Challenges in the Clinic-Laboratory Interface

Tim Tucker
M.B.Ch.B - Ph.D. - F.C.Path(SA)Viro
Why worry about the laboratory?

- Clinicians rely on a variety of skills
  - Clinical examination
  - Special investigations
  - Intuition?

Pathology tests

- Clinical decisions - diagnosis and monitoring
  - Developed countries - 70%
  - African countries - 20%
Why Clinic-Laboratory Interface?

- Complex
  - Systems approach
SA - Clinic-Laboratory Interface
28 Steps in the Process
23 Requirements for the Process

Specimen Collection: HIV and General Blood

START: Registration

28 Steps in the Process

Clinic - HCW
- Take barcode from form and paste onto insert folder
- Fasten and apply tourniquet to upper arm
- Straighten patient's arm
- Clean antecubital fossa using a swab
- Locate vein
- Insert vacutainer needle on vein
- Insert tube on the vacutainer
- Fill tube with maximum blood volume required
- Removes tube and then needle
- Place cotton wool on insertion site to stop bleeding
- Discard needle

Patient
- General or VCT consultation for HIV diagnosis
- Check protocol criteria
- Protocol criteria met?
- Yes
- Refer patient back to doctor / counselling
- No
- Explain testing process to patient
- Place consumables on the table
- Show patient that all consumables are still sealed
- Open ARV insert folder or patient folder
- Complete form and attach patient labels
- Complete form and patients details

Requirements for the Process
- Patient name folder or ARV folder
- Patient labels
- Patient medical record
- Patient state
- Patient details
- Patient history
- Patient demographics
- Patient test results
- Patient ID
- Patient address
- Patient contact number
- Patient occupation
- Patient marital status
- Patient education
- Patient income
- Patient religion
- Patient smoking status
- Patient alcohol consumption
- Patient drug use
- Patient sexually transmitted infections
- Patient sexual orientation
- Patient gender identity
- Patient mental health

End
Data is limited on performance

Pre-analytic and post-analytic
1: Guidance documents

2: HCW training on specimen collection
Guidance Documents

- **SOP's/ Guidelines/ Policies**
  - **Phlebotomy**: 57% Adequate/Present, 15% Partial/Problematic, 28% Poor/Absent
  - **Infection control**: 8% Adequate/Present, 21% Partial/Problematic, 71% Poor/Absent
  - **Biohazardous waste disposal**: 21% Adequate/Present, 27% Partial/Problematic, 52% Poor/Absent

- **Results**
  - Green: Adequate/Present
  - Orange: Partial/Problematic
  - Red: Poor/Absent

- **5 districts**
  - E. Cape and KZN

- **Does facility have sample transport SOP?**
  - 45% Adequate/Present, 50% Partial/Problematic

- **Does facility have SLA with NHLS?**
  - 88% Adequate/Present, 10% Partial/Problematic

- **Does facility have specimen collection SOP?**
  - 44% Adequate/Present, 50% Partial/Problematic

- **Does facility have specimen handling & storage SOP?**
  - 45% Adequate/Present, 50% Partial/Problematic

- **5 districts**
  - L/NW/G/WC
## Training Activities

<table>
<thead>
<tr>
<th>Training</th>
<th>% of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlebotomy &amp; specimen collection</td>
<td>64% 30% 5%</td>
</tr>
<tr>
<td>Specimen handling &amp; storage</td>
<td>77% 18%</td>
</tr>
<tr>
<td>Infection control</td>
<td>34% 34% 33%</td>
</tr>
<tr>
<td>Biohazardous waste disposal</td>
<td>43% 29% 29%</td>
</tr>
</tbody>
</table>

5 districts
E. Cape and KZN
Results management

1: Getting the result back to the patient
2: Reviewing process
### Communication Technology

#### Email access
- 64% access (Red)
- 24% access (Orange)
- 12% access (Green)

#### Fax access
- 47% access (Red)
- 29% access (Orange)
- 24% access (Green)

#### Telephone access
- 15% access (Red)
- 10% access (Orange)
- 75% access (Green)

<table>
<thead>
<tr>
<th>Method of receiving lab test results - Paper</th>
<th>% of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>96%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method of receiving lab test results - SMS Printer</th>
<th>% of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMS Printer</td>
<td>90%</td>
</tr>
</tbody>
</table>

5 districts
E. Cape and KZN

5 districts
L/NW/G/WC
### Results Management

<table>
<thead>
<tr>
<th>Question</th>
<th>Percentage</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the facility access results electronically?</td>
<td>70%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Does the facility Forum to review lab support services with NHLS and or DOH?</td>
<td>73%</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>Does the facility have SOP or system to follow up outstanding results?</td>
<td>23%</td>
<td>70%</td>
<td></td>
</tr>
<tr>
<td>Does the facility have SOP or system to monitor results TAT?</td>
<td>10%</td>
<td>18%</td>
<td>72%</td>
</tr>
<tr>
<td>Does the facility have SOP or system to receive, record &amp; file results?</td>
<td>19%</td>
<td>10%</td>
<td>71%</td>
</tr>
</tbody>
</table>

5 districts
E. Cape and KZN
## Results Management

<table>
<thead>
<tr>
<th>Laboratory test results management</th>
<th>% of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test requested in Specimen Tracking Register</td>
<td>58%</td>
</tr>
<tr>
<td>Result alerts for abnormal/ urgent specimens</td>
<td>40%</td>
</tr>
<tr>
<td>Trouble-shooting: identify &amp; resolve results</td>
<td>58%</td>
</tr>
</tbody>
</table>

Results
- **Adequate/ Present**
- **Absent/ Partial**

5 districts
E. Cape and KZN

---

**SEAD**
Strategic Evaluation, Advisory & Development Consulting
**Quality Management**

### Quality improvement system

<table>
<thead>
<tr>
<th>Quality improvement system</th>
<th>Adequate/ Present</th>
<th>Partial/ Problematic</th>
<th>Poor/ Absent</th>
<th>% of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMS/QA/QI plan</td>
<td>22%</td>
<td>30%</td>
<td>48%</td>
<td></td>
</tr>
<tr>
<td>Collection &amp; reporting performance data</td>
<td>31%</td>
<td>41%</td>
<td>28%</td>
<td></td>
</tr>
<tr>
<td>Performance data review</td>
<td>37%</td>
<td>40%</td>
<td>23%</td>
<td></td>
</tr>
</tbody>
</table>

### Results

- **Adequate/ Present**
- **Partial/ Problematic**
- **Poor/ Absent**

### Laboratory test utilisation review

<table>
<thead>
<tr>
<th>Laboratory test utilisation review</th>
<th>Adequate/ Present</th>
<th>Partial/ Problematic</th>
<th>Poor/ Absent</th>
<th>% of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pattern of expenditure of lab testing</td>
<td>82%</td>
<td>15%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Adequacy/rejected specimens sent to lab</td>
<td>45%</td>
<td>41%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>TAT from dispatch to results received</td>
<td>53%</td>
<td>35%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Trouble shooting</td>
<td>48%</td>
<td>34%</td>
<td>18%</td>
<td></td>
</tr>
</tbody>
</table>

% of facilities
CLI – overarching consensus

- Laboratory ‘value-chain’
  - does not function optimally

- Often not a “laboratory” issue

- Interface
What are the factors inhibiting the CLI?

1: where is problem?

2: responsible agency?
Factors inhibiting the CLI

- Unique identifier
- Unique identifier
- Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
  - Unique identifier
Factors inhibiting the CLI

- Lack of systems approach
- Improved training
- Better usage of phlebotomists
  - Policy and practice
- Better review of laboratory services
  - By clinics and districts
- Better utilization of CDW
  - National / provincial
Factors inhibiting the CLI

• Optimized courier service
  – Anything is possible – cost/benefit

• Possible review of NHLS operating times

• Courier – maximize opportunity
  – Link courier to supply chain management
  – Stock management

• Improved IT/communications backbone
  – Partial / limited control within health
  – Urban / rural
Factors inhibiting the CLI

Over arching themes

• Communication
  – All levels
• QA across the entire value chain
  – Have to “own” the process
• HR across entire value chain
  – Task shifting / augment
• Appropriate space, storage, training
• More POCT responsibility to NHLS
  – Task dumping
  – Role of phlebotomists
NHLS breadth of practice?
Laboratory Process Value Chain - Public

**Clinic**
- Provisioning of Consumables
- Patient Registration
- Consultation and Specimen Collection
- Clinic Specimen Dispatch

**NHLS**
- NHLS Receiving & Sorting
- NHLS Specimen Registration
- NHLS Labelling & Scanning
- NHLS Testing of Specimen
- NHLS Results Publication

**Courier**
- Results Collection, Transportation & Delivery
- Courier Transportation & Delivery

**Clinic**
- Clinic Receiving of Results and filing
- Communication of Results
Concluding thoughts

• It is clear that the system is not optimal

• Multiple areas
  – Simple to complex
  – Unique identifier
  – Getting the result back to the patient

• Multiple major stakeholders
  – Each needs to deliver
  – Relationships important

• Increasing NHLS scope of work enticing
  – Requires multi-level agreement
Acknowledgements

- PEPFAR/CDC grants since 2008

- Current partners
  - Aurum and Beyond Zero

- SEAD team leadership
  - Peter Manyike
  - Leonie Coetzee
  - Irvin Mothibi
  - Makhosazana Makhanya
  - Veronica Mbali
  - Armelia Chaponda
  - Kerrin Begg
  - CLI team
  - District-based lab coordinators
Thank you