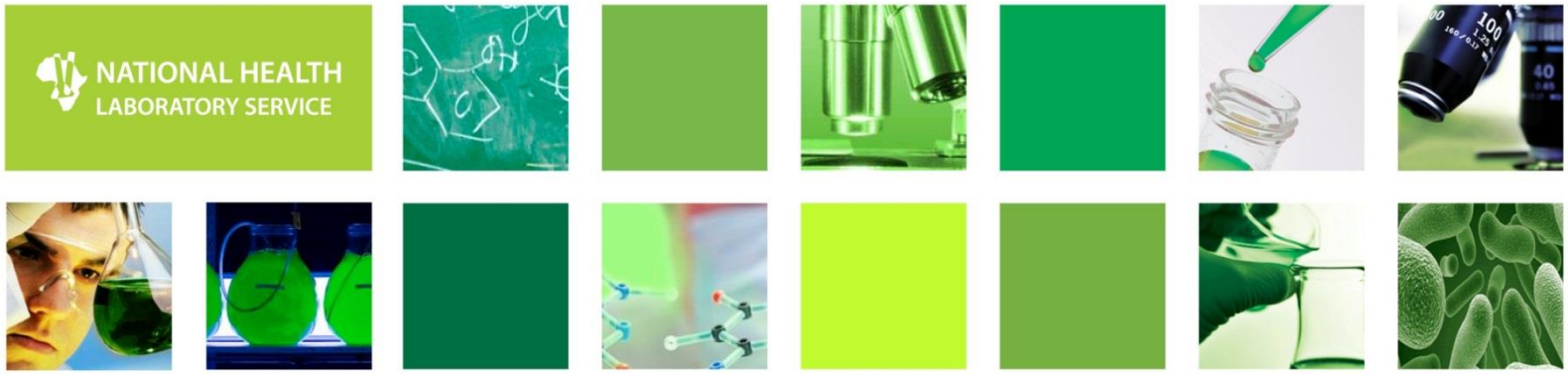


Strategic Use of Lab Results

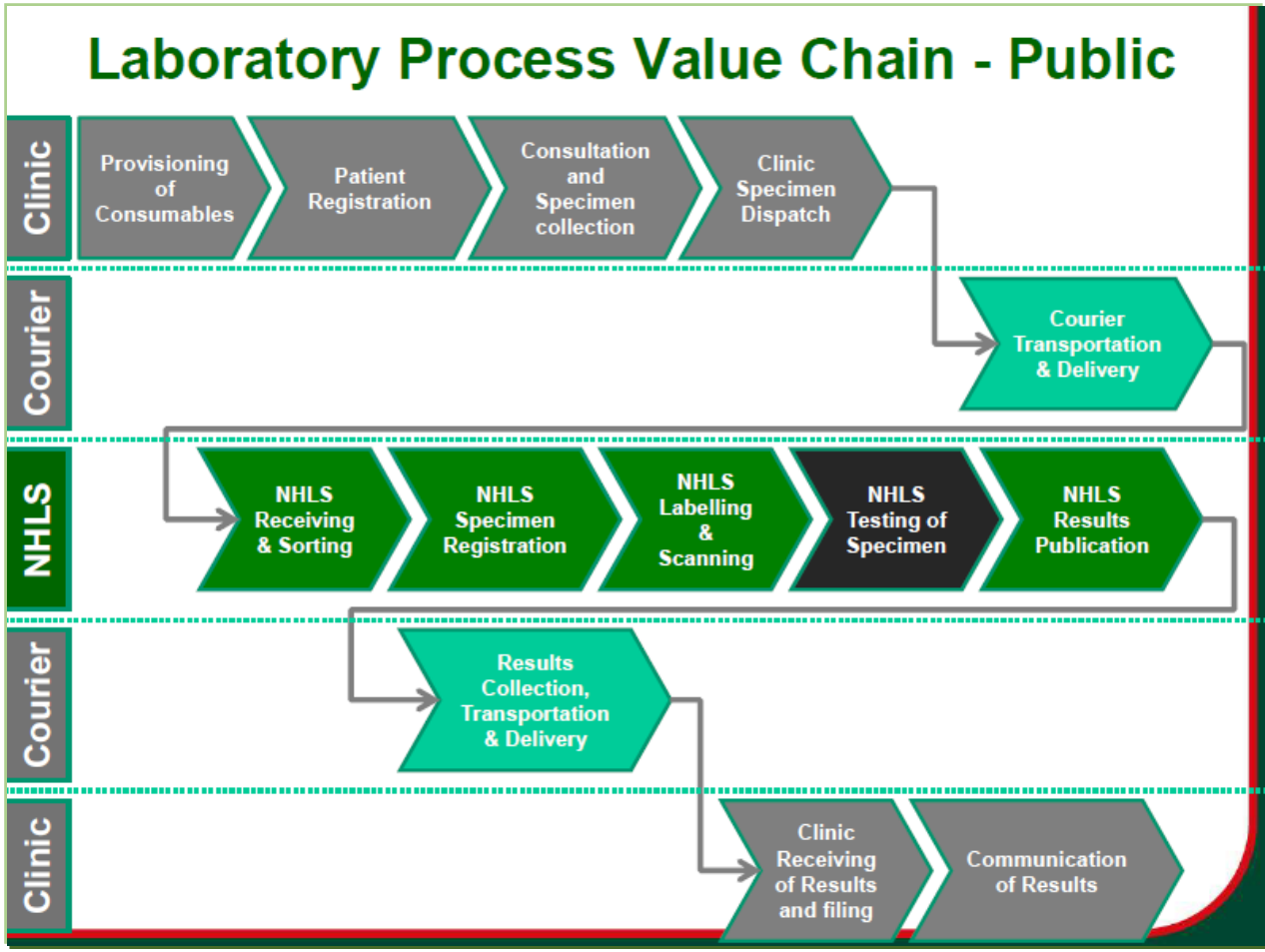
Dr Leigh Berrie

27 September 2014

SOUTHERN AFRICAN HIV CLINICIANS SOCIETY CONFERENCE 2014
CAPE TOWN – SOUTH AFRICA, 24-27 SEP 2014

Background

- South African Public health structure comprises:
  - National Department of Health - Providing clinical services at health facilities
  - National Health Laboratory Service- Providing all public sector pathology and laboratory services



http://www.sead.co.za/downloads/clinic-part-a.pdf

NATIONAL HEALTH LABORATORY SERVICE

Why is the collection and analysis of laboratory data important?

- Information collected through reports, forms, and registers is used not only for patient management but also for programmatic monitoring and management:
  - To support clinical decision making and management of individuals and programmes
  - To provide a rich source of data on the burden of disease and the effectiveness of programmatic efforts to reduce this burden

- However, available data are often underused, or not used at all, partly due to the absence of systems required as well as the absence of clear guidance on recommended approaches to the analysis of such data.

- Many high-burden countries have the inability to report on the numbers and outcomes of patients in care

Vision

- Seamless transfer of data and integrated view of data within the public health care system
  - Health facilities
  - Laboratory
  - Pharmacy

- To enable the shift to true data interchange and the ability to develop a **patient-centric data repository** using a single national Master Patient Index (MPI).
  - The benefits include the ability to follow cohorts and conduct longitudinal analyses

How will we achieve the vision?- Systems Required

- Facilities: Health Information Systems (HIS) and Patient Management Systems (PMS)
- Pre-Analytical phase: Order Entry Systems- provide a platform for capturing and managing patient information
- Analytical phase: Laboratory Information Systems- to manage data from requisition forms and to interface with equipment for results entry as well as other laboratory functions such as recording quality control
- Post-Analytical phase: systems for delivery of results- delivery of patient results into the patient record
- Post-Analytical phase: Data Warehouses- archiving and analysis of data

Gaps identified in the current systems:

- Need to move from manual reporting systems to online reporting systems
- Need to (electronically) link lab diagnosis to patient's medical records for faster turn around time as well as for continuity of care
- Need to access accurate data on national dashboards to improve service delivery in the country
- Need to link TB and HIV data such that programmes have access to both data
- Need for inter-operability of lab information systems with other databases through the use of unique patient identifier- to ensure a single national dataset (Tier.net [Three Interlinked Electronic registers], ETR.net [Electronic Tuberculosis Register], EDR.net [Electronic DR-TB register] etc)

Facilities- Three-tiered monitoring system- ARV

Osler M et al. *Journal of the International AIDS Society* 2014, **17**:18908
http://www.jiasociety.org/index.php/jias/article/view/18908 | http://dx.doi.org/10.7448/IAS.17.1.18908

JIAS Journal of the International AIDS Society

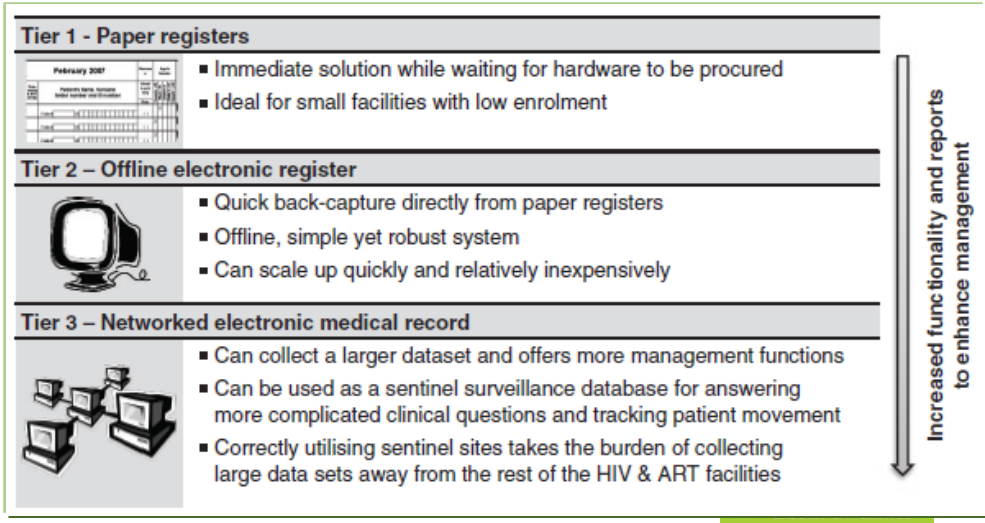
Debate

A three-tier framework for monitoring antiretroviral therapy in high HIV burden settings

Meg Osler[§,1], Katherine Hilderbrand[1,2], Claudine Hennessey[1], Juanita Arendse[3], Eric Goemaere[1,2], Nathan Ford[1] and Andrew Boulle[1,3]

[§]**Corresponding author:** Meg Osler, Centre for Infectious Disease Epidemiology and Research, School of Public Health and Family Medicine, University of Cape Town, Anzio Road, Observatory 7925, South Africa. Tel: +2721 406 6717. (Meg.Osler@uct.ac.za)

- A three-tiered monitoring approach in low- and middle-income countries
- Paper-based registers, electronic registers (offline) and electronic medical records (networked) are combined in a unified system to produce common nationally required indicators
- Choice of tier is based on context and resources at the time of implementation
- In South Africa, the three-tier monitoring and evaluation system for ART was adopted by the National Department of Health in December 2010



Three tiered monitoring system

- Outputs from the three tiers can be aggregated into a single database at any level of the health system, giving programme managers a better understanding of the burden of care, equity of access, quality of service, retention in care and other outcomes of the programme

- Efficient approach to ensuring system-wide harmonization and accurate monitoring of services, including long-term retention in care

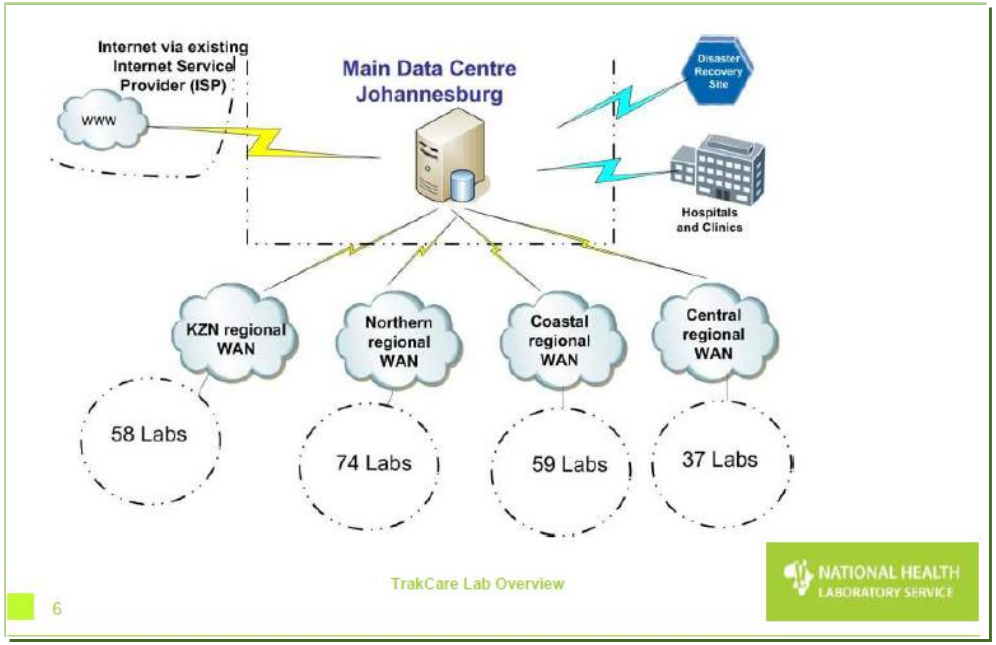
- ETR.Net (Electronic Tuberculosis Register) (offline middle tier) has been implemented in eight countries and collects and reports on demographic, case finding and outcome data for patients receiving tuberculosis treatment

- Would be a benefit of using a tiered platform across HIV, TB and Maternal and Child Health, to have a common data platform and to provide a better understanding of co-infection rates

Lab System Requirements- addressing the gaps

- Order Entry Systems-
  - Minimal clinic dataset needed for patient registration and identification
  - Needs to be brought closer to the patient- at facilities
  - Possibility to integrate with Department of Home Affairs- HANIS system
  - Online ID check or biometric scan?
  - Built in Gate Keeping needed- Test repertoire tailored for facility

- Laboratory Information Systems (LIS)-
  - E.g. DISA and TrakCare
  - Currently at over 270 NHLS labs nationwide
  - Interfacing with instruments
  - Quality control
  - Test resulting with patient history needed

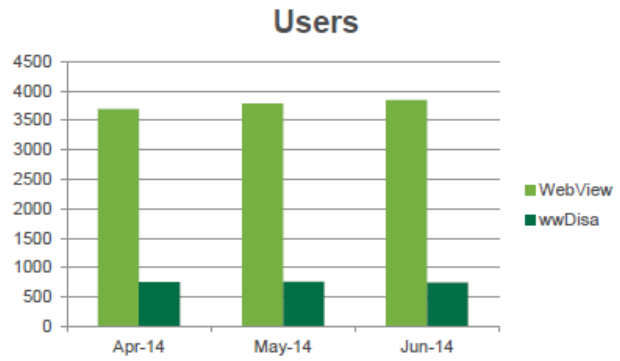


System Requirements

- Systems for delivery of results-
  - Traditional hard copy paper results
  - SMS printers (~200 000/ month, CD4, EID, HIV VL, GXP, smear microscopy)
  - Fax
  - Email
  - Telephonic enquiries
  - Web-based results
  - Webview also available on cell phones and tablets
- Limitations-
  - Limited infrastructure at facilities
  - Network connectivity varies

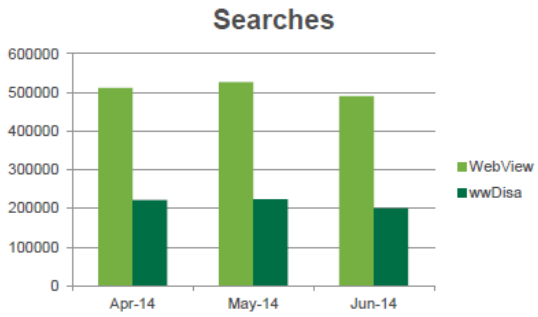
Web Based Results

- wwDisa and TrakCare Lab Web View
- ~4500 active users



Web Based Results

- wwDisa and TrakCare Lab Web View
- ~700 000 searches per month



System Requirements

Data warehousing-

- Records of all patients testing should be preserved in a permanent on-line form (R. Aller, Am.J.Clin.Path, 2003)
- Patient unique identifier needed
- Should be patient- rather than specimen- centric database
- A national Master Patient Index (MPI) will enable the development of a patient-centric data repository
- Nationally developed and managed facility list and master dataset needed (e.g. DHIS facility code)
- Need to decide on data interchange standards, e.g. HL7
- Near “real-time” reporting rather than historical reporting

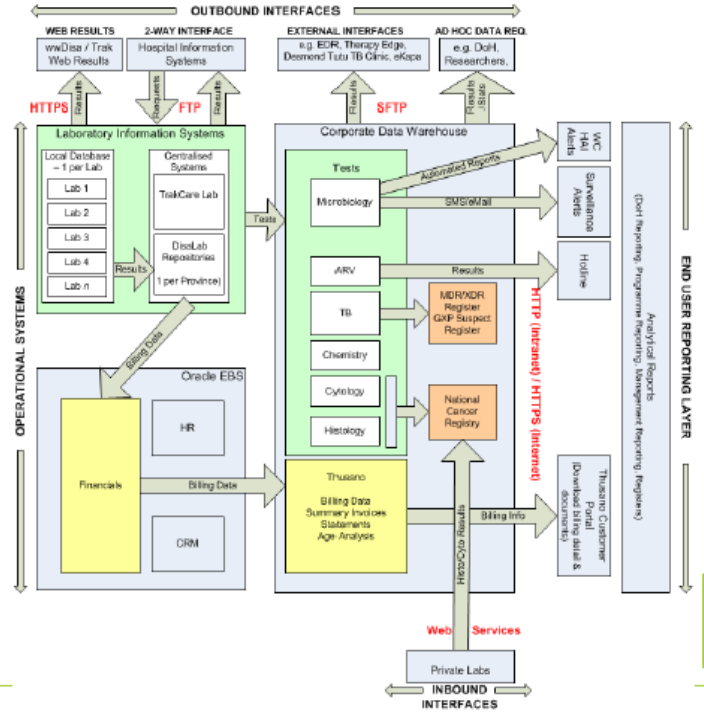
The Clinical Laboratory Data Warehouse

An Overlooked Diamond Mine

Raymond D. Aller, MD

DOI: 10.1309/TXXABU8MW75L04KF

Data Flows in & out of NHLS D/Warehouse



Potential CDW, TIER.Net & ETR.Net data interfaces

CDW-to-TIER.Net

- CDW Data feed
  - CD4, HIV Viral Load and EID results
  - ART monitoring test results, e.g. ALT

CDW-to-ETR.Net

- CDW Data Feed
  - Xpert results
  - Smear results
  - TB Culture results
  - DST results
  - LPA results

TIER.Net/ETR.Net-to-CDW

- Order entry
- MPI (Master Patient Index) and patient details
- Clinical data, e.g. months on ART

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What analyses should we be doing with collected data?

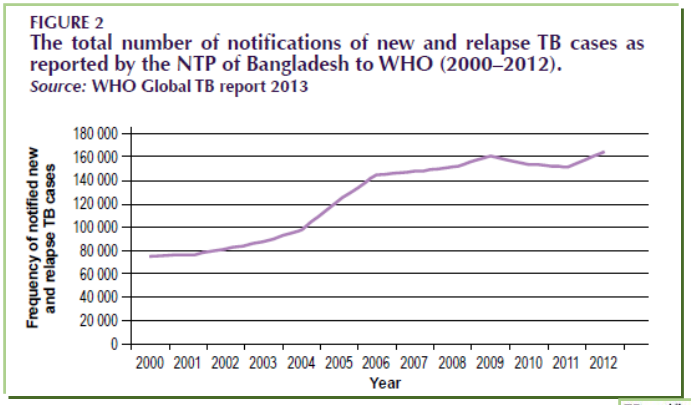
- Cross-sectional analysis
  - Counts of tests and results of tests for a time period and geographic location

- Cohort analysis-
  - Follows groups of patients over time
  - Reports on key baseline and outcome variables
    - Number of persons initiating therapy
    - CD4 count at treatment initiation
    - Proportions viralogically suppressed and failing
    - Report patient level CD4 data for pre-ART screening v/s ART monitoring
    - Loss to Follow-up rates
    - Report on toxicity monitoring for patients on ART

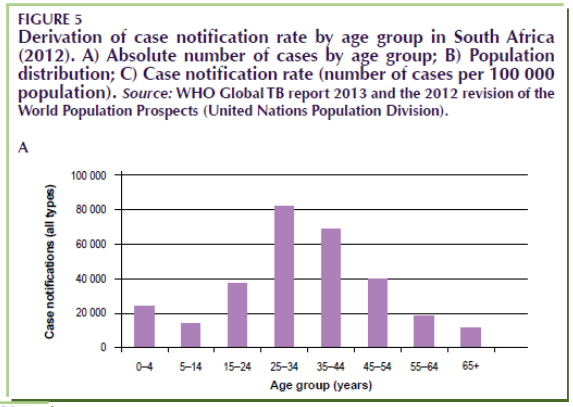
Understanding and using Tuberculosis data (WHO, 2014)

Aggregated data- TB notification data can be analysed to understand TB epidemiology, including the distribution of disease geographically, by age and gender, and among specific population groups

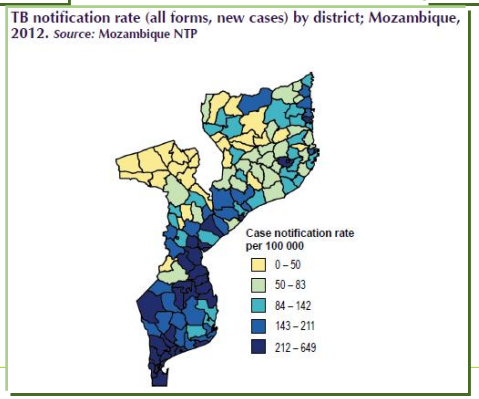
•Notification trends based on time



Notification trends based on age



•Notification trends based on geographic area



Minimum set of variables is needed: age (or age group), gender, year of registration, bacteriological test results, history of previous treatment, type of disease and geographic region

Uses of Aggregated Analyses

- TB surveillance data is essential for programme evaluation
- Helps guide decisions about case management and policy
- Allows NTPs to monitor trends in the number and distribution of TB cases across the country
- Enables NTPs to report on the country's TB epidemic and progress in reaching NTP goals and objectives
- Helps NTPs to develop targeted national strategies and funding plans

Case-based data

- An episode of TB and associated treatment information is the unit of analysis. Unique identifier needed.
- Used for clinical management of patients to ensure high quality care and to monitor treatment outcomes
- To better target interventions locally and nationally by identifying population characteristics that predispose people to higher risk of disease and poor outcomes
- To identify disease outbreaks and guide timely public health actions to ensure appropriate management of TB cases and contacts
- Inform policy by assessing progress in TB control, as compared with national and international targets

Data cannot accurately depict the current TB burden in a country if the surveillance system collects incomplete, inconsistent or incorrect information

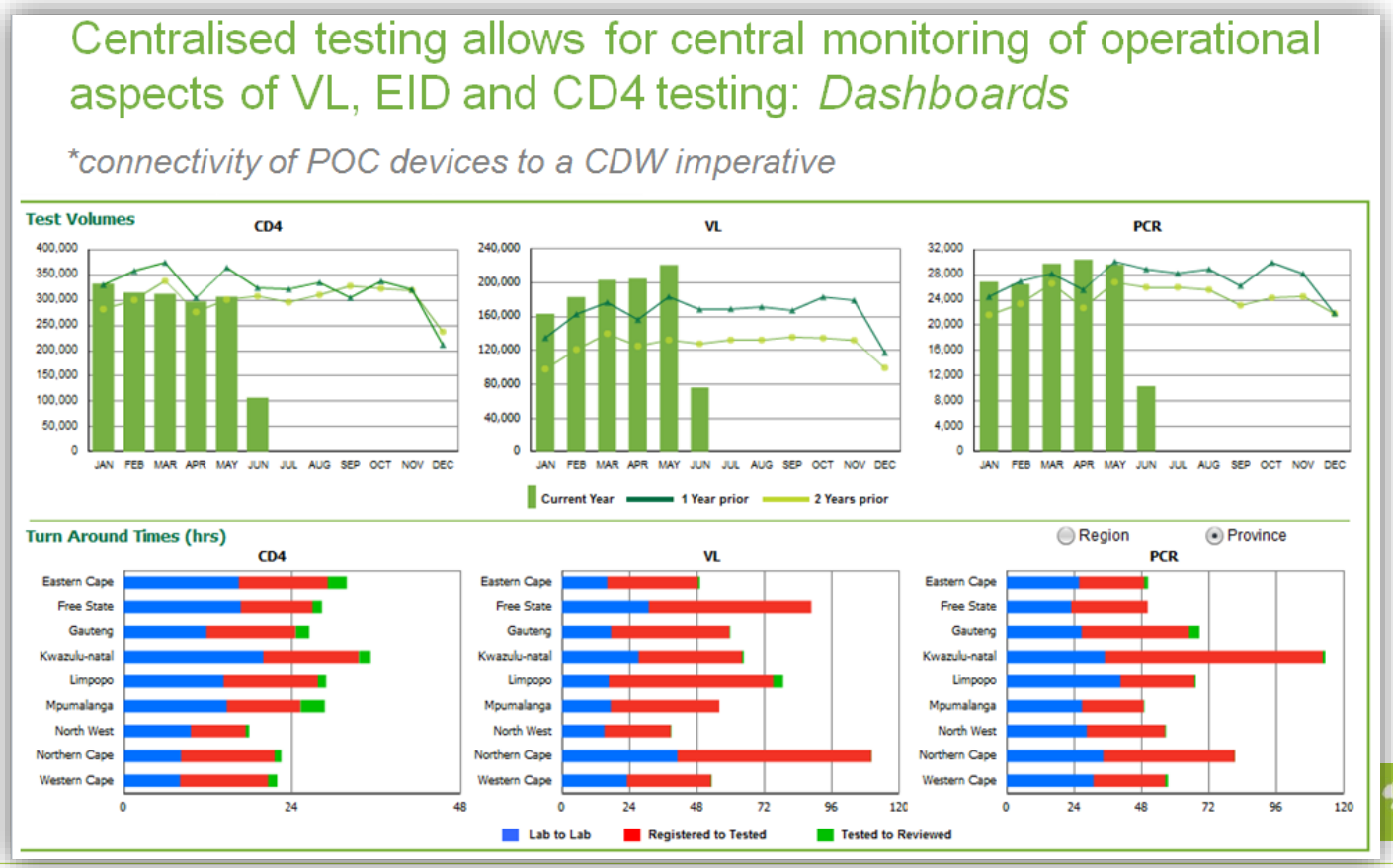
- WHO recommended checklist for TB surveillance and use of aggregated TB notification data
- Data validation, checking for duplications and checking for missing data

TABLE 1
Standards used in the *Checklist of standards and benchmarks for TB surveillance and vital registration system*

Data quality
1. Case definitions are consistent with WHO guidelines
2. TB surveillance system is designed to capture a minimum set of variables for all reported TB cases
3. All scheduled periodic data submissions have been received and processed at the national level
4. Data in quarterly reports (or equivalent) are accurate, complete and internally consistent *(For paper-based systems only)*
5. Data in national database are accurate, complete, internally consistent and free of duplicates *(For electronic case-based or patient-based systems only)*
6. TB surveillance data are externally consistent
7. Number of reported TB cases is internally consistent over time
Coverage
8. All diagnosed cases of TB are reported
9. Population has good access to health care
Vital registration
10. Vital registration system has high national coverage and quality
DR-TB, TB/HIV and children
11. Surveillance data provide a direct measure of drug-resistant TB in new cases
12. Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases
13. Surveillance data for children reported with TB are reliable and accurate, and all diagnosed childhood TB cases are reported

Current NHLS reporting

- Operational Reporting/ dashboards
  - Test volumes & “In-Lab TAT”
  - Billing – Thusano Portal



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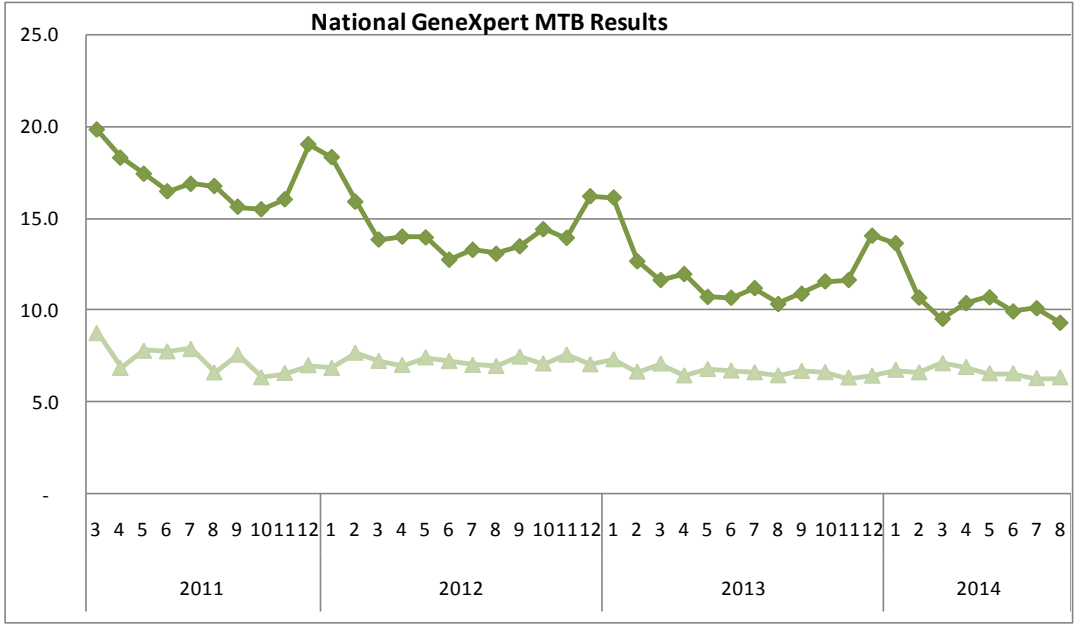
Current NHLS reporting

- Linkage to Care
  - Surveillance Alerts (NICD)
  - GeneXpert Rifampicin resistance Register- patient-level data- weekly
  - MDR/XDR-TB register (currently W. Cape only)- patient-level data- weekly

- Programme monitoring reports
  - Monthly GeneXpert report (National, provincial, district, sub-district, facility level)
  - Monthly GeneXpert and CD4 report (Correctional services- facility level)
  - Monthly CCMT report (National, provincial, district, sub-district, facility)
  - Monthly Malaria report
  - MonthlyEarly Infant Diagnosis report (National, provincial and district level)
  - Include test volumes, positivity rates, results per test range, comparison of results year on year

GeneXpert programme monitoring reports



National GeneXpert MTB Results

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
2011	34 441	165 916	5 433	**205 790**	**16.7**
2012	93 736	547 048	17 068	**657 852**	**14.2**
2013	210 455	1 540 184	53 901	**1 804 540**	**11.7**
2014	164 020	1 367 958	39 261	**1 571 239**	**10.4**
TOTAL	**502 652**	**3 621 106**	**115 663**	**4 239 421**	**11.9**
% Total	**11.9**	**85.4**	**2.7**	**100.0**	

National GeneXpert RIF Results (MTB Detected)

Year	Inconclusive	Resistant	Sensitive	No RIF Result	Total	% RIF Resistant
2011	332	2 441	31 513	155	**34 441**	**7.1**
2012	1 323	6 774	84 964	675	**93 736**	**7.2**
2013	5 376	13 965	189 967	1 147	**210 455**	**6.6**
2014	4 503	10 846	148 374	297	**164 020**	**6.6**
Total	**11 534**	**34 026**	**454 818**	**2 274**	**502 652**	**6.8**
% Total	**2.29**	**6.77**	**90.48**	**0.45**	**100**	

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CD4, HIV viral Load and HIV PCR programme monitoring report

CD4: Test Range:

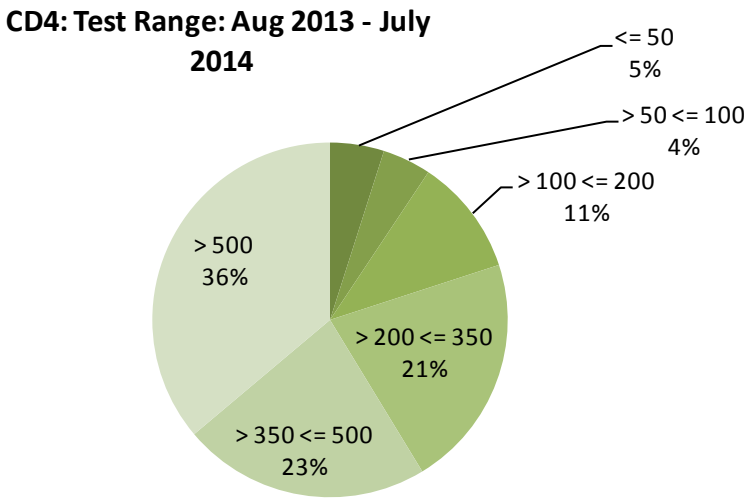
Period	<= 50	> 50 <= 100	> 100 <= 200	> 200 <= 350	> 350 <= 500	> 500	Total
Aug 2013 - July 2014	184 716	166 249	400 272	801 610	847 398	1 358 938	**3 759 183**
Aug 2012 - July 2013	199 582	183 159	446 919	885 127	874 882	1 233 005	**3 822 674**

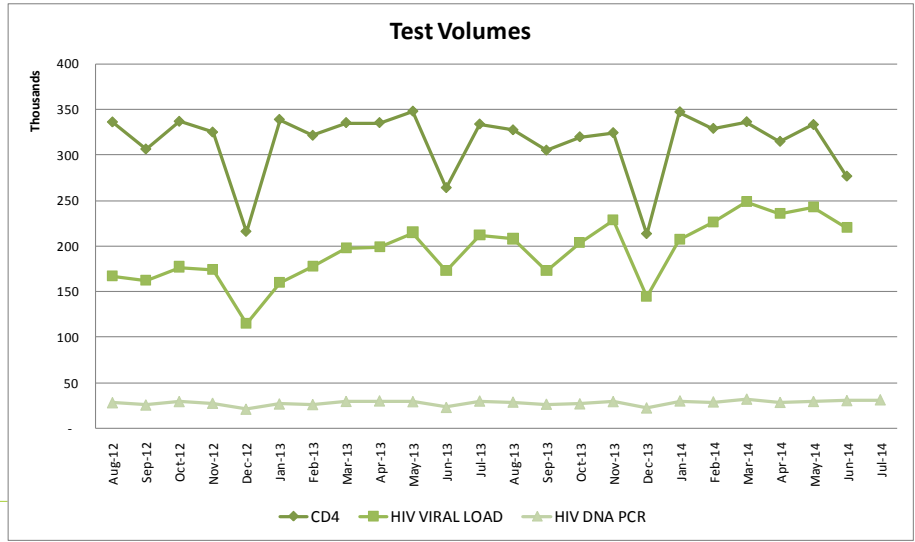
HIV DNA PCR: Test Range:

Period	Positive	Negative	Equivocal	Invalid	Total
Aug 2013 - July 2014	13 073	332 627	719	32	**346 451**
Aug 2012 - July 2013	14 768	309 210	592	6	**324 576**

HIV Viral Load: % <=1000 and >1000

Period	<=1000	>1000	Total	%<=1000
Aug 2013 - July 2014	2 051 114	613 664	**2 664 778**	**76.97**
Aug 2012 - July 2013	1 621 376	519 721	**2 141 097**	**75.73**

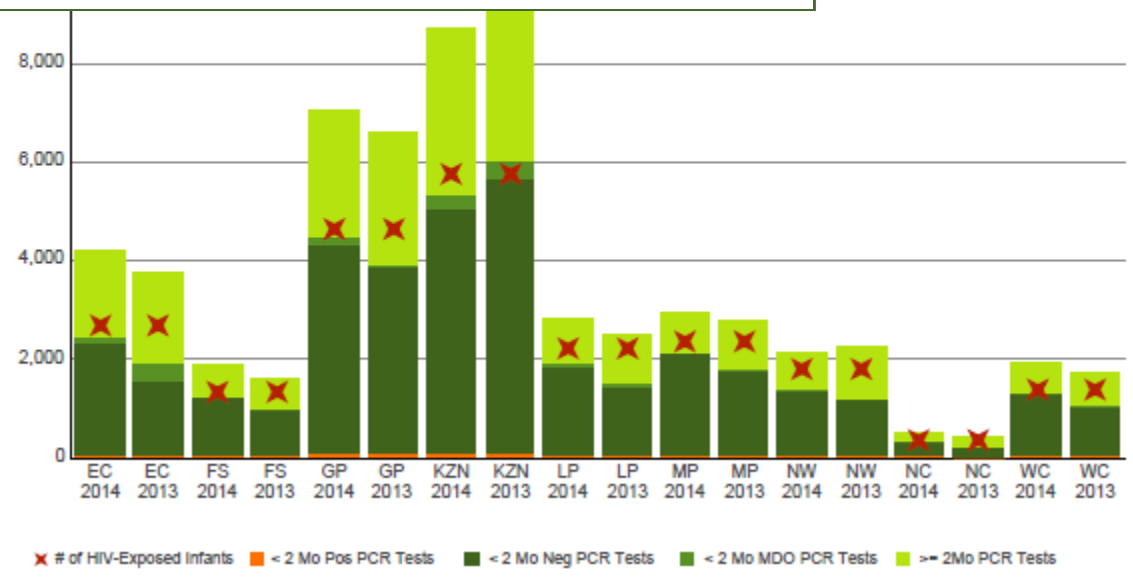




Early Infant Diagnosis reports

Province		< 2 Mo Pos PCR Tests				Estimated Coverage for Early Diagnosis (%)			
		Current	YTD	LY	LY YTD	Current	YTD	LY	LY YTD
Eastern Cape	EC	40	256	23	270	91.2	78.3	71.3	68.0
Free State	FS	13	107	19	153	92.0	80.4	72.5	77.9
Gauteng	GP	73	442	63	482	95.2	85.1	83.6	79.4
KwaZulu-Natal	KZN	69	472	95	613	92.3	85.8	104.4	82.8
Limpopo	LP	45	259	38	301	84.0	73.2	67.9	68.1
Mpumalanga	MP	43	261	36	276	91.4	82.8	77.0	76.2
North West	NW	30	154	27	197	74.3	66.1	66.3	62.7
Northern Cape	NC	12	47	7	36	89.3	80.2	64.6	65.3
Western Cape	WC	28	148	26	129	91.1	85.5	73.4	71.4
Total		**353**	**2,146**	**334**	**2,457**	**90.3**	**81.2**	**82.2**	**75.3**

YTD - Year to Date
LY - Last Year



Upcoming CD4 and Viral load reports

NATIONAL HEALTH LABORATORY SERVICE

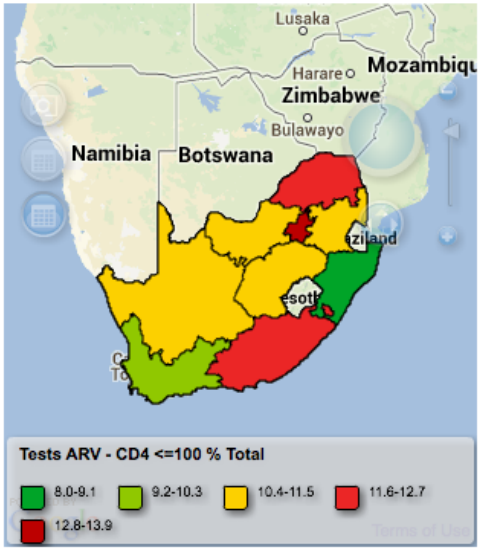
Year: 2014 | Quarter: Q1 2014 | Month: Jan 2014 | Age Range: All Ages

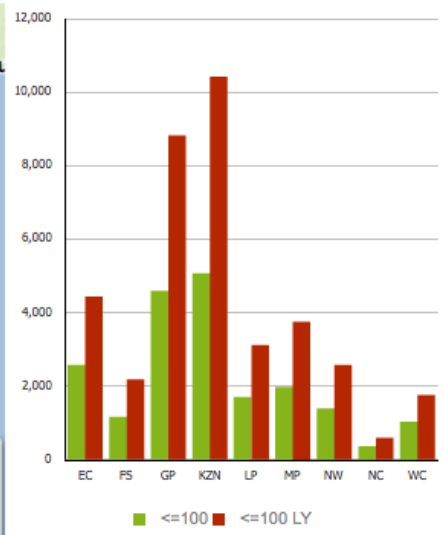
M&E Geo Analysis

National | Provincial | NHI

CD4

CD4 <= 100 (as % of Total) | CD4 <= 350 (as % of Total)

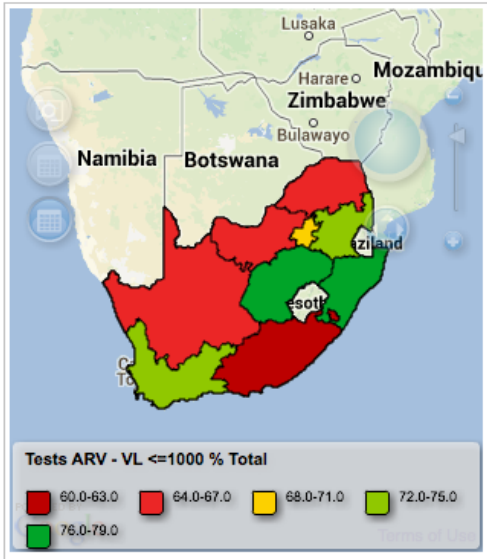


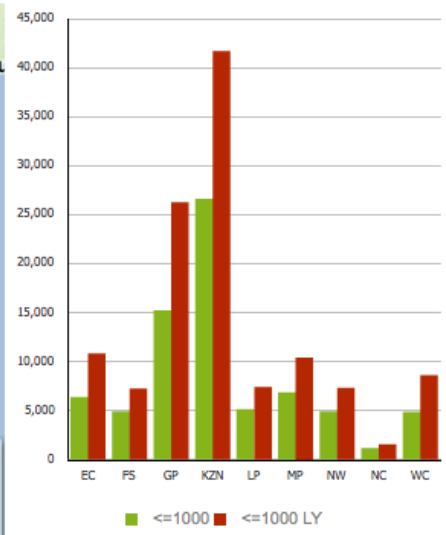


Province		Total Current	Total LY	<= 100 Current	<= 100 LY	Delta	%	% LY	
Eastern Cape	EC	20,659	37,253	2,579	4,435	(1,856)	12.5	11.9	↓
Free State	FS	10,548	19,471	1,165	2,185	(1,020)	11.0	11.2	↓
Gauteng	GP	33,613	68,753	4,593	8,818	(4,225)	13.7	12.8	↓
KwaZulu-Natal	KZN	62,563	108,538	5,069	10,417	(5,348)	8.1	9.6	↓
Limpopo	LP	13,436	23,829	1,702	3,115	(1,413)	12.7	13.1	↓
Mpumalanga	MP	17,722	31,239	1,972	3,755	(1,783)	11.1	12.0	↓
North West	NW	12,491	23,443	1,398	2,578	(1,180)	11.2	11.0	↓
Northern Cape	NC	3,343	5,873	371	596	(225)	11.1	10.1	↓
Western Cape	WC	10,223	20,173	1,036	1,756	(720)	10.1	8.7	↓
Total		184,598	338,572	19,885	37,655	(17,770)	10.8	11.1	

VL

VL <= 1000 (as % of Total) | VL > 1000 (as % of Total)





Province		Total Current	Total LY	<= 1000 Current	<= 1000 LY	Delta	%	% LY	
Eastern Cape	EC	10,013	16,089	6,395	10,843	(4,448)	63.9	67.4	↓
Free State	FS	6,324	9,584	4,936	7,254	(2,318)	78.1	75.7	↓
Gauteng	GP	21,348	34,751	15,245	26,269	(11,024)	71.4	75.6	↓
KwaZulu-Natal	KZN	34,133	53,167	26,595	41,687	(15,092)	77.9	78.4	↓
Limpopo	LP	7,579	10,375	5,150	7,401	(2,251)	68.0	71.3	↓
Mpumalanga	MP	9,478	13,772	6,853	10,420	(3,567)	72.3	75.7	↓
North West	NW	7,536	11,116	4,903	7,317	(2,414)	65.1	65.8	↓
Northern Cape	NC	1,830	2,606	1,196	1,555	(359)	65.4	59.7	↓
Western Cape	WC	6,423	10,864	4,881	8,611	(3,730)	76.0	79.3	↓
Total		104,664	162,324	76,154	121,357	(45,203)	72.8	74.8	

NATIONAL HEALTH LABORATORY SERVICE

M&E Geo Analysis

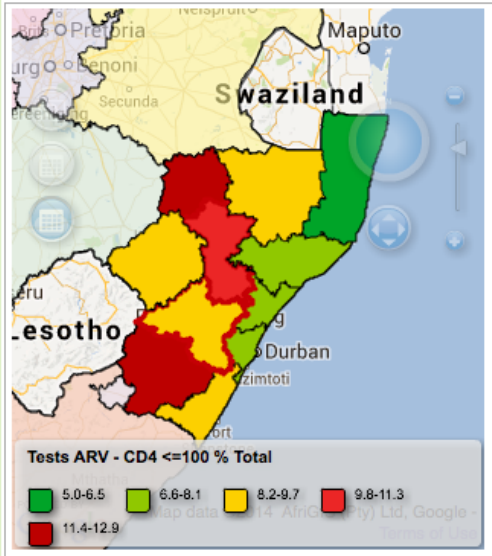
Year: 2014 | Quarter: Q1 2014 | Month: Jan 2014 | Age Range: All Ages

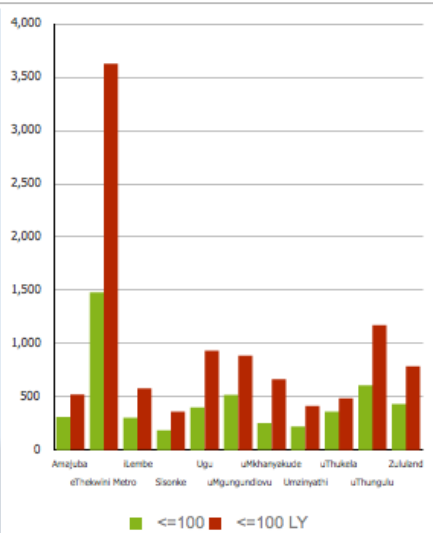
National | Provincial | NHI | Select Province: KwaZulu-Natal

KwaZulu-Natal

CD4

CD4 <= 350 (as % of Total) | CD4 <= 100 (as % of Total)

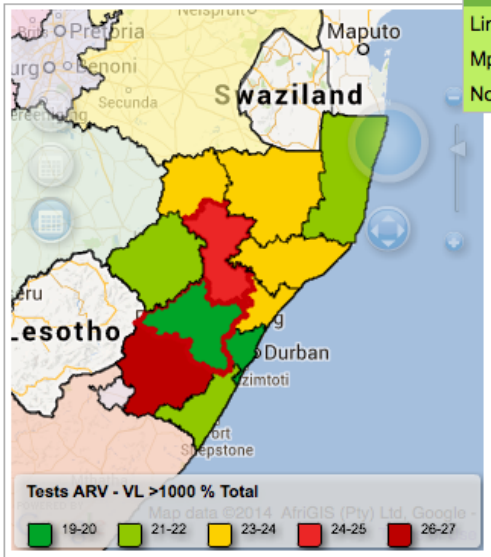


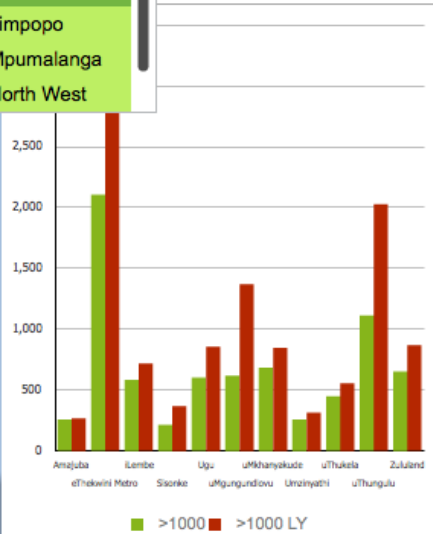


KwaZulu-Natal	Total		<= 100					
District	Current	LY	Current	LY	Delta	%	% LY	
Amajuba	2,637	4,542	310	520	(210)	11.8	11.4	
eThekwini Metro	19,427	36,265	1,480	3,624	(2,144)	7.6	10.0	
iLembe	4,099	6,899	303	577	(274)	7.4	8.4	
Sisonke	1,535	3,449	186	361	(175)	12.1	10.5	
Ugu	4,693	9,090	400	931	(531)	8.5	10.2	
uMgungundlovu	6,225	11,162	518	887	(369)	8.3	7.9	
uMkhanyakude	4,738	7,144	252	663	(411)	5.3	9.3	
Umzinyathi	2,039	3,320	222	412	(190)	10.9	12.4	
uThukela	4,120	5,299	359	485	(126)	8.7	9.2	
uThungulu	8,067	12,738	608	1,170	(562)	7.5	9.2	
Zululand	4,983	8,630	431	787	(356)	8.6	9.1	
Total	62,563	108,538	5,069	10,417	(5,348)	8.1	9.6	

VL

VL > 1000 (as % of Total)





KwaZulu-Natal	Total		> 1000					
District	Current	LY	Current	LY	Delta	%	% LY	
Amajuba	1,076	1,570	257	269	(12)	23.9	17.1	
eThekwini Metro	10,253	18,591	2,103	3,289	(1,186)	20.5	17.7	
iLembe	2,438	2,872	585	718	(133)	24.0	25.0	
Sisonke	795	1,602	215	368	(153)	27.0	23.0	
Ugu	2,765	4,142	602	856	(254)	21.8	20.7	
uMgungundlovu	3,123	6,823	619	1,370	(751)	19.8	20.1	
uMkhanyakude	3,183	3,641	684	847	(163)	21.5	23.3	
Umzinyathi	1,033	1,335	259	315	(56)	25.1	23.6	
uThukela	2,068	2,636	448	556	(108)	21.7	21.1	
uThungulu	4,652	6,711	1,112	2,025	(913)	23.9	30.2	
Zululand	2,747	3,244	654	867	(213)	23.8	26.7	
Total	34,133	53,167	7,538	11,480	(3,942)	22.1	21.6	

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But are we using the data optimally?

Innovative use of lab data- case study from Western Cape (Osler M et al. Journal of the International AIDS Society 2014)

- Western Cape monitoring and evaluation programme for ART services started in 2001 as:
  - paper registers at facilities scaling up ART services (majority) and
  - EMR software called EKAPA (Evaluation of the Khayelitsha AIDS ProgrAm) at the initial Khayelitsha sentinel sites
- This two-tier system was used to successfully monitor outcomes for the entire cohort up to 2008
- Clerical staff in large sites began to experience increasing strain maintaining the paper-based registers and extracting reports
- A stand-alone electronic HIV register had been developed by the University of Cape Town Centre for Infectious Disease Epidemiology and Research as a potential digitization option for paper registers
- This application (Tier.net) became the middle tier of the three-tier monitoring and evaluation system in 2008

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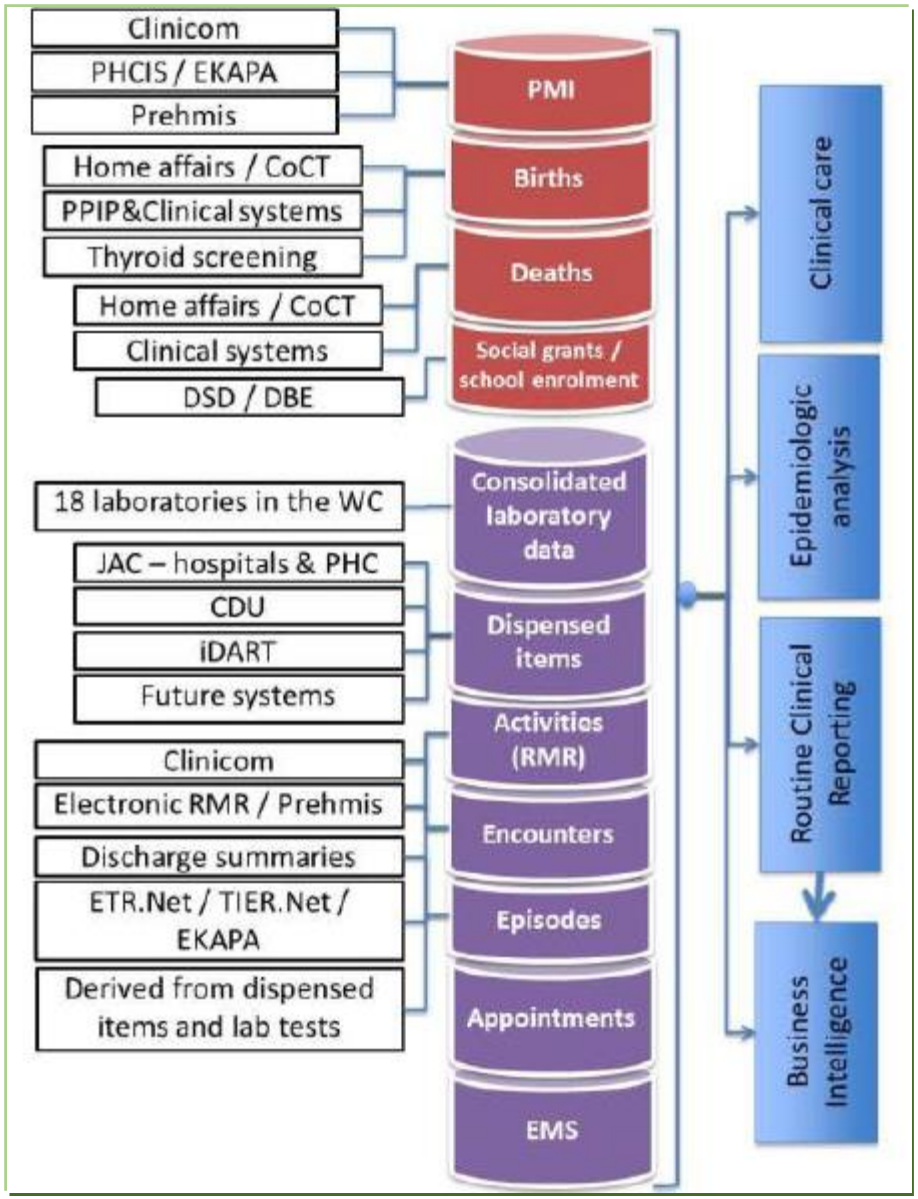
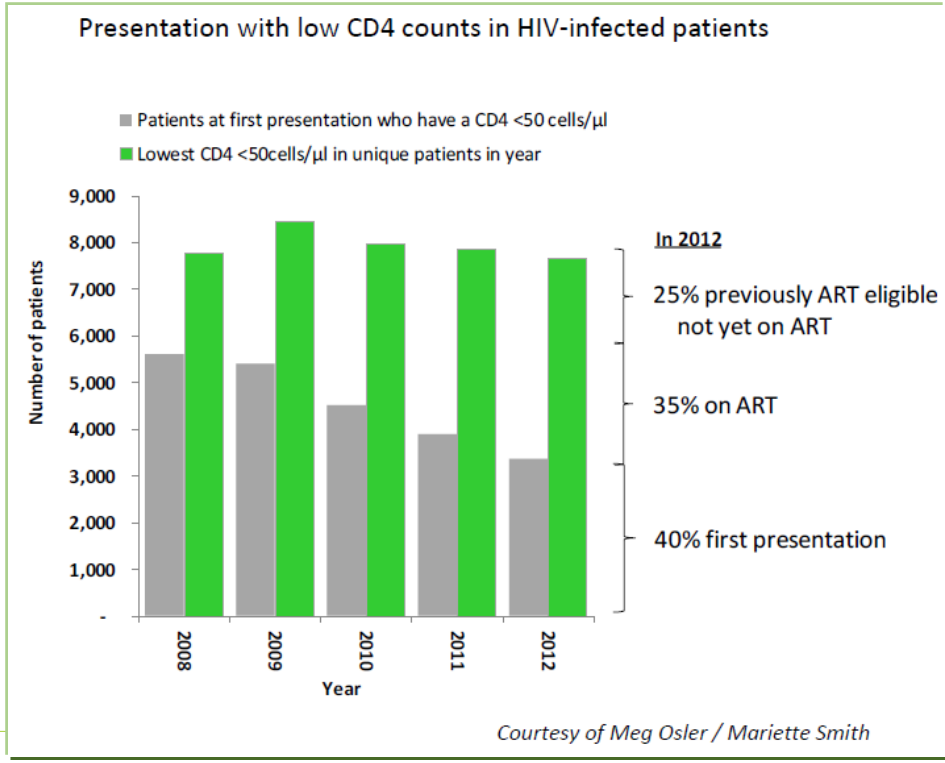
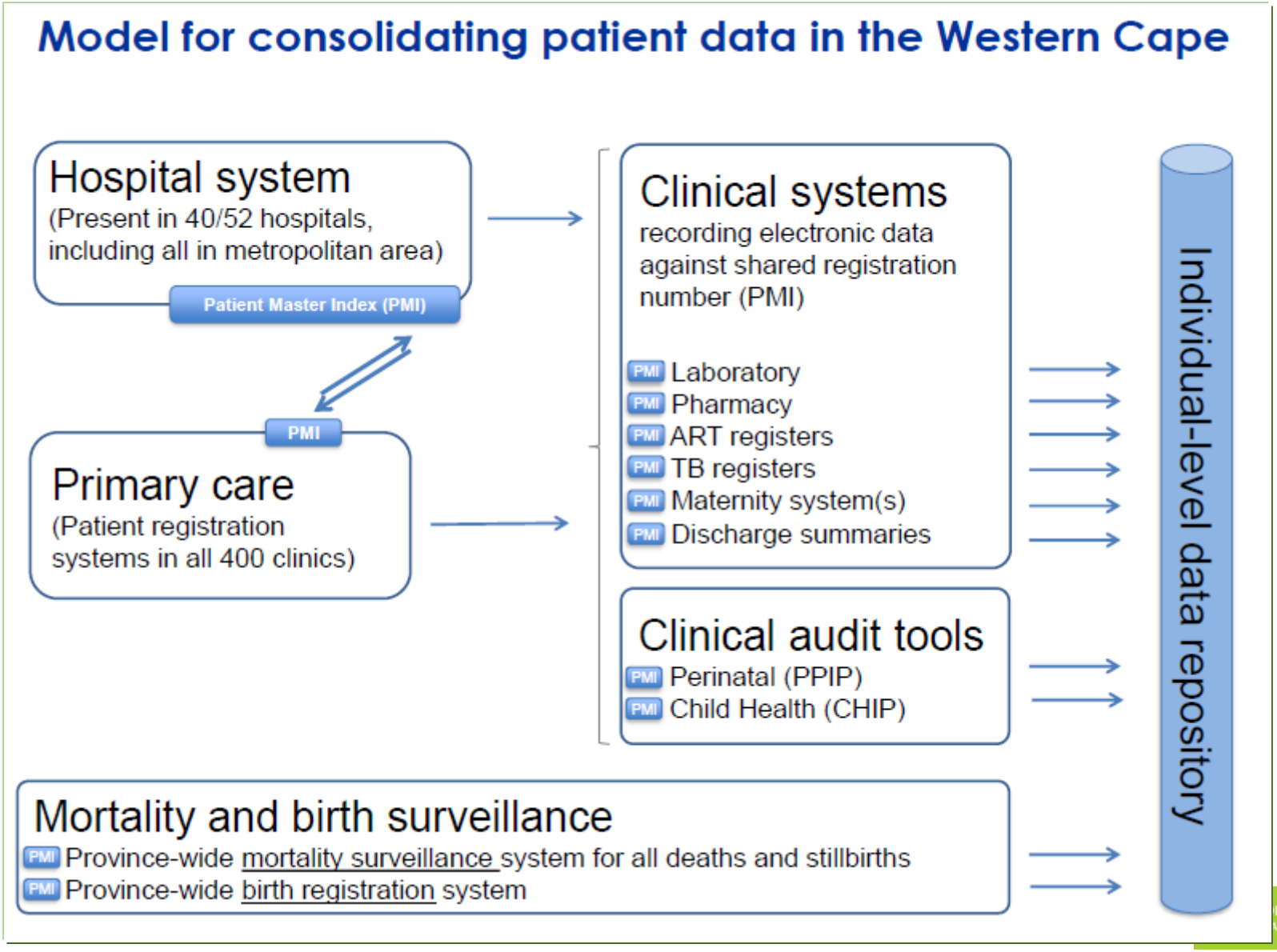


- Gathered routine cohort data from the WC ARV programme
- Combination of reports from paper antiretroviral registers, TIER.Net (the offline tier-2 software) and EKAPA (the tier-3 networked EMR)



Andrew Boulle, Centre for Infectious Disease Epidemiology and Research, UCT, CLI meeting August 2014

Master Patient Index- innovations from the Western Cape



Where do we go from here?

- Potential of CDW is vast and still underutilised

- **mHealth** solutions- Electronic interface -Simple, mobile phones/tablets
- 61 million active sim cards in SA. 14 million smart phones
- Working together with mobile networks to make this possible at every clinic
- App development, fingerprints, scanning

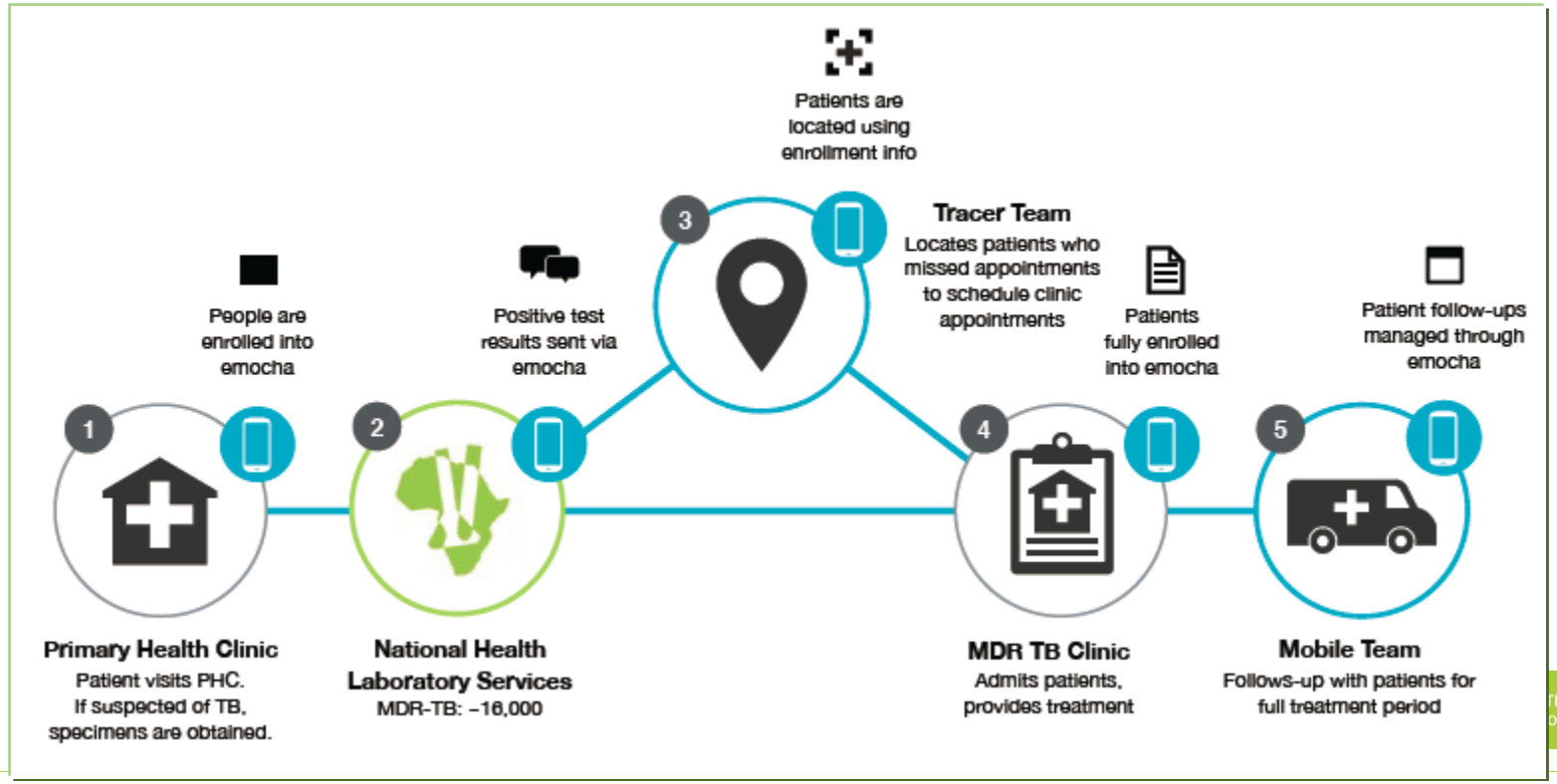
mHealth developments:

emocha®
MOBILE HEALTH INC.

a mobile health platform
for remote patient management

BALTIMORE, MARYLAND

To develop a comprehensive m-health solution to improve linkage-to-care for Rif resistant patients identified by the GeneXpert technology to ensure their rapid access to MDR-TB treatment



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Conclusion

- Systems are available in South Africa- need to make better use of them
- Guidelines are available for strategic and optimal use of data
- New mobile innovations available allowing for faster turnaround time and linkage into care

No Excuse!

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Thank You

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