Quality Assurance for NTD Diagnostics and Laboratories

Session Date: Saturday, November 4

Session Time: 1:00pm Time:pm

Session Location: Sassafras

Session Description: Both point of care (POC) and laboratory diagnostics have become increasingly important in NTD control programs. It is imperative that those utilizing these results have confidence in the accuracy and quality of these results. In order to obtain this, it is recommended that those performing diagnostic testing receive the benefits of involvement in a quality assurance program. This session will discuss how such programs may be developed and made available to diagnostic teams and laboratories worldwide.

Session Chairs: Richard Bradbury. U.S. Centers for Disease Control and Prevention
Roger Peck, PATH

Session Rapporteur: Allison Golden

Agenda:

Laboratory-based Quality Assurance	Richard Bradbury
Experiences in the implementation of Quality Assurance in Laboratories	Mabula Kasubi, Muhimbili National Hospital, Tanzania, Tanzania, United Republic of Tanzania (not present), NOTE: Piet Cools, Ghent University, presented after coffee break.
Field-based Quality Assurance Programs	Roger Peck
Experiences from implementing rapid test Quality Assurance in the field	Yaya Ibrahim Coulibaly, Mali Andreas Nshala, Tanzania
Coffee Break	2:15pm – 2:45pm
Discussion	Quality assurance program successes Challenges for implementing quality assurance Needs for implementing quality assurance Recommendations for quality assurance for NTDs

Presentations by:

1. Richard Bradbury, Centers for Disease Control, Parasitic Diseases Branch, Atlanta, GA USA
2. Roger Peck, PATH, Diagnostics Program, Seattle, WA USA
3. Yaya Coulibaly, MD, PhD, Faculty of Medicine/ICER- Mali, Filariasis Unit, Mali
4. Andreas Nshala, NTD Control Program, Tanzania
5. Piet Cools, Ghent University, Belgium presenting on STH QA program pilot in collaboration with SKML, The Dutch Foundation for Quality Assessment in Medical Laboratories (SKML) and Children Without Worms.

KEY DISCUSSION POINTS

Key findings:

- Quality is designed into medical devices and diagnostic tests. Increasing testing doesn't improve the quality of the device.
- QA is the total process that guarantees that the final results reported are as accurate as possible.
    - Ideally includes the entire process from sample intake to data reporting, and external quality assurance (EQA) control samples would be sent to all labs or to all teams using an assay from the administering group.
    - Results should be reviewed regularly and outcomes to follow a process.
    - Even if results are within criteria, it is important to review all results in order to detect trends towards non-conformity or differences between laboratories.
- Quality assurance is not currently implemented in many laboratories and programs.
- Quality assurance is a foundational element to laboratory and field work. It is the most important component to building lab capacity because QA programs:
    - Create a cycle of improving quality, as opposed to reacting to problems.
    - Improve data quality in that it can enable identification of deficient results, processes, and training.
    - Increase decision-making from data and results, which can decrease waste of resources in testing that produces untrusted results.
    - Help to prevent or detect false results which are burdens to health systems and dangerous to best patient care.
    - Improve communication of results due to the context of quality criteria.
- Some laboratories or programs do not implement a quality assurance program because of the following reasons:
    - No problem has been detected yet. However, this rationale isnance program because of the following reasons:t to building laif external quality assurance (EQA) program is implemented.
    - It requires more materials and more time. It seems expensive to ask for funds, and is too expensive when there are no funds.
    - It isn't always considered a legitimate expense for a study.
- Other resources outside of formal QA program can be leveraged
    - Supplemental processes can increase proficiency, such as CDC DPDx monthly classes:
    - https://www.cdc.gov/dpdx/index.html
    - Providing a self-guided means to teach yourself a concept prior to participating in EQA may also provide better foundation for EQA program.

KNOWLEDGE GAPS IDENTIFIED

- There is no support for NTD EQA.
- Feasibility and Logistical Challenges are associated with EQA implementation
- Budgets do not currently include sufficient support for NTD EQA and it is "the first thing to go" despite desire to implement QA by lab managers.
- Quality assurance programs need to be built level by level and get more in-country support. Some EQA consist only of an external lab in Europe or N. America that can review, but there

isn't long-term sustainability and country level doesn't build capacity to administer to multiple labs.

- More EQA is desirable to many laboratories, but they are not able to include it in budgets.

RECOMMENDED NEXT STEPS

Change the culture of QA: Communications improvement to improve uptake, use, and financial support of EQA programs

- Engage politicians and authorities alike with simple consequence-focused communications written in lay language, such as a booklet.
    - Implications and risks of bad lab results: danger to patients, can lead to poor decisions by Ministry of Health (MOH) if made using bad data, can lead to poor reputation of MOH, clinics, and labs.
    - Itde using bad data, can lead to poor reputation of MOH, clinics, and labs.
    - Save money by eliminating false results, not doing retesting. Estimates in a simulation can make the MOH pay attention.
- Engage donors
    - Emphasize the cost effectiveness. QA is a good investment.
- Engage technicians; outreach to improve uptake of QA.
    - Concern that there is a risk that they don t care. Testing is routine for them and they feel as though they are skilled already. Find ways to engage with middle technicians as target group.
- Foster culture of QA
    - Address conceptual gap in lab training. If they are to accept extra work, they need help to understand why it needs to be done.
    a. Sensitize early in school and training to emphasize the importance of QA, even in research labs. Target trainings in universities, polytechnic, public labs.
    - Certification for those who participate in and pass proficiency trainings ublic labs.ns written in lay languag
    - Certification for whole labs that participate and have good compliance to bring esteem to the lab. This can help catalyze further funding fulfillment for EQA.
- Communicate that the best systems assess the entire process from sample intake to data reporting. Ideally, external quality assurance (EQA) control samples would be sent to all labs or to all teams using an assay from the administering group. Results should be reviewed regularly and outcomes to follow a process.
    - Not just to identify after trouble has occurred. Preventative potential. Even if results are within criteria, it is important to review them to detect trends towards non-conformity or differences between laboratories. Supplemental processes and training can prevent non-conformity event.
    - Providing a self-guided means to teach yourself a concept prior to participating in EQA may also provide better foundation for EQA program. https://www.cdc.gov/dpdx/index.html

Understand if EQA can be made more feasible for labs to participate in and more cost-effective.

- Alternatives to external sample shipped to labs: Examples that were discussed included remote assessment of slides for malaria (https://vmicro.iusm.iu.edu/).

- Reduce time to review of EQA results: devise a method that can check the results of a staff member online or real-time. This can reduce the time to remedy a deficiency.
- Provide framework so that EQA results are reported automatically. Anonymous review can allow increase in training of a specific site without questioning competency of particular individual.
- Standardize the EQA materials and make them accessible to everyone using a technique so you can compare directly the performances.

Address specific "neglect" of NTD EQA:

- Look at how efforts can be synergized at the country level. Despite money limits, use programs designed for malaria, for example, and then use similar resources. Many supplies can be obtained from malaria programs and NTDs may be able to be nested into this.
- Group felt that comprehensive EQA cannot be built for NTDs alone – it must leverage EQA from other programs to minimize costs and get attention needed.

Address budget limitations which undermine EQA implementation.

- EQA programs should identify key accessories (for example, gloves) and reagents that need to be procured to support testing of quality assurance materials. Specific line items for these materials should be included in every budget to acknowledge need for QA.
- How to pay for EQA panels? Suggestions included to subsidize or absorb into other costs to make sure it cannot be eliminated during budget review. Make it integral part of the budget for testing.
- Give laboratories tools to easily quote and include these costs to enable planning and reduce time to include in budget.
- Improve communication of the benefits of EQA to those approving the budgets to understand how essential these additional materials are. Find a way to express cost-effectiveness of EQA in that it improves the outcome from ALL the results. Tangible examples can help – such as control program may have to operate additional years if prevalence is over-reported or communities risk failing elimination if evidence of ongoing transmission is underreported due to false/inaccurate results that were not detected. Identifying the consequence of inaccurate results in a way that demonstrates that money spent may help.

Address lack of stewardship of EQA programs or governing administrations of EQA:

- Equipment can be used by multiple programs.
- Need for guidance for labs or guidance for groups.
- Lab meeting website/online group should be set up.
- Online sharing of best practices: example of how to calibrate pipets or who to contact to obtain controls. This provides gap filling in absence of comprehensive EQA program.
- Come up with twin lab that can be used as reference and has facile sample and data transfer

Summary points from Discussion

Final thoughts from the group.

1. **Create a nucleus working group for EQA**. Follow up again in country and regional labs, COR-NTD. Meet again to update on strategy and progress.
2. **Training and EQA sensitization**. Make it part of routine and culture. Explore online options/courses to increase reach. Create mindset in trainees, government, donors, that EQA is integral to testing as much as the test itself e EQA program.ess of EQA in th

3. **Identify needed materials, procedures, and find stewardship of this resource**. QA cannot happen without EQA control materials. Find reliable long-term funding source for this effort. The assay manufacturer cannot be source of EQA
4. **Set up of centralized EQA system with lead laboratory is needed**. More discussion of how to do this will require larger engagement of donors, NTD and other programs, leaders.
5. **Mechanisms to recognize achievement of the labs that are doing well.** Incentivization of individuals and the whole lab in the forms of certification and recognition will help to maintain and to attract good staff.