Quicker, Better, Faster

Optimising Turn Around Time of Laboratory Results

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Outline

- Organogram
- Turn around time (TATs) for lab results
  - On-Site Testing
  - Outsourced Testing
    - Rationale for Selection of Outsourced Laboratories
    - CLS and BARC TATs
- Clinic Flow of Results
- Challenges and Resolutions
**Laboratory Organogram**

**PI/ Research Clinician:** Sinead Delany-Moretlwe

**Investigator of Record:** Thesla Palanee

**Research Clinicians:**
- Modulakgotla Sebe
- Nina Von Knorring
- Kgomotso Morakane Ramasodi
- Ogheneruemu Vincent Okwuolise

**National Regulatory Compliance Manager:** Pranitha Ramchuran

**Medical Technologists:**
- Lindelwa Nkangane (LN)
- Nomfundo Maduna (Back Up)

**Research Nurses:**
- Angel Nyathi (ATN)
- Nkgolo Gegana (NMG)
- Aloysia Makau (AM)
- Xolelwa Matikinca (XJM)
- Christine Mapule Maruma (CMM)

**Clinical Quality Improvement Mentor (CQIM):**
- Lebogang Modise (CLM)
- Busi Mnguni (BM)

**Colour Key:**
- HIV, Vaginal pH; TV; BV
- Preg, Urine Dipstick, Wet Mount, Internal QC
On-Site Laboratory Testing

Laboratory Specimens and Testing

- **Urine**
  - Urinalysis: Bayer Uristix 4/Multistix 9
  - Pregnancy Testing: Quidel QuickVue

- **Blood**
  - HIV Serology: Abbot Determine, OraSure OraQuick, Unigold Recombigen
  - SDA: GC/CT ⇒ BARC (Separation – 5ml)

- **Genital**
  - Vaginal pH
    - Machery-Nagel
  - Vaginal Gram Stain
  - Vaginal Swab
  - Endocervical Swab ⇒ MTN Network Lab
  - Rapid TV; BV
    - OSOM Trichomonas
    - BV Blue
  - KOH Wet Mount
  - MNT Network Lab
Rationale for Selection of Outsourced Laboratories

- Service providers identified
  - CLS, BARC (Jhb/Dbn), MRC Central Laboratory (Dbn)

- Technical protocols developed
  - Past experiences
  - Quickest TATs
  - Financial Penalty Clauses implemented

- Bioanalytical Research Corporation (BARC):
  - GC/CT
    - Quicker TAT than MRC Central Laboratory (Dbn)
      - (3-4 days vs 5 days)
  - Pap Smear:
    - Quicker TAT than CLS
    - 3 days vs 24 hours
    - Change from conventional smear to liquid based cytology
      - More sensitive
      - Reduces call back of ppts due to inadequate pap smears
  - Reduce time between Scr 1 and Scr 2
MTN 003 Outsourced Laboratory Testing

Laboratory Specimens and Testing

Serology:
- HBsAg
- HBsAb
- HIV Western Blot

Flow Cytometry:
- CD4+ T-cells

Haematology:
- FBC

PCR:
- Viral Load

Chemistry:
- AST; ALT;
- Phosphorous;
- Creatinine

Plasma Archive

Storage:
- Vaginal Gram Stain
- Vaginal Swab
- Endocervical Swab
  ⇒ MTN Network Lab

Urine:
- SDA: GC/CT

Pap Smear:
- BD Surepath

Flow Cytometry:
- CD4+ T-cells

PCR:
- Viral Load

Plasma Archive

Storage:
- Vaginal Gram Stain
- Vaginal Swab
- Endocervical Swab
  ⇒ MTN Network Lab

Urine:
- SDA: GC/CT

Pap Smear:
- BD Surepath
<table>
<thead>
<tr>
<th>Discipline</th>
<th>Test</th>
<th>Turn around time (TAT)</th>
<th>Lab Performing the Assay</th>
<th>Back-up Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serology</td>
<td>HBsAg</td>
<td>2 working days</td>
<td>CLS Jhb</td>
<td>National Health Laboratory Services (NHLS)</td>
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<tr>
<td></td>
<td>HBsAb</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Syphilis</td>
<td>3 working days</td>
<td>CLS Jhb</td>
<td>NHLS Jhb</td>
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<tr>
<td></td>
<td>HIV Western Blot</td>
<td>5 working days</td>
<td>National Institute of Communicable Diseases (NICD)</td>
<td>NHLS Jhb</td>
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<td>Haematology</td>
<td>Full Blood Count</td>
<td>48 hours</td>
<td>CLS Jhb</td>
<td>NHLS Jhb</td>
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<tr>
<td>Chemistry</td>
<td>AST; ALT; Phosphorous; Creatinine</td>
<td>24 hours</td>
<td>CLS Jhb</td>
<td>NHLS Jhb</td>
</tr>
<tr>
<td>PCR</td>
<td>Viral Load</td>
<td>5 working days</td>
<td>NHLS Jhb</td>
<td>NHLS Jhb</td>
</tr>
<tr>
<td>Flow Cytometry</td>
<td>CD4+ T-cells</td>
<td>24 hours-weekdays; 72 hours-weekends and public holidays</td>
<td>NHLS Jhb</td>
<td>NHLS Jhb</td>
</tr>
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<tr>
<td>Molecular Biology</td>
<td>SDA – GC/CT</td>
<td>3-4 days</td>
<td>BARC KZN</td>
<td>Lancet Jhb</td>
</tr>
<tr>
<td>Cytology</td>
<td>Pap Smear (BD Surepath – Liquid based cytology)</td>
<td>24 hours</td>
<td>Lancet Cytology Jhb</td>
<td>BARC In-house Multiple back-ups</td>
</tr>
</tbody>
</table>
Outsourced Testing

- Visit-specific sample requisition forms
  - Volumes
  - If indicated samples

- Urgent Samples requiring testing
  - Use of “URGENT” stickers
  - Phone calls and emails to CLS/BARC
    - Accrual Phase: Urgent Screening Samples
    - Follow-up Phase:
      - AE Follow-up
      - Seroconvertor Samples

- Communication with CLS and BARC
  - Equipment and Consumable related delays
Flow of Laboratory Results

- QC of Requisition form
- Clinical Review and Management
- Shipping of samples
- Receipt and QC of Results
- Generation of DCFs
Challenges: Staff Capacity

- One Clinician
  - Transcription delays
  - High freq of DCFs

- Additional clinicians employed
  - Med Tech employed

- QC systems improved
  - Requisition forms
  - Lab Result Reports
  - Shipping Logs
  - DCF Resolution within 24 hours
Acknowledgements

- Lab and Clinical Team at Wits Reproductive Health and HIV Institute