VCT in the field:
A comprehensive evaluation of how staff perform VCT in primary health clinics in SA.
Opportunities to improve this service to the community

SA HIV Clinicians’ Society Meeting

20 January 2011
Integrated Clinical- Laboratory System Interface Analysis:
How to improve the pre-analytical and post-analytical phases of specialist laboratory tests at South African PHC clinics
Acknowledgements

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- Maggie Mphahlwa
- Cobi Kruger
- Pam Stone
- Tracy-Anne Castle
- Tilly Meyer
Scope of work 2

- Laboratory tests:
  - **Point-of-Care:**
    - VCT Rapid Test
  - **HIV:**
    - **Virology & Molecular Genetics:** ELISA, Viral Load, PCR
    - **Haematology:** FBC, CD4
    - **Chemistry:** U&E, Lactic Acid
  - **TB:**
    - **Microbiology:** TB microscopy, TB culture, DST sensitivity, Line-probe assay
  - **Cervical CA**
    - **Cytology:** Cervical smears (Population screening)
  - **STIs**
    - **Serology:** VDRL
Analysis sites

• Targeted Site selection
  by Provincial Lab Services Co-ordinators

• Facility types: Primary Health Care Clinics / Health Centres
  • All 9 provinces
  • Intended minimum 36 clinics/health care centres + related drainage laboratories (*Actual = 38 clinics*)
    • 2 anecdotally “poorly functioning” clinic/province (based on the 18 “priority district” list)
    • 2 anecdotally “well functioning” clinics/province
  • A reasonable rural : urban spread
CLI process structure – Process & Activity Group

- Provisioning of Consumables
- Patient Registration
- Consultation and Specimen collection
- Clinic Specimen Dispatch

Value Chain Category

Process

Activity Group

- Pre-test counselling
- Identify, History, Register, Gloves
- Test 1
- Test 1 Incubation
- Test 1 Results
- Test 2
- Test 1 incubation & Results
- Post-test counselling & HIV Bloods

e.g. HIV VCT
CLI full process maps

CLINIC – LABORATORY INTERFACE PROCESS

Funded by:
Specimen Collection: HIV Rapid Test

27 Steps in the Process
9 Requirements for the Process

Clinic - HCW

Start

1. Prick finger and swipe first blood
2. Put blood drop on test strip
3. Place test strip / kit, patients details & switch timer on

V

4. Ask a patient to step outside for required time
5. Call patient
6. Show patient results

Results positive?

- Ask patient to come after 3 months for another test
- Wait for required time as per test instruction

Results negative?

- Conduct confirmatory test
- Clean tip of the finger

Yes

- Take patient for post-counselling
- Specimen collection HIV, CD4 & VL

No

- Specimen collection for ELISA

END
Specimen Collection: HIV and General Blood

28 Steps in the Process
23 Requirements for 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
- Remove tube and then needle
- Place cotton wool on insertion site to stop bleeding
- Discard needle

Patient
- Registration
- General or VDT consultation for HIV diagnosis
- Check protocol criteria
- Refer patient back to doctor / counselling
- 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

- The following consumables used:
  - Tourniquet
  - Swabs
  - Vacutainer needle
  - Vacutainer
  - Specimen tube

NHLs CD4 and/or Pathology laboratory request form
- Complete the form with:
  - Demographics
  - Test required
  - ID number

Clinic Specimen Dispatch
- Take specimen to dispatch
- Complete internal register with patient details
- Discharge patient with appointment to return for results
- Take specimen to laboratory

* All sharp objects are placed in the sharps container
* Register is used to track patients results

Discard other consumables in waste and general bins
- Apply barcode from form to tube
- Put form and specimen tube into bag
- Explain to patient duration of test
- Complete HIV counselling & testing client records register
- Complete internal register with patient details
- Take specimen to laboratory
- Complete HIV counselling & testing client records register
- HIV counselling & testing client records register
- Place cotton wool on insertion site to stop bleeding
- Discard needle
Data collection – Definitions

• Process Compliance:

Data Collectors observed the way in which the Clinic / Lab staff conducted every activity step in the process and checked against the pre-defined “Good Practice” Procedures defined in the Process Mapping phase.
Data collection - Definitions

• Requirement Availability Compliance:

Data Collectors observed whether all requirements (consumables, forms etc) were available in order to conduct the Process appropriately
Data collection - Definitions

- Requirement Usage Compliance:
  - defined as using the necessary requirements as specified in the process map.
Data collection - Definitions

• Turn-around Time:

*Data Collectors observed the time it took the Clinic / Lab staff to conduct each of the activity groups in the process*
DEMOGRAPHIC ANALYSIS
Clinic Demographics

Clinic Demographics - Staffing Profile by Geographic Location

- Rural:
  - Other: 20%
  - Lay HCW: 33%
  - Professional HCW: 47%

- Small Town:
  - Other: 25%
  - Lay HCW: 20%
  - Professional HCW: 54%

- Urban:
  - Other: 21%
  - Lay HCW: 21%
  - Professional HCW: 59%
VCT Process compliance

- How compliant were the 265 observations with the witnessed “good practice” described in the “as designed” phase?
  - At Activity Step Level
  - At Activity Group level
  - At overall Process level

- Analyzed by:
  - National perspective
  - Provincial perspective
  - Geographical location (Urban, Rural, Rural-remote)
  - “Good” vs “Poor”
  - HCW Workload

- What were the reasons for non-compliance?
Test 2 results to be viewed in light of next graph.
HIV VCT Rapid Test Process Compliance
- at Activity Group level (National)
Test 2 Analysed - when actually performed

- Identify patient: 72.83%
- Register, history and gloves: 28.30%
- Test 1: 29.06%
- Test 1 Incubation: 27.17%
- Test 1 Results: 66.42%
- Test 2: 18.52%
- Test 2 Results: 12.96%
- Post Counseling: 16.60%
## VCT Rapid Test Process Compliance - at Activity Group Level (Province)

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<tr>
<th>Province</th>
<th>Scenarios</th>
<th>Identify patient</th>
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<th>Test 1 Incubation</th>
<th>Test 1 Results</th>
<th>Test 2</th>
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<th>Post-counseling</th>
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HIV VCT Rapid Test Process Compliance – at Activity Group level (HCW Workload)

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<td>53%</td>
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<tr>
<td>Test 1</td>
<td>20%</td>
<td>34%</td>
<td>32%</td>
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<tr>
<td>Test 1 Incubation</td>
<td>7%</td>
<td>39%</td>
<td>32%</td>
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<tr>
<td>Test 1 Results</td>
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<td>Test 2</td>
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<tr>
<td>Test 2 Results</td>
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<td>68%</td>
<td>85%</td>
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<tr>
<td>Post Counseling</td>
<td>13%</td>
<td>19%</td>
<td>18%</td>
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</table>
HIV VCT Rapid Test Process Compliance – at Role level (National)

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<td>13%</td>
<td>53%</td>
<td>81%</td>
<td>81%</td>
<td>11%</td>
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</table>
VCT Rapid Test Process Compliance
– at Process level (National)

National: 3.40%
VCT Rapid Test Process Compliance – at Process level (Province)
VCT Rapid Test Process Compliance – at Process level (Geographical Location)

- Rural: 6.90%
- Small town: 0.00%
- Urban: 1.72%
VCT Rapid Test Process Compliance – at Process level ("Good" vs "Poor")

- Good: 3.33%
- Poor: 3.53%
HIV VCT Rapid Test Process Compliance
- at Process Level (HCW Workload)

- 1-300: 2.13%
- 301-600: 2.92%
- 601-1200: 8.82%
VCT Requirement compliance

1. What proportion of the 265 observations had all requirements available? (Requirement availability)

2. And used the requirements appropriately? (Requirement Usage)
   - At Activity Step Level
   - At Activity Group level
   - At overall Process level

   Analysed by:
   - National perspective
   - Provincial perspective
   - Geographical location (Urban, Rural, Rural-remote)
   - “Good” vs “Poor”
   - HCW Workload

What were the reasons for non-compliance?
### VCT Rapid Test - Requirement Availability by Item (Province)

<table>
<thead>
<tr>
<th>Province</th>
<th>Swab</th>
<th>VCT register</th>
<th>Weekly HIV Register</th>
<th>Test 1 strip</th>
<th>Test 1 buffer</th>
<th>Timer</th>
<th>Finger prick device</th>
<th>Test 2 strip</th>
<th>Test 2 buffer</th>
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<tr>
<td>LP</td>
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<td>100%</td>
<td>100%</td>
<td>49%</td>
<td>80%</td>
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<tr>
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<td>100%</td>
<td>33%</td>
<td>96%</td>
<td>96%</td>
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</table>
VCT Rapid Test - Requirement Availability Compliance - at Process level (Province)

- Eastern Cape: 0.00%
- Free State: 8.82%
- Gauteng: 0.00%
- KwaZulu-Natal: 32.26%
- Limpopo: 42.86%
- Mpumalanga: 78.57%
- North West: 25.00%
- Northern Cape: 38.46%
- Western Cape: 22.22%
VCT Rapid Test - Requirement Availability Compliance - at Process level (Geographic Location)

- Rural: 31.90%
- Small town: 24.18%
- Urban: 12.07%
VCT Rapid Test - Requirement Availability Compliance - at Process level ("Good" vs. "Poor")

26.11%

22.35%

Good

Poor
VCT Rapid Test Requirements Availability Compliance - Process Level (HCW Workload)

- 1-300: 14.89%
- 301-600: 27.74%
- 601-1200: 41.18%
HIV VCT Rapid Test - Requirement Usage Compliance – Activity Group level (National)

- Register, history and gloves: 49.06%
- Test 1: 85.66%
- Test 2: 9.81%
<table>
<thead>
<tr>
<th>Province</th>
<th>Scenarios</th>
<th>History, Register, Gloves</th>
<th>Test 1</th>
<th>Test 2</th>
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<td>13%</td>
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</table>
HIV VCT Rapid Test - Requirement Usage Compliance
- Process level ("Good" vs "Poor")

- Good: 6.11%
- Poor: 4.71%
HIV VCT Rapid Test - Requirement Usage Compliance – at Process level (HCW Workload)
VCT Turnaround Time

• How long did the 265 observations take to complete in minutes?
  
  • At overall Process level
  
  • At Activity Group level
    • Focus on incubation time
# VCT Rapid Test Process - Turnaround Time

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<th>Test 1</th>
<th>Test 1-Incubation</th>
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# VCT Rapid Test Kits - Test 1 Incubation time (Province)

<table>
<thead>
<tr>
<th>Province</th>
<th>Test 1</th>
<th>Test 1 - Required Incubation time</th>
<th>Test 1 - Actual Incubation time</th>
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<tbody>
<tr>
<td>Free State</td>
<td>First Response</td>
<td>5 minutes</td>
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<tr>
<td>North West</td>
<td>First Response</td>
<td>5 minutes</td>
<td>7 minutes</td>
</tr>
<tr>
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<td>Determine x 3</td>
<td>15 minutes</td>
<td></td>
</tr>
<tr>
<td>Northern Cape</td>
<td>Determine x 3</td>
<td>15 minutes</td>
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<td>Bioline</td>
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<tr>
<td>Gauteng</td>
<td>Advanced Quality</td>
<td>15 minutes</td>
<td>4 minutes</td>
</tr>
<tr>
<td></td>
<td>Advanced Quality</td>
<td>15 minutes</td>
<td></td>
</tr>
<tr>
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<td>Determine x 2</td>
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<tr>
<td>Limpopo</td>
<td>One step Anti-HIV ½ Test</td>
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<td>Eastern Cape</td>
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## VCT Rapid Test Kits - Used vs. Tender (Province)

<table>
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<tr>
<th>Province</th>
<th>Test 1 - Used</th>
<th>Test 1 - Tender</th>
<th>Concordance</th>
<th>Test 2 - Used</th>
<th>Test 2 - Tender</th>
<th>Concordance</th>
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<tbody>
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<td>First Response</td>
<td>G.Ocean</td>
<td>0%</td>
<td>SD Bioline</td>
<td>Determine</td>
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<tr>
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<td></td>
<td>Sensa x 2</td>
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</tr>
<tr>
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<td>Determine</td>
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<td></td>
<td>Determine</td>
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</tr>
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<td>North West</td>
<td>First Response</td>
<td>SD Bioline</td>
<td>0%</td>
<td>Sensa x 3</td>
<td>Determine</td>
<td>0%</td>
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<tr>
<td>Northern Cape</td>
<td>Determine x 3</td>
<td>SD Bioline</td>
<td>25%</td>
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<td></td>
<td>SD Bioline</td>
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<td>Gauteng</td>
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<td>Advanced Quality</td>
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<td>First Response</td>
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<tr>
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<td>Determine x 2</td>
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<tr>
<td>Kwazulu-Natal</td>
<td>Determine x 4</td>
<td>G.Ocean</td>
<td>0%</td>
<td>Sensa</td>
<td>Determine</td>
<td>0%</td>
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<tr>
<td>Western Cape</td>
<td>Determine x 4</td>
<td>SD Bioline</td>
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<td>Sensa</td>
<td>Determine</td>
<td>0%</td>
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<tr>
<td>Mpumalanga</td>
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<td>0%</td>
<td>Sensa</td>
<td>First Response</td>
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<tr>
<td>Eastern Cape</td>
<td>Determine x 4</td>
<td>G.Ocean</td>
<td>0%</td>
<td>Sensa</td>
<td>First Response</td>
<td>0%</td>
</tr>
</tbody>
</table>
Semi-structured Interview Question:

Does the clinic conduct QA for VCT kits?

- Only 9 out of 37 (24%) clinics responded to this question positively
  - 13.5% of clinics conduct confirmatory ELISA testing on regular basis
  - 1 clinic -- only conduct QA on Determine (Test 1) test kits
  - 2 clinics -- only conduct QA when they receive new stock
  - 1 clinic -- conduct QA per batch
  - 1 clinic -- check Lot numbers and expiry dates daily
VCT General Risk Areas - QA

Semi-structured Interview Question:

*If yes, what steps do they take? And how frequently does the QA happen?*

• 9 of 37 clinics check expiry dates daily or every time before they perform a test
• 14 of 37 clinics check expiry dates when they receive new stock
• 1 of 37 conduct checks expiry data on weekly basis
• 1 of 37 conduct checks expiry dates on quarterly basis
• 5 of 37 clinics conduct QA (confirmatory ELISA) once per month
• 4 of 37 clinics conduct QA (confirmatory ELISA) per batch
VCT Summary of Key Findings

• Overall process compliance is very low with some provinces having 0% overall compliance.

• Greater compliance at
  – activity group level
  – step level

• Consistent weaknesses in steps associated with “rigor”
  – Time
  – Registers
  – QA
  – etc
VCT Summary of Key Findings

- Little association with:
  - Geographic Location
    - Urban, Small town, Rural
  - Perceived “good” or “poor” performing clinics

- Association with Workload: “busier = better”

- All provinces require assistance
  - National approach
VCT Summary of Key Findings

• Specific areas of concern include
  – inconsistent/absent quality assurance practices
  – specimen collection method
  – wrong staff performing collection
  – procurement
  – usage (even when available)
  – short incubation times for VCT result
  – training
  – HCW safety
  – Post-test counseling
  – ELISA testing
VCT Key Recommendations

• Not simple to remedy
  – Systems approach essential
  – Clinics with lower workloads more error-prone
  – Interventions needed in urban and rural areas
  – Data not supporting certain clinics “poor performance”

• Quality assurance is critical
  • Ongoing monitoring and oversight

• Training and mentoring

• Procurement systems

• User-friendly SOP required

• Staff responsibilities
  – Untrained/wrong staff make more errors
  – Safety of staff
VCT Conclusions

- VCT a critical step in empowering
- This study documents key steps that need addressing
- Systems approach essential
- POCT testing complex and introduces new errors
- Can learn from VCT for later POCT proposals
- This data:
  - data driven
  - opportunity to improve systems and service delivery
THANK YOU!