Ministry of Health

Consolidated Report on 4th Quarter 2008 Provincial Technical Support Supervision Visit Findings and Recommendations

Prepared By:

"The Project for Strengthening HIV/AIDS Laboratory Network Services"

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1.0 Introduction

The baseline assessment report of all the provincial and central hospital reference laboratories that was conducted in 2007 by the Project team provided an insight into what was obtaining in terms of laboratory testing and some of the salient challenges that each of the provincial and central hospitals was facing. This was the basis and barometer that necessitated that certain indicators had to be met by the Project before any further support supervision visits could be conducted. This included the revision and updating of Standard Operating Procedures (SOPs) for all levels, formulation of the national QA guidelines and formulation of Internal Quality Control (IQC) forms among other milestones.

As could be deduced from the above, these were critical national strategic documents that required the support of Ministry of Health by cooperating partners in achieving the desired outcome both technically and financially. It also meant that it took a long time before these documents could be finalized and henceforth this was the main reason why the provincial and central hospital laboratories' support supervision visits delayed until the 4th quarter. By the beginning of the 4th quarter, the IQC forms were finalized and hence it was then appropriate to conduct these visits although it was also desirable that the SOPs for level II and level III Laboratories also be used and distributed. However, this was not possible due to the fact that one component of the Biochemistry SOPs on the Cobas Integra 400+ was not finalized as yet.

It was also important to mention that whereas the baseline assessment required only the Project consultant and the laboratory specialist to conduct, the follow up visits necessitated a bigger and more broadened group of technocrats from the national reference laboratory at UTH. This was mainly due to the fact that the provincial laboratory staff needed detailed orientation on the IQC forms that covered practically all disciplines save for cellular pathology. It was therefore important that each of the disciplines was represented very well especially the Biochemistry and Bacteriology disciplines.

The 4th quarter visits particularly took longer from the end of August 2008 through to Mid-December 2008 due to overlapping programs that required that the team returns to base.

2.0 Background

The Ministry of Health with support from JICA (and other Cooperating Partners), through the Project for Strengthening HIV/AIDS Laboratory Network Services, has been implementing a national quality assurance program for HIV and related testing since June 2007 as part of technical and operational support to the "3 Year Operational Plan for the National Laboratory" which plan came to an end this past December 2008. Quality laboratory services are critical to the success of health programs in the country and particularly in supporting the ART Program.

Within the Ministry of Health Operational Plan for the National Laboratory, this project aims to improve the quality of HIV and other related laboratory testing in the country by strengthening operations and capacities of provincial and national reference laboratories through a well defined quality assurance network. It is also envisaged that the project will work closely with the Laboratory Quality Assurance Specialist in the Ministry of Health to enhance coordination of QA activities for the smooth implementation of the 'Operational Plan for the National Laboratory' based on the '3 ones principle.'

The Technical Consultant was engaged by JICA Zambia Office to provide technical and operational support in facilitating and working with the Laboratory QA Specialist in the Ministry of Health in planning and implementing the project objectives based on the project design matrix (PDM) which buys into the Operational Plan for the National Laboratory.

3.0 Visiting Team Composition

The visiting team mainly comprised of the Project staff led by the consultant and two University Teaching Hospital laboratory staff (e.g. Biochemistry and Bacteriology or Haematology.)

4.0 Objectives of the Provincial Visits

The terms of reference (TORs) for the provincial and central hospital laboratory visits by the team were as follows:

- To conduct monitoring and technical support supervision visits to all the 10 provincial and central reference laboratories.
- To conduct orientation of laboratory staff on the newly formulated Standardized Internal Quality Control forms that will be used nationally at all levels of health care delivery. This was initially targeted at the provincial laboratory staff so that once capacity had been built, the provincial laboratories could then orient the lower level laboratories.
- To address all laboratory equipment operational challenges with senior management when these arose and were evident.
- To discuss with the Chief Medical Laboratory Technologist and/or the Hospital Laboratory In-Charge on the need to strengthen Laboratory quality control and assurance for HIV tests and other related tests.
- To ascertain the Internal Quality Control/Assurance practices of the laboratory in view of the quality control reagents that were regularly sent to the laboratory
- To follow up on the database of all laboratory staff at the hospital and determine attrition rates

5.0 Official Notification of Team's Visit

Prior official notification to the health facility being visited was given by the Project Monitoring Expert Mr. Shinya Matsuura. This was mainly done in the form of a fax. The faxed letters were signed by the Director of Clinical Care and Diagnostic Services in the Ministry of Health.

While this process of prior notification through faxing worked well for some hospitals, it did not work well in a few hospitals were the senior management expressed ignorance on our visit. A case in point was at Ndola Central Hospital and Kabwe General Hospital where both senior management and laboratory staff were unaware of our visits.

In follow up supervision visits, it has been strongly recommended that the faxed letters be augmented with telephone calls especially to the respective laboratories so that staff make adequate preparations in advance as our visits were not meant to be surprise visits.

Courtesy calls were usually made first thing in the morning of the first day of the visit by having the CMLT or laboratory in-charge accompany the visiting team to the Executive Director's office. Often times the courtesy calls were delayed as the hospital senior management team would be having their early morning briefings. However, it was very interesting to note that the laboratory was conspicuously absent in these early morning briefings except in a few cases like at Mansa General Hospital where the laboratory was well represented in these meetings.

The visiting team advised the respective Executive Directors to ensure that the laboratory was represented in these meetings. Most often the directors concurred with the team's views and indicated that the laboratory staff were just not proactive in such instances as they were officially part of these morning meetings.

The courtesy calls were much more effective and appreciated when the Executive Directors were available. However, the situation was not the same when the team was received by some senior staff that was in "Acting Capacity". An example was at Solwezi General Hospital where the doctor who was acting as Executive Director at the time refused to meet us in the directors' office and instead preferred to be followed to the screening room where he was seeing patients. These conditions were not suitable

for discussions and so the discussions were ineffective, not focused and lacked conciseness and precision.

6.0 Modes of Technical Support Supervision

The technical team was mainly composed of University Teaching Hospital Laboratory staff and the technical consultant for the Project, the short-term expert and the monitoring expert from the Project. In total, the team composition was almost always 5.

The main objective of the big and all inclusive team was that the orientation on the IQC forms required each discipline to be handled by staff specialized in respective disciplines. The preferred staff were those that greatly provided technical input that led to the consensus-building meetings and finalization of these IQC forms.

The team was also very useful in that challenges found with operating equipments were addressed by the specialized staff on the spot and if such problems were more complex in nature the vendor was informed.

The team administered the MOH monitoring tool which included the following particularly on quality assurance:

- The name of the facility and contact details
- List of laboratory staff and their designation
- Designated staff to oversee QA
- Infrastructure and equipment
- Laboratory Health and Safety
- Quality Assurance
- Logistics Management of laboratory commodities including HIV test kits
- Stores Management
- Overall management in terms of the facility

7.0 The Report

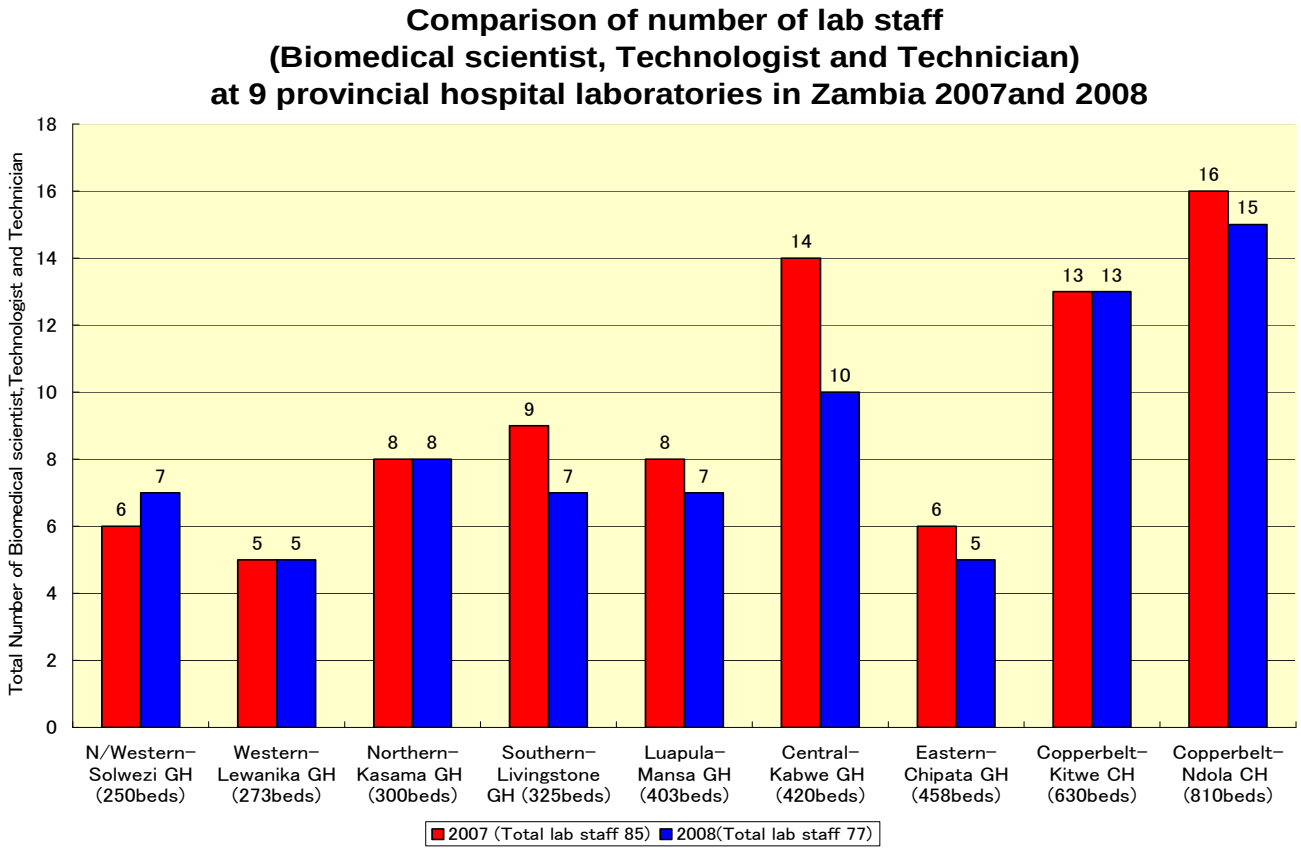
7.1 Human Resources – Laboratory

The table below gives a summary of the human resources that were available in the provincial and central hospital laboratories.

Table1. HUMAN RESOURCE BASE IN THE PROVINCIAL HOSPITAL LABS

Province	Biomedical Scientist		Technologist		Technician		Total	
	2007	2008	2007	2008	2007	2008	2007	2008
Central-Kabwe General Hospital	2	2	3	4	9	4	14	10
Copperbelt-Kitwe Central Hospital	2	3	5	4	6	6	13	13
Copperbelt-Ndola Central Hospital	3	2	3	5	10	8	16	15
Eastern-Chipata General Hospital	2	3	4	2	0	0	6	5
Luapula-Mansa General Hospital	0	2	6	3	2	2	8	7
N/Western-Solwezi General Hospital	1	1	4	4	1	2	6	7
Northern-Kasama General Hospital	2	1	2	2	4	5	8	8
Southern-Livingstone General Hospital	3	2	3	3	3	2	9	7
Western-Lewanika General Hospital	0	0	3	3	2	2	5	5
Total	**15**	**16**	**33**	**30**	**37**	**31**	**85**	**77**

Figure 1



7.1.1 Analysis

- From a total figure of 85 laboratory staff in the provincial hospitals in August 2007, the Ministry had lost 8 laboratory staff in approximately 1 year bringing the total number to 77 as at the December 2008 visit.
- The majority of laboratory staff at the provincial and central hospitals were technicians followed by technologists and lastly Biomedical Scientists.
- There was no Biomedical Scientist at Lewanika General Hospital.
- The female to male ratio was 1: 4
- The worst situation in terms of staff numbers was at Lewanika and Chipata General Hospitals (Chipata had received an additional 2 technologists as evidenced in the first follow-up visit in 2009).
- Kabwe General Hospital had the greatest attrition rate (-4).
- The number of working staff during day time at the main laboratory will be the total number of staff available at the facility minus 2 (CMLT working at Blood Bank and one staff who would have worked the previous night). For example if there were 8 staff in total at a facility, only 6 staff would be working at the main lab during day time.
- It is also important to mention that while the figures given in the table reflect the official staff in the MOH Establishment, another important cadre was the Laboratory Assistant who in most cases added significantly to the smooth running of the laboratories.
- Arthur Davison Children's Hospital was not reflected in this analysis as it was not included in the baseline survey. However, we will from now start reflecting it as it is part of the target laboratories.

7.1.2 Staff Motivation/Demotivation

There was generally a demotivated laboratory workforce in the majority of the provincial and central hospitals visited. However, there were a few cases where staff seemed to be motivated not because conditions were different but because they were very organized among themselves and tried to be content within the circumstances. This was particularly so for Mansa General Hospital and to some extent Kitwe Central Hospital.

This demotivation crisis prompted the team to develop a simple questionnaire which was administered to all the laboratory staff in the follow up visits to try and find out causes of the demotivation and how such challenges could be addressed.

From the 1st quarter 2009 follow up visits, the team of Provincial Technical Support Supervision will conduct a survey on what factors lead to motivation/demotivation in order to address these challenges so that motivation to work is improved.

7.2 Infrastructure, Equipment, and Quality Control

7.2.0 Infrastructure

The laboratory infrastructure in almost all the provincial and central hospitals was overally good. However, there was need to ensure that the laboratory infrastructure at Livingstone General Hospital was expanded. The rooms were too small and some tests were being conducted on different floors of the hospital.

The best and well spaced infrastructure was found at Kasama General Hospital and Kitwe Central Hospital. The rooms were adequately spaced and compartmentalization according to the various Units namely Haematology, Serology, Parasitology, Clinical Chemistry, Bacteriology, Blood Bank and +/- Cellular Pathology was to standard.

Generally Storerooms needed particular attention in all the laboratories. Some of them were not secured by grill-doors, had poor ventilation and FIFO or FEFO was not being adhered to. There were also a lot of expired reagents. A case in point was Ndola Central Hospital where a lot of clinical chemistry reagents were expired. A lot of reagent boxes were also haphazardly placed on the floor and the use of pellets in case of a flood of water was non-existent. Inventory management of Stores was generally poor.

All the provincial and central hospital laboratories had standard and appropriate equipment for a level II and III health facility respectively. In addition Chipata, Livingstone and Lewanika General Hospitals had additional Haematology equipment namely Sysmex XS 800i. These were not on the MOH approved list of laboratory equipment and as such, CDC was procuring all reagent supplies and controls for them.

Suffice to mention that there were particular equipments that were commonly found in all the facilities visited which had not worked since installation or no follow up was done in terms of training or orientation. These are as itemized below:

7.2.1 Equipment

7.2.1.1 Class II Safety Cabinets

In general, in order to process sputum specimens for TB diagnosis at the laboratory, there is always need for a Safety cabinet Class **II** Type B3. This Safety cabinet Class **II** Type B3 takes air through HEPA filters into the cabinet and exhaust the air through HEPA filters into exhaust duct which is connected to the outside. These Class **II** safety cabinets at the labs in the provincial hospitals were installed 3-4 years ago but were found to be defective or never been used as the HEPA filters were not functional. A directive was therefore generated from MOH that instructed all the facilities that had received this equipment to stop using it. Further detailed follow up will be required:

- To correctly identify the type of safety cabinet (Class **II** Type A or Class **II** Type B3).
- To correctly check the functioning of the filters and any other problems.

- To ensure that an exhaust duct can be attached to the cabinet. If the cabinet is a Class **II** Type A, there is need for the duct attachment to be made through an opening in the wall.
- To negotiate with the manufacturers or venders in a bid to either repair the filters and attach the exhaust air duct or simply take them back and replace these ones with Class **II** Type B3 safety cabinets.

The lack of such Safety Cabinets had put the laboratory staff at risk of exposure to infectious materials e.g. in TB sputum processing. In some cases staff had improvised the use of fans with windows as outlets for air flow further putting the public at risk (at Lewanika laboratory the opened window was directly in front of a busy path that was used by clients and their relatives).

7.2.1.2 L4 Diamond Distilling Machines (Water still, Manesty L4 DIAMOND),

Refer to Attachment 1

The distilling equipment was critical to the laboratory as it was able to make distilled water which was required in the laboratory for various processes. In addition, there was urgent need for labs to obtain De-ionizer machines for making pure water for automated biochemical analyzers like the Cobas Integra 400 plus and the Olympus AU 400+.

Apart from Kasama and Mansa General Hospitals, the Diamond Distilling Machines were not functional in the other provincial and central hospital reference laboratories. The main reason was that they required a difference in gradient for the water to flow under gradient pressure. On the contrary, GFL Distillers were working and were easy to connect at the laboratories.

The lack of distilled water and de ionized water was having serious consequences for the operation of laboratories. A case in point was at Ndola Central Hospital were management was procuring 40litres of distilled water from some named company in order to run and operate the Olympus AU 400 + in the Clinical Chemistry Unit of the laboratory. The quality of the distilled water from this known company was doubtful as there was a lot of clogging in the filtration system and the machine showed unbelievably poor results of all control runs. Unfortunately at the Ndola Central Hospital laboratory, there was no working de-ionizer for making pure water. As a fundamental condition, automated biochemical analyzers like Cobas Integra 400 plus and the Olympus AU 400+ need pure water made from a de-ionizer machine. However, because of these circumstances management at the hospital had recently procured another distiller which was awaiting installation.

7.2.1.3 ELISA Testing Equipment

The ELISA equipment was procured through ZANARA (Zambia National Response to HIV and AIDS) 2-3 years ago. The background to the ELISA testing equipment was that each provincial hospital laboratory was provided with 2 ELISA machines, 1 for the Blood Bank and 1 for the hospital main laboratory. The Blood Bank ELISA machines were being used in all the provincial Blood Banks while the ELISA equipment for the main laboratories had been packed with the reasoning that no follow up orientation or training had been conducted by MOH as ZANARA were just an institution that procured these machines.

The ELISA machines for the Blood Banks were TECAN while those for the main laboratories were MULTISKAN machines.

The ELISA equipment in the main laboratories had never worked or been installed mainly because no follow up training nor orientation had been carried out with this equipment. The only facility where this equipment had been put to use was at Mansa General Hospital where it was discovered that the Washer and Pump on the Blood Bank equipment was not working. Otherwise no other provincial or central hospital reference laboratory had put it to use.

From using both machines, the laboratory staff at Mansa General Hospital had discovered that the most encountered technical problem with the TECAN was the fact that the pump connecting to the Washer

was not strong enough and persistently gave a problem. The MULTISKAN was better in this aspect as it had a very strong and durable pumping system. However, the MULTISKAN's problem after prolonged use was the fact that the 8 nozzle rubbers get eaten away making the washing process inadequate and ineffective. It appears the "cleaning solution" used at the end of the washing cycles eats away the rubbers. The team did bring a washer probe with such a problem to inform MOH on this issue.
The ELISA equipment in the provincial and central reference hospital laboratories was mainly intended for the HIV testing in the QA Program with the DBS (Dried Blood Spots) samples. The DBS samples would be coming from all testing centers in a particular district (10% of all tested clients-at that time although this % was likely to have a significant reduction in the current national program analyses). The district would then facilitate the process of transporting these DBS samples to the respective provincial or central reference laboratory where all the DBS collected would be tested using ELISA. Under this national QA program, the provincial or central reference laboratory would then submit 10% of all samples tested to the national HIV reference laboratory at the University Teaching Hospital. This national QA Program based on DBS had essentially not started due to the fact that the national program on trainings for the HIV finger prick rapid tests had not yet been fully implemented and this was a pre-requisite for the national HIV QA program based on DBS.

7.2.1.4 pH Meters

All the provincial and central laboratories had pH meters (Thermo 520A+ Orion A plus Bench top pH/ISE Meter) that were supplied to them sometime back. However, none of the visited laboratories so far were using them. At Mansa General Hospital laboratory, the In-charge indicated that he had tried to assemble and use the equipment, but because of the lack of an SOP manual, he had encountered problems trying to understand how to use it. Henceforth, he had packed it in the Storeroom. The visiting team was at least happy that there was an attempt by the laboratory to try to use this piece of equipment. The pH meter was important in the preparation of reagents especially in Microbiology and Parasitology. An attempt made by the team and local staff to assemble and operate this equipment revealed that it was generally not complicated to use.

7.2.1.5 Laboratory Equipment in Haematology

Equipment for Full Blood Count

The equipment in this Unit countrywide was very standardized in all the provincial and central hospitals. Each facility had two of the following equipments:

- Micros 60
- pOCH 100i
- Pentra 60

In addition, Livingstone, Chipata and Mongu had additional Haematology equipment namely the Sysmex XS800i and XT1800i procured through CDC.
The equipment mostly in use was the Micros 60. The central hospitals commonly had the Pentra and interchangeably used the Pentra with Micros as back up.
The challenge with the Sysmex Full Blood Counters had been that reagents and controls were supplied through CDC as the MSL did not have them on the MOH approved list of equipments and reagents. There were indications that CDC would not continue to procure reagents for these equipments and that MOH needed to take them over. Currently discussions were underway on how best to resolve this new development. In the meantime the affected facilities would not encounter serious stoppages of haematological tests as they had the Micros 60 equipment also.

7.2.5.1 Availability and Use of Full Blood Count Controls (Testing Procedures/Technique and Quality Control)

The reagent controls for these equipments were available. However, the use in most facilities was erratic as revealed by the quantities that were found to have expired although this was not a good indicator as some facilities apportioned blame on the delayed arrival of these controls.

It was hoped that with the newly formulated FBC quality control form, the control reagent use would be enhanced in order to improve internal quality control of tests.

The most frequently encountered challenge with the use of these equipments with reference to controls was that the laboratory staff would most often not pay attention to the background check so that even if this failed they would still go ahead to run tests giving very high values especially for WBCs and RBCs. The SOP was very simple in this case of high background count and referred to steps that could zero the equipment including "auto rinse" and "concentrated cleaning" steps. When such steps were followed, usually there would be no problems when subsequently running the controls.

7.2.5.2 CD4 Counter Equipments

All the provincial and central hospital laboratories had a FACS Calibur as first line with the FACS Count as back up. However, the demand for CD4 count equipments with high capacity of CD4 counting like the FACS Calibur at the provincial level was decreasing because the number of health facilities with CD4 FACS Counts was increasing. It was very interesting to find out that use of the FACS Calibur was limited as most of the laboratory staff preferred the use of the FACS Count as opposed to the FACS Calibur.

Both equipments had a very good and regular flow of supply reagents and the fact that the FACS Calibur was not preferred as first line had led to a lot of the facilities having near-expired reagents for the FACS Calibur.

Further insight into the reasons why this was so revealed that the orientation on the FACS Calibur was usually conducted in 2 days, the 1st day would be for installation and then the 2nd day would be for operation of the equipment. This was not sufficient as assessed by the team due to the fact that this was a more complex equipment needing both computer skill and technical know-how.

The situation was made worse and compounded by the fact that it took too long (sometimes 2-4 months) before regular reagents could be formalized between MSL and the facility. An example was at Chipata General Hospital where laboratory staff alluded to the fact that it took up to 4 months from the time of orientation before reagents could be delivered as regular supplies from MSL. The two staff that were trained on the equipment had basically forgotten most of what was learnt to an extent that not even the manual/SOP for the equipment could work.

The Laboratory In-charge had contacted the suppliers of the equipment to reorient his staff but to no avail. However, with the help of the visiting team, two scenarios were suggested: one was to have one staff sent to UTH Virology Laboratory for 1 week to get acquainted with the operation of the equipment and the other alternative was to ask BD to organize a one-off workshop for selected staff from the provinces. It had come to the attention of the visiting team that BD was in the process of organizing a workshop in Ndola in February 2009 for the purposes of orienting facilities with difficulties using the FACS Calibur.

7.2.6 Equipment in Clinical Chemistry

All the provincial general hospital laboratories had the Cobas Integra 400 plus while the central hospitals had the Olympus AU 400+as first line equipments as per MOH requirements. The Vitros DT 60 (Dry chemistry system) was the back up equipment in these facilities. However, none of the facilities visited had a functional Vitros and most of the reagents were found expired in these facilities.

In addition, some provincial laboratories had Calorimeters.

The report will immediately address the challenges with these particular equipments that were almost common to all:

- There was lack of adequate knowledge on the basic maintenance of the Cobas Integra 400 plus and also the Olympus AU 400+. This greatly affected the functioning of these equipments and consequently the quality of test results. Because of this, there was generally poor maintenance of this piece of equipment.
- There was no hard (paper-based) copy of the Cobas Integra 400+ manual in all the provinces except in Mongu (Lewanika General Hospital). This was in sharp contrast to the Olympus AU 400+ which had both a soft copy installed on the equipment and a hard copy. The Cobas Integra 400+ only had a soft copy on the computer. This made it difficult for the staff to perform "Trouble-shooting" in times of malfunctioning or unreliable and unexpected results as the majority of staff did not have basic computer skills. In addition, when the equipment could not open, it was then difficult to trouble-shoot using the software manual!
- The labs did not obtain or make water with minimum desired quality which was required by manufactures of Cobas Integra 400 plus and also the Olympus AU 400+. The Olympus AU 400+ required copious amounts of distilled deionized water and this was the reason why the equipment had an in-built water distiller de ionizer as in the attachment. However, it had been observed that this distilling component had broken down in all the tertiary institutions including the 2 at the University Teaching Hospital. It was a general problem found at Kitwe Central hospital, Ndola Central hospital, Arthur Davison Children's hospital and at the UTH. The Cobas Integra 400+ also required distilled de ionized water for proper functioning and maintenance. Because of the above challenges, the respective hospitals had to outsource the distilled water and in some cases the quality of this distilled water was very questionable and could have been a contributing factor to poor maintenance of these equipments (Refer to attachment 1).

7.2.6.1 Testing Procedures/Technique and Quality Control

- The staff had difficulties interpreting the Levey-Jennings charts and the West-Guard rules. This was such a major challenge that staff would proceed to run tests even when values based on the controls were outside the normal ranges thereby providing unreliable and incorrect results.
- Some staff had difficulties manipulating computers of Cobas Integra 400 plus and also the Olympus AU 400+.
- The venders of Cobas Integra 400 plus were not always readily available to support labs quickly and adequately.

7.2.7 Microbiology/Parasitology

This particular Unit was functioning relatively well although there were shortcomings in a few places. While it was very easy to bring the staff to required standards of performance mainly because most procedures were manual and hence principles of the tests were well understood, there were still a few challenges that needed highlighting as follows:

7.2.7.0 Safety Cabinets

- The lack of appropriate Safety Cabinets in all the provincial and central hospitals was not ideal for staff as they were exposed to risks of infection especially when dealing with sputum specimens for TB bacteria. In addition, chances of contamination when doing blood cultures were also very high when this was done in open spaces as opposed to under a Safety Cabinet.

7.2.7.1 Testing Procedures/Technique and Quality Control

- While media preparation was done to acceptable standards, there were challenges in the preparation and storage of Giemsa. The stock solution and working solutions were not made according to acceptable proportions and sometimes storage under the dark was not practiced.
- Antimicrobial Susceptibility Testing for discs as a measure of quality control was almost non-existent in all the provincial and central hospitals. In addition, antimicrobial susceptibility testing for patient sera was rarely done as the laboratory apportioned blame on lack of requests from clinicians. However further probing would reveal that it was actually the laboratory that quite often failed to inform clinicians on the availability of tests in the laboratory more so if a particular test was out of stock for sometime.
- On Antimicrobial Susceptibility Testing, turbidity for culturing microorganism on the surface of agar was not usually correct and also the number of discs for putting on the agar was over the maximum limit at some labs.
- Media and reagent preparations were performed with no pH check as none of the pH Meters supplied by MOH were in use. This made it difficult to ascertain the quality of such preparations in terms of acidity or alkalinity.

7.2.8 HIV Testing

Generally no provincial or central laboratory was conducting HIV testing using ELISA (Enzyme-Linked Immunosorbent Assay). This was only being carried out in Blood Bank. The national program on the use of DBS (Dried Blood Spots) for HIV quality control was still far from being implemented and hence the non-use of the ELISA equipment that was procured through ZANARA for the same purpose in the laboratory.

While it was observed that HIV testing using rapid kits was no longer a domain of the laboratory in line with the task shifting being propagated in resource-constrained poor countries, there were no mechanisms to ensure that quality was adhered to at these testing points within the hospital. There was therefore very little of HIV testing being done in the laboratory.

However, the laboratory had still retained the responsibility of ordering and distributing the rapid HIV test kits and compiling consumption data for further procurements. Because of this, the laboratory was therefore still responsible for ensuring that the HIV test kits reaching the laboratory were validated and that there was some form of supervision at the testing sites.

7.3.0 Orientation on the IQC (Internal Quality Control) Forms

Generally the IQC forms were well appreciated by the laboratory staff in the facilities visited. They were also perceived to be very easy to understand. Whether the implementation will be adhered to remains to be seen. There were, however, positive indications that the laboratory staff would start using the forms in order to enhance quality control as was recently evidenced by the trip undertaken to Chipata General Hospital and Lewanika General Hospital.

Despite these developments there were also situations were the staff would likely not use some of the forms due to the following:

- The Temperature Monitoring Form could not be used widely as most of the facilities did not have the necessary thermometers to record temperature with. Hence there will be need to procure such instruments if the area of monitoring temperature of equipments like refrigerators, incubators, freezers etc was to be enhanced.
- The non-availability of control strains for quality checking antimicrobial discs and prepared media performance would lead to non-use of the Antimicrobial Susceptibility Disc Quality Control Form and the Prepared Media Performance Quality Control Form. Most of the provincial and central laboratories did not have the control organisms or strains and it was important that

these were provided from the University Teaching Hospital Bacteriology Laboratory who normally stock these.

- The fact that the laboratory staff also made rotations in the various Units meant that use of the IQC forms would be affected as new staff assigned in that Unit would require some level of in-depth practical orientation. This was also the reason why some of the advanced equipment could not be well maintained with different staff using the equipments more often than not.

It is important to note that challenges had been discussed under each heading in this document and therefore the recommendations would be discussed next.

7.4 Recommendations

7.4.1 Human Resources and Human Resources Management

- Mongu, Solwezi and Chipata General Hospitals will urgently need to have additional (minimum 2) staff posted to these facilities.
- The rural retention scheme for laboratorians needed to be implemented as soon as possible to avert more personnel leaving these facilities.
- The laboratory team needed to be well represented in the daily morning briefings and clinical meetings to enhance their interactions, and image-building.
- Partners would need to involve the laboratory in any planned HIV rapid test trainings.
- The issue of being invited to participate in workshops needed to be extended to all staff. The best would be to implement this on a rotational basis except for special trainings/workshops (e.g. the trainings/workshops specified for lab in charge).
- The staff who attend such trainings/workshops should share the information/skills/technique with other lab staff through presentations at the lab or main clinical meetings.
- Leadership of the laboratory In-charge was very critical in determining how the laboratory moves forward in terms of general work and in particular in terms of quality control.
- Motivation management should be implemented from MoH to each lab and also from CMLT/Lab in Charge to subordinate staff at each lab.

7.4.2 Laboratory Equipment

- **Safety Cabinet**

  There will be need to follow up on the Safety Cabinets for fundamental solutions e.g. repairing them or returning them to manufactures or replacing them with correct ones after follow up team conducted detailed checking. These Safety Cabinets had malfunctioning HEPA filters which made filtration of air ineffective.

- **Distiller and De-ionizer for making pure water**

  Pure water with proper quality is critical for clinical chemistry and quality control in the lab. There is urgent need of repairing the non-functioning L4 Diamond distillers and procuring the MEDICA De-ionizer. Cobas Integra 400 plus and also the Olympus AU 400+ need de-ionizers. Therefore, if there is need for procuring De-ionizers, it is better for MOH to procure another type of it (e.g. ADVANTEC GS-590 AQUARIUS, this is being used at UTH labs and filter is much cheaper than that of MEDICA De-ionizer) because one filter of MEDICA De-ionizer is approximate **USD4, 000**.

- **ELISA equipment**

  The purpose of using ELISA equipment at the provincial hospital main labs was for HIV retesting. There is need to ascertain the timelines when this would start as the equipment would become a white elephant.

- **pH Meters**
  There is need of an SOP or simple usage manual of Thermo 520A+ Orion Aplus Bench top pH/ISE Meter and practical instruction at the labs by the follow up team so that this small piece of equipment can be put to use.
- **Sysmex XS 800i and XT1800i for Full Blood Count**
  The above Sysmex Full Blood Count machines were not approved by MoH. Considering the cost of procuring controls, if the controls for Sysmex XS 800i are compatible with controls for Micros 60, pOCH 100i, Pentra 60 approved by MOH, then the take over of these equipments won't have challenges. It will pose a lot of challenges if these controls were not compatible with the controls for the approved equipments.

- **FACS Calibur**
  Proper training on manipulating BD FACS Calibur by manufactures/suppliers and quick and adequate support by venders were crucial to the effective use and maintenance of this equipment.

- **Equipment in Clinical Chemistry**
  In general, to introduce the Cobas Integra 400 plus and Olympus AU 400 + to provincial hospital labs was ill-timed for the simple reasons that there was no prompt and adequate support to the machine, almost no access to pure water with adequate minimum requirements which as requested by manufactures, no stable electricity supply and difficulties of manipulating by limited number of staff with low competency. Furthermore UTH lab were using the Olympus AU 400+ which made it slightly challenging for UTH staff (Apart from Mr. Mubita Kabalanyana) to give practical advices for manipulating the Cobas Integra 400 plus to the lab staff using the Cobas at the provincial level.
  In addition, the 2 named equipment were not producing acceptable quality control results in the majority of the provincial and central hospital laboratories. As long as the labs can not meet the minimum conditions as stated above, the continued use of these two equipments would continue to be a challenge. It is therefore recommended that the use of dry chemistry equipment like the Vitros DT 60 as first line be revisited instead of the Cobas Integra 400 plus and Olympus AU 400+.
  The training/orientation on new equipment needed to be taken seriously and given ample time by country vendors and suppliers alike. The content and methods of the training/orientation on new equipment should be improved (e.g. to make lab staff manipulate the equipment on their own and the vendor as observer etc). This also applied to the servicing of equipment and repair of broken down equipment. The reports coming from the facilities were indicating that orientation was usually rushed, inadequate and that there was no time given to the trained individual to now perform the test using the equipment under the watchful direction of the vendor. These issues have already been highlighted in the document and will need to be addressed with the respective vendors under the auspices of the Ministry of Health.
- There will be need to enhance the concept of preventive maintenance on equipment.
- There was immediate need to ensure that the hard copy on the Cobas Integra 400+ was made available to all the provincial hospital laboratories
- Procurement or laboratory equipments should take into consideration the key criteria for selection of laboratory equipment and the conditions of existing laboratories where such equipments would be placed.

Key Criteria for Selection of Laboratory Equipment

- Infrastructure (power, generator, water, temperature, space)
- Environmental conditions
- Laboratory workload; staff skills and training
- Vendor support, reliability and availability (in-country or region)
- Availability, stability and temperature sensitivity of reagents, controls and calibrators
- Availability of local service, technical and training support
- Simplicity of operation; ease of maintenance and calibration
- Track record of performance (domestic and/or international)
- Analytical performance/technical quality (sensitivity, specificity, reliability, level of detection)
- Test menu (consider scalability for various volumes)
- Open or closed test/reagent system
- System costs (includes equipment, service, reagents, and supplies); cost per reported test
- Specimen types
- Throughput
- Turnaround time
- QC and QA required
- Availability of EQA and inter-laboratory comparisons
- Data management capability; interface capability
- Safety
- Availability of back-up methods
- Supply chain management capability

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7.4.3 Usage of IQC Forms

- Quality control needed to be institutionalized in the laboratories by ensuring that this responsibility was designated to a specific person who would ensure this was operationalized.
- There is need for vigorous information sharing on Westgard rules to enhance quality control in clinical chemistry for both lab staff and vendors for the Cobas Integra 400 plus and Olympus AU 400+.

7.4.4 Other Non-specific Recommendations

Pallets should be used at the store rooms to avoid damage of reagents due to flood.