Assessment of Waste Management Practices in VL/EID Testing Laboratories in Kenya

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

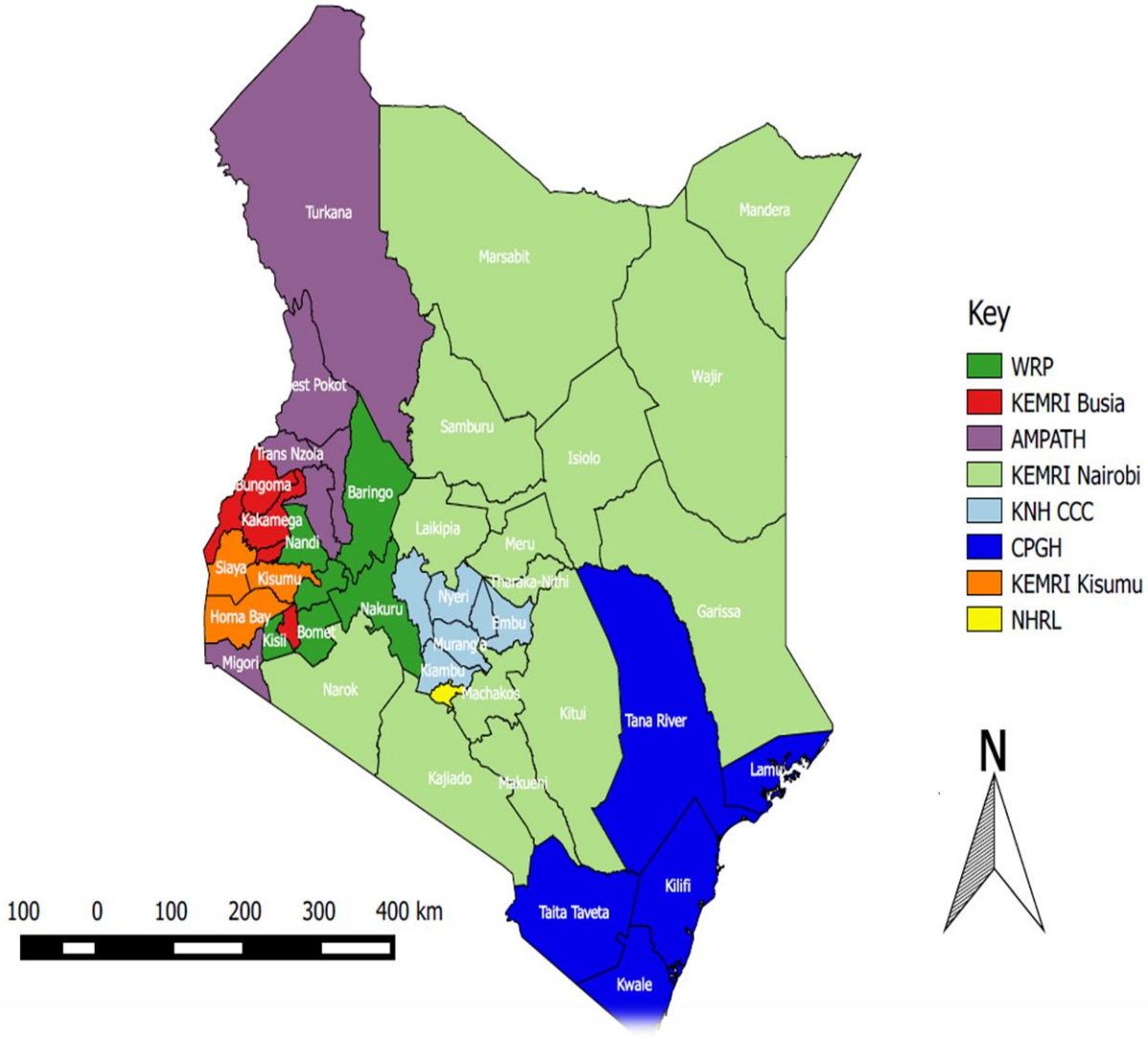
Country Context – background including (VL/EID testing Laboratories) Cont..

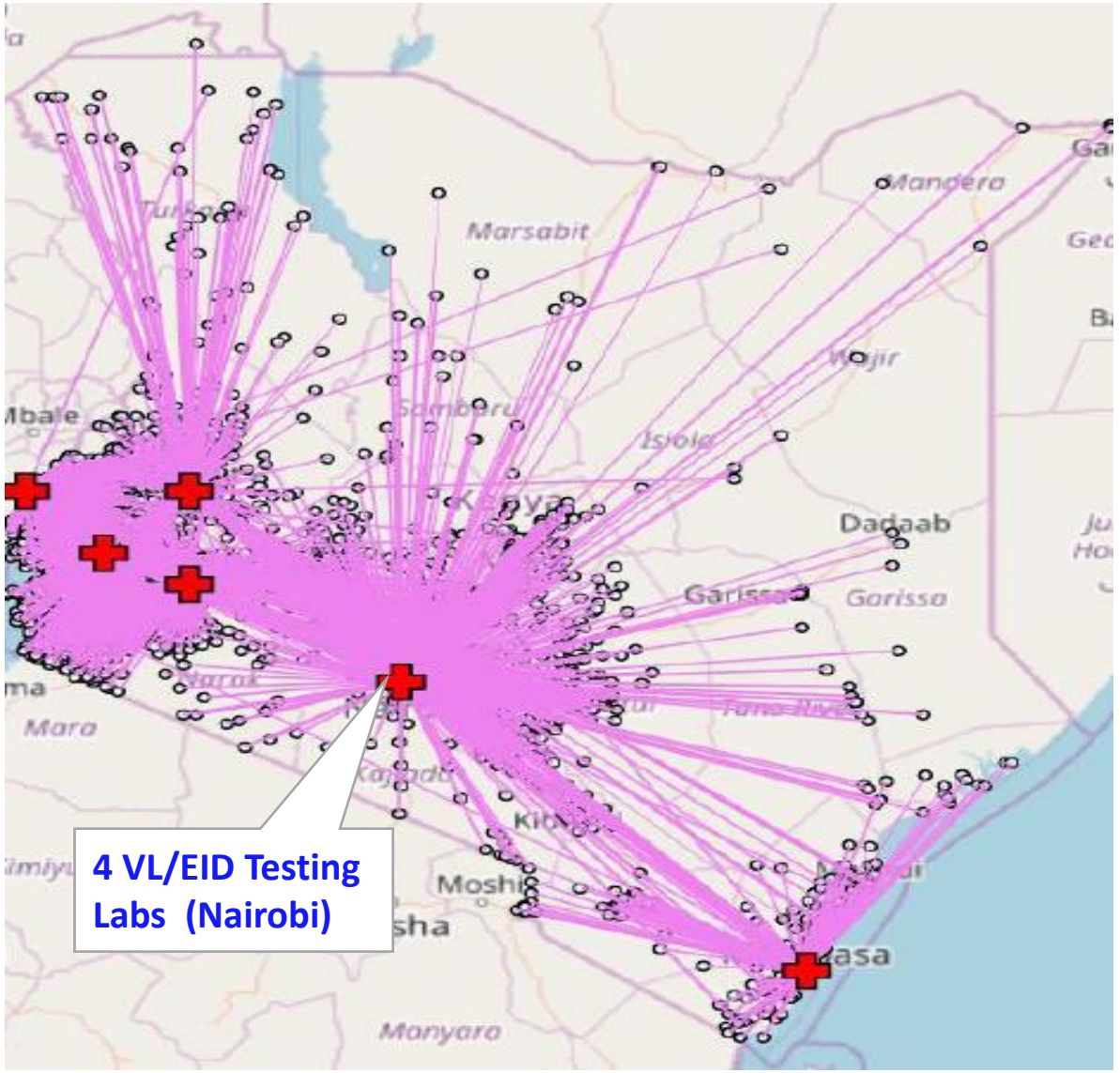
- Increased demand and to attain clinically recommended TAT necessitated the EID program expansion to other laboratories but still using Roche Amplicor v.s 1.5.
- In 2013, Publications emerged on the benefit of routine VL as opposed to targeted VL and the use of VL as the best biomarker for assessing 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





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)

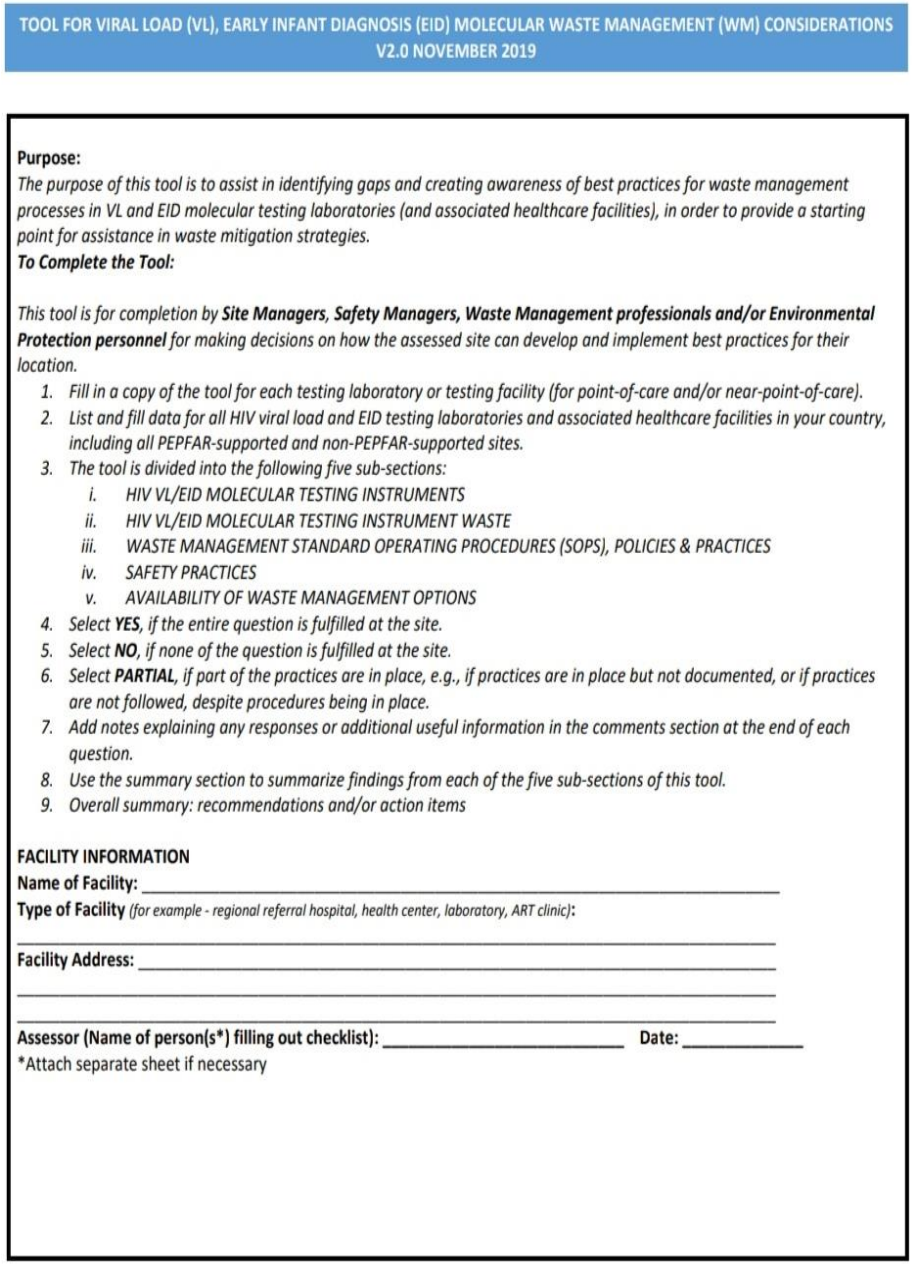
**Country has adequate capacity for current needs*

No of EID/VL HIV Molecular Platforms	
ROCHE CAPCTM	17 (to be phased out) Mar 2020
ABBOTT M2000	20
	2
ROCHE c8800	3 to be installed
ROCHE c6800	5 to be installed

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



TOOL FOR VIRAL LOAD (VL), EARLY INFANT DIAGNOSIS (EID) MOLECULAR WASTE MANAGEMENT (WM) CONSIDERATIONS V2.0 NOVEMBER 2019

Purpose:
The purpose of this tool is to assist in identifying gaps and creating awareness of best practices for waste management processes in VL and EID molecular testing laboratories (and associated healthcare facilities), in order to provide a starting point for assistance in waste mitigation strategies.
To Complete the Tool:

*This tool is for completion by **Site Managers, Safety Managers, Waste Management professionals and/or Environmental Protection personnel** for making decisions on how the assessed site can develop and implement best practices for their location.*

1. *Fill in a copy of the tool for each testing laboratory or testing facility (for point-of-care and/or near-point-of-care).*
2. *List and fill data for all HIV viral load and EID testing laboratories and associated healthcare facilities in your country, including all PEPFAR-supported and non-PEPFAR-supported sites.*
3. *The tool is divided into the following five sub-sections:*
   i. *HIV VL/EID MOLECULAR TESTING INSTRUMENTS*
   ii. *HIV VL/EID MOLECULAR TESTING INSTRUMENT WASTE*
   iii. *WASTE MANAGEMENT STANDARD OPERATING PROCEDURES (SOPS), POLICIES & PRACTICES*
   iv. *SAFETY PRACTICES*
   v. *AVAILABILITY OF WASTE MANAGEMENT OPTIONS*
4. *Select **YES**, if the entire question is fulfilled at the site.*
5. *Select **NO**, if none of the question is fulfilled at the site.*
6. *Select **PARTIAL**, if part of the practices are in place, e.g., if practices are in place but not documented, or if practices are not followed, despite procedures being in place.*
7. *Add notes explaining any responses or additional useful information in the comments section at the end of each question.*
8. *Use the summary section to summarize findings from each of the five sub-sections of this tool.*
9. *Overall summary: recommendations and/or action items*

FACILITY INFORMATION
Name of Facility: _____
Type of Facility *(for example - regional referral hospital, health center, laboratory, ART clinic)*:
_____
Facility Address: _____
_____
_____
Assessor (Name of person(s*) filling out checklist): _____ **Date:** _____
*Attach separate sheet if necessary

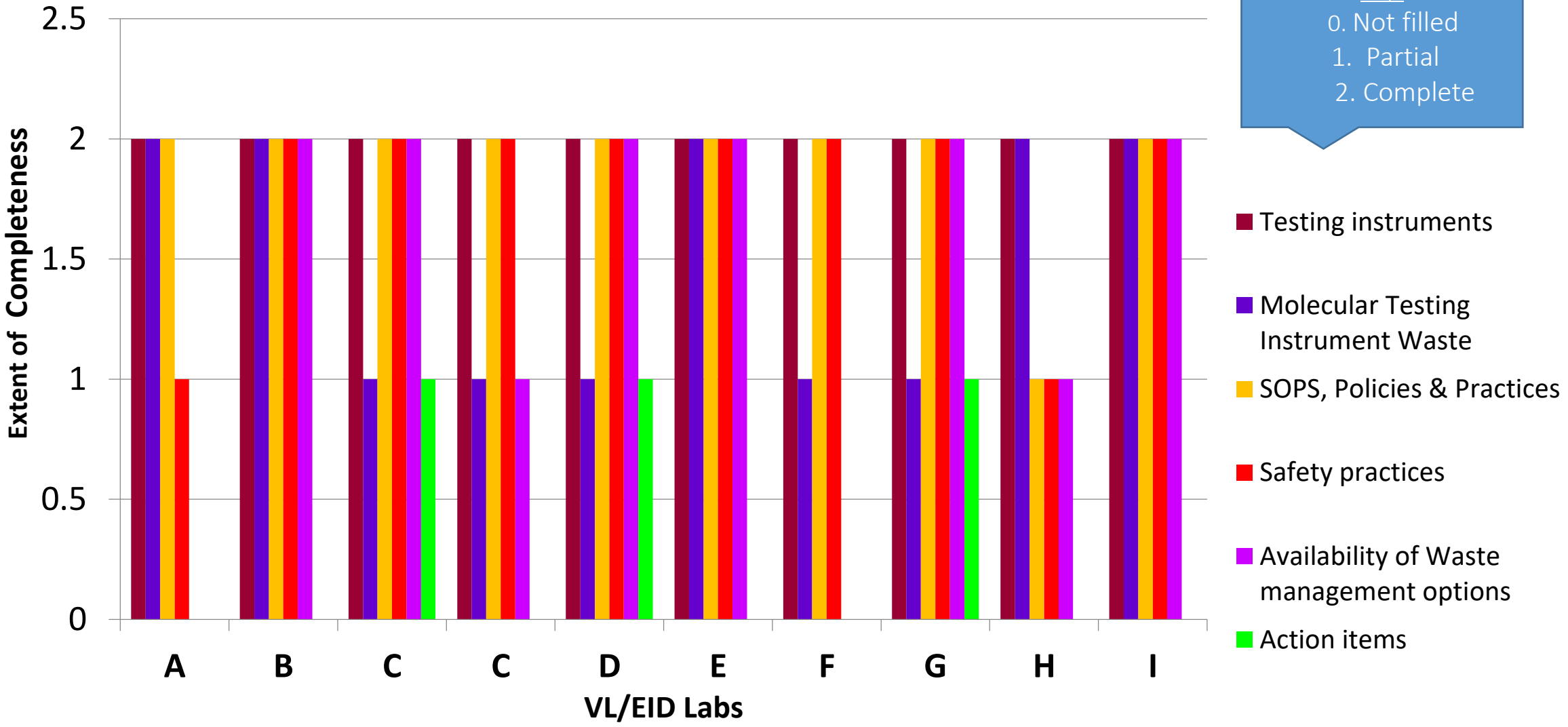
How we Carried out the Self- Assessment using the Checklist?

- 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



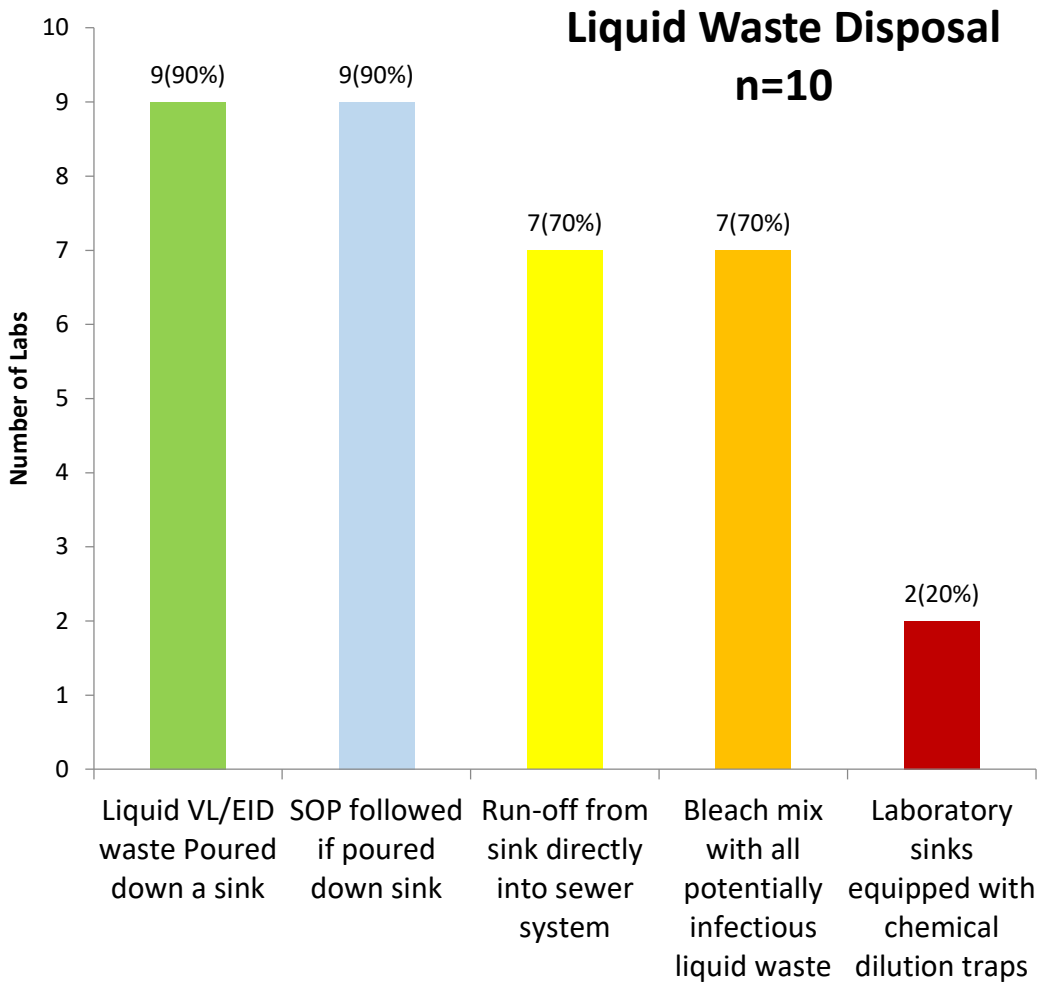
Results, what did we make out of the data/findings

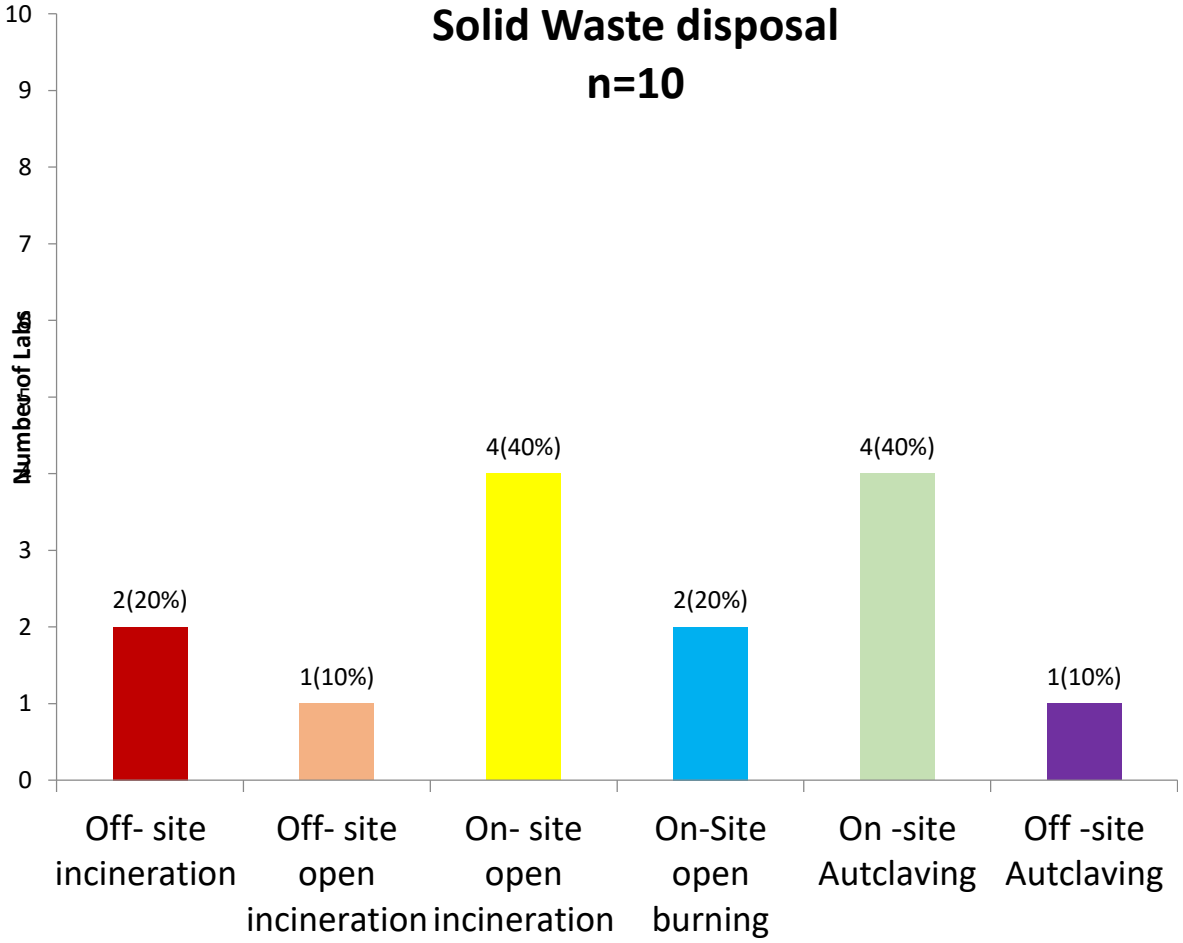
HIV Molecular Testing Instruments

Volume of testing on each platform per month			
Laboratory	Abbott	CAPCTM	C8800
CPGH	8000	2500	0
AMPATH	14000	8400	0
KEMRI P3	12276	2500	2000
KEMRI KSM	5000	0	18000
KEMRI Alupe	12000	4800	0
KEMRI WRP	11160	6721	0
KNH CCC	6000	4000	0
EDARP	0	3000	0
Nyumbani	672	0	0
NHRL	7680	15360	0
Total each equip	76788	47281	20000
Grand Total (All equipment)			144069

- 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

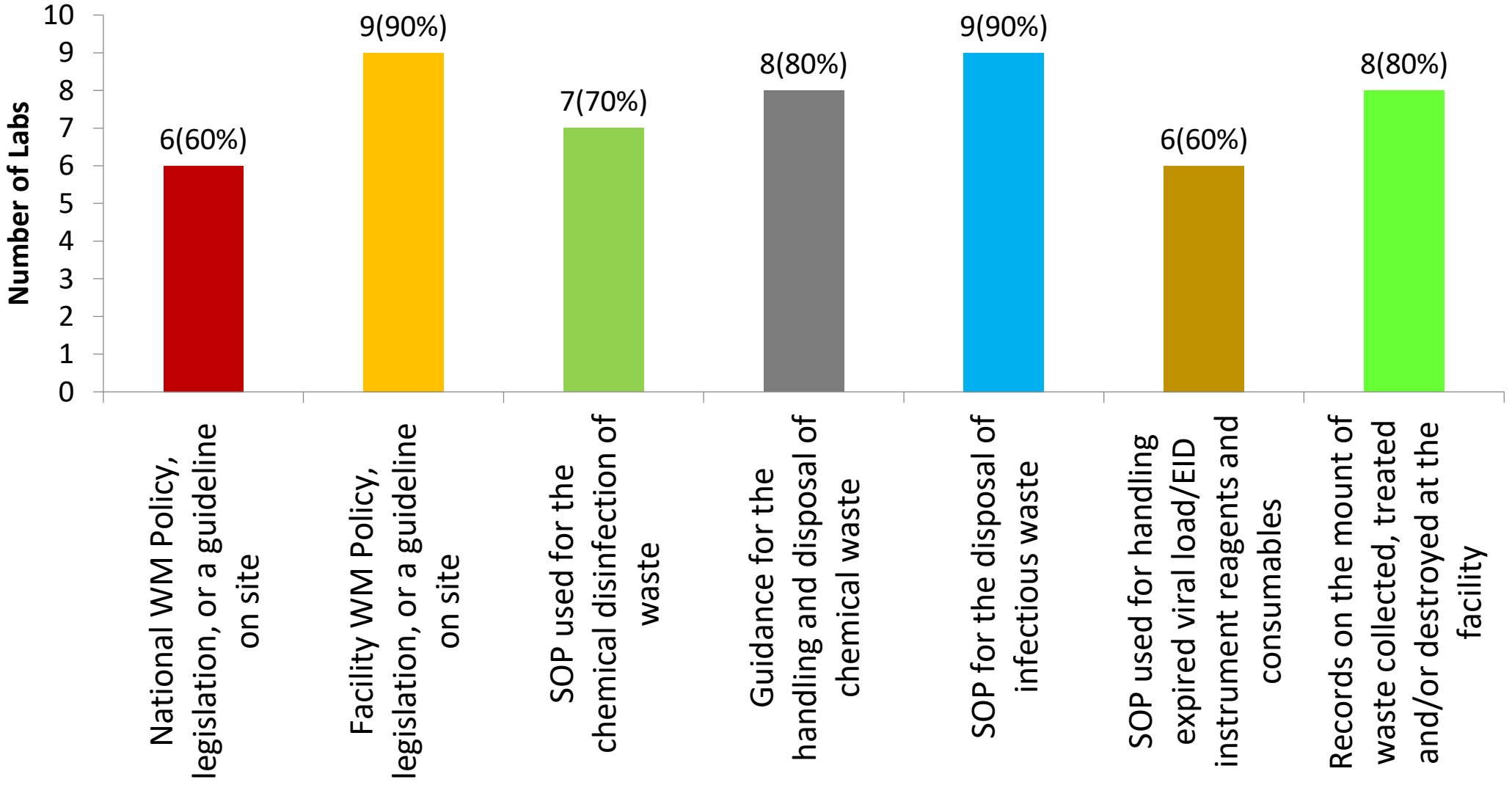
HIV VL/EID Molecular Testing – Instrument Waste



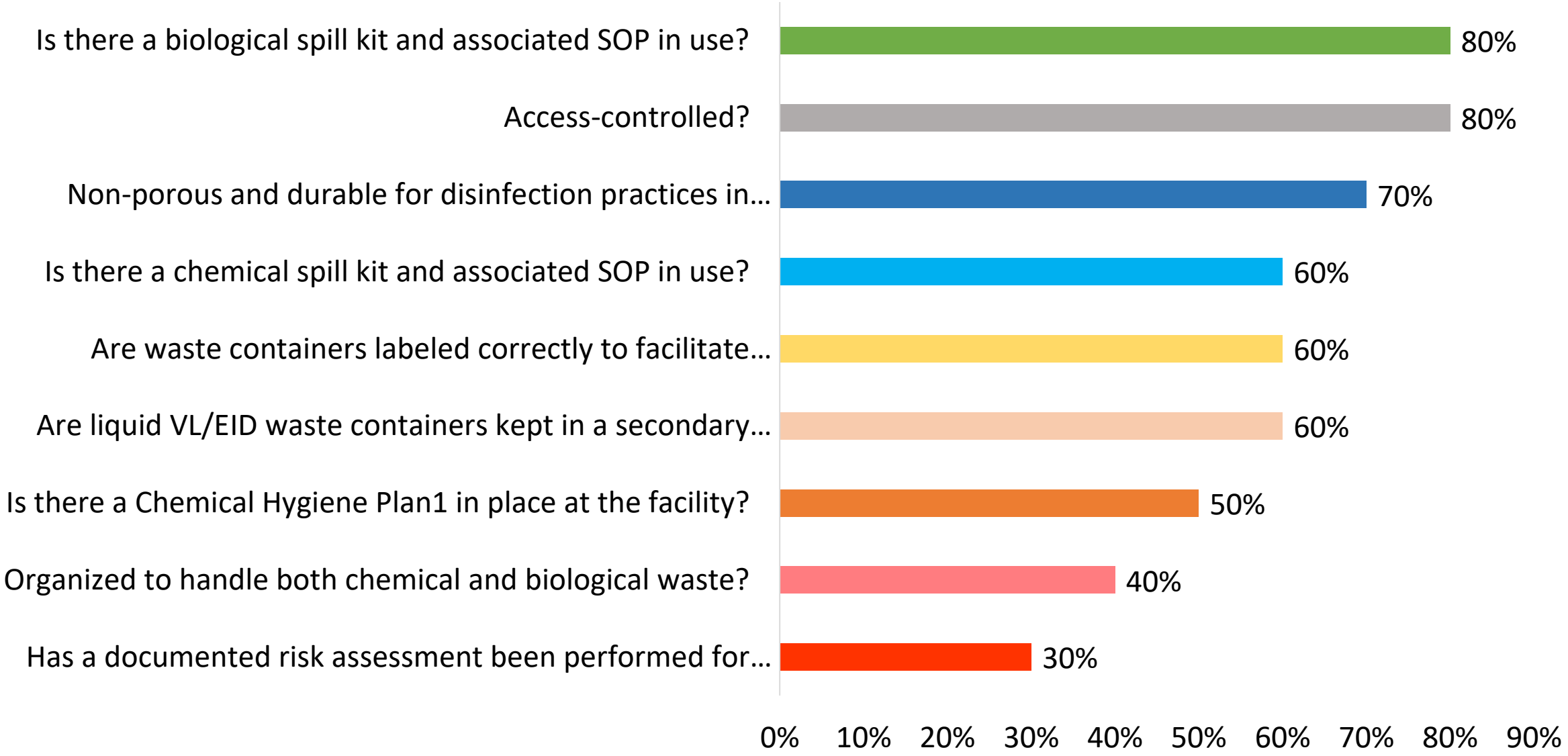


Waste Management SOPs, Policies & Practices at Facility Level

n=10

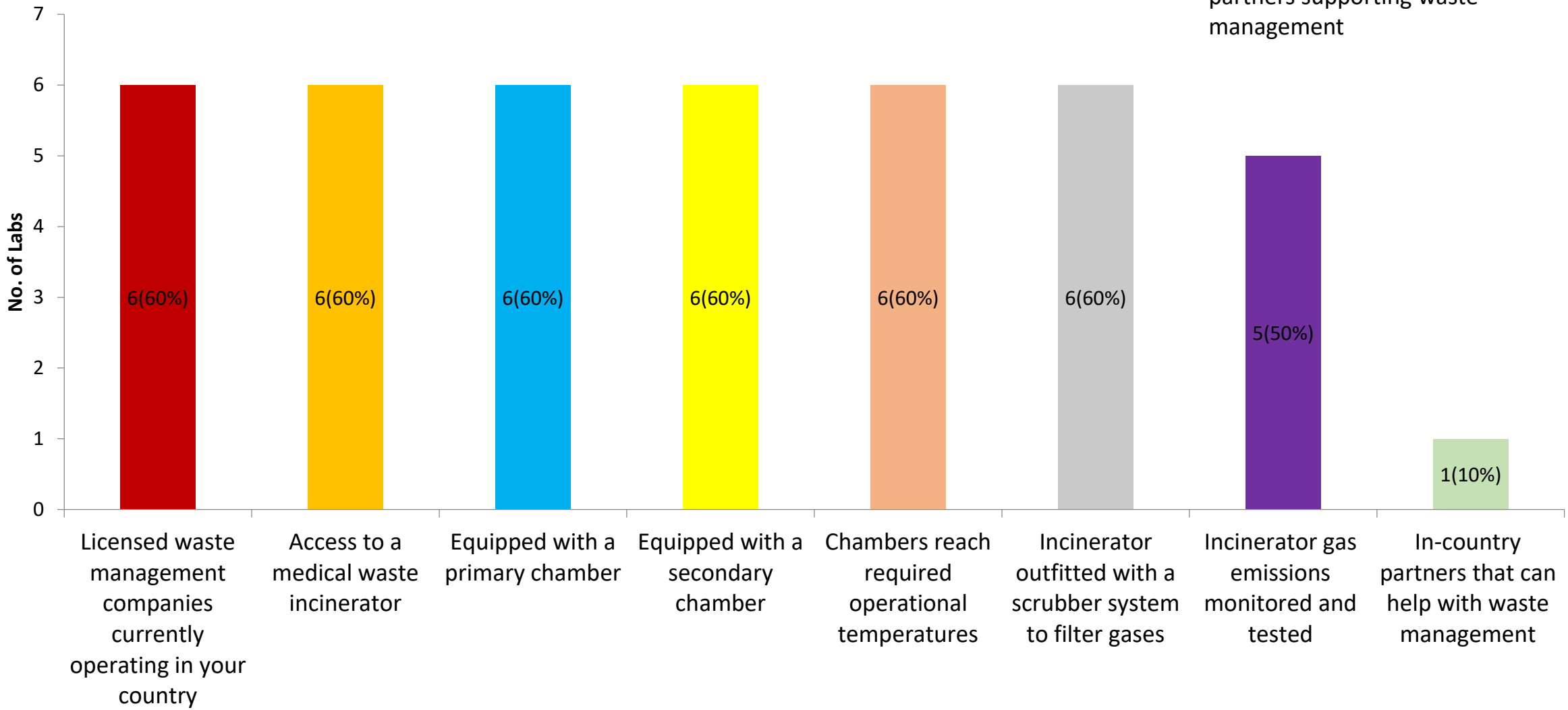


Safety Practices at Facility Level



Availability of waste management options

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!