

A WORKSHOP ON LABORATORY QUALITY ASSURANCE – AN EVALUATION OF THE QUALITY OF CLINICAL TESTING USING HIV RAPID TESTING AS THE PORT OF ENTRY IN THREE HEALTH DISTRICTS IN SOUTH WEST REGION OF CAMEROON

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ACRONYMS

AFENET: African Field Epidemiology Network

AIDS: Acquired Immunodeficiency Syndrome

CDC: Centers for Disease Control and Prevention

DTS: Dried tube specimen

EQA: External Quality Assurance

FELTP: Field Epidemiology and Laboratory Training Program

GHSS: Global Health Systems Solutions

HIV: Human Immunodeficiency Virus

IHR: International Health Regulations

ISO: International Organization for Standards

NGO: Non-government organization

PT: Proficiency Testing

QA: Quality Assurance

SARS: Severe Acute Respiratory Syndrome

SLMTA: Strengthening Laboratory Management towards Accreditation

TB: Tuberculosis

WHO: World Health Organization

WHO AFRO: World Health Organization Regional Office for Africa.

BACKGROUND

As HIV rapid testing expands to non-laboratory settings, ensuring the quality and accuracy of HIV test results becomes more critical in HIV diagnosis, care and treatment. A number of tools to monitor and improve test accuracy such as hands-on workshop, liquid or dried tube specimen-based proficiency testing programs, retesting strategies, and supervisory visits have been implemented as part of a national quality assurance (QA) program in resource limited settings.

Dried Tube Specimen (DTS) is a QA tool which was developed by GAP/International laboratory Branch at CDC (Centers for Disease Control and Prevention) for monitoring and evaluating the quality of HIV testing in laboratories. It is especially adapted for use in resource limited countries because it is lyophilized and can be stored at room temperature for up to four weeks.

The standardized logbook was developed as an ongoing QA tool to monitor and evaluate the performance of the HIV testing sites, personnel competence, view testing trends and evaluate the different types of tests used. The goal of the logbook database is to capture all data from the monthly summaries and provide a detailed analysis that will identify key areas of improvement at the site, district, or national level.

INTRODUCTION

Quality Assurance involves all steps and procedures taken by the laboratory to ensure the reliability of results and that the results are achieved in a standard, reproducible and traceable manner. These steps are from the preparation and collection of specimens, reviewing transcriptional measures, using the most reliable assays, techniques used and the manipulation procedures, transcription as well as the delivery of test results.

Efficient and reliable laboratory services and networks are essential and fundamental components of effective, well-functioning health systems. High-quality laboratory testing is critical for patient care, prevention, disease surveillance, and outbreak investigations.

In sub-Saharan Africa, laboratory infrastructure and personnel are adversely affected by a lack of resources and prioritization, hampering laboratory systems in efforts to fulfill their important role in the fight against infectious and chronic diseases. As a result, the accessibility of laboratory testing and the quality of available services remains a serious challenge. It is therefore imperative

that laboratory systems be strengthened within broader efforts toward health system strengthening.

In an effort to continue strengthening laboratory systems in Cameroon, CDC/DGHA Cameroon with its implementing partner for laboratory activities, Global Health Systems Solutions (GHSS) intends to rolled out the Quality Assurance (QA) training in all health institutions within the national laboratory tiered system. In April 2009, CDC in collaboration with the Ministry of Public Health launched the Cameroon National External Quality Assessment Scheme (CAMNEQAS) for HIV rapid testing using the DTS method. 28 labs (14 Regional, 2 District, 2 blood banks, 4 private, 5 confessionals and 1 reference lab) are currently enrolled and actively participating in CAMNEQAS. About 300 lab staff had been trained on basic QA elements including the DTS method and use of a standardized logbook for recording HIV test results. It's worth mentioning that AFENET (African Field Epidemiology Network) Uganda and Global Health Systems Solutions (GHSS) Cameroon are implementing DTS.

In November 2011, CDC in collaboration with GHSS launched CAMNEQAS for HIV rapid testing using the DTS method in the Far Northern region of Cameroon which has not been involved in the program since 2009. While launching CAMNEQAS in the far northern region, CDC and GHSS used the opportunity to roll-out DTS to some districts and integrated health centers in the Adamawa and the Northern region.

Owing to the improvements measured overtime the ministry plans to roll this out to the entire tiered system with support from CDC/GAP Cameroon and this began with labs in the Fako Health District in September 2012 and in June 2013 Kumba, Tombel and Ekondo Titi health district using HIV testing as a port of entry. This training was offered to head of facilities, laboratory personnel, nurses and midwives currently involved in HIV testing as it included; basic concepts of HIV serology, proper recording of results in a logbook and all participating labs were enrolled in the Cameroon National External Quality Assessment Scheme (CAMNEQAS), an HIV serology Proficiency Testing (PT) program that was launched in 2009 together with the use of the logbook as a Quality Assurance monitoring tool.

The training was held in Kumba and the participants from the other health districts had to come to Kumba. The Centers for Disease Control (CDC) through its implementing partner GHSS supported all the logistics for the training. This forum also served as an excellent opportunity for enhancing networking amongst laboratories and learning from each other's experiences. The training session took place from the 18-20th June, 2012.

Fifty two (52) participants from Forty five (45) health facilities who were either head of facilities, laboratory staff, nurses or midwives participated in the training. For better understanding and support, the Chief Medical Officers or upper management and one or two health personnel involve in HIV rapid testing from each health facility were present to ensure sustainability and continuity.

OBJECTIVES

- To roll out the basic components of quality Assurance within the laboratories through a skill transfer workshop
- To acquire knowledge and skills to perform HIV Rapid Tests accurately, interpret and report results reliably in a safe and professional manner in an era of expanding programs

LITERATURE REVIEW

Laboratory is one of the core capacities that countries must develop for the implementation of the International Health Regulations (IHR [2005]) since laboratory services play a major role in all the key processes of detection, assessment, response, notification, and monitoring of events. While developed countries easily adapt their well-organized routine laboratory services, resource-limited countries need considerable capacity building as many gaps still exist.

Sufficient laboratory capacity is essential to effective infectious disease surveillance and control. This is recognized in the current International Health Regulations (IHR), which identify laboratory services as a category of core capacities that all the World Health Organization (WHO) Member States are expected to develop and maintain. IHR Core Capacity 8 requires laboratory services for every phase of real-time event management (i.e. detection, investigation, and response), with sample analysis being performed either domestically or through collaboration centers. Laboratory services are considered a key component of national health systems, with the Integrated Disease Surveillance and Response (IDSR) utilizing the structures, processes and personnel of national clinical laboratory services for disease surveillance. However, laboratory services for both patient care and disease surveillance remain among the most neglected components of the overall health system in resource-poor countries. Challenges include lack of national laboratory policy and strategic planning, insufficient numbers of trained professionals, poor laboratory infrastructures, and absence of quality management systems.

In 2008, WHO and the US Centers for Disease Control and Prevention (CDC), Atlanta, USA, convened in Lyon, France, an international conference on laboratory quality systems. During that meeting, the need for accurate laboratory testing was stressed, with poor quality laboratory services in resource-constrained countries leading to untold misery in human lives and unnecessary expenditures due to inadequate treatment.

Eight key interventions were identified: (i) strengthening laboratory management at all levels; (ii) strengthening infrastructure and support systems; (iii) developing human capacity; (iv) establishing a national laboratory referral network; (v) establishing a national quality assurance program; (vi) developing a comprehensive monitoring system including laboratory information management system; (vii) coordinating government and partner support activities; and (viii) mobilizing resources to finance the strategic plan. The need to integrate networks that already exist – mostly those related to malaria, tuberculosis and HIV/AIDS – was also stressed.

In response to these calls, several international development partners have been implementing capacity building programs that include the training of laboratory personnel in epidemiology, microbiology and quality assurance.

The cost of carrying analytical measurement is high and additional costs may rise from decisions made on the basis of incorrect test results, therefore it is very important to determine the correct test results and to be able to show that they are actually correct. While developed countries have made a significant achievement in laboratory quality system, developing countries like Cameroon are still facing a lot of challenges in this area, as there are a lot of gaps in the whole process of laboratory quality systems. The workshop on basic concepts on quality assurance will assist in addressing these gaps. The aim is to ensure that the laboratories obtain the competence required to produce unquestionable results.

In today's interconnected world, the risk of international spread of infectious diseases has greatly increased. This was well illustrated by the rapid spread of the recent influenza (H1N1) and severe acute respiratory syndrome (SARS) epidemics, where all continents were quickly threatened by an emergent pathogen in one corner of the world. The purpose of International Health Regulations (IHR [2005]) is to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

Core capacity 8 of IHR (2005) obligates World Health Organization (WHO) Member States to establish mechanisms for providing reliable and timely laboratory identification and characterization of infectious agents and other hazards likely to cause public health emergencies of national and international concern, including shipment of specimens to the appropriate laboratories if necessary. Laboratory services therefore play a major role in all the key processes of the IHR, including detection, assessment, response, notification, and monitoring of events. Developed countries with well-organized routine laboratory services can easily meet this core capacity through existing systems. However, resource-limited countries, especially those in sub-Saharan Africa, need considerable capacity building. Attaining adequate capacities will require functional community, sub-national and national systems. Therefore, laboratory capacity building for IHR core capacity 8 must by necessity focus on strengthening the routine systems within which events are detected and reported.

For a long time, laboratory services were not considered a priority for most resource-limited health care systems in Africa, resulting in poor infrastructure, low human resource capacity and inappropriate technologies.

The need for building laboratory diagnostic capacity in Africa has been well articulated over the recent past. Consequently, there have been efforts to enhance laboratory capacity over the past five years in many sub-Saharan countries. These efforts have largely been driven by the need for

improved laboratory support to surveillance and treatment programs for specific diseases such as HIV/ AIDS, malaria, tuberculosis (TB) and avian influenza at national and a few regional centers. Indeed, a recent review by Olmsted et al (2010) suggests a general improvement in infrastructure and service provision. However, more challenges still exist, including the lack of sufficient numbers of well-trained laboratory scientists in public health service and inadequate laboratory management and leadership skills. There is no or limited distribution of available national laboratory guidelines and a lack of internal and external quality assurance systems, which is usually accompanied by low appreciation of quality control. No efforts have been made towards assisting laboratories to attain international standards such as ISO 15189 and hence slow progress to accreditation. Other challenges have been the poor quality, limited analysis and utilization of laboratory data; inconsistent and inadequate reagent supply chains; and lack of equipment maintenance

The African Field Epidemiology Network (AFENET) is a coalition of Field Epidemiology Training Programs (FETPs) in Africa, initiated in 2005 out of a need to network and facilitate the strengthening of disease surveillance and public health responses to epidemics in the region.

LABORATORY QUALITY ASSURANCE: THE HIV EXTERNAL QUALITY ASSURANCE (EQA) PROGRAM

The unreliability of laboratory results is cited as one of the major limitations to laboratory support for health care in Africa. The utility of laboratory systems in the implementation of the IHR is also greatly dependent on the reliability and quality of laboratory results. However, applicable and cost-effective models for achieving accurate and reliable laboratory results in the low-income African countries have yet to be optimized.

One of the areas where external quality assurance (EQA) is critical is in the monitoring of the routine HIV rapid testing. Most countries in the region depend on re-testing as the primary means of monitoring the quality of HIV serologic testing. This approach is expensive, time-consuming and logistically challenging in decentralized settings. Traditionally, HIV external quality assurance programs use liquid serum or plasma specimens that require special cold storage and transportation conditions. The biohazard risks and costs of this approach have resulted in national quality assurance programs being weak, and consistent quality assurance is generally lacking in lower-tier laboratories.

The DTS is a cost-effective approach and is easy to prepare, stable at high temperatures and can be transported by mail to any part of the country. DTS panels are produced by the CDC reference laboratory assisted by GHSS staff and distributed to these sites on a quarterly basis through the postal services. After testing at the sites, the results are sent back to the reference laboratory for analysis and scoring. Feedback reports are generated and poorly performing sites are provided with support supervision visits and/or retraining. The project supports the mailing costs, data entry and laboratory scientists to provide technical backup.

Common problem areas include failing to follow national testing algorithms, not mastering proper pipetting technique, failing to follow DTS reconstitution procedures, new or untrained testing staff, and clerical errors in recording test results in both registers and PT report forms. Proper corrective actions, including on-site training and demonstrations, are taken.

Where resources are scarce and inequitably distributed, networking may reduce the gaps between different populations. WHO advocates for the establishment of national public health networks to ensure the timely exchange of information and the adequate support of laboratory services at all levels. At both the national and sub-national levels, only a few countries have functional public health laboratory networks in place.

ACCREDITATION

Accreditation is a means of certifying the competence of a laboratory to perform specific types of testing and it enhances customer confidence in accepting testing results. Medical laboratories are accredited by attaining requirements for quality and competency based on international standards, namely ISO 15189. Accredited laboratories therefore play a critical role in providing reliable information to inform IHR decision-making and guiding public health response. Currently, there are only 340 accredited laboratories in Africa and most of these belong to private sector or international research organizations. To address the paucity of accredited laboratories in the African region, the WHO Regional Office for Africa (WHO AFRO) established a stepwise approach for laboratories to attain the required standards. This approach supports laboratories at all levels through a series of evaluations using demonstrated improvements, which are recognized and rewarded for the progress.

To support this accreditation process, the Strengthening Laboratory Management Towards Accreditation (SLMTA) program — a training and mentoring toolkit for laboratory improvement and accreditation was developed. The purpose of the SLMTA trainings is to strengthen laboratory management for immediate and measurable laboratory improvement and to accelerate the process toward lab accreditation by WHO AFRO. Laboratory equipment maintenance and calibration is one of the key components of improving the quality of laboratory services, and is also critical in moving laboratories towards the stepwise WHO AFRO accreditation scheme. Additionally, quality equipment is essential to produce the valid and reliable laboratory results needed to inform decision-making in outbreak situations. The lack of working equipment has affected the effective delivery of health care in resource-poor settings. Often, laboratory equipment does not function properly because regular maintenance services are unavailable, particularly for ancillary equipment. AFENET, in collaboration with CDC and other partners such as Global Health Systems Solutions (GHSS), has organized training sessions to create a pool of local and regional biomedical engineers and equipment technicians able to meet the demands of laboratory equipment maintenance and calibration on a regular basis. This training creates regional capacity that reduces the costs of having the laboratory equipment serviced and calibrated.

Efforts to strengthen laboratory systems in the African region have received increased attention in recent years. In the 2008–2009 period, 6 landmark events were of particular significance for national health laboratory services. These events are described below:

1. January 2008 (Maputo, Mozambique): Thirty-three (33) countries—together with the World Health Organization (WHO), the World Bank, and the Global Fund for AIDS, Tuberculosis and Malaria—issued the Maputo Declaration to strengthen laboratory systems in developing countries. Meeting participants called on national governments to develop national laboratory policies and to provide laboratory support for diseases of public health importance; and they called on donors and development partners to commit to work collaboratively with each other and with coordination from national governments to strengthen laboratory systems.
2. April 2008 (Lyon, France): WHO and the US Centers for Disease Control and Prevention (CDC) issued a statement regarding laboratory quality systems, calling for countries with limited resources to consider a staged approach toward laboratory accreditation. It was suggested that national laboratory standards establish minimum requirements for all laboratories, although national reference laboratories were encouraged to meet international standards, such as ISO 15189.
3. September 2008 (Yaounde, Cameroon): During the 58th session of the Regional Committee, member states adopted the resolution AFR/RC58/R2, strengthening public health laboratories in the WHO African region, emphasizing the urgency to strengthen public health laboratories at all levels of the health care system in addition to requesting that the WHO Regional Office for Africa (AFRO) support member states to mobilize, access, and sustain resources to strengthen laboratory services.
4. September 2008 (Dakar, Senegal): At the fifth meeting of the Regional HIV/AIDS Network for Public Health Laboratories, it was agreed that the network should broaden its scope beyond HIV/AIDS and HIV/AIDS-associated diseases to become an integrated network encompassing all laboratories, without the limitation of a disease specific designation.
5. July 2009 (Kigali, Rwanda): WHO AFRO, in collaboration with the CDC, the Clinton Health Access Initiative, the American Society for Clinical Pathology, and other partners, launched a stepwise laboratory accreditation process in the presence of government health officials from 13 African countries. The WHO-AFRO accreditation process will recognize and encourage year-over-year progress toward fulfillment of the requirements of ISO 15189.
6. September 2009 (Kigali, Rwanda): During the 59th session of the Regional Committee, member states adopted the following resolutions: AFR/RC59/R2, drug resistance related to AIDS, tuberculosis, and malaria: issues, challenges, and the way forward; and AFR/RC59/WP/3, policy orientations on the establishment of centers of excellence for disease surveillance, public health laboratories, food, and medicines regulation. These

resolutions call for the strengthening of public health laboratories and other centers of excellence to improve disease prevention and control.

These meetings built consensus and focused critical attention on the call for systematic and standardized approaches for strengthening the African region's national health laboratory systems and the attendant need for national and regional efforts to implement laboratory quality standards.

METHODS

The training workshop was scheduled for three days and the activities carried out are as described below.

Upon arrival at the training hall, there was the registration of the participants and a welcome address from the Hospital Directors. Participants were congratulated for honoring the invitation for the training and encouraged to concentrate and understand well the lessons, because they are going to help improve their services. This was then followed by an introduction of the participants and trainers, and later group photos. Next were the discussion of the goals and the objectives of the training workshop followed by a pre-training assessment.

An overview of assuring the quality of HIV testing and the key elements in quality assurance and the national algorithm was introduced, followed by an introduction to the logbook. The participants were given some exercises on rapid HIV testing for better understanding.

The following day, a summary of the previous day's activities was given by one of the participants and clarification by the trainer where the participants had doubts followed by activities on how to enter data into logbook and a presentation on stock management and inventory. The DTS panels and its use in proficiency program were introduced to the participants and practical sessions followed thereafter characterized by reconstitution of the panels. Shipment forms were explained.

Day 3 started with a review of the previous day's work. Next was the hands-on practical by testing the panels following the national algorithm with Determine for first line test and Immunocomb for second line test. The QA implementation and rollout plans were discussed. The training was conducted by GHSS staff. The training ended with a post training assessment, participants signed an engagement form to participate in EQA programs and filled feedbacks from the participants. The training ended at 2.p.m with lunch. The questions of the pre/post tests are discussed by the trainer and participants.

RESULTS AND DISCUSSION

There were twenty five (25) questions in all and each scored one mark.

Table 1 Pre and post test performance scores of the Quality Assurance Training Workshop

Participant Code	Pre-test Score	Post-test score	Score Increase	Participant Code	Pre-test Score	Post-test score	Score Increase
A	10	18	8	A1	18	22	4
B	3	20	17	B1	14	16	4
C	16	20	4	C1	13	21	8
D	12	16	4	D1	14	22	8
E	19	20	1	E1	16	19	3
F	18	20	2	F1	8	9	1
G	16	15	-1	G1	6	12	6
H	17	23	6	H1	13	19	6
I	16	19	3	I1	11	22	11
J	14	12	-2	J1	13	18	5
K	13	18	5	K1	12	20	8
L	12	18	6	L1	16	18	2
M	13	18	5	M1	11	17	6
N	12	9	-3	N1	15	18	3
O	8	18	10	O1	13	18	5
P	14	20	6	P1	16	18	2
Q	14	20	6	Q1	14	16	2
R	12	13	1	R1	15	22	7
S	12	15	3	S1	13	21	8
T	20	22	2	T1	10	17	7
U	14	22	8	U1	18	19	1

V	17	19	2	V1	15	22	7
W	3	7	4	W1	12	17	5
X	12	16	4	X1	18	23	5
Y	18	21	3	Y1	15	17	2
Z	16	17	1	Z1	18	22	4

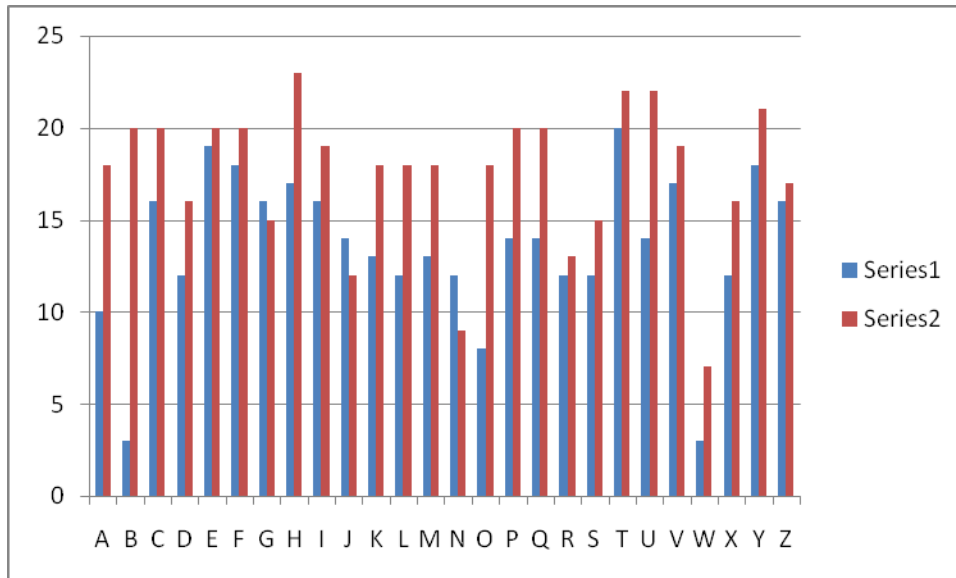


Figure 1 Bar Chart comparing the pre and post test for participants A-Z

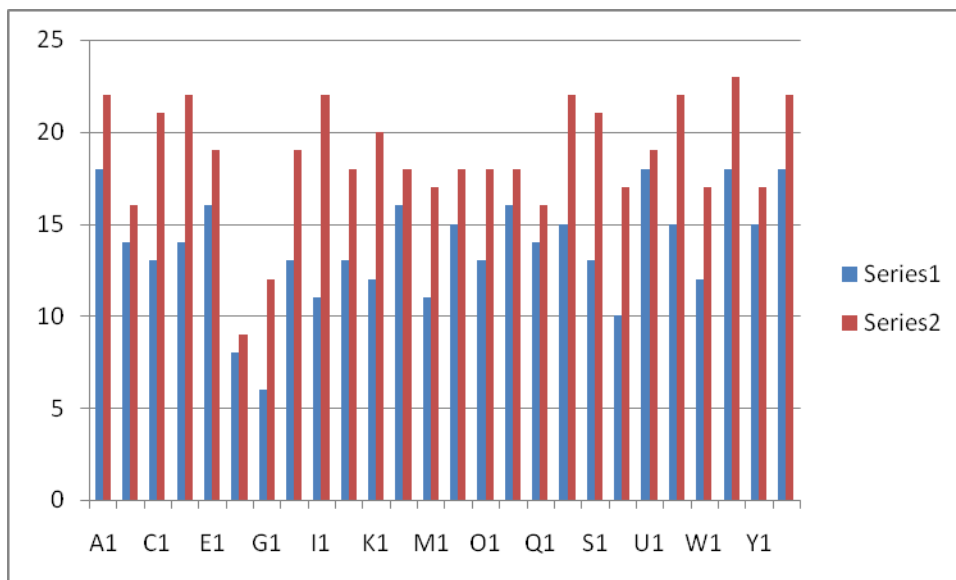


Figure 2 Bar Chart comparing the pre and post test for participants A1-Z1

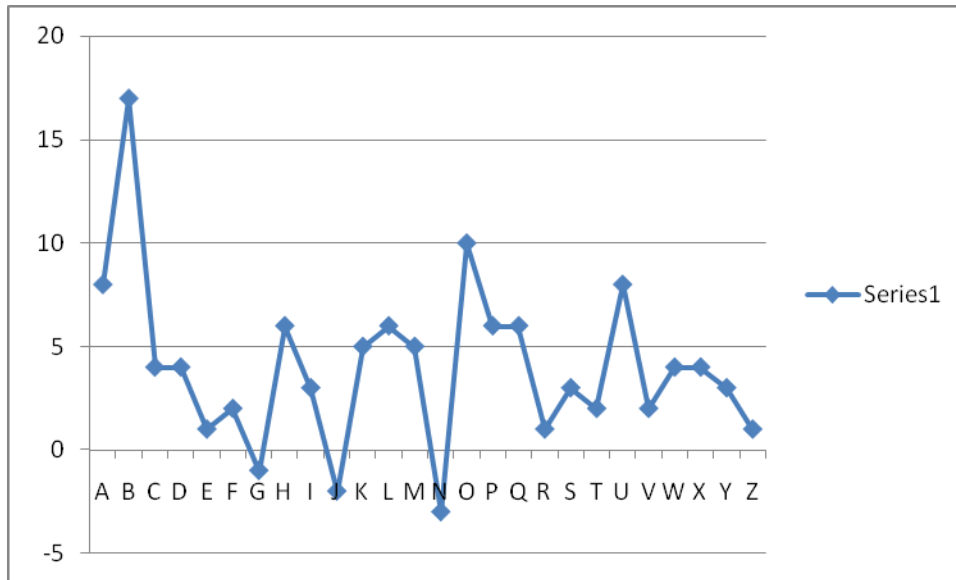


Figure 3 A line graph showing increase score of participants A-Z

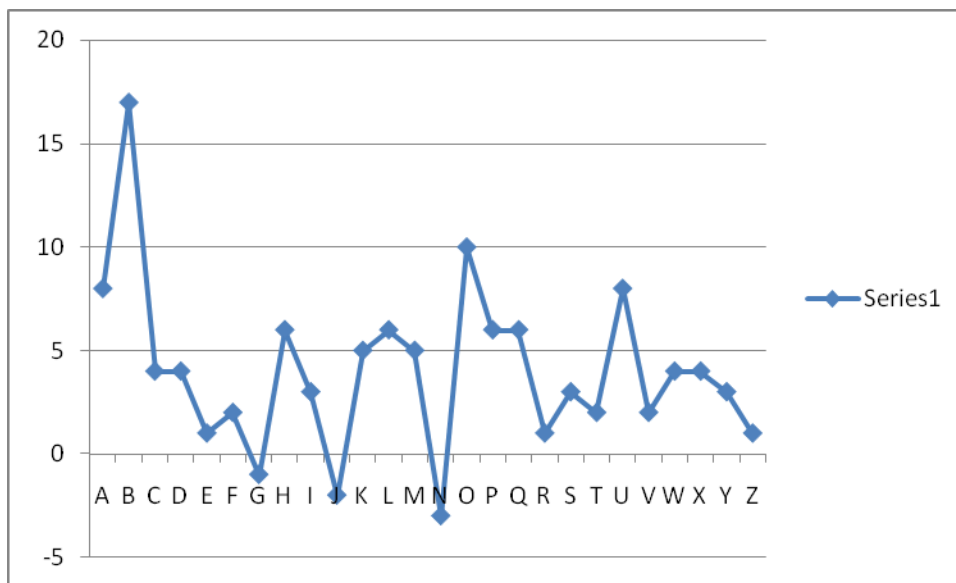


Figure 4 A line graph showing increase score for participants A1-Z1

From the bar chart above, for the pre test 35 (67.31%) participants had pass scores of 13 and above, 17 (32.69%) participants failed with scores below 13 and just 1 (1.92%) participant scored 20.

There was general improvement in the post test score with 47 (90.38%) participants having a pass mark of above 13, 20 (38.46%) participant scored 20 and above and 5 (9.62%) participants had a fail mark of 12 and below. 3 (5.77%) participants dropped in the post test from what they scored in the pre test.

With the general improvement in the post test, I can say that most of the participants actually understood the concept of Quality Assurance.

RECOMMENDATIONS

1. Follow-up and supervisory site visits should be conducted to the various health facilities to make sure what was learned during the training is being implemented.
2. Corrective actions for gaps that are noticed during supervisory visits should be discussed with the staff of the health facilities and give them a timeline to implement.
3. Make sure those sites that finally attain the desired quality outcome should be able to sustain it.

CONCLUSION

Detection, response, notification and monitoring of PHEICs are the key components of the IHR and all require robust laboratory support. Therefore, capacity building for the IHR must by necessity also focus on strengthening the routine laboratory systems within which events are detected and reported. GHSS is purposefully building capacity that runs through the entire laboratory structure from the lowest level to referral facilities by leveraging on the network approach. We believe this approach will build laboratory capacity at lower levels where these events usually occur, and thus ensure timely and adequate laboratory support. With adequate support, GHSS's approach provides a logical, sustainable and strategic model with a multiplicative effect that can enable Cameroon a resource limited country attain and sustain the IHR laboratory capacity (core capacity 8).

If a test cannot be trusted then it has little value. Customers expect to trust the results reported, thus laboratory staff have a clear responsibility to justify the customer's trust by providing the right answer which fits for purpose. For an analytical result to be fit for its intended purpose it must be sufficiently reliable that any decision based on it can be taken with confidence.

This training was timely for the rollout to the district level considering the non-conformances realized in conducting HIV testing in these health areas. If fully acceptable, then the logbook will be an effective QA tool to monitor and evaluate the quality of HIV testing in our laboratories. Participants must pass knowledge learned during training to their colleagues. Certificates will only be awarded to those who will put into practice what they learned during the training in their various health facilities.

Training fulfills requirements and supports the laboratory's role in the provision of high quality health care services. Effective training ensures consistent and predictable staff performance which is fundamental to the delivery of quality laboratory services and optimal patient outcomes.

There is therefore the need for more Quality Assurance training for all health facilities in Cameroon.

PHOTOS

		
<p>Participants during the practical session at the training site</p>		<p>HIV Rapid Testing Logbook</p>

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