Accelerating Progress Towards Accreditation Through Rapid Result Initiative (RRI) - The Kenya Experience

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SLIPTA/SLMTA Symposium, ASLM 2018, Abuja, December, 08, 2018
Outline

• Kenya SLMTA

• Getting there:
  – Creative partnerships
  – Addressing challenges—stagnation and staff turn over
  – The RRI process and results
  – Using the e-SLIPTA tool
  – Outcomes

• Staying there:
  – Post-accreditation support
  – Accreditation surveillance support

• Conclusions
Kenya SLMTA

- Kenya is one of the biggest SLMTA countries - 185 laboratories enrolled into SLMTA since 2010
- By September 2017, only 15 laboratories were ISO 15189 accredited
- SLIPTA Star 3 is the tipping point
- Stagnation is a factor of 4 QSEs associated with continuous measurement and improvements:
  - Management Reviews
  - Evaluation and audits
  - Corrective and Preventive Actions
  - Occurrence/Incidence, process control
- CDC Kenya/MOH target for laboratory accreditation by end of FY2017 was 20 laboratories.
Objectives for RRI

- To accelerate the number of labs accredited
- To meet PEPFAR-Kenya lab accreditation targets of 20 labs by end of FY 2017
Rationale for Rapid Results Initiative (RRI)

What?
- A rapid but result-driven process lasting 3 months: May-July, 2017
- Rapid and targeted mentorship to laboratories that had stagnated (0-3 SLIPTA stars for more than 2 years)

By whom?
- Coordinated by CDC/MOH
- Facilitated by 5 laboratory implementing partners
- Implemented by 42 laboratory mentors using SLIPTA e-Tool to audit and report progress

Aim:
All laboratories to achieve 5 SLIPTA Stars in 100 days
Methods – RRI Stakeholders

National and County MOH

CDC
(RRI Desk)

42 Laboratories

4 Regional Lab Implementing partners

1 Lead IP

On SLMTA @ 0-3 stars for >2 years
RRI Process: Three Months

Focused trainings & document development
- Stakeholder engagement
- Team Formation
- Baseline audits (BA) using e-SLIPTA Tool
- Develop and realign Lab Quality Documents

On-site implementation of activities
- On-site mentorship
- CDC TA visits
- Mid-term audits (MTA) using e-SLIPTA tool

On-going mentorship and monitoring
- End-term audits (ETA) using e-SLIPTA Tool
# Tailored interventions by Lab Category

<table>
<thead>
<tr>
<th>RRI Lab Category</th>
<th>A</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>&lt;50% (0-1 stars)</td>
</tr>
<tr>
<td></td>
<td><strong>Intensive/aggressive training across all QSEs</strong></td>
</tr>
<tr>
<td></td>
<td>10 labs</td>
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<table>
<thead>
<tr>
<th>RRI Lab Category</th>
<th>B</th>
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<tbody>
<tr>
<td></td>
<td>56-69% (1-2 stars)</td>
</tr>
<tr>
<td></td>
<td><strong>Targeted problematic QSEs</strong></td>
</tr>
<tr>
<td></td>
<td>17 labs</td>
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</table>

<table>
<thead>
<tr>
<th>RRI Lab Category</th>
<th>C</th>
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<tbody>
<tr>
<td></td>
<td>&gt;70% (3 stars and above)</td>
</tr>
<tr>
<td></td>
<td><strong>Addressing continuous measurement and improvement QSEs</strong></td>
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<tr>
<td></td>
<td>15 labs</td>
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## RRI Results

<table>
<thead>
<tr>
<th>RRI Baseline Audit Star Rating</th>
<th>STAR 0</th>
<th>STAR 1</th>
<th>STAR 2</th>
<th>STAR 3</th>
<th>STAR 4</th>
<th>STAR 5</th>
<th>Total</th>
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<tbody>
<tr>
<td>STAR 0</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td><strong>8</strong></td>
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<tr>
<td>STAR 1</td>
<td>0</td>
<td>4</td>
<td>9</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td><strong>18</strong></td>
</tr>
<tr>
<td>STAR 2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td><strong>9</strong></td>
</tr>
<tr>
<td>STAR 3</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td><strong>5</strong></td>
</tr>
<tr>
<td>STAR 4</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td><strong>2</strong></td>
</tr>
<tr>
<td>STAR 5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td><strong>0</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1</strong></td>
<td><strong>5</strong></td>
<td><strong>21</strong></td>
<td><strong>8</strong></td>
<td><strong>3</strong></td>
<td><strong>2</strong></td>
<td><strong>39</strong></td>
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Overall RRI Gains

RRI SLIPTA star rating

Number of SLMTA Labs

0 star: 10
1-2 stars: 25 baseline, 13 exit
3-5 stars: 7 baseline, 24 exit

Baseline audit  Exit audit
The Most Improved Laboratory

Key:
BA - Baseline Audit score
ETA - End term Audit score
A Stagnated Laboratory

Key:
BA - Baseline Audit score
ETA - End term Audit score
Overall Outcome of RRI

- 15 ISO Accr
- 42 RRI Labs

2017

18 recommended for ISO

- 20- ASLM Audits
- 15- ISO Assess

18 awaiting ISO certificates
+ 15 labs ISO accredited

2018

33 Labs ISO Accredited
Lessons Learnt

• Stakeholder engagement and management support are kings
• Intense CAPA and extended mentorships period
• Well defined TORs for mentors, based on lab categories as identified at baseline audit
• Use of the e-SLIPTA Checklist to decrease TAT for audit reports, lesson learned and decision making
Staying accredited—lessons from 9 labs accredited for 4-6 Years

<table>
<thead>
<tr>
<th>Lab Tier</th>
<th>#Enrolled</th>
<th># Accredited</th>
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<tbody>
<tr>
<td>National</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Regional/County</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>District/Sub-County</td>
<td>98</td>
<td>2</td>
</tr>
<tr>
<td>Faith Based/NGO</td>
<td>28</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9</strong></td>
<td><strong>9</strong></td>
</tr>
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Maintaining ISO 15189 Status

• Cross-train all lab staff
• Ensure job security and conducive work environment
• Engage management to ensure a budget line for QMS
• Form quality committee and meet regularly
• Train lab staff on occurrence management – identification and reporting of non-conformances, root cause analysis, closure and monitoring
• Establish CME programs to ensure competence with job duties, internal audits, method validation, UM, CAPA/RCA

No lab has had its accreditation certificate withdrawn or even surveillance audits conducted more frequently than once per year.
Staying there—other strategies

• Budget allocation for laboratory commodities and fees for accreditation surveillance
• Job security and defined contract duration
• Formation of work improvement team in the lab (WITs)
Conclusions

• A well-coordinated partnership structure and lab-specific mentorship approach accelerated lab QMS improvement across most labs
• Timely review of progress and audit reports and use of SMART objectives ensured success of this RRI
• The RRI period acted as a catalyst for lab acceleration towards ISO 15189 assessment
Questions?

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