Laboratory Services in the context of Prevention of Mother-to-Child Transmission of HIV testing requirements in Copperbelt Province, Zambia. A qualitative inquiry

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Abstract

Introduction

Reliable and timely laboratory results are crucial for monitoring the Prevention of Mother-to-Child Transmission (PMTCT) cascade, particularly to enable early HIV diagnosis and early intervention. We sought to explore whether and how laboratory services have been prepared to absorb new testing requirements following PMTCT Test-and-Treat policy changes in three districts of Zambia.

Method

This qualitative study was conducted in three local government areas in the Copperbelt Province (one urban and two rural) between February 2019 and July 2020. Document review and in-depth interviews with 26 purposively sampled health workers were undertaken. All interviews were analyzed using thematic data analysis, informed by the health system dynamic framework.

Results

The findings revealed that the health system inputs (infrastructure and supplies, human resources, knowledge and information and finance) and service delivery were unequal between the rural and urban sites and this affected the ability of health facilities to apply the new testing requirements, especially, in the rural based health facilities. The major barriers identified include gaps in the capacity of the existing laboratory system to perform crucial PMTCT clinical and surveillance functions in a coordinated manner and insufficient skilled human resources to absorb the increased testing demands. The centralized laboratory system for HIV testing of mothers and exposed neonates meant facilities had to send specimens to other facilities and districts which resulted in high turnaround time and hence delayed HIV diagnosis.

Conclusion

New guidelines implemented without sufficient capacitation of health system inputs and service delivery resulted in gaps in the capacity of the existing laboratory system to perform and meet the diagnostic and treatment needs for PMTCT. This study documented the areas relating to health system inputs and laboratory service delivery where greater investment and support is needed to enable absorption of the new testing requirements.

Background

Globally, 1.4 million pregnant women living with HIV are receiving ART and the Mother-to-Child Transmission (MTCT) rate is 13% making it a significant contributor to the HIV pandemic, accounting for 9% of new infections globally [1]. In Zambia, the HIV epidemic is generalized, with a national prevalence of about 11.1% in adults 15–49 years and the HIV prevalence is higher among women than men – 14.2% versus 7.5% [2]. The preliminary findings from a prevention of mother-to-child transmission (PMTCT) evaluation study conducted in Zambia between 2014 and 2016 showed an overall cumulative 9-month MTCT rate of 2.59% [3]. The majority of new HIV infections among children occur through MTCT. As a result the target set for elimination of new pediatric HIV infections due to MTCT is a case rate of 50/100,000 live births or less and a MTCT of HIV rate of 5% or less by 2023 [1]

Laboratory services are a critical step in the PMTCT of HIV cascade (diagnosis, linkage to care, engagement in care, retention in care, initiation of antiretroviral therapy and viral suppression) and Zambia over the years has been revising PMTCT testing requirements following policy changes (Table 1) [4; 5].

In Zambia, laboratory services are offered within the public Health Sector by the Ministry of Health and form an essential part of the health system; as diagnostic testing is critical for identifying specific diseases, guiding treatment, determining drug resistance and supporting disease surveillance [6]. This service is delivered through the provincial referral network of laboratories ranging from higher tier (high throughput) laboratories to lower tier (primary healthcare facilities) offering laboratory or no laboratory services dotted across the province. Laboratory services are mainly offered using a tiered laboratory service approach [7; 8].

Presently, the Ministry of Health (MOH), and its cooperating partners have expanded the laboratory system and developed various blood-based HIV test strategies for diverse sub-populations and installing polymerase chain reaction (PCR) testing machines in three tertiary hospitals, each servicing the province and other neighboring provinces or regions[7; 9]. The MOH in the province also employs a “hub and spoke” approach whereby facilities offering basic laboratory services receive samples from multiple source laboratories [10]

Despite these strategies, there has never been a study in Zambia that examined the laboratory system in the context of PMTCT of HIV testing requirements. Therefore, understanding that laboratory services are a sub-system of the overall health system, this study, used the health system dynamic framework [13; 14] to explore the barriers and strategies, if any, which have been applied to capacitate the laboratory services in Zambia to absorb the revised PMTCT testing requirements. This framework was selected as it enabled us to explore health system inputs essential for laboratory services (infrastructure and supplies, human resource, knowledge and information and Finance) as well as service delivery aspects of the laboratory services.

Method

Study Setting and Design

This qualitative study utilized document review and in-depth interviews with health workers from three districts, Lufwanyama (rural) and Kitwe and Ndola (urban), out of the 10 districts in the Copperbelt province, and three main referral hospitals Kitwe Central Hospital, Arthur Davison Children Hospital and Ndola Central Hospital.

Selection of Study participants

The study was performed in eighteen purposively selected primary healthcare facilities (six in each of the three districts), district health offices in Lufwanyama, Ndola, Kitwe and in the three main referral hospitals in the Copperbelt Province. Primary healthcare facilities where patients requiring laboratory services are typically seen before being referred to referral health facilities/hospitals were purposively selected for their characteristics (availability of the basic laboratory services and access to these services). The three tertiary hospitals were selected because they were the only facilities at the time of the research offering PCR services in the entire province.

We used snowballing sampling where participants were identified through referrals from health facility in-charges and purposive sampling of interviewees who were health workers familiar with the topic and involved in the PMTCT program in Lufwanyama, Ndola, Kitwe and in the three tertiary hospitals. The interviewees had experience with and were involved in the PMTCT program planning and decision making in their respective health facilities and institutions. Health workers were recruited into the study only if they had work experience in the public sector (Ministry of Health) for five years or more and consented to participate (**Table 2**).

Table 1. Testing requirements in the PMTCT program of Zambia

Specific Population	When to test	Type of test
Pregnant women, breastfeeding women (and their sexual partners)	During antenatal care (ANC): at first ANC visit and every 3 months if negative In labor and delivery (L&D): test if last test >6 weeks ago During postnatal care (PNC): test at first contact if unknown status. Serological test at 6 weeks if negative. If breastfeeding: retest every 3 months if negative until cessation of breastfeeding Partner testing: same time points	Serological HIV test
0 to <10 years old	At birth, 6 weeks of life or at first contact	NAT or DBS (which should be sent for HIV DNA PCR)
	6 weeks, 6 months,9 months, 12months and 18 months old	12-18 months (serological test)
	24 months old	Serological test

MOH GRZ, “Guidelines for Treatment and Prevention of HIV Infection,” 2020.

NAT= ; DNA PCR =

Table 2. Interview participants

Health Worker Type	Primary Health Care Facility	Tertiary	District
Laboratory Personnel	4	3	3
Nurse (Maternal & Child Health Department)	14		
Program Officer- Cooperating Partner			2

Data collection

Document review

The first step in data collection involved the review of documents to map the laboratory system in the province and to achieve this, we reviewed relevant policy documents and the literature on laboratory services in the context of PMTCT. These documents were identified through the MOH website and included technical briefs/reports, published articles and strategic documents **(Table 3).**

Table 3. Documents reviewed

Document/Report	Year/Period	Relevance to the study
1. B. E. Nichols et al., "Impact of a borderless sample transport network for scaling up viral load monitoring: results of a geospatial optimization model for Zambia," J. Int. AIDS Soc., vol. 21, no. 12, 2018, doi: 10.1002/jia2.25206	2018	Provides insights into the sample network for VL in Zambia
2. C. Kankasa, J,., Simbaya, K., Musokotwane, M.C.,Nambao, E.,Yam, T.,Moyo, L.,Phiri, S.,Kalibala, & A., Moonga, (2018). Evaluation of the prevention of mother-to- child transmission of HIV program in Zambia,1(1),48. Unpublished manuscript.	2016	Provided insights into the eMTCT program in Zambia
3. K. Nichols, "Viral Load Specimen Referral Network Report Zambia," no. November 2016, [Online]. Available: https://aidsfree.usaid.gov/sites/default/files/2017.5.16_vl-eid-ref_zambia.pdf.	2016	Document provides insights on the national VL specimen referral network
4. Ministry of Health-MOH GRZ, "Guidelines for Treatment and Prevention of HIV Infection," 2020	2020	The document provided an understanding of the PMTCT testing requirements
5. Ministry of Health GRZ, "National biomedical laboratory strategic plan 2018 - 2022," pp. 1–57, 2018, [Online]. Available: https://www.moh.gov.zm/?wpfb_dl=113. Accessed July 10, 2019.	2018	It gives the MOH strategic priorities and direction on biomedical laboratory.

Individual interviews

The PI (Principal Investigator) booked appointments and interviewed individual health workers using in-depth interview guides. Interviews were done during their free time to avoid disruption of service provision. We used in-depth interviews because they offer more time for a detailed understanding of a complex issue and enable researchers to get an insight into the phenomenon or experience of interest from the participants' perspective [15, 16]. The interviews allowed us to gain insights from the people who were more conversant about the topic [14].

The interview guides were piloted in a nearby district within the Copperbelt Province. The broad questions that guided the interviews were: *Please describe the laboratory and diagnostic services offered in the district health facilities in relation to PMTCT guideline changes; can you tell me more about the laboratory system for PMTCT services within the district from the point of sample collection to referring the samples to a tertiary hospital.*

After each broad question, we probed further to achieve a deeper understanding of the laboratory system offered in the districts under study. JM, together with research assistants, conducted all the interviews. All interviews were conducted in English, audio- recorded and lasted for thirty to forty-five minutes all IDIs were conducted within a health facility. In the course of data collection, the researchers met and discussed the key findings to ascertain the saturation of ideas. To achieve credibility of our findings at the end of each interview session, the research team consisting of the PI and four research assistants summarized the information provided by the participants [15].

Data Analysis

The Van Olman health system dynamic framework[13; 14] was used to guide the analysis. This strengthens our understanding of interactions and dynamic relationships between health system inputs and service delivery and the context in which they are implemented.

All IDIs were transcribed verbatim. The transcripts were analyzed using a thematic approach suggested by Braun and Clerk [16] and using Nvivo software (add citation). The transcripts were read multiple times for data absorption and familiarization and also to get meaningful segments and essence [17] while noting ideas of interest and checking the transcripts back against the original audio recording for accuracy [18]. During this process, notes and markings were made within the transcript for coding. Codes **(Table 4)** were deductively derived by identifying recurrent ideas as the data manifest to match the objective of the study. Different codes were sorted into potential themes and the data extracted were put within the identified themes. All themes that seemed to be related to the same idea were categorized together. An inductive approach was also applied to allow emerging themes to be included in the analysis. Finally, all the documents reviewed were read for familiarization of the laboratory structure and to map the laboratory system in the Copperbelt Province. Special attention was given to the content of the documents describing PMTCT specimen referral networks

Results

Socio-demographic characteristics of the participants

There were twenty-six health workers aged 30–57 years; midwives: fourteen (females); laboratory: ten (4 females, 6 males); program Officers: 2 females.

Table 4
gives a summary of the main themes, codes and sub-codes. These findings are shown in **Fig. 1** in relation to the health system dynamic framework.

Elements of the Health System Dynamics framework	Codes	Sub-codes	
		Barriers to absorption of PMTCT testing requirements	Existing strategies to support absorption
Resources (health system inputs)	Infrastructure & Supply	• Inadequate functional laboratory infrastructure • Supply chain failures	
	Human Resource	• Insufficient laboratory personnel • Inadequately trained personnel • Low knowledge on new PMTCT testing requirements	• More staff by donors • Job aids to guide practice
	Knowledge and Information	• Largely paper-based records system	• Electronic laboratory records system – by donors
	Finance	• Lack of cooperating partners in rural districts to compliment government financial support.	
Service Delivery	Specimen collection and transportation:	• Undefined laboratory network • Unreliable cold chain • Undefined transportation system	• "hub and spoke" • Expanded cold chain in selected PHCs in urban areas
	Specimen processing and Transmitting of results:	• Centralized PCR service points • Designated dates • Lab to lab TAT • Poor inter and intra laboratory sample referral processes	• Work shifts • Courier motorbike or vehicle

Health system and laboratory network

The document review demonstrated that the laboratory system in the province begins with health posts, which are usually manned by one or two health personnel. Health posts are usually attached to a health facility which are above this tier. Health facilities with laboratory infrastructure are expected to provide essential laboratory services such as HIV, TB, Malaria diagnostics and other rapid tests, whereas district hospitals and some larger health centres have laboratories staffed with trained technologists who can perform more complex analyses, such as clinical chemistry, haematology, CD4 count, tuberculosis (TB) microscopy, etc. While the majority of hospitals have laboratories attached to them, this is not true for health centres, as only a small number have laboratories. The situation is worse for rural districts as shown in **Figure 2.** Above this tier tertiary hospitals have high specimen loads [19] that are facilitated by using more sophisticated, high throughput analyzers in three tertiary hospitals found in Ndola and Kitwe out of the 10 districts servicing other districts and nearby provinces. In Copperbelt Province, samples are collected on specific days from primary health care facilities which are the first contact with clients through a network of couriers and transported to the local source laboratory using the hub and spoke approach. The hub and spoke facilities, are higher tier facilities chosen to service surrounding low tier facilities on a weekly basis to perform a basic repertoire of tests[10]. These facilities also act as storage facilities for specialized tests referred to the nearest testing laboratory with an expanded test repertoire such as VL and DBS which is done in PCR centralized tertiary hospitals.

The movement of specimens and results takes much longer in rural districts following this process and results are sent back using the same channels as specimens as shown in **Figure 3.** The dotted lines (shorter route) shows the intermittent route of the samples and results when using the eLab system, a mobile workflow solution that electronically registers VL or DBS samples at the facility, tracks the samples from the facility to delivery and registration at the testing laboratory using a vehicle or motorbike and delivers an electronic result back to the facility with full integration with the in-country laboratory information system[20]. The straight lines (longer route) shows the main route of the samples and results when using the paper-based system.

Resource: Health System Inputs

Barriers to absorption of PMTCT testing requirements

Infrastructure and Supply

Participants revealed varying experiences regarding the barriers to the provision of PMTCT services within the laboratory system in the province. These barriers were identified as inadequate laboratory infrastructure, supply chain failures and unequal distribution of medical equipment between urban and rural districts as shown in **Table 5.**

Participants cited increased numbers of specimens as a result of the Test and Treat Policy with limited infrastructure **(Table. 5)**. As a result, absorption of the PMTCT policies is not possible due to supply chain failures at every point-of-care and this limits the public health impact of the program.

"Laboratory services are free at the point of use; However, accessing testing seems to be higher in urban than rural areas. Health facilities in rural areas struggle to access the laboratory logistics on time and distributing this logistics to health facilities just adds to the problem. As you know the guidelines now has changed and we have to do more laboratory tests which is not supported by improved infrastructure and supply chain. Government does provide us with the reagents, but there are times when supply takes longer than expected." (Laboratory Personnel, PHC Facility)

Participants believed that the current Hub and spoke approach and centralized PCR service points were causing delay in receiving Dry Blood Spot (DBS), Viral Load (VL) and other testing results, especially for the rural areas which were further from the centralized service points. As shown on **Figure. 2**

"Most of the facilities in our district do not have laboratory and diagnostic equipment to conduct baseline tests. As a result, our samples are referred to referral facilities which in some case are very far. In other cases, we remain with no option but to initiate clients on ART without baseline laboratory results" (ART Nurse, PHC Facility)

Table 5. Availability of laboratory infrastructure in the study sites and laboratory services provided.

District	Lufwanyama	Kitwe	Ndola
PHCs without Laboratory	26	22	22
PHCs with Laboratory	6	21	17
Number of PHCs (inclusive health posts)	32	43	39
Tertiary institutions with Polymerase Chain Reaction on HIV Machines	0	1	3
PMTCT test requirements	**Primary Health Facilities:** Primary health laboratory services. **CHEMISTRY** Liver, Kidney function tests **HIV** Polymerase Chain Reaction for HIV DNA sample for referral. **HAEMATOLOGY** Full blood count.	**Primary Health Facilities:** Primary health laboratory services. **CHEMISTRY** Liver, Kidney function tests **HIV** Rapid Tests, Polymerase Chain Reaction for HIV DNA sample for referral. **HAEMATOLOGY** Full blood count **TERTIARY:** **NTH:** Polymerase Chain Reaction for HIV DNA tests, Early Infant Diagnosis	**Primary Health Facilities:** Primary health laboratory services. **CHEMISTRY** Liver, Kidney function tests except (1) **HIV** Rapid Tests for HIV, Polymerase Chain Reaction for HIV DNA sample for referral **HAEMATOLOGY** Full blood count **TERTIARY:** **ADCH:** Polymerase Chain Reaction for HIV DNA tests, Early Infant Diagnosis (EID) **NTH:** Polymerase Chain Reaction for HIV DNA tests, Early Infant Diagnosis (EID) **Northern Command Military Hospital:** Polymerase Chain Reaction for HIV DNA tests, Early Infant Diagnosis
District Population	105,156	762,974	585,974
Distance to the nearest PCR Machine Laboratory	**102km** partly by gravel and tarmac road (nearest is Kitwe)	Chavuma Clinic to KTH is 22Km representing the longest distance. Most facilities fall within 5 Kms to the PCR lab PCR Lab service the whole Province including neighboring Provinces	NTH to ADCH **5km** NTH to Northern Command Military Hospital **4km** Northern Command Military Hospital to ADCH **7km** PCR Lab services the whole Province including neighboring Provinces

NB: Populations are based on the population and demographic projections 2011-2035[21].

Laboratory Human Resources

As identified by participants, insufficient and overburdened health professionals, poor training and lack of knowledge on PMTCT testing requirements were all considered barriers to the absorption of PMTCT policies. As mentioned by one laboratory staff, changes in the PMTCT cascade made laboratory staff to keep changing how they operated as more human resource was needed.

"The PMTCT guidelines keeps changing and it affects us so much that we have to keep changing our structures. When I came here, we were doing an average of 1000 tests per day but today we are doing over 10,000 tests because the demand for tests is now higher. This is what is prevailing when you put new guidelines into practice" (Laboratory Personnel, PHC Facility)

Some respondents stated that there was inadequate time to participate in onsite trainings whenever there are new guidelines or new updates on PMTCT.

" *Laboratory personnel in most cases remain behind to catch up with the new guidelines due to low laboratory personal. The demand for VL and DBS tests is too high such that we cannot afford to be away from work otherwise we will have a backlog of specimens requiring to be processed*" (Laboratory Personnel, Tertiary Institution)

"The amount of work required to process the samples is a lot compared with available human resource and as you might know the new policy of test and treat provides that all pregnant women need to be tested for HIV and if they are positive there are more tests that we do before initiation on therapy." (Laboratory Personnel, Tertiary Institution*)*

Knowledge and Information

Information: Document and Record Control System

Participants reported that the government had set up the eLab in selected health facilities. However, the initiative is underutilized and to a certain extent the provided internet on mobile phones for receiving VL and DBS results is abused for other things. As two respondents explained.

"The facilities using this strategy face a lot of challenges in receiving DBS and VL results for DBS. For example, the system requires internet between the tertiary hospital and the receiving PHC facility which is not always the case especially for PHCs as some end users hotspot the internet provided on the phones and in the process deplete all the internet bundles browsing on the internet. Further, the system is underutilized as clinicians still prefer the paper-based system." (Laboratory Personnel, PHC)

"eLab is not user friendly considering due to the mobile phones provided are too small to manually capture results. When you receive 100 results you will have to read all the results and transfer them on a paper and that what most people avoid because that is extra work". (Nurse, PHC Facility)

Financial Resources

Participants reported the lack of funding from government to effectively run the laboratory services which according to them is given low priority. An interviewee alluded to the fact that:

"This is very challenging especially with rural districts which do not have the presence of cooperating partners to supplement government in the districts. As rural districts we have to fund transportation of specimen and results at district costs. And as you know our district is very vast and when our vehicle breakdown that basically disrupt the referral network because we will have to wait for central government grant to repair the vehicle" (Nurse, Maternal & Child Health Department, PHC Facility)

Service Delivery:

Specimen collection and transportation

Not all health facilities have a laboratory on-site, so specimens have to be transported elsewhere, this requires transport, functional and reliable cold chain and timely delivery of the specimens. A respondent stated: *"due to the new policy [test and treat] the referral system has witnessed increased volume of tests for viral load and dry blood spot specimen which has resulted in inadequate packaging containers and poor cold chain maintenance."* (Laboratory Personnel, PHC Facility)

The other challenge which respondents stressed was poor cold chain by transporters of specimens

"The main challenge has been cold chain maintenance not within control of laboratory system such as cold chain on motorbikes that transport specimens from one facility to another" (Laboratory Personnel, tertiary Institution.)

Specimen Processing and transmitting of results

Health workers recognized that the new guidelines on UTT meant more tests have to be done in the laboratory **(Table. 3)** However, as a participant articulated, adhering to the new guidelines requirement was a challenge. As explained by one respondent "*A referral system will not run out of samples, right now, we have two machines down and we are waiting for an engineer to come and work on the machines, but we never run out of samples. Instead we always have a backlog of specimens and that delays processing and transmitting of results."* (Laboratory Personnel, Tertiary Institution)

The health workers felt the current TAT of VL and DBS (2-3 weeks in urban districts and 4 weeks in rural areas) was a source of frustration. As explained by one health worker: "*It makes our work difficult and makes you feel like you are not working especially when the results don't come back and you are made to ask your client to make fresh submission of samples. Right now, we receive VL and DBS results between 2/4 weeks. Really there is no quality in that".* (Nurse, Maternal & Child Health Department, PHC Facility)

Health workers reported that they were experiencing mismatch of results and some results going missing which is contributing to delays communicating the results to the clients. Health workers feared communicating results to the wrong clients "*I feel there is a lot of room for improvement in the way the referral*

system network is designed. For instance, collection, sending, courier system and storage is good except for the receipt of the results, which is inconsistent and affect the whole system" (Laboratory Personnel, PHC Facility)

"I have observed miss match of the dates between the samples taken for PCR and the results that we get as a facility. The details of the results that we would receive for a particular month will be different from what we have in the register. These samples are captured electronically so we do not know how the dates are mixed up and that affects communicating the results to the clients" (Laboratory Personnel, PHC Facility*)*

Existing Strategies to support Absorption of the Test and Treat Policy

Participants stated that the majority of the primary healthcare facilities that lacked the laboratory infrastructure to perform basic repertoire of tests send their PMTCT laboratory specimens to the nearest testing laboratory with an expanded test repertoire; referred to as Hub and Spoke facilities and tertiary hospitals. These health facilities were also connected to the electronic logistic management information system (eLMIS).

"Not all health facilities are linked to the eLMIS, which connects health facilities with the central store (medical stores limited) to collect and distribute logistics in real time. For a health facility to be connected to eLMIS they needed to have been assessed by the regulatory body and accreditation certification. Unfortunately, what has been happening is that most of the PHCs lower in the tier cannot order medical supplies and logistics from the central level but instead depend on health facilities higher in the tier to be supplied with PMTCT medical supplies and logistics" (Laboratory Personnel, PHC Facility)

Participants described a range of strategies currently being practiced within their workspaces.

"..Our partners have really helped us a lot to reduce some of the challenges we face in the department. They have recruited laboratory personnel who come in different work shifts" (Laboratory Personnel, Tertiary Institution)

One laboratory staff member pointed out that the recruitment of more health workers has reduced some of the challenges they face.

"We have now created more working schedules to meet demand of VL and DBS tests and now our laboratory operates 24hrs and we have plenty of job aid to help us follow and read the new guidelines on our own" (Laboratory Personnel, Tertiary Institution & Nurse PHC)

One existing strategy was the involvement of cooperating partners who have provided specific mobile phones.

"Currently, there has been a lot of improvement in tracking of the specimens and receiving of the results. We have witnessed an improvement in TAT and results not missing. If this can be perfected and adhered it will help us to improve the referral network in the province especially with rural facilities which are very far from PCR " (Midwife nurse, PHC facility)

"The eLab was started in July, 2019 and from the experience it is a good system as you can see from the referral pathways for PMTCT samples, receiving of the results through a mobile phone was very quick, consistent and reduced the turnaround time as results will be transmitted straight to the PHCs from tertiary hospitals" (Laboratory Personnel, PHC Facility)

Respondents did not highlight any strategies relating to finance, but that they propose that government needed to prioritize districts that relied on government funding alone especially the rural districts

However, the health professionals appreciated the existence of cooperating partners in their facilities who have helped to improve cold chain storage capacity. As one responded explained: *"In our urban facility we have enough storage capacity to take in as many samples as possible at the health facilities because our partners have supplied us with enough fridges. Unfortunately, as someone who has also worked in rural facilities, this is not the case because rural districts do not have this privilege of having partners to supplement government efforts."* (Nurse, Maternal & Child Health Department, PHC Facility)

Proposed strategies from the perspective of participants

Study participants were asked to list strategies for improving absorption of PMTCT guidelines within the laboratory system in the province. Their responses are presented in **Table 6.** Health workers were of the view that the laboratory network can be strengthened by introducing new innovations such as Data to Care, which uses different surveillance and other data on clients who come into contact with the primary healthcare facilities by identifying those who are in need of care or have fallen out of care through collaboration with other departments within the facility. As described by one health worker:

"I would suggest we introduce Data to Care as it is in the TB program all departments are linked to look out for anyone with signs and symptoms of TB or had fallen out by linking them to the TB nurse or a TB treatment supporter. I feel this system if it can be introduced in the PMTCT program it will help improve the program ultimate goal." (Laboratory personnel, tertiary Institution)

Other respondents were of the opinion that government needed to invest more in upgrading health facilities with the latest information, communication and technology infrastructure so as to meet some of the requirements as provided by the guidelines.

"*Most of the hub and spoke facilities have been upgraded with support from cooperating partners. Unfortunately, not all facilities can be supported, and we feel this is where the government should come in and support the rest of the health facilities with either ICT infrastructure or mobile communication facilities so that the entire referral network is fully electronically integrated. As you can see PCR machines are only found in 2 districts out of 10 districts in the Province.*" (Program Officer, International NGO)

A programs manager from an international organization working in the province described how the strategy of working with government and cooperating partners was important as it enabled introduction of an innovation to strengthen the integrated lab referral network in the province: *"We have lined up with partnership activities with health institutions to improve the information system and record control so that there is an efficient and effective information system and record control within the referral pathway and at facility."* (Program Officer, International NGO)

Table. 6 Proposed Strategies

Resource
Infrastructure and supply
-Expand and build laboratory infrastructure and system to non-hub and spoke facilities
-Availability of logistics should reflect the changes in the policies
-Facilitate timely delivery of laboratory logistics and supplies
Human Resources
-Human resource support by cooperating partners
-Incentivizing extra working hours for government workers
-Need for government to absorb human resource employed by cooperating partners when their contracts ended
-During the rollout of new guidelines Laboratory staff needed to be among those prioritized since they fall among frontline staff
-Incentive extra working hours for human personnel especially those working in PCR to meet the demand of test and treat
Knowledge and Information
-Replacing the paper-based system of reporting to eLab system
-Investment in information, communication and technology infrastructure (computers and internet to facilitate computerization of all or nearly all types of patient data (eRecords) and platforms for communicating and sharing clinical and other data between patients, providers and among providers)
Finance
-Government needed to prioritize districts that relied on government funding especially rural districts that did not have other funding opportunities.
Service Delivery
-Investment in an inter and intra laboratory network system between facilities, districts and the province
-Introduce Data to Care- system that uses surveillance and other data to identify persons with HIV possibly in need of HIV medical care, investigate their vital and care status, locate them and link them to care[22]

Discussion

In this study, we collected qualitative data to explore how laboratory services could meet the needs of the current PMTCT guidelines and what the shortfalls are. The principal factors impeding laboratory services were inadequate laboratory infrastructure and inconsistent supply chain management of laboratory reagents, supplies, and consumables. Also, inadequate modern equipment in the province such as PCR services which are only concentrated in two urban districts out of ten districts in the province. A similar drawback to the provision of strategic interventions was identified as undefined laboratory networks which were insufficient and affected the quality of PMTCT provision at point-of-care. Human and financial resources were not increased sufficiently to meet the increased demand for testing. Other studies have suggested that reliable laboratory services in limited- resource settings such as Zambia ,is critical for the achievement of global HIV/AIDS targets of eliminating Mother-to-Child Transmission of HIV by 2030[19; 20; 21]and Sustainable Development Goals. Similar studies conducted elsewhere equally suggest that functional laboratory services at each tier of health care provision, underpin the successful care and treatment of the PMTCT program[22; 23; 24].

Findings from this study show that despite the existence of PCR and other PMTCT diagnostic service in the province, there are still a number of barriers to accessing the services such as financial resources to access these services especially among rural districts that primarily depend on government support and longer TAT which leads to delays in starting ART. Issues impeding the process particularly relate to increased specimen volume, workload and inadequate transport for specimen transfer and logistical problems relating to shortages of laboratory logistics. However, there seems to be a focus on innovations as a result of strong partnership between the government and cooperating partners. Other studies exploring laboratory challenges in the scaling up of HIV, confirm that the strategies that ensure the existence of an integrated laboratory network and system, sustained financial, logistics management and presence of medical equipment to conduct VL and EID, as a key component of the health system, are essential for effective implementation of PMTCT [25; 26; 27;]. In our study there was a focus on strong partnerships between the government and cooperating partners to overcome challenges. Although this is positive, there is need to consider sustainability of reliance on donors[30].

Another important result of this study is that it will be difficult for the country to achieve and sustain eMTCT goals. The allocation of laboratory infrastructure should not be seen as a reserve for urban settings but must be expanded throughout the entire national health system with a major emphasis on the rural areas [28; 29]. According to Gilson and Schneider, an advocacy drive should be focused and targeted at both the political leadership as well as the public through lobbying in order to frame public opinion and set agenda for policy makers. [31]

Although health workers in this study described how overwhelmed they were due to the PMTCT guidelines changes on laboratory tests, they were quick to appreciate the presence of cooperating partners who recruited extra laboratory personnel, however this was limited to urban areas. Participants felt that government needed to develop a strategy to employ more personnel or incentivize extra working hours for laboratory health personnel working in PCR laboratory in view of the increased workload. Evidence abound that strategies meant to increase and motivate health care workers result in increased access to healthcare and health innovation and improve the quality of care [32][33]

Our findings further revealed that TAT of 2 to 4 weeks presented a source of frustration for health workers working in PMTCT and laboratory, as they could not perform to their full capacity to eliminate mother to child transmission of HIV/AIDS. The most likely interpretation of these findings is that most HIV infected pregnant/postpartum women and exposed children are initiated on ART without baseline tests, which possibly result in poor clinical decisions and PMTCT management. These findings are consistent with findings of other studies which were done on the interaction of health and laboratory systems in Africa [33; 34] which showed that access to reliable diagnostic testing is severely limited and misdiagnosis commonly occurs resulting in poor clinical decisions.

This study further revealed that investment in strategies such as an integrated approach to laboratory strengthening had the potential to improve specimen collection, processing and reporting, which are critical to ensuring early testing for HIV and ensuring appropriate care and treatment. This finding corresponds with other studies which confirmed that national HIV/AIDS programs are required to strengthen the capacity of laboratory services to respond to the demands and needs of population health [34; 35]

The limitation of this study was that it was conducted in the three districts out of ten districts present in the province due to financial resources. The strength of the study is the inclusion of both urban and rural areas.

Conclusion

This study shows that new guidelines implemented without sufficient capacitation of health system inputs and service delivery resulted in gaps in the capacity of the existing laboratory system to perform and meet the diagnostic and treatment needs for PMTCT and other diseases of public health and national importance. Our study documented the areas relating to health system inputs and laboratory service delivery where greater investment and support is needed to support absorption of the new testing requirements. These range from strengthening and integrating specimen transport and data networks; building effective public–private partnerships to scale up laboratory services especially in rural areas, increasing coverage and improving quality of care; introducing new innovations such as investment in renewable energy, data to care and point-of-care technologies should be given a higher priority. It is anticipated that the challenges and proposed strategies from this study would be applicable to other low resource settings similar to Zambia.

List Of Abbreviations

ANC	Antenatal Car
ART	Antiretroviral Drugs
DBS	Dry Blood Spot
eLMIS	Electronic Logistics Management Information System
eMTCT	Elimination of Mother-to-Child Transmission of HIV
HEI	HIV exposed Infants
HIV	Human Immunodeficiency Virus
IDI	In-depth Interview
MOH	Ministry of Health
PCR	Polymerase Chain Reaction
PHC	Primary Health Care
PMTCT	Prevention of Mother-to-Child Transmission of HIV
TAT	Turnaround Time
TB	Tuberculosis
VL	Viral Load

Declarations

Ethical approval and consent to participate

This study is approved by Tropical Diseases Research Centre Ethics Review Committee, ref. nr(s): TRC/C4/04/2018, TRC/C4/08/2020 and the University of the Witwatersrand Human Research Ethics Committee (Medical) clearance certificate nr: M180228.

All methods were carried out in accordance with relevant guidelines and regulations. The Protocol for this qualitative study was approved by the University of the Witwatersrand Human Research Ethics Committee (Medical) and the Tropical Disease Research Centre Ethics Review Committee. All participants signed written informed consent to participate in the study and were informed that they at any point were free to redraw their participation.

Consent for publication

NA.

Availability of data and materials

The data generated and analyzed during the currently study are not publicly available as the contain information that would make the participants identifiable, compromising their confidentiality, but are available from the corresponding author on reasonable request

Competing Interests/ Disclosure statement

No potential conflict of interest was reported by the author(s)

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Author's contributions.

JM[a], TD[b] , GG[d], WM[e] and MK[f] conceptualized the study and developed the protocol for data collection. JM[a] analysed the transcripts, data collection, document review. JM[a] and MK[f] prepared the first draft of the article. JM[a], TD[b], MLK[c] and MK[f] contributed with significant input to drafts and revisions. All authors have read and approved the final manuscript.

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Figures

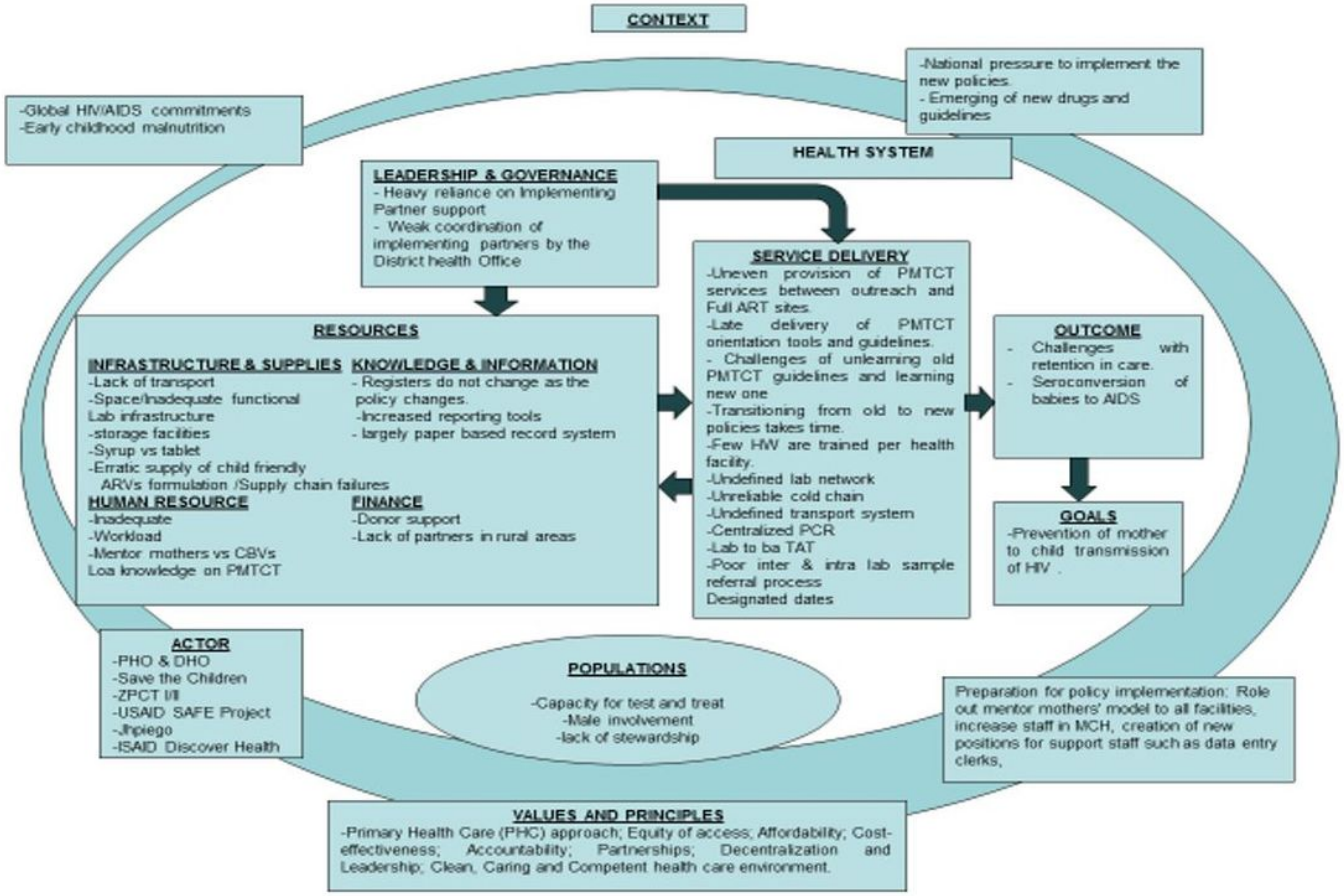

Figure 1

The Health System Dynamics Framework adapted from Van Olmen populated with the findings from this study

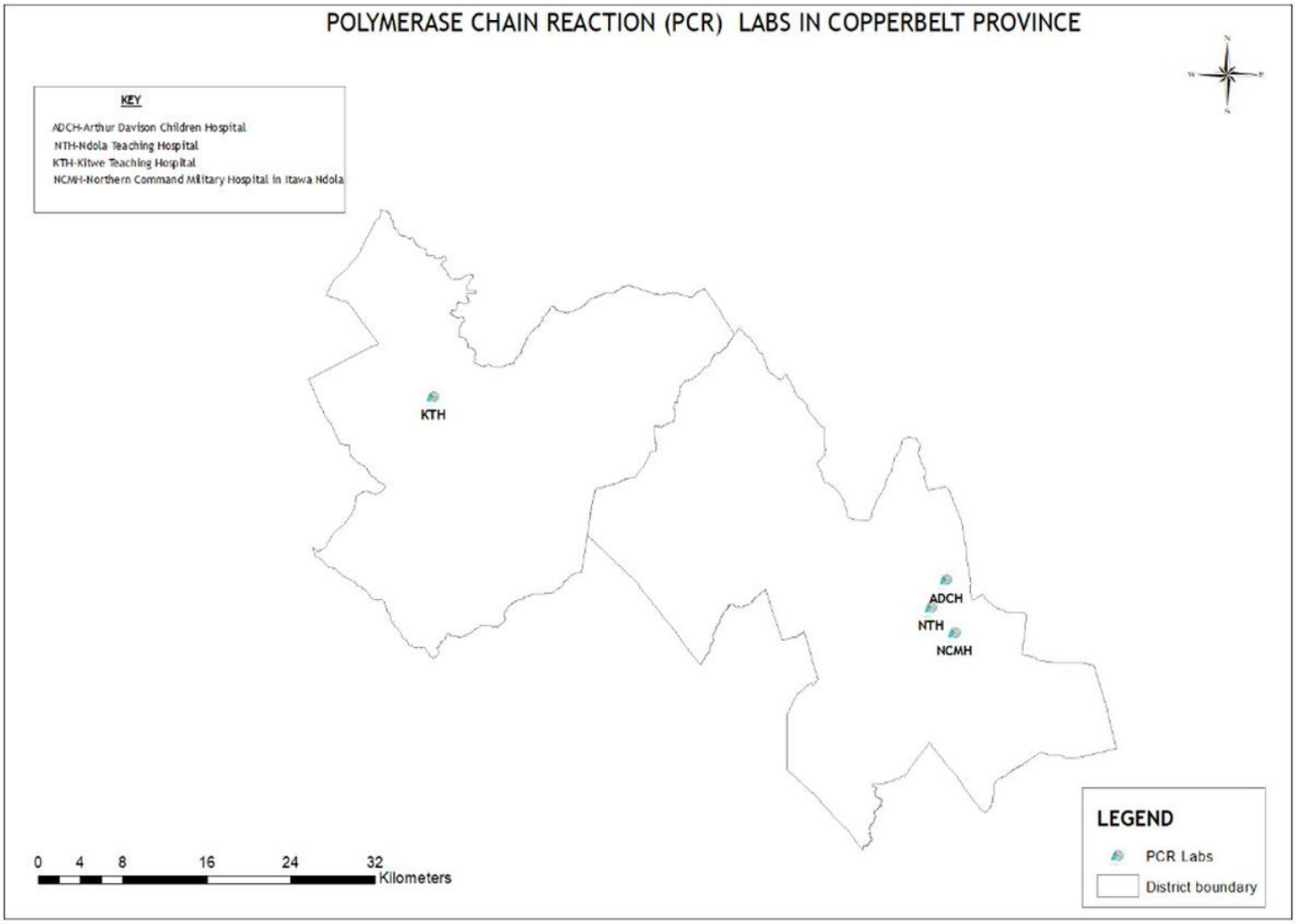

Figure 2

Distribution of polymerase chain reaction machines on the Copperbelt Province.

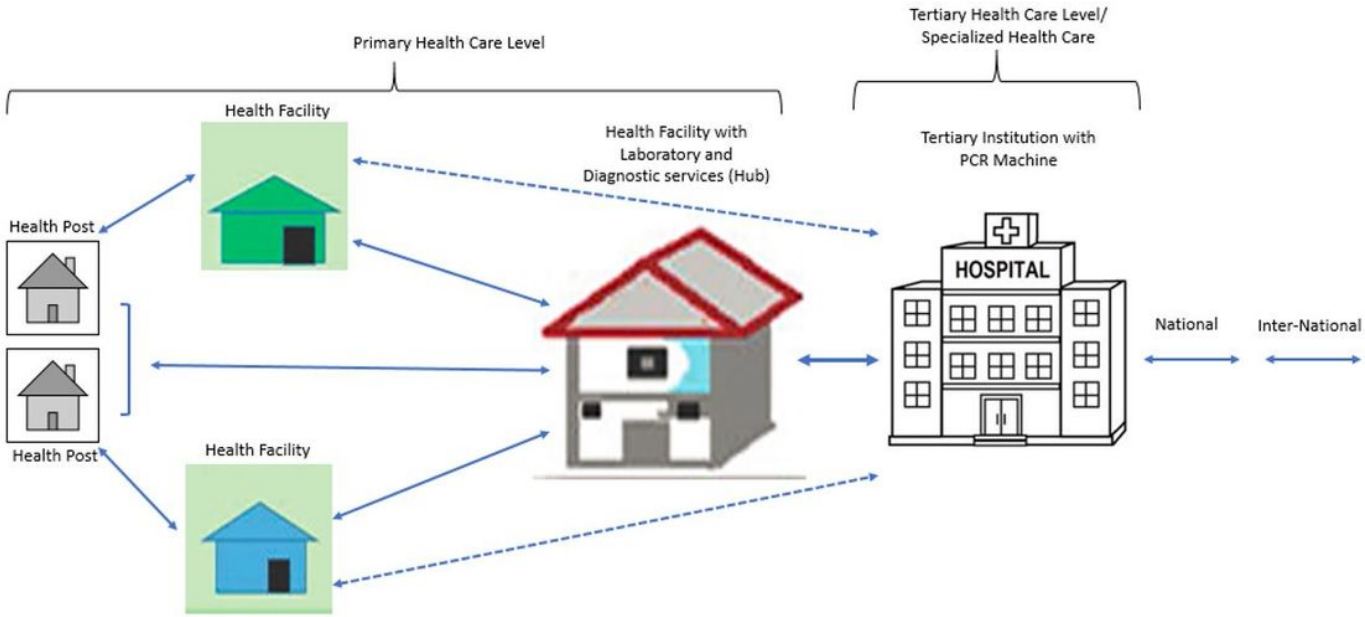

Figure 3

Referral pathways for VL and DBS samples in the Copperbelt Province.