

Building A Regional Network for Better Audit Practices

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Presentation Outline

- Introduction
 - SLMTA/SLIPTA coverage
 - Observed challenges in current audit practices
- Terms of reference for SLIPTA auditors
- Auditors experience, observed challenges and deficiencies of present system
- Knowledge and skills required for auditors
- Call to Action!



SLIPTA Coverage (2013 – 2018)

WRAIR
Walter Reed Army
Institute of Research

125
YEARS
1893-2018

- 20 Countries
- 452 medical laboratories
- >173 ASLM certified auditors





Terms of Reference of SLIPTA Auditors

- Conduct the audit using SLIPTA checklist
- De-brief the facility; stating performance without star rating
- Provide written report of audit to ASLM
- Maintain objectivity and impartiality
- Other audit requirements as outlined in ISO15189 standard and ISO 19011 Guidelines



Auditors' Performance Vs TOR

- What is the knowledge and skill required for an auditor to adequately achieve the tasks as outlined in the ToR?
- What strategy in place to ensure that adequate knowledge and skill are provided before an auditor is selected?
- What criteria available for knowing that the auditor is qualified to perform the task as outlined in the ToR?
- If the criteria mentioned above are available, to what extent are they adhered to?



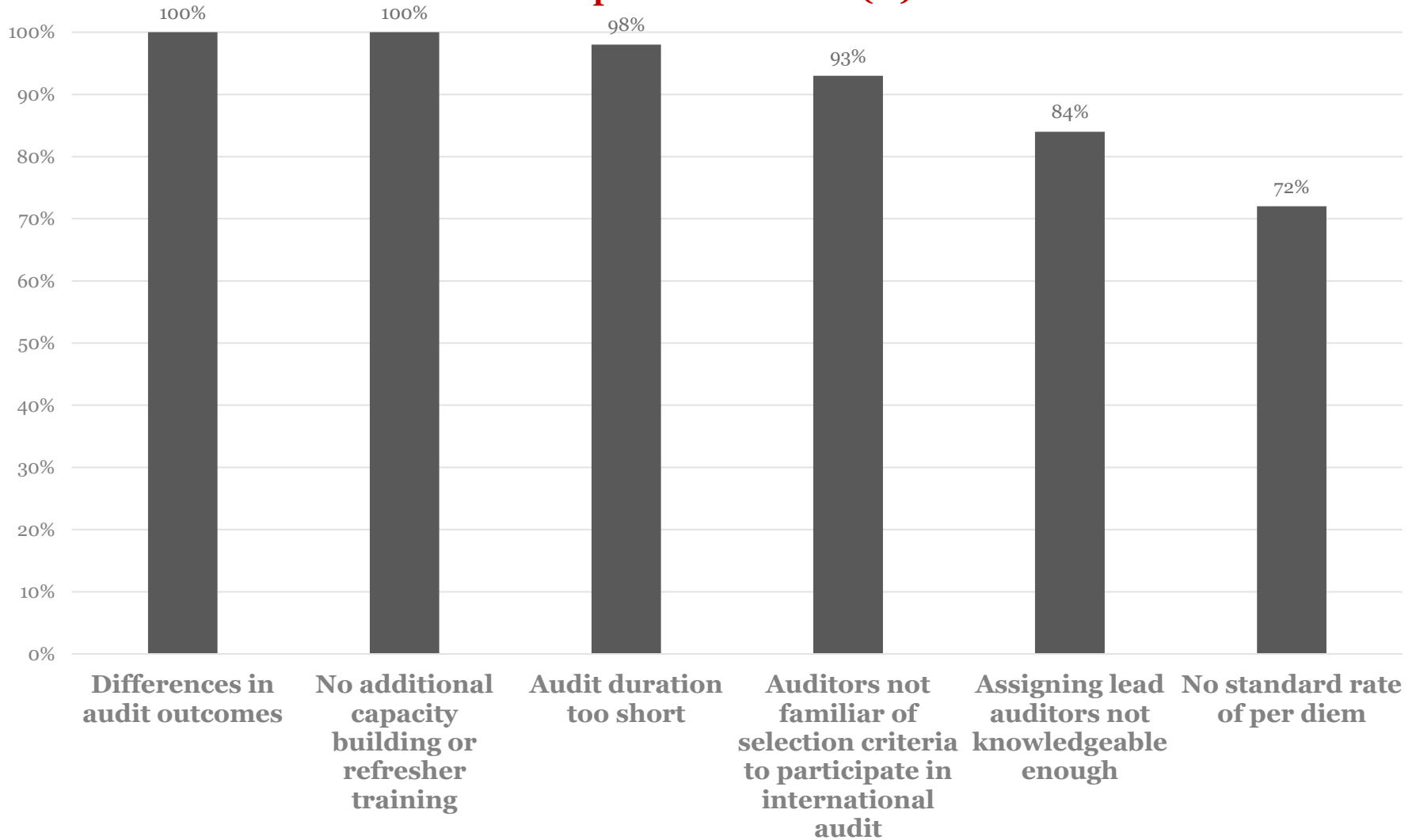
Auditors' Experiences so Far...

- Challenging due to lack of experience - lab audit is a completely new experience different from routine bench work or program implementation
- The exercise is demanding in terms of workload and encounters with difficult auditees
- Good learning opportunities for most of the auditors
- No forum for regular networking with fellow auditors to share experiences and learn from each other



Observed Challenges – Interview Results of Survey

Perception of Auditors (%)





Deficiencies

- Auditor training and capacity building is donor dependent and not sustainable
- System for mentorship of junior auditors not available
- Lack of refresher training and certification
- Lack of common platform for networking
- Lack of standardization of audit practices



The Impact on Quality of Audit

- Poor quality of audit reports
- Differences in audit outcomes
- Insufficient time to mentor the audited labs
- Disputes between assessors and auditees
- Lack of trust in findings of ASLM certified auditors



Knowledge and Skills Required

- Training to update auditors' knowledge and skills - effective networking forum
- Curricula could be developed for:
 - Lead Auditor training
 - Senior Auditor/Assessor training
 - Auditor/Assessor training



Training – Effective Tool for Networking



Internal Audit Course for Clinical/Medical Laboratories under 15189

Training for internal auditors in clinical/medical laboratories with quality systems conformant to ISO 15189.

Learn how to conduct Assessments for Accreditation.

Quality managers in clinical laboratories with a quality system cannot do it all on their own. An internal audit program is not a quality-only activity. It is an operational activity as important as all other quality activities in the laboratory.

The Internal audit is the absolute best tool the laboratory can use to determine the health of their quality system – and its ability to support the production of technically valid results for patients and physicians.....

.....CERTIFICATES

All participants who take and qualify a written exam will receive a Certificate of Successful Completion.

Ref: International Accreditation Service. Available online at:
<https://www.iasonline.org/training/internal-audit-course-clinicalmedical-laboratories-15189/>





Training – Effective Tool for Networking Cont'd



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Refresher Training & Twinning

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125
YEARS
1893-2018

- Annual refresher training using case studies from different audits
- Certificates of competency to be renewed every two years
- Twinning experienced auditor with junior ones for mentorship
- Create platform for auditors to interact with each other



Call to Action!

There is need to create platform for auditors to regularly network with each other for standardization of practice



Networking Opportunities...

- Associations' meetings
- Seminars and conferences
- Participation in training
- Social gathering
- Social media





A Case for Association

Having certified auditors coming together to form an association at national and international level will:

1. Ensure regular meeting of members to improve networking
2. Facilitate organization of regional conferences and seminars – lessons from Nigeria and other countries
3. Allow us to speak with one voice for advocacy, public relations and international standardization
4. Facilitate participation of junior auditors in laboratory audits to under study more experienced and certified auditors
5. Liaise with relevant stakeholders to certify auditors periodically
6. Track locations and availability of auditors for service provision
7. Provide opportunity for other accrediting bodies to use services of ASLM certified auditors
8. Membership directory
9. Web based education and webinars – accredited courses
10. Discussion forum
11. Enhances leadership skills as we get more involved in association political activities



Advantages of Common Platform

- Knowledge sharing and skill acquisition
- Standardization of audit practices
- Networking for effective leadership –networking skills make leaders more effective
- Critical for success of SLMTA/SLIPTA
 - Sustainability of the program
 - Improved quality of audit outcome
 - ASLM will deal with organized professional body for auditors – to be represented by elected leaders



Other Advantages....

- Int'l accrediting bodies are looking for trained African assessors to fill in the gap of the few and available assessors
- Opportunity not only for ASLM certified assessors but for accrediting bodies



Thank you for your interest in serving as an assessor for the American Association for Laboratory Accreditation (A2LA).

Please complete the following information and provide a rating for all applicable technical areas in which you are technically qualified. Please attach your resume detailing your direct conformity assessment related experience (i.e. laboratory testing/calibration, inspection body, proficiency testing, product certification, reference material production), and the technologies and products, material or equipment directly related to your experience.

If A2LA has an immediate need for your services, we will provide you with information concerning the assessor position. Once we have identified an appropriate assessment, we will provide you with a contract and start you on an assessment as a technical assessor, working with a veteran assessor or a staff person. Once you qualify as a technical assessor you will be asked to serve as a lead assessor with staff oversight. Once that is completed, you will be qualified to perform assessments on your own.

Somewhere in this time frame you will also have to take our Assessor Orientation Course during our annual A2LA Technical Forum and Annual Meeting normally held in the spring. You would receive a special invitation to attend. This is a mandatory course that you would attend at our expense.

Please forward this application/questionnaire and your resume to me at tmcinturff@A2LA.org. Do not hesitate to contact me if you have any questions or need any additional information.

Respectfully,



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Examples Associations ...

- Clinical Laboratory Management Association (CLMA)
- International Society for Laboratory Haematology
- American Public Health Laboratory
 1. Laboratory Biosafety Community
 2. Microbiology Discussion Community
 3. Quality Assurance Community



Conclusion

- As the number of ASLM certified auditors increases, there is need for an auditors to network more for knowledge and skill sharing
- Need for system of certification and periodic competency assessment
- Need to create associations of certified auditors at local and regional levels to improve networking
- Call for action – now!



Acknowledgment

- Reviewers
 - ASLM Certified Auditors
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- Staff and Management of ASLM
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- DG and entire staff of Nigerian Ministry of Defense Health Implementation Program
- USG Family (CDC, USAID & State colleagues)



Thank You