Strategic Use of Lab Results

Dr Leigh Berrie
27 September 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

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)
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

![Users](chart1.png)

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

![Searches](chart2.png)
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
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
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 virally 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>
<thead>
<tr>
<th>TABLE 1 Standards used in the Checklist of standards and benchmarks for TB surveillance and vital registration system</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data quality</strong></td>
</tr>
<tr>
<td>1. Case definitions are consistent with WHO guidelines</td>
</tr>
<tr>
<td>2. TB surveillance system is designed to capture a minimum set of variables for all reported TB cases</td>
</tr>
<tr>
<td>3. All scheduled periodic data submissions have been received and processed at the national level</td>
</tr>
<tr>
<td>4. Data in quarterly reports (or equivalent) are accurate, complete and internally consistent <em>(For paper-based systems only)</em></td>
</tr>
<tr>
<td>5. Data in national database are accurate, complete, internally consistent and free of duplicates <em>(For electronic case-based or patient-based systems only)</em></td>
</tr>
<tr>
<td>6. TB surveillance data are externally consistent</td>
</tr>
<tr>
<td>7. Number of reported TB cases is internally consistent over time</td>
</tr>
<tr>
<td><strong>Coverage</strong></td>
</tr>
<tr>
<td>8. All diagnosed cases of TB are reported</td>
</tr>
<tr>
<td>9. Population has good access to health care</td>
</tr>
<tr>
<td><strong>Vital registration</strong></td>
</tr>
<tr>
<td>10. Vital registration system has high national coverage and quality</td>
</tr>
<tr>
<td><strong>DR-TB, TB/HIV and children</strong></td>
</tr>
<tr>
<td>11. Surveillance data provide a direct measure of drug-resistant TB in new cases</td>
</tr>
<tr>
<td>12. Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases</td>
</tr>
<tr>
<td>13. Surveillance data for children reported with TB are reliable and accurate, and all diagnosed childhood TB cases are reported</td>
</tr>
</tbody>
</table>
Current NHLS reporting

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

Centralised testing allows for central monitoring of operational aspects of VL, EID and CD4 testing: Dashboards

*connectivity of POC devices to a CDW imperative
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
  - Monthly Early 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

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

% Total 11.9 85.4 2.7 100.0

### National GeneXpert RIF Results (MTB Detected)

<table>
<thead>
<tr>
<th>Year</th>
<th>Inconclusive</th>
<th>Resistant</th>
<th>Sensitive</th>
<th>No RIF Result</th>
<th>Total</th>
<th>% RIF Resistant</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>332</td>
<td>2 441</td>
<td>31 513</td>
<td>155</td>
<td>34 441</td>
<td>7.1</td>
</tr>
<tr>
<td>2012</td>
<td>1 323</td>
<td>6 774</td>
<td>84 964</td>
<td>675</td>
<td>93 736</td>
<td>7.2</td>
</tr>
<tr>
<td>2013</td>
<td>5 376</td>
<td>13 965</td>
<td>189 967</td>
<td>1 147</td>
<td>210 455</td>
<td>6.6</td>
</tr>
<tr>
<td>2014</td>
<td>4 503</td>
<td>10 846</td>
<td>148 374</td>
<td>297</td>
<td>164 020</td>
<td>6.6</td>
</tr>
<tr>
<td>TOTAL</td>
<td>11 534</td>
<td>34 026</td>
<td>454 818</td>
<td>2 274</td>
<td>502 652</td>
<td>6.8</td>
</tr>
</tbody>
</table>

% Total 2.29 6.77 90.48 0.45 100
CD4, HIV viral Load and HIV PCR programme monitoring report

**CD4: Test Range:**

<table>
<thead>
<tr>
<th>Period</th>
<th>&lt;= 50</th>
<th>&gt; 50 &lt;= 100</th>
<th>&gt; 100 &lt;= 200</th>
<th>&gt; 200 &lt;= 350</th>
<th>&gt; 350 &lt;= 500</th>
<th>&gt; 500</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2013 - July 2014</td>
<td>184 716</td>
<td>166 249</td>
<td>400 272</td>
<td>801 610</td>
<td>847 398</td>
<td>1 358 938</td>
<td>3 759 183</td>
</tr>
<tr>
<td>Aug 2012 - July 2013</td>
<td>199 582</td>
<td>183 159</td>
<td>446 919</td>
<td>885 127</td>
<td>874 882</td>
<td>1 233 005</td>
<td>3 822 674</td>
</tr>
</tbody>
</table>

**HIV DNA PCR: Test Range:**

<table>
<thead>
<tr>
<th>Period</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal</th>
<th>Invalid</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2012 - July 2013</td>
<td>14 768</td>
<td>309 210</td>
<td>592</td>
<td>6</td>
<td>324 576</td>
</tr>
</tbody>
</table>

**HIV Viral Load: % <=1000 and >1000**

<table>
<thead>
<tr>
<th>Period</th>
<th>&lt;=1000</th>
<th>&gt;1000</th>
<th>Total</th>
<th>%&lt;=1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2013 - July 2014</td>
<td>2 051 114</td>
<td>613 664</td>
<td>2 664 778</td>
<td>76.97</td>
</tr>
<tr>
<td>Aug 2012 - July 2013</td>
<td>1 621 376</td>
<td>519 721</td>
<td>2 141 097</td>
<td>75.73</td>
</tr>
</tbody>
</table>

**Test Volumes**

- CD4
- HIV VIRAL LOAD
- HIV DNA PCR

**CD4: Test Range: Aug 2013 - July 2014**

- <= 50: 5%
- > 50 <= 100: 4%
- > 100 <= 200: 11%
- > 200 <= 350: 21%
- > 350 <= 500: 23%
- > 500: 36%
Early Infant Diagnosis reports

<table>
<thead>
<tr>
<th>Province</th>
<th>Current</th>
<th>YTD</th>
<th>LY</th>
<th>LY YTD</th>
<th>Current</th>
<th>YTD</th>
<th>LY</th>
<th>LY YTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eastern Cape</td>
<td>EC</td>
<td>40</td>
<td>256</td>
<td>23</td>
<td>270</td>
<td>91.2</td>
<td>78.3</td>
<td>71.3</td>
</tr>
<tr>
<td>Free State</td>
<td>FS</td>
<td>13</td>
<td>107</td>
<td>19</td>
<td>153</td>
<td>92.0</td>
<td>80.4</td>
<td>72.5</td>
</tr>
<tr>
<td>Gauteng</td>
<td>GP</td>
<td>73</td>
<td>442</td>
<td>63</td>
<td>482</td>
<td>95.2</td>
<td>85.1</td>
<td>83.6</td>
</tr>
<tr>
<td>KwaZulu-Natal</td>
<td>KZN</td>
<td>60</td>
<td>472</td>
<td>95</td>
<td>613</td>
<td>92.3</td>
<td>85.8</td>
<td>104.4</td>
</tr>
<tr>
<td>Limpopo</td>
<td>LP</td>
<td>45</td>
<td>259</td>
<td>38</td>
<td>301</td>
<td>84.0</td>
<td>73.2</td>
<td>67.9</td>
</tr>
<tr>
<td>Mpumalanga</td>
<td>MP</td>
<td>43</td>
<td>261</td>
<td>36</td>
<td>278</td>
<td>91.4</td>
<td>82.8</td>
<td>77.0</td>
</tr>
<tr>
<td>North West</td>
<td>NW</td>
<td>30</td>
<td>154</td>
<td>27</td>
<td>197</td>
<td>74.3</td>
<td>66.1</td>
<td>66.3</td>
</tr>
<tr>
<td>Northern Cape</td>
<td>NC</td>
<td>12</td>
<td>47</td>
<td>7</td>
<td>36</td>
<td>89.3</td>
<td>80.2</td>
<td>64.6</td>
</tr>
<tr>
<td>Western Cape</td>
<td>WC</td>
<td>26</td>
<td>148</td>
<td>26</td>
<td>129</td>
<td>91.1</td>
<td>85.5</td>
<td>73.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>353</td>
<td>2,146</td>
<td>334</td>
<td>2,457</td>
<td>90.3</td>
<td>81.2</td>
<td>82.2</td>
</tr>
</tbody>
</table>

YTD - Year to Date
LY - Last Year
Upcoming CD4 and Viral load reports
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
• 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

Model for consolidating patient data in the Western Cape

Hospital system
(Present in 40/52 hospitals, including all in metropolitan area)

Patient Master Index (PMI)

Primary care
(Patient registration systems in all 400 clinics)

Clinical systems
recording electronic data against shared registration number (PMI)

PMI Laboratory
PMI Pharmacy
PMI ART registers
PMI TB registers
PMI Maternity system(s)
PMI Discharge summaries

Clinical audit tools
PMI Perinatal (PPIP)
PMI Child Health (CHIP)

Individual-level data repository

Mortality and birth surveillance
Province-wide mortality surveillance system for all deaths and stillbirths
Province-wide birth registration system

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

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.
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!
Acknowledgements

- Prof Wendy Stevens and the NPP team
- Dr Sergio Carmona
- Prof Lesley Scott
- Prof Gayle Sherman
- Mr Sebaka Molapo
- Sue Candy and NHLS CDW
- Lynsey Isherwood and Floyd Olsen
- Naseem Cassim and Oriel Mahlatsi
- National Department of Health

Thank You