
By

K. K. Yatich
Head, Biosafety and Biosecurity Program
National Public Health Laboratory
Ministry of Health, Kenya
Presentation Outline

• Country Context – background including (Viral Load testing Laboratories)

• How we carried out the self-assessment using the Checklist

• Challenges and solutions

• Results, what did we make out of the data/findings

• How we are using the data/findings – Next steps

• Recommendations for other countries.
Country Context – background including (VL/EID testing Laboratories)

- In 2008, EID and VL started with one testing lab in KEMRI HIV-R Laboratory, Kisumu
  - used Roche Amplicor v.s 1.5.
  - Extraction and purification method – manual
  - Though extraction reagents contained Guanidinium thiocyanate (GITC - chemical compound used for DNA extraction & Purification), waste quantities were low due to low sample volume hence laboratory dilution trap could comfortably handle the waste
Country Context – background including (VL/EID testing Laboratories) Cont..

• Increased demand and to attain clinically recommended TAT necessitated the EID program expansion to other laboratories but still using Roche Amplicor v.s 1.5.

• In 2013, Publications emerged on the benefit of routine VL as opposed to targeted VL and the use of VL as the best biomarker for assessing treatment failure as opposed to CD4

• Lead to expansion of the VL testing program to the current 10 testing laboratories to ensure that TAT is met
Country Context – background including (VL/EID testing Laboratories) Cont..

• With the test and treat strategy, the VL testing program has expanded to be supporting close to 1.1 million patients
  • This further necessitated the start of the near POC testing sites that use molecular technologies/platforms.

• Combined waste output from the automated equipment (large conventional and near POC) has put a strain on the management of Guanidinium thiocyanate based waste
Viral Load testing Laboratories and Networks

Key
- WRP
- KEMRI Busia
- AMPATH
- KEMRI Nairobi
- KNH CCC
- CPGH
- KEMRI Kisumu
- NHRL

4 VL/EID Testing Labs (Nairobi)
Viral Load Testing Laboratories Capacity

- Current 39 conventional platforms in 10 VL/EID testing labs
  - Current total Capacity/Year with CAPCTM, Abott M2000, C8800 = 2,039,040
  - Current functional capacity (all equip)/Year = 1,631,232
  - Total Utilization (all equip)/(Year 2019) = 1,581,277
  - Percent Utilization = 96.9%
  - Anticipated total Capacity/Year with C8800/6800 is 2,800,800 (by March 2020)

*Country has adequate capacity for current needs

<table>
<thead>
<tr>
<th>No of EID/VL HIV Molecular Platforms</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ROCHE CAPCTM 17 (to be phased out)</td>
<td>Mar 2020</td>
</tr>
<tr>
<td>ABBOTT M2000 20</td>
<td></td>
</tr>
<tr>
<td>ROCHE c8800 3 to be installed</td>
<td></td>
</tr>
<tr>
<td>ROCHE c6800 5 to be installed</td>
<td></td>
</tr>
</tbody>
</table>

For Kenya: functional capacity considered at 80% of total instrument capacity: equipment downtime, power interruptions, running of QC
Introduction to the Checklist

• Name
  • Tool For Viral Load (VL), Early Infant Diagnosis (EID) Molecular Waste Management (WM) Considerations V2.0 November 2019

• Purpose
  • assist in identifying gaps and creating awareness of best practices for waste management processes in VL and EID molecular testing laboratories

• Checklist Sections
  • HIV molecular testing instruments
  • Instrument waste
  • Waste management SOPs, Policies & Practices at facility level
  • Safety Practices
  • Availability of waste management options
  • Action items
How we Carried out the Self-Assessment using the Checklist?

• Lab self assessment of the 10 VL/EID testing sites
  • Kenya provided input in development of checklist
  • Lab directors sensitized on the purpose of the assessment (via e-mail)
  • Checklist shared with the labs followed by phone calls and follow-emails
  • Lab QA and Biosafety officers completed the checklist
  • Checklist data analyzed

• Site visit for data verification (Planned)
  • 4 Labs identified & selected for site visit
Challenges and solutions

• Delay in completing checklist and analysis
  • Tool to be available online e.g. through ODK for ease of filling and prompt analysis
  • Follow-up emails & phone calls

• Parts of a some questions not clear
  • introduce N/A column

• Incompleteness of checklist
  • Planned sensitization of lab managers/biosafety officers

• In adequate funds to make prompt site visits
  • Planned budget for the activity for sustainability
Completeness of checklist/section

Key:
0. Not filled
1. Partial
2. Complete

- Testing instruments
- Molecular Testing Instrument Waste
- SOPS, Policies & Practices
- Safety practices
- Availability of Waste management options
- Action items
### Results, what did we make out of the data/findings

**HIV Molecular Testing Instruments**

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Abbott</th>
<th>CAPCTM</th>
<th>C8800</th>
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</thead>
<tbody>
<tr>
<td>CPGH</td>
<td>8000</td>
<td>2500</td>
<td>0</td>
</tr>
<tr>
<td>AMPATH</td>
<td>14000</td>
<td>8400</td>
<td>0</td>
</tr>
<tr>
<td>KEMRI P3</td>
<td>12276</td>
<td>2500</td>
<td>2000</td>
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<tr>
<td>KEMRI KSM</td>
<td>5000</td>
<td>0</td>
<td>18000</td>
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<tr>
<td>KEMRI Alupe</td>
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<tr>
<td>KEMRI WRP</td>
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<td>6721</td>
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<tr>
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<td>4000</td>
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</tr>
<tr>
<td>EDARP</td>
<td>0</td>
<td>3000</td>
<td>0</td>
</tr>
<tr>
<td>Nyumbani</td>
<td>672</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NHRL</td>
<td>7680</td>
<td>15360</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total each equip</strong></td>
<td>76788</td>
<td>47281</td>
<td>20000</td>
</tr>
<tr>
<td><strong>Grand Total (All equipment)</strong></td>
<td><strong>144069</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Number of the tests (volume) known but no quantification of either liquid or Solid waste

- One lab reported an obsolete equipment (FACs Caliber-1)- no decontamination, removal procedure
HIV VL/EID Molecular Testing – Instrument Waste

**Liquid Waste Disposal**
n=10

- Liquid VL/EID waste poured down a sink: 9 (90%)
- SOP followed if poured down sink: 9 (90%)
- Run-off from sink directly into sewer system: 7 (70%)
- Bleach mix with all potentially infectious liquid waste: 7 (70%)
- Laboratory sinks equipped with chemical dilution traps: 2 (20%)

**Solid Waste disposal**
n=10

- Off-site incineration: 2 (20%)
- Off-site open incineration: 1 (10%)
- On-site open incineration: 4 (40%)
- On-Site open burning: 2 (20%)
- On-site Autoclaving: 4 (40%)
- Off-site Autoclaving: 1 (10%)
Waste Management SOPs, Policies & Practices at Facility Level

- National WM Policy, legislation, or a guideline on site: 6 (60%)
- Facility WM Policy, legislation, or a guideline on site: 9 (90%)
- SOP used for the chemical disinfection of waste: 7 (70%)
- Guidance for the handling and disposal of chemical waste: 8 (80%)
- SOP for the disposal of infectious waste: 9 (90%)
- SOP used for handling expired viral load/EID instrument reagents and consumables: 6 (60%)
- Records on the amount of waste collected, treated and/or destroyed at the facility: 8 (80%)

{n=10}
Safety Practices at Facility Level

- Is there a biological spill kit and associated SOP in use? 80%
- Access-controlled? 80%
- Non-porous and durable for disinfection practices in... 70%
- Is there a chemical spill kit and associated SOP in use? 60%
- Are waste containers labeled correctly to facilitate... 60%
- Are liquid VL/EID waste containers kept in a secondary... 60%
- Is there a Chemical Hygiene Plan1 in place at the facility? 50%
- Organized to handle both chemical and biological waste? 40%
- Has a documented risk assessment been performed for... 30%
Availability of waste management options

- Licensed waste management companies currently operating in your country: 6 (60%)
- Access to a medical waste incinerator: 6 (60%)
- Equipped with a primary chamber: 6 (60%)
- Equipped with a secondary chamber: 6 (60%)
- Chambers reach required operational temperatures: 6 (60%)
- Incinerator outfitted with a scrubber system to filter gases: 6 (60%)
- Incinerator gas emissions monitored and tested: 5 (50%)
- In-country partners that can help with waste management: 1 (10%)

**NB:** 1 lab reported partial gas emission monitoring
1 lab reported partial in-country partners supporting waste management
How we are using the data/findings – Next steps

- Have site visits (follow-up) to verify data
- Stratify, weigh/quantify waste per equipment (Roche provide support)
- Work with the labs to develop action items, plans and responsible persons for targeted interventions for site specific gaps
- Identify cross cutting gaps for to inform development of country action plan
- Scheduled zoom calls with the labs to review progress
How we are using the data/findings – Next steps cont..

• Conduct similar assessment on existing POC (VL/EID) testing sites

• Planned bench marking visit; South to South collaboration

• Strengthening incinerator capacities
  • Mapp incinerators
  • Waste referral systems from service delivery points
    • Health facility level – Genexpert cartridges (TB), Alere Q (EID)
    • Community level- Malaria RDTs

• Review policies and guidelines (National level & Facility level)
Recommendations for other countries.

- Independent filling of the checklist by persons other than facility staff.

- Sensitization of lab directors and managers/biosafety officers on the check list

- Include component of VL/EID waste management in the in country waste management policies & guidelines

- Proper waste management training & strengthen lab Biosafety/Biosecurity practices
  - EID/VL HIV Molecular Platforms
  - Initiate facility sustainable measures
  - Risk assessments

- Routine waste management monitoring & evaluation framework or tools for EID/VL HIV Molecular Platforms
Acknowledgement

• Kenya MOH - through NPHL

• ASLM

• All the VL/EID testing labs directors

• In country supporting partners (PEPFAR team ; CDC-through UMB, USAID, DOD/WRP)
ASANTE SANA
Thank you very much!