The University Of Zambia

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MPH-Population Studies

PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV DATA QUALITY ASSESSMENT IN SELECTED HEALTH FACILITIES OF THE SOUTHERN REGION OF ZAMBIA

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The University of Zambia approves this dissertation of Arthur M. Moonga in partial fulfilment of the requirements for the award of the degree in Master of Public Health – Environmental Health.

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DEDICATION

I dedicate this paper with deepest love to the almighty God, my father, mother and my prospective wife Maria.

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ABSTRACT

Background: Although substantial investments have been made in Zambia to expand prevention of mother-to-child transmission of HIV (PMTCT) services, the quality of patient data recording and reporting remains a challenge. The study aimed at assessing the quality of PMTCT programme data at selected PMTCT sites in the southern region of Zambia.

Methods: This was a quantitative study which followed two protocols. The first was a retrospective record review which involved collecting PMTCT data on selected PMTCT indicators. The second one was a cross-sectional systems assessment of the relative strengths and weaknesses of the functional areas of the data management and reporting systems. It covered 66 PMTCT sites from four randomly selected districts. Data was collected using record review forms and structured questionnaires and was entered and cleaned in Epi-Data Version 3.1. Analysis involving descriptive statistics was done in SPSS version 16. Data quality was determined through assessment of dimensions of quality[1]. A Likert scale was used to score and categorize data.

Results: The quality of PMTCT data was above average at just over two-thirds (67.11%). Data accuracy, completeness and timeliness levels were found to be below 50% for all indicators (48.23%, 49.23% and 44.65% respectively). However, confidentiality, reliability, integrity and precision levels of PMTCT data were 75.11%, 76%, 88% and 88.69% respectively. Data was least accurate for infant indicators (32.3%-34.33%) while data completeness was lowest for the antenatal indicators (26.50% - 33.33%) and was least timely for the antenatal indicators (23.85% - 31.43%).

Discussion: This study underscores a low level of quality for the PMTCT programme data due to low levels of accuracy, completeness and timeliness on infant and antenatal indicators. It was found that the main problem revolved around CD4 count and PCR testing. Materials needed for testing were inadequately and erratically supplied to health facilities. Most of the test results were not being received and those received were rarely received in time and some were coming as invalid results. Other factors affecting data quality included: low staffing levels, lack of training for staff involved in data management at service delivery points and involvement of unqualified people in the recording and reporting of patient data. Lack of adequate storage facilities for documents also affected data quality.

Conclusion: It can be concluded that the quality of PMTCT data was lower than expected. To improve data quality, healthcare data must be appropriate, accurate, timely, reliable, complete, precise, and must be handled confidentially with integrity. Data entry checks are also critical for accurate data reporting. Hence, having dedicated personnel in each facility would improve data recording and reporting significantly. The limitations of the study was that it only covered four districts due to limited funding, this can be addressed by further studies.

Key words: Data quality, Likert scale, data verification, systems assessment, dimensions of quality

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List of Acronyms

ANC	Ante Natal Clinic
ASHA	Advancing Surveillance, Policies, Prevention, Care and Support to Fight HIV/AIDS
CDC	Centers for Disease Control and Prevention
CIDRZ	Centre for Infectious Disease Research in Zambia
CSF	Civil Society Fund
DHIS	District Health Information System
DM	Data Management
DQ	Data Quality
DQA	Data Quality Assessment
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EMTCT	Elimination of Mother to Child Transmission of HIV AIDs
FHI 360	Family Health International
GoK	Government of Kenya
HMIS	Health Management Information System
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
JSS	Joint Support Supervision
M&E	Monitoring and Evaluation
MCH	Maternal and child health
MoH	Ministry of Health
NAC	National AIDS/STI/TB Council
NCASC	National Centre for AIDS and STD Control
NNGOs	National Non-Governmental Organizations
RDQA	Routine Data Quality Assessment
UNICEF	United Nations Children's Fund

CHAPTER 1: INTRODUCTION

1.1. Background

The international community plan towards the elimination of new HIV infections among children and keeping their mothers alive and well appears to be well underway, with ambitious goals of reducing the number of new HIV infections in children by ninety percent (90%) and HIV related maternal deaths by fifty percent (50%) (UNAIDS 2012). There is now unprecedented collaboration and political will to accomplish these goals.

Zambia is working towards achieving ambitious goals related to the fight against vertical transmission of HIV. Measuring the success and improving the management of these initiatives is predicated on strong monitoring and evaluation (M&E) systems that produce quality data related to Prevention of Mother to Child Transmission of HIV (PMTCT) programme implementation.

Data quality is essential for effective use of PMTCT programme data in decision-making. Quality is what creates trust in data, and data perceived to be of poor quality are unlikely to be used. Besides, stakeholders require accurate, complete, and timely data in order to accurately target resources for effective management of the PMTCT programme. Data quality involves a complex variety of issues relating to organizational procedures, processes, and institutional capacity, and cannot be assessed just by looking at one factor in isolation (Heywood, 2014).

Data Quality

Quality PMTCT data is essential for the elimination of mother to child transmission of HIV (MTCT) and keeping their mothers alive and well because only quality data can effectively inform the design of PMTCT programme interventions, help monitor and evaluate the programme's quantitative progress toward pre-determined treatment, prevention, and care targets. Measure Evaluation contends that PMTCT partner organizations[1] are committed to accuracy of information for purposes of accountability

[1] Partner organizations include: Center for Disease Control and Prevention (CDC), Elizabeth Glazer Pediatric AIDS Foundation (EGPAF), National HIV/AIDS/STI/TB Council (NAC), Ministry of Health (MoH), United Nations Children's Fund (UNICEF) and Centre for Infectious Disease Research in Zambia (CIDRZ)

and, more importantly, for use of quality data to improve the programme (Measure Evaluation, 2008).

Literature shows that PMTCT data provided by routine health systems in the African Region are not always available for most countries, and even when they are, they are not always comprehensive, complete or up to date hence the need for routine data quality assessments (Ndira, 2008).

Data Quality Assessment

Data Quality Assessment (DQA) is the scientific and statistical evaluation of data to determine if data obtained are of the right type, quality, and quantity to support their intended use. Quality data on the other hand refers to data which is accurate, reliable, timely, complete, precise, and of high integrity and confidentiality. This DQA focused on PMTCT programme data (Measure Evaluation, 2008).

The last and only external PMTCT DQA in Zambia was conducted in 2012 and its results informed the development of the Impact Study Protocol on Prevention of Mother to Child Transmission (PMTCT) in Zambia (Macw'angi, 2013). This paper therefore presents a PMTCT DQA which followed a descriptive cross-sectional design. The assessment utilized a quantitative method to verify the data from source documents for selected indicators (antenatal, postnatal, maternal and child indicators) against reported data in the District Health Information System, collected during the period January 2015 to December 2015. The study further assessed the relative strengths and weaknesses of the functional areas of the data management and reporting system.

1.2. Problem Statement

Quality of PMTCT programme data should be assessed periodically to enhance confidence in the data and promote the use of the data for decision-making. Quality of data should be assessed routinely for high-priority indicators as a part of regular supervision, and less often, although periodically, for other indicators. A periodic assessment of PMTCT programme performance should include both internal and external data quality assessment to ensure elimination of bias.

Quality of routinely collected PMTCT programme data in Zambia is moderated by internal monthly data audits carried out by the district information officers. However, there is lack of external DQA of PMTCT programme data. Since the introduction of the PMTCT programme in 1999 in Zambia, the programme has only had one National DQA which was conducted in the year 2012.

Recent research shows that quality of PMTCT programme data recording and reporting is poor which leads to limited utilization of available data hence the need for Routine Data Quality Assessments (RDQA). Reviewed literature further indicates that PMTCT data is usually not available and even when it is available it is usually not comprehensive or complete.

Several challenges seem to exist which contribute to inconsistent PMTCT data quality and this leads to limited utilization of the available data and information and data flow bottlenecks, these challenges include data recording discrepancies at facility level in case registers as well as incomplete recording of data.

1.3. Conceptual Framework

The conceptual framework for the study is illustrated in **Figure 1** (below). Generally, the quality of reported PMTCT data is dependent on the underlying data management and reporting systems. Stronger systems should ideally produce better PMTCT data. In other words, for good quality data to be produced by and flow through a data management system, key functional components need to be in place at all levels of the system. These being: the points of service delivery (health facilities), the intermediate levels where the data are aggregated (e.g. districts, provinces, regions), and the M&E unit at the highest level (national) to which data are reported.

The PMTCT programme DQA was grounded in the components of data quality, given that the programme needs accurate, reliable, precise, complete and timely data reports that M&E units can use to measure MTCT rates as well as effectively direct available resources appropriately, and to evaluate progress toward established goals. Furthermore, the data must have integrity to be considered credible and should be produced ensuring standards of confidentiality.

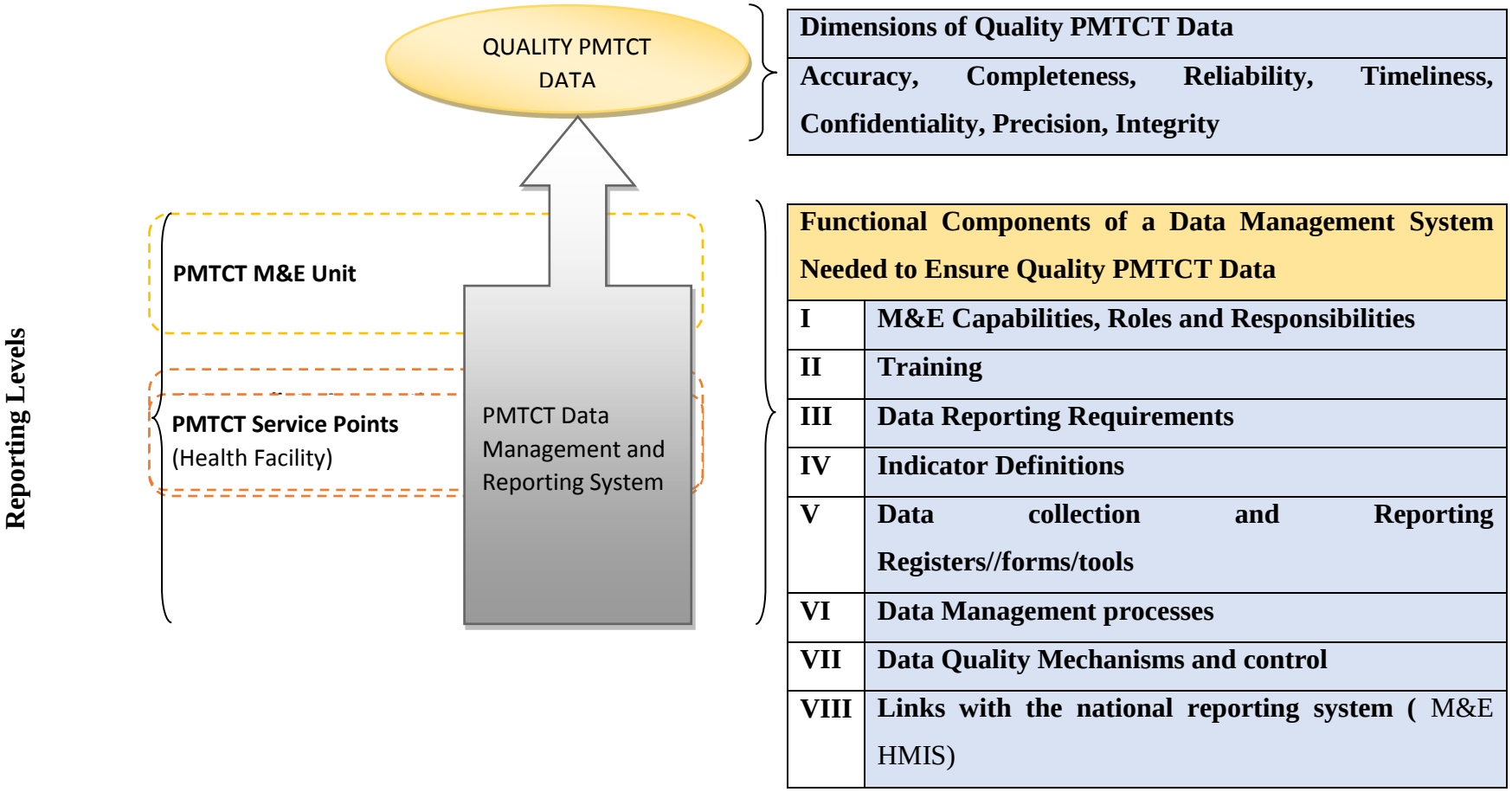


Figure 1: Conceptual Framework (Adopted from Measure Evaluation, 2008)

1.4. Rationale

The DQA study is very important at best as it can pave way for developing an action plan for implementing corrective measures for strengthening the data management and reporting system and improving data quality. Collecting accurate information on the PMTCT data elements would not only strengthen the existing PMTCT services, but would also ensure timely and accurate measurement of MTCT rates and broaden areas of further intervention as part of comprehensive patient care. Data of high quality is required at all levels of the healthcare system as it helps in ensuring that evidence-based decisions are made. At the facility level, the information is used for care delivery and the details about prior events should be recognized and incorporated into current care decisions (Reid et al, 2008).

The DQA will further help improve data quality by presenting factors affecting data quality. Knowing about these problems will allow PMTCT stakeholders to develop data quality improvement interventions such as; refresher training on indicator compilation or revision of data collection tools (Heywood et al, 2014).

Despite the fact that the DQA study is not designed to assess the quality of services provided, its use could facilitate improvements in service quality as a result of the availability of better quality data related to program performance. (Measure Evaluation, 2008).

Additionally, data collected at facility level can be used to make decisions and improve the quality of healthcare services (Garrib' *et al*. 2008). Moreover, quality data is required for advocating, designing, planning and evaluating public health actions (WHO, 2004) and to inform health policy and resource allocation. The global interests in the monitoring of development, as illustrated by the Millennium Development Goals (MDGs), generate pressure for quality and timely data in order to demonstrate country progress (Boerma et al, 2007).

1.5. Research Questions

- What are the levels of Accuracy, Completeness, Reliability, Timeliness, Confidentiality, Precision and Integrity for the PMTCT programme data?
- Does the HMIS and DHIS systems have the capacity to produce quality PMTCT data?
- Can PMTCT programme data be used to measure MTCT rates?

1.6. General Objective

- To assess PMTCT data quality at Zambian health service delivery points to national level in order to assist with the improvement of the PMTCT data management and reporting.

1.7. Specific Objectives

- To verify the dimensions[2] of quality for the PMTCT programme data.
- Assess the capacity of the HMIS and DHIS systems to produce quality PMTCT data
- To assess the possibility of using PMTCT programme data to measure MTCT rates

[2] Accuracy, Completeness, Reliability, Timeliness, Confidentiality, Precision and Integrity of PMTCT programme data

CHAPTER 2: REVIEW OF LITERATURE

In order to appreciate the need and importance of PMTCT data quality assessment, various studies were reviewed. This section features the reviewed literature on DQAs which have been carried out in Zambia and other countries.

Mlambo et al (2014), conducted a similar study called the PMTCT data completeness and accuracy assessment in health facilities of the Nkanga District. The objective of the study was to assess PMTCT data completeness and accuracy at primary healthcare level to district level in order to assist with the improvement of the PMTCT data recording. This was a retrospective record review study, which involved collecting PMTCT data on antenatal, Maternity and infant indicators, which was for the period of August 2009 to January 2010.

This was a baseline facility assessment, which included seventy-two (72) PMTCT sites in one health district of South Africa, Nkangala. The study assessed the data completeness and accuracy of the data values recorded on the seven PMTCT data elements. Results of the study showed that problem of data incompleteness were about fifty six percent (56 %) for antenatal indicators and eighty nine percent (89 %) for maternity indicators. It was hence observed in the study that there was need for ongoing training on data recording procedures at all levels. And it was recommended that healthcare data must be appropriate, organized, timely, available, accurate and complete in order to maintain data quality (Mlambo et al, 2014).

The major limitation for this study is that it only considered two parameters of data quality (accuracy and completeness) hence the need for a DQA covering all the seven parameters.

Another study was conducted in Kenya to Evaluate Kenya's readiness to transition from sentinel surveillance to routine HIV testing for antenatal clinic-based HIV surveillance, the study was concerned with describing the availability and quality of line-listed PMTCT registry. Despite the study establishing an overall high data quality, it was also recognized that there was a level of missing HIV test results in the PMTCT registry which limited use of these data for HIV surveillance. Additionally, the study also

established that the PMTCT laboratory quality assurance is in place but it was however observed that there was poor HIV testing performance (Sirengo et al, 2012).

The study recommended that there was need for implementation of the new standardized ANC/PMTCT registers at facilities and need to discontinue use of non-MOH registers. It also recommended the provision of regular training on proper data recording in registers at the facility as well as conducting regular data quality assessments to monitor and evaluate improvements in data recording. It further emphasized the need for provision of feedback to sites on HIV testing and provision of retraining as needed. Another recommendation was that all pregnant women testing HIV-negative in the first and second trimester should be retested in the third trimester, not only to detect inter-current infection but also to try to identify false negatives (ibid, 2012). One noticeable limitation of this study is that it focused more on quality of services offered and not quality of data.

Young et al (2013) conducted a similar study in Mozambique. This was a retrospective analysis of matched test results. The study assessed the efficacy of routine HIV testing data from prevention of mother-to-child transmission programs for estimating the prevalence of HIV infection among pregnant women. Matched routine PMTCT and ANC surveillance test results collected during 2007 and 2009 ANC surveillance surveys from 36 sentinel sites were compared.

Study results indicated low Positive percent agreement (PPA) of PMTCT test results compared to surveillance data, which was indicative either of testing errors or of data reporting problems. Nonetheless, PPA improved significantly from 2007 to 2009, a possible positive trend that requires further investigation. While use of PMTCT test results would not dramatically change HIV prevalence estimates among pregnant women, it was recommended that the impact of site-level differences on surveillance models should be evaluated before these data are used to replace or complement ANC surveillance surveys (Young et al, 2013). However, this study only focused on accuracy, a single parameter of data quality and overlooked other parameters, hence its conclusions cannot be used to ascertain the level of data quality as they only review the level of accuracy.

Msofe et al (2012), highlights the importance of DQA by elaborating how Tanzania has benefitted from RDQA. According to Msofe et al, Tanzania in collaboration with CDC conducted a baseline DQA in 2009 in 126 (75%) facilities. The DQA revealed data discrepancies in 98% of these facilities and on average, a 45% discrepancy was revealed between reported and observed numbers of patients currently on ART. More than 80% of staff reported minimal data use and knowledge of data management.

Following the baseline DQA, specific strategies were developed and implemented from October 2009 to September 2010. One strategy was the creation of a dedicated Data Management (DM) department to support DQ improvement process. Other strategies included the development of the M&E and DM departments and the routinization of DQAs during supportive supervision to health facilities (Msofe et al, 2012).

Overall, in November 2010, repeat DQA in ninety seven (97) health facilities reported a 25% increase in the number of facilities with accurate reporting. The average rate of discrepancies reduced from 45% to six percent. Additionally 80% of staff interviewed displayed improved knowledge of data use and management, evidenced through improved reports and survey responses (ibid, 2012).

One programme that has notably benefited from DQAs is the USAID-funded Advancing Surveillance, Policies, Prevention, Care and Support to Fight HIV/AIDS (ASHA) Project, which was managed by FHI 360 (Family Health International) Nepal. DQA was central to routine data monitoring and quality assurance in the project. Under ASHA Project, a systematic implementation of DQA was first initiated in 2007 and repeated annually until the end of the project in September 2011. The DQAs involved ASHA Project NGO staff members who generated, monitored, reported and used the data (UNAIDS, 2012).

The DQA rounds used a standard tool with six dimensions, that is, M&E administration and management, data and system integrity, validity, reliability, accuracy and data use and feedback. Methods used for information collection included management and staff interviews, record reviews and observations. The overall composite score was calculated and expressed in terms of percentage. Based on the recommendations of each DQA exercise, necessary updates were made in the recording, reporting mechanism and

database system, additional training was planned and a regular internal DQA was planned at each NGO. As a result, the average composite score increased from 80% in the first year (2007) to 87% in 2008 and 90% in 2009, that is, an increase of 10 per cent. This score was maintained above 90% in all subsequent years (ibid, 2012).

Building upon this experience, in 2010, the ASHA Project extended support to National Centre for AIDS and STD Control (NCASC) in developing and piloting the DQA of HIV data reported by selected government service sites from all five regions. The objective of this mini-pilot project was to utilize the findings to plan the DQA for NCASC and its partners in order to institutionalize a collaborative system for ensuring better quality data for national response. Findings of the mini-piloting were utilized to publish a DQA plan in 2011 using a refined DQA tool that is suitable for a national data reporting system. This plan is being institutionalized by NCASC (op cit, 2012).

It is evident from the Nepal experience that the DQA process ensures the quality of collected and reported data by service sites to strengthen the M&E system and establish the credibility of the information being reported for the National HIV Program. It enables the government, donor communities and other stakeholders to have access to reliable evidence for making informed decisions for instituting an effective national HIV response (UNAIDS, 2012).

A study in Bayelsa state of Nigeria in 2013 confirmed that PMTCT data is affected by incomplete reporting from the public sector, and lack of reporting from the private health sector and community based interventions. An operational plan for EMTCT of HIV 2013 – 2015 was formulated and the following measures were included in the plan to ensure data quality: Recruitment of data entry clerks to support electronic data entry and transmission. Procurement and distribution of twenty four (24) (solar powered) laptops to support electronic data entry and transmission, provision of internet support for electronic data transmission, inaugurating of an integrated statewide M&E and review the existing integrated state M&E plan (FHI 360, 2013.

The plan further suggested holding of a consensus building meeting with M&E stakeholders on integrated health data management, conducting of sensitization meetings with the leadership of public and all private sector health practitioners on an integrated

M&E system, and conducting of advocacy visits to heads of health departments/agencies/units on plans for integrated health data management system (ibid, 2013).

Civil Society Fund (CSF) 2013 Annual report for Uganda showed that a DQA exercise conducted in the seven National Non-Governmental Organizations (NNGOs) showed improvement in the quality of data reported and counted, taking into consideration the four quality assurance standards (validity, reliability, integrity and timeliness), although some variations of over and under reporting were discovered between the NNGO implementation sites and the headquarters, and data reported to CSF.

With respect to quality assurance all eight NNGO proposals met the required standards (technical, targeting, and value for money). Follow up visits conducted during the June 2013 Joint Support Supervision (JSS) with current sub-grantees also showed that 57.5% demonstrated capacity to collect, analyze, report and use the data collected. Specifically 90% were using appropriate data collection tools, 60% were reporting in a timely manner, while 60% demonstrated satisfactory levels of data analysis. Performance on these indicators was lower than the previous year and this was mainly because CSF brought on board new sub-grantees (HIV 3) during this particular year whose M&E capacity was still developing (CSF, 2013).

The 2014 Kenyan National DQA is another study that can also be considered. This was the first nation-wide DQA in Kenya since the rolling out of the DHIS reporting platform in 2011 for routine health facility service delivery and community health services. The previous DQA was conducted in 2010 and its results informed the development of the DQA protocol. A descriptive cross-sectional design was utilized to collect data from 178 facilities. Both qualitative and quantitative methods were used to verify the data from source documents for selected indicators against summary data, DHIS data, and Kenya HIV/AIDS Program Monitoring System (KePMS) data collected during the months of July- September 2013 (Government of Kenya, 2014).

From the findings, it was noted that the reporting rates for the summary sheets/reporting forms for the assessed indicators was fairly high with MOH 711 (Integrated RH,

HIV/AIDS, Malaria, TB and Nutrition) and MoH 705 A & B (Outpatient Morbidity) having a reporting rate of about 90%. MOH 515 (Community Health Extension Worker Summary) and MOH 710 (Immunization summary) had the lowest reporting rates ranging from 34.6% to 64.8%. The availability of audit documents ranged from 91.1% for number of women of reproductive age receiving family planning to number of pregnant women referred for ANC at 39.1%. However, the caliber of available documents ranged from the standard registers to improvised counter books to older versions of the registers. The number of fully immunized children had the least complete audit documents at 64%. Notably the private facilities had the highest rate of missing audit documents with availability of documents being as low as 29.4% for some indicators (ibid, 2014).

The first PMTCT DQA in Zambia was conducted in 2013 and it facilitated the development of the impact study protocol on PMTCT in Zambia. This was a facility-based survey which aimed at monitoring the effectiveness of the PMTCT program in Zambia while providing baseline data for the new five year national PMTCT scale-up plan and simultaneously building the national capacity to periodically assess the PMTCT program performance (Macw'angi et al, 2012).

The data for the study was collected in four provinces (Central, Copperbelt, Luapula and Western provinces), twelve districts and 21 facilities that ranged from clinics to the Provincial Health Offices. The interviewees ranged from the District Health Information Officers to Data Entry Clerks. Study findings indicated that all three levels (Clinics, Hospitals and the District Health Offices) had issues with recording data. Partners (CDC and ZPCT) were expected to pick up such issues (data discrepancies at all level) and provide capacity building because in as far as the system is concerned that is the role of the partners (ibid, 2012).

Macw'angi et al (2012) indicated that PMTCT partners reported that they were aware of the gaps in documenting service provision at all levels and that they relied on MoH to strengthen reporting systems hence they had continued to offer training and mentorship to MoH staff. They also reported that where there was strong leadership such as committed facility in-charges, reports were usually accurate. Partners also urged

government to show ownership of the programs for them to work effectively. It was highlighted that most of the gaps in reporting were due to human resource constraints and this was one of the major findings from the DQA study.

It was concluded that on the issue of data accuracy, there was a need to engage district health staff and also when reporting systems are being modeled, they should start with big hospitals and then roll out to health facilities. An example was given on the shortcomings of the SMARTCARE program; they developed the programs without consulting clinicians and as such the systems failed to work because it highly depended on data clerks who did not understand the clinical aspect of the data they were recording. It was concluded that clinicians themselves should enter most of the data as they attend to the patient (Macw'angi, 2013).

Despite being called a national DQA, the study left out most of the southern region as it mainly concentrated on the northern region hence the need for a DQA focusing on the southern region. The 2013 DQA only covered 21 facilities and only assessed data prospectively. This DQA was necessitated by the need to have a PMTCT DQA that covered more facilities (66 in this case), besides, DQAs are supposed to be carried out periodically hence the need for the PMTCT DQA.

Despite Zambia's health care system having internal routine data quality audit in place, the reviewed literature has shown that the country has only had one external PMTCT DQA. Not only did this previous DQA cover less ground to meet the definition of a national study, but it also missed out a number of data quality parameters such as confidentiality, integrity and precision. Quality of data cannot be ascertained by considering one or two parameters in isolation, but can only be determined by collectively considering all of them. This applies to most of the reviewed studies; they mostly focused on accuracy, completeness, reliability and timeliness hence the need for a study covering all parameters.

CHAPTER 3: METHODOLOGY

3.1 Study design

This was a descriptive quantitative study which followed two protocols (Data verifications and systems assessment protocols). The study therefore involved a quantitative retrospective review of facility records and a cross-sectional assessment of the district health information system. The study was grounded in the components or rather dimensions of data quality based on the argument that PMTCT programme needs accurate, reliable, precise, complete and timely data reports that stakeholders can use to effectively direct available resources and to evaluate progress toward established goals (see Annex 1). Furthermore, the data must have integrity to be considered credible and should be produced ensuring standards of confidentiality.

Based on the dimensions of data quality (accuracy, completeness, timeliness, reliability, precision, confidentiality and integrity), the DQA comprised of two protocols namely;

- Part 1 - **Data verifications protocol**: quantitative comparison of recounted to reported data for ascertainment of accuracy, timeliness and completeness of PMTCT programme data;
- Part 2 - **Systems Assessment protocol**: assessment of the relative strengths and weaknesses of functional areas of the data management and reporting system for ascertainment of precision, confidentiality and integrity of PMTCT programme data.

The data verifications protocol focused on reviewing the eight PMTCT data elements namely:

Antenatal and postnatal indicators:

1. Antenatal care (ANC) clients pre-test counselled for HIV at first visit
2. ANC clients tested positive for HIV at first test (new positives)
3. HIV-positive ANC clients tested for CD4 count
4. ANC clients initiated on ART.

Maternity indicators:

5. Women receiving Nevirapine (NVP) in labour.

Infant indicators:

6. Babies given NVP and Septrin
7. Polymerase chain reaction (PCR) test done on babies born to HIV-positive mothers at six weeks or later, that were reported routinely during the period January 2015 to December 2015
8. Rapid antibody HIV tests done on children born to HIV- positive mothers

3.2 Data Sources

The study relied on both primary (for systems assessment) and secondary data (for data verifications). Primary data was collected with aid of structured questionnaires with key informants who were personnel directly involved in the managing and reporting of PMTCT data. Secondary data on the other hand was sourced through a review of facility records which included; patient files, tally sheets and facility registers (PMTCT registers, ANC registers, DBS registers, Integrated PMTCT delivery registers, Counseling and Testing registers, Postnatal and Admission registers, Safe Motherhood Registers, Baby-Mother Follow-up registers, PCR registers).

3.3 Study Area

Zambia is divided into two regions in terms of the PMTCT programme (Northern and Southern region). The focus of the study was the southern region of Zambia (Lusaka, Western, Southern and Eastern provinces) because it was neglected in the previous DQA. The study only covered one district in each province due to limited funding. All PMTCT sites were covered in the selected districts. The region was purposively selected because it was neglected in the previous DQA and due to availability of resources in the region, while the districts were randomly selected to enable generalization of study findings to the whole southern region.

3.4 Study population

The study comprised of health facilities offering PMTCT services and personnel that were responsible for managing and reporting of PMTCT data at all levels of the data flow. Both data verification and systems assessment started from health facilities up to the national level.

Inclusion Criteria

Data Verifications

- All provinces in the southern region
- Four (4) districts from all the four (4) provinces in the southern region
- All health facilities in the selected districts
- Health facilities offering PMTCT services

Systems Assessment

- Personnel in-charge of managing and reporting of PMTCT data at each level (Service delivery point, district, provincial and national) with at least one year of experience.

Exclusion Criteria

Data Verifications

- The study excluded health facilities that were less than a year old (as of 1st January 2015).

Systems Assessment

- Excluded data management staff recently transferred to the location of interest

3.5 Sample size and sampling strategy

The DQA employed a simple random sampling design to select the districts.

The study set out to cover covered all provinces in the southern region from which one district was randomly selected using STATA version 12.

The DQA targeted 75 participants for systems assessment (4 Senior Information Officers, 4 District Information Officers and 66 personnel in charge of the service delivery points). Sixty six PMTCT sites were targeted for record review.

3.6 Data collection techniques and tools

Data verification was done with the aid of record extraction forms and structured questionnaires were used for interviews with key informants. Eight research assistants were recruited and trained on how to extract data from the records, and on how to conduct interviews with key informants. These research assistants worked under close supervision of the Principal Investigator (PI).

The record extraction forms were used at service delivery points for record review while key informant interview guides were used at all levels; (1) at service delivery points, (2) at intermediate aggregation sites (district and provincial, offices), and (3) at the National M&E Unit.

The initial part of the DQA (Part 1) intended to assess, on a limited scale, if service delivery and intermediate aggregation sites were collecting and reporting data to measure the audited indicator(s) accurately and in a timely manner, and to cross-check the reported results with other data sources. To do this, the DQA had to determine if a sample of Service Delivery Sites had accurately recorded the activity related to the selected indicator(s) on source documents. It then traced the data, to see if it had been correctly aggregated and/or otherwise manipulated as it was submitted from the initial Service Delivery Sites through intermediary levels to the National M&E Unit.

At the Service Delivery Points, the data verification part of the DQA (Part 1) had three sub-components (See Annex 1):

- Reviewing of source documentations: The study reviewed the availability and completeness of all indicator source documents for the 2015 (January to December) reporting period.

- Verification of reported results: The study recounted the reported numbers from available source documents, compared the verified counts to the site reported numbers and identified reasons for differences (if any).
- Cross-checking of reported results with other data sources: Cross-checks of the verified report totals with other data-sources (e.g. patient/ client files).

At the Intermediate Aggregation Sites and the M&E Unit, the data verification part of the DQA (Part 1) had two sub-components:

- Reviewing of site reports: The DQA reviewed the availability, timeliness, and completeness of expected reports from Service Delivery Sites for the January 2015 to December 2015 reporting period.
- Verifying reported results: Re-aggregate the numbers from the reports submitted by the Service Delivery Points, compare the verified counts to the numbers submitted to the next level (e.g.; M&E Unit), and identified reasons for any differences.

Part 2 of the DQA served the purpose of identifying potential threats to data quality posed by the design and implementation of the data management and reporting system at three levels: (1) the National M&E Unit, (2) the Service Delivery Points, and (3) Intermediary Aggregation Site (district and provincial offices) at which reports from Service Delivery Points were aggregated before being sent to the national M&E Unit.

3.7 Pre-test

Pre-testing of the study was done in order to test the effectiveness of record extraction tool and clarity of questions (on Interview guides) and study logistics. Pre-testing was also done to help research assistants to exercise flexibility in the wording of questions and probing. For this study, pre-testing was conducted at Kalingalinga clinic in Lusaka district.

3.8 Data Processing and Analysis

Data Verifications:

Through a quantitative comparison of recounted to reported data and review of timeliness, completeness and availability of reports; the DQA assessed, on a limited scale, if service delivery

and intermediate aggregation sites were collecting and reporting data to measure the indicators (Antenatal, Postnatal, maternal and infant indicators) accurately and on time and to cross check

the reported results with other data sources. To do this, the DQA had to determine if a sample of 66 health facilities had accurately recorded the activity related to the selected indicators on source documents. It then traced that data to see if it had been correctly aggregated and/or otherwise manipulated as it was submitted from the initial service delivery sites through intermediary (district, province and region) levels to the national level.

Systems Assessment

Through the systems assessment protocol, the study assessed the relative strengths and weaknesses of the functional areas of the data management and reporting system. The study identified potential threats to data quality posed by the design and implementation of the data management and reporting system at three levels: (1) the programme M&E Unit (at national level), (2) the Service Delivery Points, and (3) all Intermediary Aggregation Site (district and provincial offices) at which reports from Service Delivery Points were aggregated prior to being sent to the national level.

1.4. Variables

Table 1: Data Quality Dimensions: Dependent and Independent variables

Dependent Variable	Operational Definitions
Quality	Quality Data means data which is of high Accuracy, Completeness, Reliability, Timeliness, Confidentiality, Precision and Integrity
Independent Variables	**Operational Definitions**
Accuracy	Also known as validity. Accurate data are considered correct: the data measure what they are intended to measure. Accurate data minimize errors (e.g., recording or interviewer bias, transcription error, sampling error) to a point of being negligible.
Reliability	The data generated by a program's information system are based on protocols and procedures that do not change according to who are using them and when or how often they are used. The data are reliable because they are measured and collected consistently.
Precision	This means that the data have sufficient detail. For example, an indicator requires the number of individuals who received HIV counseling & testing and received their test results, by sex of the individual. An information system lacks precision if it is not designed to record the sex of the individual who received counseling and testing.
Completeness	Completeness means that an information system from which the results are derived is appropriately inclusive: it represents the complete list of eligible persons or units and not just a fraction of the list.
Timeliness	Data are timely when they are up-to-date (current), and when the information is available on time. Timeliness is affected by: (1) the rate at which the program's information system is updated; (2) the rate of change of actual program activities; and (3) when the information is actually used or required.
Integrity	Data have integrity when the system used to generate them is protected from deliberate bias or manipulation for political or personal reasons.
Confidentiality	Confidentiality means that clients are assured that their data will be maintained according to national and/or international standards. This means that personal data are not disclosed inappropriately, and that data in hard copy and electronic form are treated with appropriate levels of security (e.g. kept in locked cabinets and in password protected files).

Table 2: Variables (continued)

Type of variable	Variable	Indicator	Measurement scale
Dependent	Data Quality	• Percentage of facilities with accurate, complete, reliable, timely, precise PMTCT data • Percentage of facilities handling data with confidentiality and integrity	ratio
Independent	Accuracy	• Percentage of cases in registers matching with cases in DHIS system • Percentage of cases in patient files matching with cases in registers	ratio
	Reliability	• Percentage of facilities using same data collection and reporting tools • Percentage of facilities measuring and collecting PMTCT data consistently	ratio
	Precision	• Percentage of facilities collecting PMTCT data with sufficient details • Percentage of facilities reporting PMTCT data with sufficient details	ratio
	Completeness	• Percentage of antenatal, maternal and infant indicators recorded in facility registers	ratio
	Timeliness	• Percentage of antenatal, maternal and infant indicators recorded in facility registers in time • Percentage of antenatal, maternal and infant indicators reported to the district in time	ratio
	Integrity	• Percentage of facilities whose data is free from deliberate bias or manipulation for political or personal reasons.	ratio
	Confidentiality	• Percentage of facilities with lockable storage for data collection and reporting tools • Percentage of facilities with password protected data management computers.	ratio
	Location	Rural/Urban	ratio

A Likert scale was used to score and categorize data quality as either being Very Good (81%-100%), Good (61%-80%), Average (41%-60%), Poor (21%-40%) or Very Poor (0%-20%). The quality of data was classified as being Very Good if the data quality parameters were met for all four data reporting quarters of 2015, ***Good*** for at least three quarters, ***Average*** for at least two quarters, ***Poor*** for at least one quarter and ***Very Poor*** if the data quality parameters were not met in all the four quarters. Data of High quality in this case entailed data meeting all the dimensions

The whole process of data collection and questionnaire completion was supervised by the PI to ensure quality control. Data extracted from records on daily basis by research assistants was submitted to PI for data cleaning, coding and entering using Epi data software version 3.1, the data was validated through double entry and was exported to SPSS version 16 for further cleaning.

Data Analysis

The data was analyzed using SPSS version 16. Figures and tables were done in Microsoft Excel. Refer to Annex 3.3 for the full data analysis plan.

Descriptive statistics

Variables were categorized using a Likert scale and were analyzed using percentages, rates & proportions.

Control for Bias in the DQA

Selection bias: Systematic error in the selection of participants was avoided through; a random selection of the districts to include in the study.

Information bias: Systematic error due to inaccurate measurement or classification of disease, exposure or other variables was avoided through ensuring that if the respondent did not recall the required information, they would be allowed to consult other sources (e.g. reports or DHIS system). Missing data was minimized through exclusion of facilities that were not operational for the whole year of 2015. Collection of socially

desirable responses was minimized by ensuring that interviewer bias was minimized by avoiding leading questions.

3.9 Ethical considerations

The study was likely to raise ethical issues given the sensitive nature of the study area, disclosure of participants identifying information may cause them harm given that HIV-related stigma was still relatively high in Zambia.

The study however addressed the above ethical concern through ensuring maximum anonymity and confidentiality by avoiding extraction of identifying information (such as names) from the health facility records. Names of participating health facilities were also kept confidential

The DQA was conducted with the utmost adherence to the ethical standards of Zambia and PMTCT partner organizations. Although the study team required access to personal information (such as patient files) for the purposes of recounting and cross checking reported results, under no circumstances was any personal information disclosed to anyone outside the study team in relation to the conduct of the study or the reporting of findings and recommendations. The study team neither photocopied nor removed documents from sites.

In addition, the study members did not accept or solicit directly or indirectly anything of economic value as a gift, gratuity, favor, entertainment or loan that would or appeared to be designed in any manner to influence official conduct, particularly from one who had interests that might substantially affect the performance or nonperformance of the study member's duty. This provision did not prohibit the acceptance of food and refreshments of insignificant value on infrequent occasions in the ordinary course of a meeting or other occasions where the study team was properly in attendance, nor the acceptance of unsolicited promotional material such as pens, calendars, and/or other items of nominal intrinsic value.

In the process of adhering to ethical standards, ethical clearance was sought and obtained from University of Zambia Research and Ethics Committee (UNZAREC) prior to the

study. Furthermore, informed consent was sought and obtained from participants prior to their participation in the study. Specifically, participants were informed about the objectives of the study and the voluntary aspect of participation was emphasized, meaning, the participants were free to decline or withdraw before or during the interview without facing any repercussions.

CHAPTER 4: FINDINGS AND INTEPRETATIONS

The DQA focused on the southern region of Zambia and was able to cover one district in each of the four provinces. The study was however unable to cover all the sampled facilities due to poor road networks. Only 94.6 percent of the sampled sites were covered

4.1. Background characteristics of Study Sites

Table 3: Distribution of type of facility/site by Province (N=71)

Type of Facility	Eastern	Lusaka	Southern	Western	All
Rural Health Centre (RHC)	16	8	-	10	34
Urban Health Centre (UHC)	1	2	13	-	16
Health Post (HP)	1	2	6	1	10
Level 1 Hospital	1	-	-	-	1
Level 2 Hospital	-	-	1	-	1
District Medical Office (DMO)	1	1	1	1	4
Provincial Medical Office (PMO)	1	1	1	1	4
M&E Unit	-	1		-	1
Total	21	14	22	13	71

The study covered a total 71 sites, that is, 66 PMTCT sites, four District Medical Offices, four Provincial Medical Offices and the National M&E unit. The majority of the PMTCT sites were Rural Health Centers (34) followed by Urban Health Centers (16), while Health Posts were at 10. Only two hospitals (Levels one and two) were covered. Eastern, Lusaka and Southern were mostly rural, whereas Southern brought out an urban perspective.

4.2. Overview of quality of PMTCT programme data

The main aim of the study was to determine the quality of PMTCT programme data. As alluded to above, quality of data cannot be measured by considering its parameters in isolation but by considering all the parameters. Using both the systems assessment and data verification protocols, the DQA was able to assess the quality of PMTCT data at

primary healthcare level to national level and established the factors affecting quality which was the main aim of the study. Through the record verification protocol, the DQA assessed the accuracy, completeness and timeliness of PMTCT data for selected indicators. Precision, confidentiality, reliability and integrity was assessed through the systems assessment protocol.

Table 4: Quality of PMTCT data (N=71)

Dimension of Data Quality		LEVEL*
Accuracy	48.23 %	Average
Completeness	49.08 %	Poor
Confidentiality	75.11 %	Good
Integrity	88.00 %	Very Good
Precision	88.69 %	Very Good
Reliability	76.00 %	Good
Timeliness	44.65 %	Poor
All	67.11 %	Good

*Classification: 0-20=Very Poor, 21-40=Poor, 41-60=Average, 61-80=Good, 81-100=Very Good.

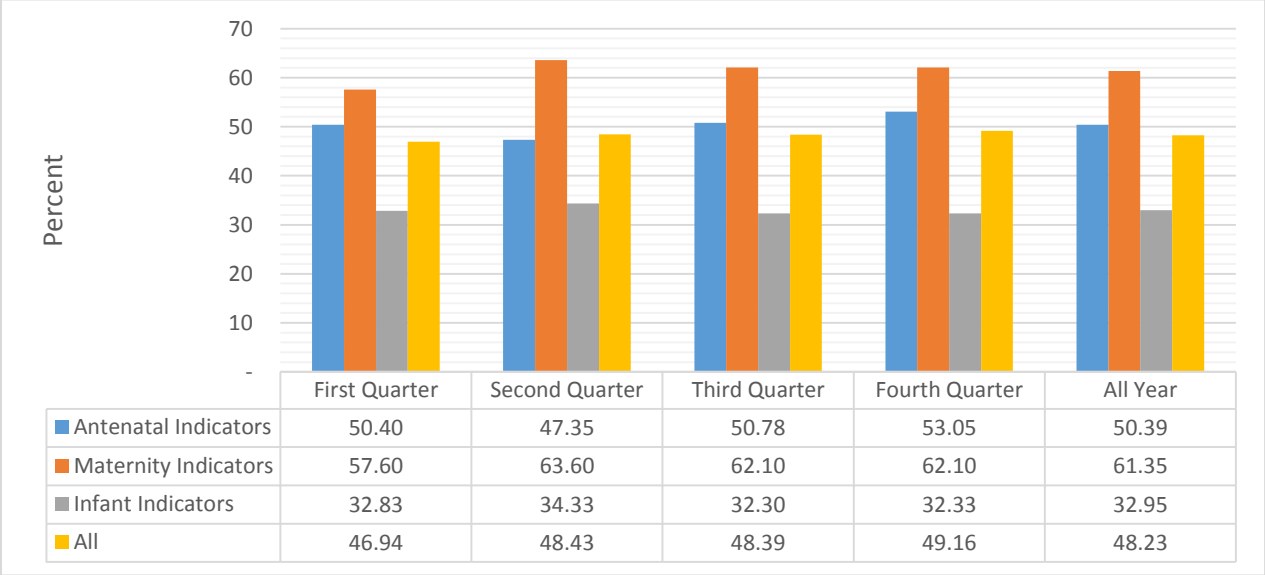
Overall, the quality of PMTCT data was found to be of good quality (67.11 %) as shown in table five below which provides an overview of the levels of quality disaggregated by the dimensions of data quality in line with the first objective of the DQA. The figure shows that precision was the highest (88.69%) while timelines was the least at 34.88 percent.

4.3. Verification of Data Accuracy, Completeness, Timeliness, Reliability, Precision, Confidentiality and Integrity

The first objective of the study was to verify the accuracy, completeness, timeliness, reliability, precision, confidentiality and integrity of PMTCT programme data. The verifications of these data quality parameters are shown below.

4.3.1. Accuracy

Accuracy was assessed through a recount of reported figures and quantitative comparison of the recorded and reported data for the selected indicators, information in source documents was further compared with patient files. Figure three above shows that data was more accurate for Maternity indicators and was least for the Infant indicators.



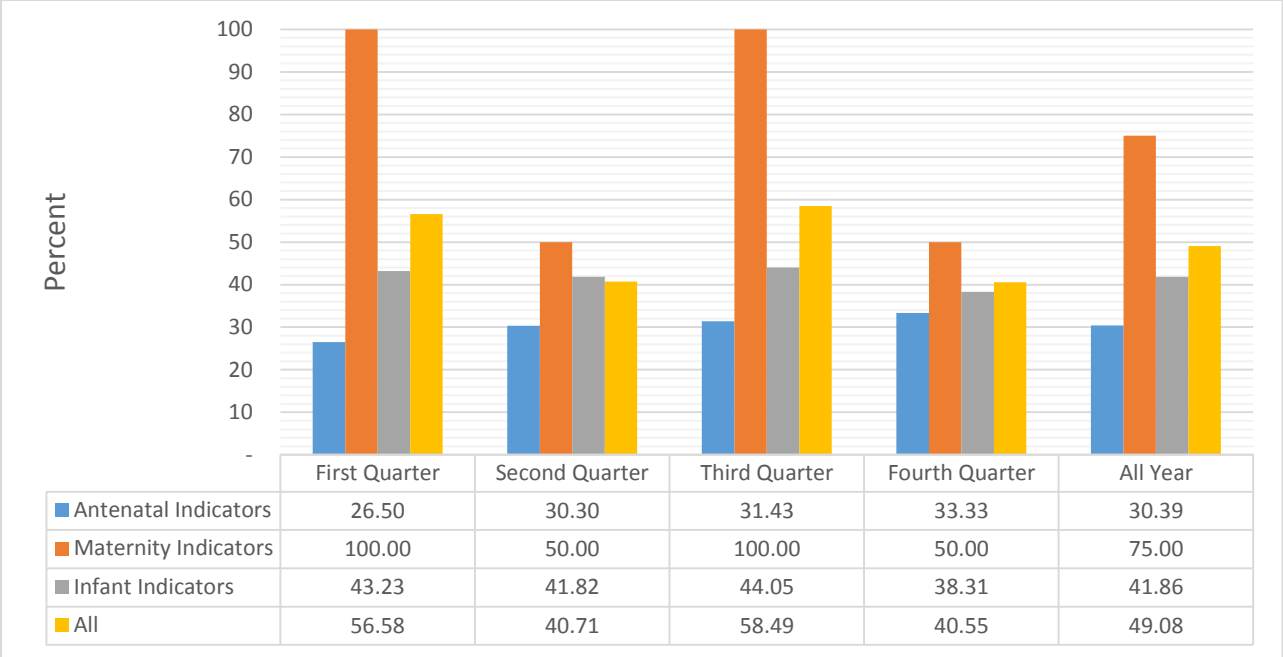
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	All Year
Antenatal Indicators	50.40	47.35	50.78	53.05	50.39
Maternity Indicators	57.60	63.60	62.10	62.10	61.35
Infant Indicators	32.83	34.33	32.30	32.33	32.95
All	46.94	48.43	48.39	49.16	48.23

Figure 2: Level of accuracy of PMTCT data by quarter (N=66)

Overall, the accuracy of PMTCT programme data found to be less that 50 percent for all quarters for the year 2015. Infant indicators registered the lowest levels of accuracy followed by antenatal indicators.

4.3.2. Completeness

Source documents were further assessed for completeness for selected indicators. Figure four below shows that data completeness was lowest for the antenatal indicators (26.50% - 33.33%) followed by infant indicators (38.31% - 44.05%). Data was more complete for maternity indicators (50% - 100 %). Overall, the level of completeness was between 40.55% and 56.58%.



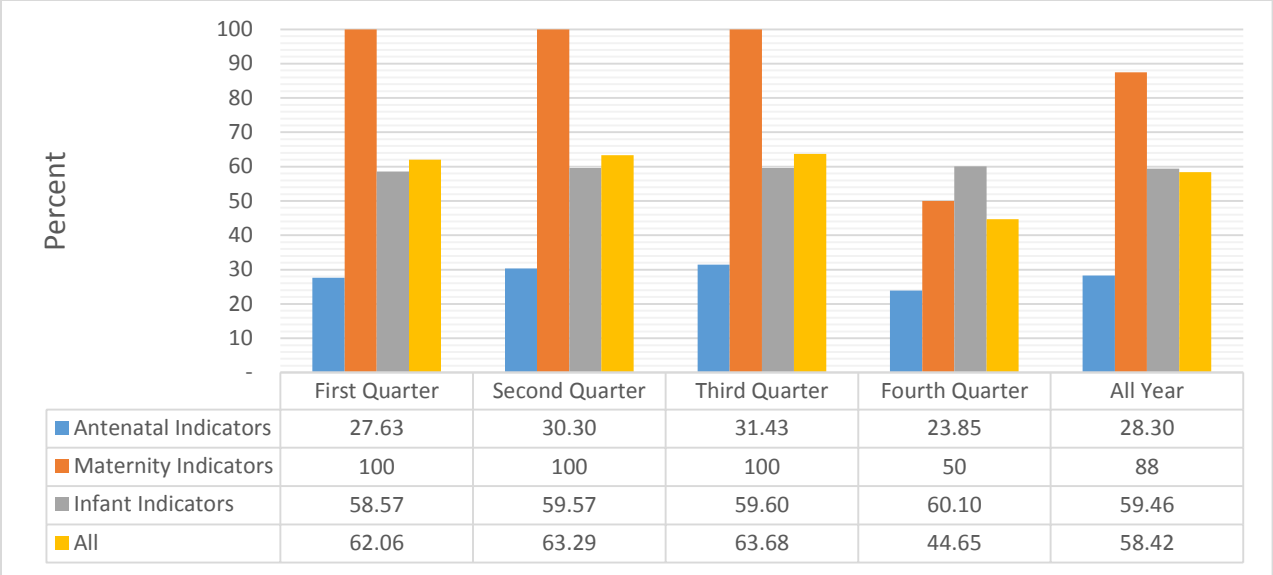
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	All Year
Antenatal Indicators	26.50	30.30	31.43	33.33	30.39
Maternity Indicators	100.00	50.00	100.00	50.00	75.00
Infant Indicators	43.23	41.82	44.05	38.31	41.86
All	56.58	40.71	58.49	40.55	49.08

Figure 3: Completeness of source documents by quarter (N=66**)**

4.3.3. Timeliness

The study assessed the extent to which PMTCT data was being collected and reported in time through reviewing the recording and reporting dates. Maternal indicators recorded and reported in time for three quarters of the reporting period. It was only during the fourth quarter that the data on maternity indicators was affected, only 50 percent of the facilities were able to record and report in time.

The results from figure 5 below show that the data was timelier for the maternity indicators (50% - 100%) and was least timely for the antenatal indicator (23.85% - 31.43%).

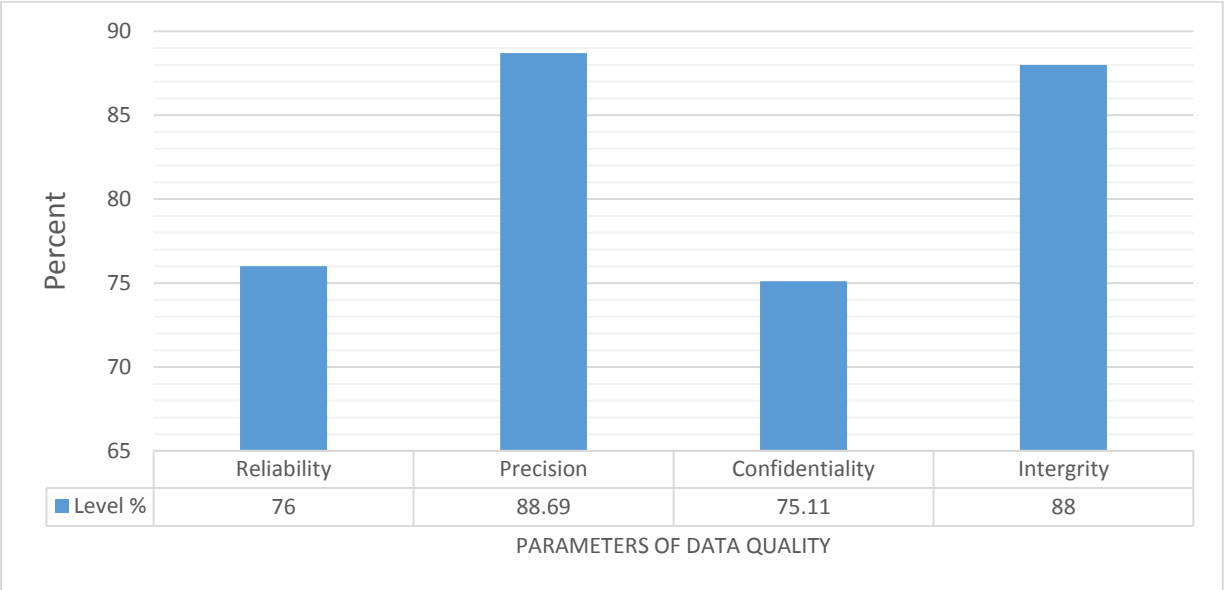


	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	All Year
Antenatal Indicators	27.63	30.30	31.43	23.85	28.30
Maternity Indicators	100	100	100	50	88
Infant Indicators	58.57	59.57	59.60	60.10	59.46
All	62.06	63.29	63.68	44.65	58.42

Figure 4: Timeliness of PMTCT data disaggregated by quarter (N=66)

4.3.4. Reliability, Confidentiality, Precision and Integrity

Through a systems assessment protocol, the DQA was able to assess the reliability, precision, confidentiality and integrity levels of PMTCT data. As shown in figure six below, the precision of the data was at 88.69% followed by integrity at 88%. Reliability and confidentiality were at 76% and 75.11% respectively.



	Reliability	Precision	Confidentiality	Intergrity
Level %	76	88.69	75.11	88

PARAMETERS OF DATA QUALITY

Figure 5: Reliability, Confidentiality, Precision and Integrity levels of PMTCT data

4.4. Capacity of HMIS and DHIS Systems in Managing PMTCT Data

The third objective of the study was to assess the capacity of the HMIS and DHIS systems to produce quality PMTCT Data. This was due to the argument that determining the quality of PMTCT data goes beyond assessment of the parameters of data quality (Accuracy, completeness, timeliness, reliability, precision, confidentiality and integrity). The study therefore assessed the relative weaknesses and strengths of the system responsible for producing this data (HMIS and DHIS systems)

In attempting to assess the capacity of the HMIS & DHIS systems in managing and reporting quality PMTCT programme data, the study assessed the relative strengths and weaknesses of the functional areas of the these data management and reporting systems with help of the systems assessment protocol. The key functional areas assessed included:

I. M&E Capacities, Roles and Responsibilities
II. Training
III. Indicator Definitions
IV. Data Reporting Requirements
V. Data-collection and Reporting Forms and Tools
VI. Data Management Processes and Data Quality Controls
VII. Links with National Reporting System

M&E Capacities, Roles and Responsibilities

A check at Ministry of Health Monitoring and Evaluation unit reviewed that there is a documented organizational chart that clearly identifies positions that have data management responsibilities at the M&E Unit. It was interesting and positive to note that all staff positions dedicated to M&E and data management systems are filled in and the unit had a senior staff member responsible for reviewing the aggregated numbers prior to the release of reports from the unit.

Visits at PMO and DCMO offices also reviewed that there were designated staff responsible for reviewing the quality of data such as accuracy, completeness, timeliness and confidentiality received from sub-reporting levels such as districts, service points.

The PMO's office had Senior Information Officers (PMO) overseeing the management and reporting of PMTCT data while the DCMOs had the District Information Officers. Recording of data in source registers and reporting was handle by facility In-Charge with the help of MCH In-Charge and daily classified employees.

The challenges discovered at service delivery point were that the facility In-charge assigned to handle recording and reporting responsibilities were usually overwhelmed with work due to low staffing levels which lead to untimely recording and reporting of data, daily classified employees on the other hand were not well equipped to handle the task given their low literacy levels.

Training

The MoH M&E unit confirmed the existence of a training plan for staff responsible for data management and reporting at national, provincial and district level. However, there was no training plan at service delivery points. The staffs at this level were not comprehensively trained on data recording and reporting, they instead were just oriented and they relied on the written instructions on the source and reporting documents.

Indicator Definitions

The M&E Unit has documented and shared the definition of the indicator(s) with all relevant levels of the reporting system. Instructions on how to complete source and reporting documents have for instance been attached to the documents for easy reference and there is a description of the services that are related to each indicator measured by the PMTCT program.

Data Reporting Requirements

The M&E Unit has provided written guidelines to all reporting entities (such as provinces, districts and service points) on reporting requirements and deadlines.

Data collection and reporting forms and tools

The DQA confirmed that the M&E Unit has identified standard source documents and reporting forms, which are used by all service delivery points to record and report service delivery. Furthermore, clear instructions on how to complete the data collection and reporting forms/tools have been attached to these documents.

The DQA further established that data collected by the M&E system has sufficient precision to measure the antenatal, maternal and postnatal indicators. It was also interesting to note that the unit has a written policy stating how long source documents and reporting forms need to be retained.

All data management levels were able to demonstrate that source documents and reporting forms relevant for measuring the indicators of interest were available for auditing purposes.

Data Management processes and data quality controls

The M&E Unit has clearly documented data aggregation, analysis and/or manipulation steps performed at each level of the reporting system and feedback is systematically provided to all sub-reporting levels on the quality of their reporting (i.e., accuracy, completeness and timeliness).

There are also quality controls in place for when data from paper-based forms (HMIS) are entered into a computer (DHIS). The computer based DHIS system for instance is designed to detect duplicate files hence avoiding double counting. All paper based are archived at respective districts after entering the information in the DHIS system which is backed up at national M&E unit.

Links with national reporting system

The DQA reviewed that PMTCT programme data, like other routinely collected health data, are reported through a single channel of the national reporting system (HMIS), The system records and collects PMTCT data and includes information about where the service is delivered (i.e. district and facility) and the place names are recorded using standardized naming conventions.

4.5. Possibility of using PMTCT programme data to measure MTCT rates

The fourth specific objective of the study was to assess the possibility of using PMTCT programme data to measure the MTCT rates. The DQA hence assessed the possibility of using PMTCT programme data in measuring the MTCT rates through verifying the

availability and completeness of the PCR source documents. The reported results were also recounted and crosschecked with patient files.

Table 5: Completeness and timeliness of PCR source documents (PCR registers)

Reporting Period	**Fully Completed**	**Partially Completed**	**Completed in Time ***
1st Quarter (Jan –Mar 2015)	35 (53%)	31 (47%)	27 (40.9%)
2nd Quarter (Apr – Jun 2015)	37 (56.1%)	29 (43.9%)	29 (43.9%)
3rd Quarter (Jul – Sep 2015)	38 (57.6%)	28 (42.4%)	30 (45.5%
4th Quarter (Oct – Dec 2015)	34 (51.5%)	32 (48.5%)	26 (39.4%)

*values on *completed in time* were computed using the total number of facilities (N=66).

Only slightly above half (51.5% - 57.6%) of the facilities had fully completed PCR source documents for each quarter, and less than half of the facilities had their source documents completed in time (39.4% - 45.5%). Source documents for infant HIV antibody tests were however fully completed and in time for all facilities for all the four reporting periods. A cross check of random 10 patient files with source documents per facility reviewed that most of the facilities only had an average of seven matching files.

CHAPTER 5: DISCUSSION CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

The study set out to assess the quality of PMTCT programme data at primary healthcare level (PMTCT sites) to national level in the Southern region of Zambia. The results of this study have shown that the recording and reporting of quality patient data remains a challenge because of lack of accurate data recording by the healthcare professionals at service delivery points, incomplete recording of data and untimely recording and reporting.

The study found that the inaccurate data recording was mainly due lack of a double-checking system for the data recorded on the monthly summary sheets before they are submitted to the district to be recorded in the DHIS. There are quite a number of registers that are used to collect PMTCT related data including the baby mother registers, DBS registers, PMTCT register, tally sheet register, drug register, PCR register, HIV testing register and CD4 count register. All of these registers cover the information that is recorded on the case registers and that is summarized on the monthly summary sheet which is then sent to DHIS. The results indicate that because of many PMTCT registers, there is non-verification of data that are being transferred from one register to another. ANC clients tested positive for HIV at first test (new positives) exhibited the highest level of accuracy

When assessing data completeness for the seven PMTCT data elements, it was found that the best reported data element, showing maximum completeness, was ‘women receiving Nevirapine (NVP) in labour’. Data incompleteness was mainly attributed to low staffing levels and erratic supply of source documents.

The findings regarding the completeness of the PMTCT data are in accordance to other studies conducted in South Africa (Mlambo et al. 2014); (Mate *et al*. 2009; Mphatswe *et al*. 2012:176). This is worrying considering that the inaccuracy and incompleteness of data frustrates the efforts aimed at improving the healthcare systems that provide PMTCT interventions (Mate *et al*. 2009).

The results further reviewed a challenge regarding timelines in submission of patient data from the service delivery points to the districts. The level of timeliness was found to be poor (44.65%). However, a look at individual data elements showed that data on women receiving NVP in labour and rapid HIV test done to babies born to HIV-positive mothers at 12 months was recorded and reported in time throughout the reporting period. The levels of timeliness were however below 50% for the rest of the data elements. The DQA attributed the untimely availability of information on HIV-positive ANC clients tested for CD4 count and PCR test done on babies born to HIV-positive mothers to lack of specimen bottles and prolonged turnaround time of test results.

Interestingly, when assessing data confidentiality, it was found that the extent to which health professionals handled PMTCT programme data with confidentiality was 75.11%. This implied that most clients were assured that their data would be maintained according to national and international standards. This meant that personal data were not being disclosed inappropriately, and that data in hard copy and electronic form were being treated with appropriate levels of security. Most of the hard copy data was being kept under lock and key at both service delivery and district levels and the electronic form was password protected. The only threat to confidentiality that was found was the inadequate supply of storage facilities at service delivery point. About 24.89% of the facilities did not have enough lockers for storing source and reporting documents.

When assessing the integrity of PMTCT programme data, The DQA reviewed that the extent to which the HMIS and DHIS systems was protected from deliberate bias or manipulation for political or personal reasons was at 88%. The 12% lack of integrity stems from inadequate staff for recording and reporting patient data at service delivery point. It was found that the handling of patient data was being delegated to daily classified employees who were not ill equipped to handle patient data given no programme existed for training them except mere orientation which was not adequate.

While assessing precision levels, the study reviewed that the extent to which PMTCT programme data had sufficient detail was 88.69%. Precision scored the highest among the data quality parameters, this was because the data management systems where deliberately designed to cover as much detail as possible. The 11.31% lack of precision

was largely due to involvement of daily classified employees in recording and reporting of patient data at service delivery points that were not trained in data management. While the system was designed to cover sufficient detail, some data gaps existed.

When assessing reliability of the PMTCT data, it was found that data generated by the programme was based on protocols and procedures which were adhered to across facilities, the data was mostly measured and collected consistently, the only challenge was that there were delays in replenishing of source and reporting documents when they got filled up. Some facilities resorted to improvising by way of designing hardcover books in to registers, the downside was that these books varied by facility and were not designed to cover as much details as the standard registers.

As eluded to above, the study assessed the capacity of the data management systems responsible for managing and reporting the PMTCT programme data.

For a data management and reporting system to produce quality data, it should have in place a documented organizational structure or chat that clearly identifies positions that have data management responsibilities at the M&E Unit with all staff positions dedicated to M&E and data management systems filled. There should also be a senior staff member responsible for reviewing the aggregated numbers prior to submission or release of reports from the M&E Unit and there should be designated staff responsible for reviewing the quality of data received from sub-reporting levels. Additionally, there should be designated staff responsible for reviewing aggregated numbers prior to submission to the next level and the responsibility of recording the delivery of services on source documents should be clearly assigned to the relevant staff.

An assessment of the ability of the HMIS and DHIS system in managing PMTCT data reviewed that the system had a few flows which required attention if data of high quality was to come from the systems. One weakness of the system was the lack of trained professionals in data management at service delivery point. Data collection and reporting was left to either nurses or daily classified employees who had no business handling data as they were not trained to handle data, no plan existed for training these staff except for what they called “occasional orientation”. Another weakness that came up was that of

data collection and reporting forms not being availed to service delivery points in time which affected the timeliness, completeness as well as the accuracy of PMTCT data.

The study also assessed the feasibility of using routinely collected PMTCT programme data to measure MTCT rates given that Zambia currently has no reliable means of measuring the rates. It was reviewed that programme data cannot be relied on for measuring the rates given the untimeliness, inaccuracy and incompleteness affecting the data. Inaccuracy levels were found to be at 75.4% for PCR test done on babies born to HIV-positive mothers at six weeks or later. Untimeliness was at 57.58% while incompleteness was found to be at 45.4%.

The untimeliness was mainly attributed to prolonged turnaround time or the PCR test results. In most cases, babies reached 12 months without receiving PCR results. This was mainly due to lack of reagents for processing the DBS samples. It was further found that incompleteness and inaccuracy stems out from lack of lab requisition forms at service delivery points. Without lab requisition forms to accompany the DBS samples, most of them get misplaced hence the incompleteness and inaccuracy levels.

The DQA endeavored to establish factors limiting the quality of PMTCT programme data. Key factors that came out included the untimely supply of source (registers) and reporting documents. Some facilities resorted to using improvised hardcover books and later on transferred to the standardized source documents when they were availed. The down side was that the improvised books were not as comprehensive as the standardized documents.

Erratic and inadequate supply of MCH supplies such as specimen bottles, DBS kits, laboratory requisition forms were noted. The study reviewed that not only were there irregular supplies but they were also delivered in less than the requested quantities which affected the timely recording of PMTCT data.

Another factor that came out was that of delayed turnaround time for PCR test results. The service delivery points bemoaned the poor turnaround time for PCR test results which they attributed to the incompleteness of infant indicators. It was reviewed that some infants even reached 12 months of age without receiving their first PCR test results.

The DQA further reviewed that low turn up infants for rapid antibody test was challenge to data quality as it affected the completeness of infant indicators. Data for HIV rates for infants at 12 and 18 months were not conclusive given that most of the infants were not brought back for the rapid HIV/AIDS tests

Low staffing levels was another factor affecting quality of data especially in rural sites. Low staffing levels affected the completeness as well as the timely recording and reporting of data. The recording and reporting of data was assigned to the facility in-charge of the sites who were already overwhelmed with work hence making it difficult for data to be recorded alongside service delivery.

Additionally, lack of adequate storage facilities for source and reporting documents came out as a huge challenge to data quality. The available lockers were not adequate for storage of source and reporting documents, this affected data quality because it is a threat to confidentiality of data. Lack of adequate storage facilities further exposed the documents to the risk of being damaged, lost or misplaced.

5.2 Strengths and Limitations

One would argue that the study cannot be generalized to the entire southern region given that only four districts were covered in the region. However, generalizability of findings is order because the study at least covered a district in each province of the region and it further considered all PMTCT sites in the selected districts, both rural and urban sites.

5.3 Conclusion and recommendations

It can be concluded that the quality of PMTCT data was lower than expected mainly due to high levels of inaccuracy, incompleteness and untimeliness hence its limited usage. This observation was attributed to low staffing levels, lack of training for staff involved in data management at service delivery points and involvement of unqualified people in the recording and reporting of patient data at service delivery point. Additional threats to quality were due to erratic and inadequate supply of source and reporting documents, laboratory requisition forms, specimen bottles, and lack of adequate storage facilities for documents.

To improve data quality, healthcare data must be appropriate, accurate, timely, reliable, complete, precise, and must be handled confidentially with integrity. Data entry checks are also critical for accurate data reporting. For this reason, having dedicated personnel in each facility would improve data recording and reporting significantly. There is need for further research to determine causal relationships for the observed levels of inaccuracy, incompleteness and untimeliness.

REFERENCES

Abah, R. C. (2012). "The Importance of Data Quality Assurance in Improving Grant Implementation: An Example from Nigeria.".

Adeleke, I. T., et al. (2012). "Data quality assessment in healthcare: A 365-day chart review of impatientsss' health records at a Nigerian tertiary hospital." Journal of the Americans Medical Informatics Association.

Andersen, R. N., J. (1993). "Societal and Individual Determinants of Medical Care Utilization in United States. Health and Society." **Volume 51,No. 1**: 95-124.

Anderson, J. E., et al. (2004). "Women's Knowledge about treatment to Prevent Mother-to-Child Human Immunodeficiency Virus Transmission." Retrieved 18/11/14http://www.greenjournal.org/cgi/content/full/103/1/165, 2014.

Arulogun, O. S., et al. (2007). "Community gate keepers' awareness and perception of prevention of mother-to-child transmission of HIV services in Ibadan, Nigeria." Afr J Reprod Health.

Babakian, G. (2005). "Positively abandoned: Stigma and discrimination against HIV-Positive Mothers and their children in Russia." Human Rights Watch.

Boema, J. T. and S. K. Stansfield (2007). "Health Statistics Now: Are we making the right Investments."

Boffl, L. (1980). "Way of the cross œ way of justice. Maryknoll, New York." 43.

Bollinger, L. and J. Stover (1999). "*The Economic Impact of AIDS in Botswana*. The Policy Project. Septmber."

CBS (2003). Kenya Demographic and Health Survey. Kenya, Central Bureau of Statistics

CSF (2013). Annual Report July 2012-June 2013. Uganda, Civil Society Fund.

Deressa, e. a. (2014). "*Utilization of PMTCT Services and Associated Factors among Pregnant Women Attending Antenatal Clinics in Addis Ababa, Ethiopia*. BMC Pregnancy and Childbirth 2014." 14:328.

Doherty, T. M., et al. (2005). "*Health Systems Constraints to Optimal Coverage of PMTCT programme in South Africa*: Lessons from the Implementation of the National Pilot Programme." Africa Health Sciences **5 (3)**: 213 -218.

EGPAF HIV Clinical Services Program End-of-Project Report: Rwanda 2007-2012. Washington D. C, Elizabeth Glaser Pediatric AIDS Foundation.

Eide, M., et al. (2003). "*Social Consequences of HIV œ positive Women's participation in Prevention of Mother to Child Transmission Programmes*, Elsevier; Patient Education and Counselling." **60**(2).

FHI-360 and B. S. M. o. Health (2013). Bayelsa State-wide Rapid Health Facility Assessment,
Nigeria. Nigeria, FHI 360 & Bayelsa State Ministry of Health.
Fowler, M. G., et al. (2000). "*Prevention of Mother-to-Child HIV Transmission in Resource-*
Poor Countries: Translating Research into Policy and Practice." JAMA **283**: 1175-1182.
Garibb, A., et al. (2008). "An Evaluation of the District Information System in Rural South
Africa." South Africa Medical Journal.
Getaneh, M. (2013). 2011/12 Annual Report for Ethiopian Public Health Association (EPHA).
Addis Ababa, Ethiopia, Ethiopian Public Health Association (EPHA).
Hausmann, M. S., et al. (2003). *Health-Seeking Behavior and the Health System Response*. .
DCPP Working Paper No. 14.
Heywood, A. and D. Boone (2014). Guidelines for Data Management Standards in Routine
Health Information Systems, Measure Evaluation. International, P. (2014). "PMTCT." Retrieved 12/12/2014, 2014, from http://www.pathfind.org/site/PageServer?pagename=Programs_Kenya_Projects_PMTCT.
Jones, C. O. H. and H. A. Williams (2004). "The Social Burden of Malaria: What are we Measuring?". Retrieved 18/11/2014, 2014, from http://www.ncbi.nlm.nih.gov/books/bookres.fcgi/malaria/p156.pdf
Kahn, M. G., et al. (2012). "A Pragmatic Framework for Single-site and Multisite Data Quality
Assessment in Electronic Health Record--based Clinical Research. Med Care.".
Kalibala, S. (2010). "Monitoring and Evaluation of the Emergency Plan Progress (MEEPP):
End-of-Project Evaluation" Final Report, Population Council.
Kenya, G. o. (2014). Data Quality Audit Report, August 2014. Naorobi, Kenya.
Kiberu (2014). "strengthening district-based health reporting through the district health management information software system: Ugandan experience."
Kroeger, A. (1983). "*Anthropological and Socio-Medical Health Care Research in Developing*
Countrie." Social Science & Medicine, **17**: 147-161.
Macw'angi, M., et al. (2013). Prevention of Mother to Child Transmission of HIV/AIDS Data Quality Assessment, INESOR and NAC.
Mahdi, M. (2008). Pregnant women Still Struggle to Prevent HIV. Swaziland, Pregnant women
Still Struggle to Prevent HIV. Elizabeth Glaser Paediatric AIDS Foundation (EGPAF).
Mahmood, S. and M. Ayub (2010). "Accuracy of primary health care statistics reported by

community based lady health workers in district Lahore." Journal of Pakistan Medical Association **60, No. 8, 6499 - 53**.

Mate, K. S., et al. (2009). "Challenges for Routine Health System Data Management in a Large Public Programme to Prevent Mother-to-Child HIV Transmission in South Africa.".

Measure-Evaluation (2007). Data Quality Assurance Tool for Program-Level Indicators.

Measure-Evaluation (2007). Monitoring and Evaluation Systems Strengthening Tool, Measure Evaluation.

Measure-Evaluation (2008). Data Quality Audit Tool; Guidelines for Implementation, Measure Evaluation.

Mlambo, M. G., et al. (2014). "Prevention of Mother-to-Child Transmission of HIV data completeness and accuracy assessment in health facilities of the Nkangala District." Health SA Gesondheid 19(1), **774**.

Msofe, J. Y., et al. (2012). Project Heart End of Project report: Tanzania, Eight years of Scaling up HIV Prevention, Care, and Treatment Services and Savings. Tanzania, Elizabeth Glaser Pediatric AIDS Foundation.

Mungure, E. (2012). "Using Data Quality Assessment (DQA) to Highlight Gaps in the Quality of Maternal and Child Health Care in Dar es Salaam, Tanzania."

Ndira, S. P., et al. (2008). "Assessment of data quality of and staff satisfaction with an electronic health record system in a developing country (Uganda): A qualitative and quantitative comparative study', Methods of Information in Medicine 47(6), 489–498.".

Nicholas, M. (2012). A progress report on the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive, UNAIDS.

Nisingwe, M. P., et al. (2014). "Toward Utilization of Data for Program management and Evaluation: Quality Assessment of Five Years of Health Management Information System Data in Rwanda." **Vol 7**.

Orfanidis, L., et al. (2009). "Data Quality Issues in Electronic Health Records: An Adaptation Framework for the Greek Health System." Health Informatics Journal **15 NO. 4 305-319**.

Qayad, M. G. and H. Zhang (2009). "Accuracy of public health data linkages." Maternal and Child Health Journal.

Richard, C. and F. Mulenga (2003). Access to Care, 13thInternationalConference on AIDS and STIs in Africa (ICASA). Access to Care, 13thInternationalConference on AIDS and STIs in Africa (ICASA). Nairobi**:** 93. Abstract book No. 382439

Rodriguez, G. R., et al. (2012). "Methodology for the Assessment of Data Quality: Application to HIV and AIDS Programs in Latin America."

Sarin, A., R (1997). "Underutilization of Maternal Health Services." World Health Forum **18 (1)**: 67-68.

Semo, B.-w. Strategic Plan 2009-2014. Botswana, International Training and Education Center on HIV.

Silverman, R. and A. Glassman (2013). Measurement Obstacles to Achieving Value for Money at the Global Fund: A Problem Statement.

Sirengo, M., et al. (2012). Evaluating Kenya's readiness to transition from sentinel surveillance to routine HIV testing for antenatal clinic-based HIV surveillance.
SUSTAIN (2012). SUSTAIN Quarterly Report: October 1 to December 31, 2011. Uganda, Strengthening Uganda's Systems for Treating AIDS Nationally (SUSTAIN).
Ukaid (2014). NU HEALTH Improving Access to Healthcare for the Poor in Northern Uganda: Lessons Learned Report.
UNAIDS (May 2005). UNGASS: Monitoring the Declaration of Commitment on HIV/AIDS: Guidelines on construction of core indicators, 2006 reporting. Geneva, Switzerland.
UNAIDS and WHO (2004). "Guidelines for Conducting HIV Sentinel Serosurveys and Pregnant Women and Other Groups." Retrieved 10/6/2013, 2013, from http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub06/jc954-anc-serosurveys_guidelines_en.
UNFPA (2014). UNFPA Nigeria 6th Country Programme Evaluation: Final Report 2012.
UNICEF (2005). Guide to Monitoring and Evaluation of the national response for Children Orphaned and Made Vulnerable by HIV/AIDS. Geneva, UNICEF.
WHO (2005). "National AIDS Programmes: A Guide to Monitoring and Evaluating Antiretroviral Programmes. Geneva: WHO."
WHO (2012). Measuring the Impact of National PMTCT Programmes - Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive: A Short Guide on Methods. Geneva, Switzerland, WHO.
WHO (2013). "Guidelines for assessing the utility of data from prevention of mother-to-child transmission (PMTCT) programmes for HIV sentinel surveillance among pregnant women. UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance."
WHO and UNAIDS (2004). "Guide to Monitoring and Evaluating National HIV/AIDS Programmes for Young People."
Young, P. W., et al. (2013). "Routine data from prevention of mother-to-child transmission (PMTCT) HIV testing not yet ready for HIV surveillance in Mozambique: a retrospective analysis of matched test results." BMC Infectious Diseases 2013 13:96.

ANNEXES

Annex 1: System Assessment Questions and Links to Dimensions of Data Quality

Table 6: System Assessment Questions and Links to Dimensions of Data Quality

System Assessment Questions and Links to Dimensions of Data Quality											
Functional Area	**Level**			**Dimension of Data Quality**							
M&E Unit	M & E Unit	Aggregation Levels	Service Points	Accuracy	Reliability	Timeliness	Completeness	Precision	Confidentiality	Integrity
I - M&E Capacities, Roles and Responsibilities										
There is a documented organizational structure/chart that clearly identifies positions that have data management responsibilities at the M&E Unit. (to specify which Unit: e.g. MoH, NAP, GF, World Bank)	□□	□	□	□□	□□	□□	□	□	□	□
All staff positions dedicated to M&E and data management systems are filled.	□□	□	□	□□	□□	□□	□	□	□	□
A senior staff member (e.g., the Program Manager) is responsible for reviewing the aggregated numbers prior to the submission/release of reports from the M&E Unit.	□□	□	□	□□	□□	□	□□	□□	□	□
There are designated staff responsible for reviewing the quality of data (i.e., accuracy, completeness, timeliness and confidentiality) received from sub-	□□	□□	□	□□	□□	□□	□□	□□	□□	□

reporting levels (e.g., regions, districts, service points).										
There are designated staff responsible for reviewing aggregated numbers prior to submission to the next level (e.g., to the central M&E Unit).	□	□□	□□	□□	□□	□	□	□	□	□
The responsibility for recording the delivery of services on source documents is clearly assigned to the relevant staff.	□	□	□□	□□	□□	□	□	□	□	□
II – Training										
There is a training plan which includes staff involved in data-collection and reporting at all levels in the reporting process.	□□□			□□	□□	□□	□□ □		□□ □	
All relevant staff have received training on the data management processes and tools.	□□	□	□□	□□	□□	□□	□□	□□	□□	
III - Indictor Definitions										
The M&E Unit has documented and shared the definition of the indicator(s) with all relevant levels of the reporting system (e.g., regions, districts, service points).	□□□			□□	□□ □					
There is a description of the services that are related to each indicator measured by the Program/project.	□□□			□□	□□ □					
IV - Data Reporting Requirements										
The M&E Unit has provided written guidelines to all reporting entities (e.g., regions, districts, service points) on reporting requirements and deadlines.	□□	□□	□□	□□	□□	□□	□□ □			
V - Data-collection and Reporting Forms and Tools										
If multiple organizations are implementing activities under the Program/project, they all use the same reporting forms and report according	□□□			□□	□□ □					

to the same reporting timelines.											
The M&E Unit has identified a standard source document (e.g., medical record, client intake form, register, etc.) to be used by all service delivery points to record service delivery.	□□□			□□	□□ □						
The M&E Unit has identified standard reporting forms/tools to be used by all reporting levels / the forms/tools are consistently used by all levels.	□□	□□	□□	□□	□□ □						
Clear instructions have been provided by the M&E Unit on how to complete the data collection and reporting forms/tools.	□□	□□	□□	□□	□□ □						
The data collected by the M&E system has sufficient precision to measure the indicator(s) (i.e., relevant data are collected by sex, age, etc. if the indicator specifies disaggregation by these characteristics).	□□□		□□□					□□ □			
There is a written policy that states for how long source documents and reporting forms need to be retained.	□□□			□□	□□	□□	□□	□□ □	□	□	
All source documents and reporting forms relevant for measuring the indicator(s) are available for auditing purposes (including dated print-outs in case of computerized system).	□□	□□	□□	□□	□□	□□	□□	□□ □		□□	
VI - Data Management Processes and Data Quality Controls											
The M&E Unit has clearly documented data aggregation, analysis and/or manipulation steps performed at each level of the reporting system.	□□□			□□	□□	□□	□□	□□ □			
Feedback is systematically provided to all sub-reporting levels on the quality of their reporting (i.e., accuracy, completeness and timeliness).	□□	□□ □		□□	□□	□□	□□	□□ □			
[If applicable] There are quality controls in place for when data from paper-	□□	□□	□□	□□	□□	□□	□□	□□		□□	

based forms are entered into a computer (e.g., double entry, post-data entry verification, etc).								□		
[If applicable] There is a written back-up procedure for when data entry or data processing is computerized.	□□	□□	□□	□□	□□	□□	□□	□□ □		□□
If yes, the latest date of back-up is appropriate given the frequency of update of the computerized system (e.g., back-ups are weekly or monthly).	□□	□□	□□	□□	□□	□□	□□	□□ □		□□
Relevant personal data are maintained according to national or international confidentiality guidelines.	□□	□□	□□□						□□ □	
The recording and reporting system avoids double counting people within and across Service Delivery Points (e.g., a person receiving the same service twice in a reporting period, a person registered as receiving the same service in two different locations, etc).	□□	□□	□□	□□	□□ □					
The reporting system enables the identification and recording of a "drop out", a person "lost to follow-up" and a person who died.	□□	□□	□□	□□	□□ □					
There is a written procedure to address late, incomplete, inaccurate and missing reports; including following-up with sub-reporting levels on data quality issues.	□□	□□ □		□□	□□	□□	□□	□□ □		□□
If data discrepancies have been uncovered in reports from sub-reporting levels, the M&E Unit (e.g., districts or regions) has documented how these inconsistencies have been resolved.	□□	□□ □		□□	□□	□□	□□	□□ □		□□
The M&E Unit can demonstrate that regular supervisory site visits have taken place and that data quality has been reviewed.	□□□			□□	□□	□□	□□	□□	□□	□□

VII - Links with National Reporting System				
When applicable, the data are reported through a single channel of the national reporting system.	□□	□□	□□□	
The system records information about where the service is delivered (i.e. region, district, ward, etc.)	□□	□□	□□□	□□ □
….if yes, place names are recorded using standarized naming conventions.	□□	□□	□□□	□□ □

Annex 2: Informed Consent Form

University of Zambia School of Medicine

Department of Public Health

Public Health in Population & Health Studies

INFORMED CONSENT FORM

Study Title: Prevention of Mother to Child Transmission of HIV Programme Data Quality Assessment and Associated Factors in the Southern Region of Zambia.

Principal Investigator: Moonga Arthur M.

IRB No.:

Purpose of research project

This study is a requirement for partial fulfilment of my Master's degree in Public Health, which I am doing with the University of Zambia School of Medicine (UNZASOM). The purpose of the study is to perform a Data Quality Assessment (DQA) for the Prevention of Mother to Child Transmission of HIV (PMTCT) programme in forty eight (48) health facilities in the Southern region of Zambia. The DQA is an attempt at addressing the perceived problem of poor quality of routinely collected PMTCT data through verifying

the quality (completeness, timeliness, confidentiality, precision, integrity and accuracy) of reported data for key selected indicators (Antenatal, Postnatal, Maternity and Infant indicators) at primary healthcare level to national level.

I will also assess the ability of the health management information system (HMIS) and implementing partner monitoring and evaluation (M&E) systems to collect, manage and report quality PMTCT data, and will establish the factors affecting the quality of data. I further intend to present corrective measures for strengthening the PMTCT programme data management and reporting system and improving data quality in the southern region of Zambia.

Why you are being asked to participate?

Potential participants for the study are all personnel directly involved in the collection, management and reporting of PMTCT programme data in the Ministry of Health, Ministry of Community Development, Mother and Child Health, and PMTCT implementing partners. You have been asked to participate because you fit these descriptions. Overall, I expect about 71 participants.

Procedures

If you agree to participate in the DQA:

- I will ask you to take part in an interview which will take about 20 minutes. It will be done in a private place. If you permit me, I will tape record the interview to help pick all you will say. If not, I will ask you if it will be ok for me to write notes. The information from tape or notes will be typed in full, to help me to fully understand what you will say. Your name will not be included in the tape recording and the typed documents.

Risks/discomforts

There are no physical risks to participating in the DQA. However, I recognize some information you may tell me or fill in in the questionnaires maybe sensitive to other stakeholders. However, I would like to assure you the information that i get from you will not be shared with anyone outside the research team.

Benefits

There are no direct benefits to you but you will contribute to the development of corrective measures for strengthening the PMTCT programme data management and reporting system and improving data quality in the southern region of Zambia.

Payment

There is no payment for participating in the DQA.

Protecting data confidentiality

I have put up measures to protect the information I will get from you. Firstly, only members of the study team will have access to the information. The collected data will be locked in a secure place. I will destroy all data within 3 years after typing the information. I will keep copies of typed information on CDs in case we have a problem with the computer. The CDs will also be kept under lock and key.

What happens if you do not want to participate in the DQA?

You are free to decide whether you want to take part in the DQA. This will not bring any problem to you.

Who do you call if you have questions or problems?

- **Principal Investigator**: Arthur Moonga M. at +260966213386 if you have questions and complaints about the study.
- Call or contact the University of Zambia Biomedical Research Committee (UNZABREC) for any ethical queries: Tel: +260-1-256067, Email: unzarec@unza.zm Box 50110 Lusaka Zambia
- **Supervisor**: Dr Likwa Ndonyo R. University of Zambia School of Medicine

  Department of Public health Box 50110 Lusaka Zambia Email: 'drndonyo@yahoo.com'

- **Co-Supervisor**: Prof S. Baboo. University of Zambia School of Medicine Department of Public health, Box 50110 Lusaka Zambia. Cell: 0978-774068.

What does your signature (or thumbprint/mark) on this consent form mean?

Your signature (or thumbprint/mark) on this form means:

- You have been informed about the program's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this DQA

_____ _____ _____

Print name of Participant Signature of Participant Date

_____ _____ _____

Print name of Person Obtaining Signature of Person Obtaining Consent Date

Consent

Ask the participant to mark a "left thumb impression" in the box below if the participant (or participant's parent) is unable to provide a signature above.

Annex 3.1 – Data collection Tools: Record Extraction Form

<table>
<tr><th colspan="4">DATA VERIFICATIONS</th></tr>
<tr><td colspan="4">A - Documentation Review:</td></tr>
<tr><td>Q. #</td><td colspan="3">Review availability and completeness of all indicator source documents for January 2015 to December 2015.</td></tr>
<tr><td>Q101</td><td>Review available source documents for the year 2015

Are the PMTCT source documents available?</td><td>PMTCT Registers
ANC Registers
ART Registers
DBS Registers
PMTCT Delivery Registers
Integrated PMTCT Delivery Registers
Safe Motherhood Registers
Baby-Mother Follow-up Registers
PCR Registers
Others
Specify…….
…….
…….</td><td>Yes No
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]
[1] [2]</td></tr>
<tr><td>Q102</td><td colspan="3">For all <u>MISSING</u> source documents, inquire from In-charge how this may have affected reported numbers (circle missing documents, indicate affected indicator and highlight how missing document may have affected reported numbers for the indicator).
I. PMTCT Registers……
……
II. ANC Registers…..……</td></tr>
</table>

	…… III. ART Registers…..…… …… IV. DBS Registers…… …… V. PMTCT Delivery Registers…..…… …… VI. Integrated PMTCT Delivery Registers…… …… VII. Safe Motherhood Registers…… …… VIII. Baby-Mother Follow-up Registers…..…… …… IX. PCR Registers…..…… …… X. Other, Specify …… …… ***Indicators:*** Number of ANC clients counselled and tested for HIV at first visit; Number of ANC clients tested positive for HIV at first test (new); umber of HIV-positive ANC clients tested for CD4 count.; Number of ANC clients initiated on Azidothymidine (AZT) at 28 weeks or later; Number of women receiving Nevirapine (NVP) in labour; Number of

	babies given AZT; Number of Polymerase chain reaction (PCR) test done on babies born to HIV-positive mothers at six weeks; **Number of rapid Antibody HIV test done to children born to HIV-positive mothers**														
Q103	Are the PMTCT source documents complete? **(Confirm by ticking for each quarter)** **Note: Y =Yes - completely YC =Yes partly N = No – not at all**		1ST			2nd			3rd			4th		
			Y	YC	N	Y	YC	N	Y	YC	N	Y	YC	N
		PMTCT Registers												
		ANC Registers												
		ART Registers												
		DBS Registers												
		PMTCT Delivery Registers												
		Integrated PMTCT Delivery Reg												
		Safe Motherhood Registers												
		Baby-Mother Follow-up Registers												
		PCR Registers												
		Others Specify: …… …… …… …… ……												
Q104	***For all <u>INCOMPLETE</u> source documents, inquire from In-charge how this may have affected reported numbers (circle incomplete documents, indicate affected indicator and highlight how incomplete document may have affected reported numbers for the***													

	indicator). I. PMTCT Registers…… …… II. ANC Registers…..…… …… III. ART Registers…..…… …… IV. DBS Registers…… …… V. PMTCT Delivery Registers…...…… …… VI. Integrated PMTCT Delivery Registers…… …… VII. Safe Motherhood Registers…… …… VIII. Baby-Mother Follow-up Registers…...…… …… IX. PCR Registers…...…… …… X. Other, Specify …… ……

	Indicators: Number of ANC clients counselled and tested for HIV at first visit; Number of ANC clients tested positive for HIV at first test (new); umber of HIV-positive ANC clients tested for CD4 count.; Number of ANC clients initiated on Azidothymidine (AZT) at 28 weeks or later; Number of women receiving Nevirapine (NVP) in labour; Number of babies given AZT; Number of Polymerase chain reaction (PCR) test done on babies born to HIV-positive mothers at six weeks; **Number of rapid Antibody HIV test done to children born to HIV-positive mothers**																		
Q105	**Review the dates on the source documents.** Do all dates on PMTCT source documents fall within the reporting period for each quarter? **Note: Y**		1ST			2nd			3rd			4th							
			Y	YC	N	Y	YC	N	Y	YC	N	Y	YC	N					
		PMTCT Registers																	
		ANC Registers																	
		ART Registers																	
		DBS Registers																	
		PMTCT Delivery Registers																	
		Integrated PMTCT Delivery Reg																	
		Safe Motherhood Registers																	
		Baby-Mother Follow-up Registers																	
		PCR Registers																	
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	=Yes - completely **YC =Yes partly** **N = No – not at all**		
Q 106	***For each source documents with reporting dates not falling within reporting period, inquire from In-charge how this may have affected reported numbers (circle documents, indicate affected indicator and highlight how dates may have affected reported numbers for the indicator).*** I. PMTCT Registers…… …… II. ANC Registers…..…… …… III. ART Registers…..…… …… IV. DBS Registers…… …… V. PMTCT Delivery Registers…..…… …… VI. Integrated PMTCT Delivery Registers…… ……		

	VII. Safe Motherhood Registers…… ……
	VIII. Baby-Mother Follow-up Registers…..…… ……
	IX. PCR Registers…..…… ……
	X. Other, Specify …… ……
	Indicators: Number of ANC clients counselled and tested for HIV at first visit; Number of ANC clients tested positive for HIV at first test (new); umber of HIV-positive ANC clients tested for CD4 count.; Number of ANC clients initiated on Azidothymidine (AZT) at 28 weeks or later; Number of women receiving Nevirapine (NVP) in labour; Number of babies given AZT; Number of Polymerase chain reaction (PCR) test done on babies born to HIV-positive mothers at six weeks; **Number of rapid Antibody HIV test done to children born to HIV-positive mothers**

Q107	***Identify means of verification (main source documents) for selected indicators and review completeness and timeliness*** **Antenatal and postnatal indicators:** 5.2 ANC clients pre-tested counselled for HIV at 1 visit 5.3 ANC clients tested +ve for HIV at first test (new) 5.4 HIV-positive ANC clients tested for CD4 count 5.5 ANC clients initiated on Azidothymidine (AZT) at 28 weeks or later. **Maternity indicators:**	**Means of verification (Source Document)** **a) ……** **b) ……** **c) ……** **d) ……** **e) ……** **f) ……** **g) ……**	**MOV complete (per quarter)** 1st 2nd 3rd 4th [ ]	**MOV completed in time (per quarter)** 1st 2nd 3rd 4th [ ]

	5.6 Women receiving Nevirapine (NVP) in labour. **Infant indicators:** 5.7 Babies given AZT **5.8** Polymerase chain reaction (PCR) test done on babies born to HIV-positive mothers at six weeks. **5.9 Rapid Antibody HIV test done to children born to HIV-positive mothers**	**h) ……**	]	[ ] [ ] [ ] [ ]

B - Recounting reported Results (*Recount results from source documents, compare the verified numbers to the site reported numbers and explain discrepancies (if any)****)***

		Numbers from Source documents for 2015				**Site reported numbers for 2015**			
Q 2 0 1	a) Number of ANC clients counselled and	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**

	tested for HIV at first visit. b) Number of ANC clients tested positive for HIV at first test (new) c) Number of HIV-positive ANC clients tested for CD4 count. d) Number of ANC clients initiated on Azidothymidine (AZT) at 28 weeks								

	or later. e) Number of women receiving Nevirapine (NVP) in labour. f) Number of babies given ART **g)** Number of Polymerase chain reaction (PCR) test done on babies born to HIV-positive mothers								

	at six weeks. h) **Number of rapid Antibody HIV test done to children born to HIV-positive mothers**								
Q202	Consult the In-charge of MCH for reasons for the discrepancies (if any) observed between the verified and reported numbers (i.e., data entry								

	errors, arithmetic errors, missing source documents, other).		
C - Cross-check reported results with other data sources *(Randomly select 10 patient files and confirm if they were recorded in the registers, and randomly select 10 records from the registers and trace their corresponding patient files)*:			
Q301	Where the selected patient files recorded in the registers?	Yes, all of them Yes, some of them No, none of them Number of matching cases	1. 2. 3. ……..
Q302	Q	Yes, all of them Yes, some of them No, none of them Number of matching cases	1. 2. 3. ……..
Q303	Find out the reasons for the discrepancies (if any) from the In-charge of MCH	_____ _____ _____ _____ _____ _____	

Annex 3.2: Data collection tools: Questionnaire

Assessment of Data Management and Reporting Systems:				
I - M&E Capacities, Roles and Responsibilities				
Q. No	Level	Question	Response	Skip Pattern
Q101	M&E Unit	Is there a documented organizational structure/chart that clearly identifies positions that have data management responsibilities at the M&E Unit?	Yes No D/K N/A	1. 2. 88. 99.
Q102	M&E Unit	Are all staff positions dedicated to M&E and data management systems filled in?	Yes No D/K N/A	1. 2. 88. 99.
Q103	M&E Unit	Is there someone responsible for reviewing the aggregated numbers prior to the submission/release of reports from the M&E Unit?	Yes No D/K N/A	1. 2. →**Skip to Q105** 88. →**Skip to Q105** 99. →**Skip to Q105**
Q104	M&E Unit	Who is responsible for reviewing the aggregated numbers prior to the submission/release of reports from the M&E Unit?	Yes No D/K	1. 2. 88.

			N/A	99.
Q105	M&E Unit District Province	Do you have designated staff responsible for reviewing the quality of data (i.e., accuracy, completeness, timeliness and confidentiality) received from sub-reporting levels (e.g., regions, districts, service points)?	Yes No D/K N/A	1. 2. 88. 99.
Q106	District Province Service Point	Do you have designated staff responsible for reviewing aggregated numbers prior to submission to the next level (e.g., to the central M&E Unit)?	Yes No D/K N/A	1. 2. 88. 99.
Q107	Service Point	Is the responsibility for recording the delivery of services on source documents clearly assigned to the relevant staff	Yes No D/K N/A	1. 2. →**Skip to Q201** 88. →**Skip to Q201** 99. →**Skip to Q201**
Q108	Service Point	***Indicate staff (by tittle i.e. program officer) responsible for recording on source each document*** PMTCT Registers …… …… ANC Registers…… ……. ART Registers…… ……. DBS Registers……		

		…… PMTCT Delivery Registers…… …… Integrated PMTCT Delivery Registers…… …… Safe Motherhood Registers…… …… Baby-Mother Follow-up Registers…… ……... PCR Registers…… …… Other source documents (Specify)…… ……..		
II – Training				
Q201	M&E Unit	Do you have a training plan for members of staff?	Yes No D/K N/A	1. 2. →**Skip to Q203** 88. →**Skip to Q203** 99. →**Skip to Q203**
Q202	M&E Unit	Does the training plan include staff involved in data-collection and reporting at all levels in the reporting process?	Yes No D/K	1. 2. 88.

			N/A	99.
Q203	M&E Unit District Province Service Point	Have all the relevant staff received training on the data management processes and tools?	Yes No D/K N/A	1. 2. 88. 99.
III - Indictor Definitions				
Q301	M&E Unit	Has the M&E Unit documented and shared the definition of the indicator(s) with all relevant levels of the reporting system (e.g., regions, provinces districts, service points).	Yes No D/K N/A	1. 2. 88. 99.
Q302	M&E Unit	Is there a description of the services that are related to each indicator measured by the Program/project?	Yes No D/K N/A	1. 2. 88. 99.
IV - Data Reporting Requirements				
Q401	M&E Unit District Province Service Point	Has the M&E Unit provided written guidelines to all reporting entities (e.g., regions, provinces, districts, service points) on reporting requirements and deadlines?	Yes No D/K N/A	1. 2. 88. 99.
V - Data-collection and Reporting Forms and Tools				
Q501	M&E Unit	Are there other organizations implementing activities under the PMTCT Programme?	Yes No D/K N/A	1. 2. →**Skip to Q503** 88. →**Skip to Q503** 99. →**Skip to Q503**
Q502	M&E Unit	Do all the organizations use the same reporting forms and report according to the same reporting timelines?	Yes No	1. 2.

			D/K N/A	88. 99.
Q503	M&E Unit	Has the M&E Unit identified a standard source document (e.g., medical record, client intake form, register, etc.) to be used by all service delivery points to record service delivery?	Yes No D/K N/A	1. 2. →**Skip to Q506** 88. →**Skip to Q506** 99. →**Skip to Q506**
Q504	M&E Unit	List all the identified source documents	1……..…… …….. 2……..…… …….. 3……..…… …….. 4…….…… …….. 5…….…… …….. 6…….…… …….. 7…….…… …….. 8…….…… …….. 9…….…… …….. 10……..…… ……..	

Q505	M&E Unit District Province Service Point	Have clear instructions been provided by the M&E Unit on how to complete the data collection forms/tools/registers?	1. Yes No	
Q506	M&E Unit District Province Service Point	Has the M&E Unit identified standard reporting forms/tools to be used by all reporting levels?	Yes No D/K N/A	1. 2. →**Skip to Q508** 88. →**Skip to Q508** 99. →**Skip to Q508**
Q507	M&E Unit District Province Service Point	List all the identified reporting forms/tools	1……..…… …….. 2……..…… …….. 3……..…… …….. 4…….…… …….. 5…….…… …….. 6…….…… …….. 7…….…… …….. 8…….…… …….. 9…….…… …….. 10……..……	

			……..	
Q508	M&E Unit District Province Service Point	Are the forms/tools used consistently by all levels?	1. Yes 2. No	
Q509	M&E Unit District Province Service Point	Have clear instructions been provided by the M&E Unit on how to complete the data reporting forms/tools?	2. Yes 3. No	
Q510	M&E Unit Service Point	Does the data collected by the M&E system have sufficient precision to measure the indicator(s) (i.e., relevant data are collected by sex, age, etc. if the indicator specifies disaggregation by these characteristics)?	1. Yes 2. No	
Q511	M&E Unit	***Is there a written policy that states for how long source documents and reporting forms need to be retained?*** 1. Source documents . 2. Reporting forms/ tools	**Yes No** [1] [2] [1] [2]	
Q512	M&E Unit District Province Service Point	***Are all source documents and reporting forms relevant for measuring the indicator(s) available for auditing purposes (including dated print-outs in case of computerized system)?*** 1. Source documents .	**Yes No** [1] [2]	

		2. Reporting forms/ tools	[1] [2]	
VI - Data Management Processes and Data Quality Controls				
Q601	M&E Unit	***Does the M&E Unit has clearly documented;*** 1. Data aggregation at each level of the reporting system? 2. Analysis and/or manipulation steps performed at each level of the reporting system?	**Yes No** [1] [2] [1] [2]	
Q602	M&E Unit District Province	Is feedback systematically provided to all sub-reporting levels on the quality of their reporting (i.e., accuracy, completeness and timeliness)?	1. Yes 2. No	
Q603	M&E Unit District Province Service Point	[If applicable] Are there quality controls in place for when data from paper-based forms are entered into a computer (e.g., double entry, post-data entry verification, etc.)?	1. Yes 2. No	**→Skip to Q605**
Q604	M&E Unit District Province Service Point	List down all quality control measures	a) …… b) …… c) …… d) …… e) …… f) ……	
Q605	M&E Unit District	Is there a written back-up procedure for when data entry or data processing is computerized?	1. Yes 2. No	**→Skip to Q608**

	Province Service Point			
Q606	M&E Unit District Province Service Point	Frequency of back-up	1. Daily 2. Weekly 3. Monthly 4. Quarterly	
Q607	M&E Unit District Province Service Point	Indicate date of last back-up	_ _/__ __/__ __ __ __(dd/mm/yr)	
Q608	M&E Unit District Province Service Point	Are relevant personal data maintained according to national or international confidentiality guidelines.	1. Yes 2. No	
Q609	M&E Unit District Province Service Point	Does the recording and reporting system avoid double counting people within and across Service Delivery Points (e.g., a person receiving the same service twice in a reporting period, a person registered as receiving the same service in two different locations, etc)?.	1. Yes 2. No	**→Skip to Q611**
Q610	M&E Unit District Province Service Point	What measures are in place to ensure no double counting? a. …… …… b. …… …… c. ……		

		…… d. …… …… e. …… …… f. …… …… g. …… …… h. …… …… i. …… …… j. …… ……		
Q611	M&E Unit District Province Service Point	Does the reporting system enable the identification and recording of a "drop out", a person "lost to follow-up" and a person who died?	1. Yes 2. No	→**Skip to Q613**
Q612	M&E Unit District Province	Is there a written procedure to address: a. Late report b. Incomplete report c. Inaccurate report d. Missing reports e. Following-up with sub-reporting levels on data quality issues?	**Yes No** [1] [2] [1] [2] [1] [2] [1] [2] [1] [2]	
Q613	M&E Unit District	Did you uncover any data discrepancies in reports from sub reporting levels in the year 2015?	**Yes No**	**If no on all, skip to Q616**

	Province	a. Province level b. District level c. Service points level	[1] [2] [1] [2] [1] [2]	
Q614	M&E Unit District Province	Have the M&E Unit documented how these inconsistencies have been resolved at. a. Province level b. District level c. Service points level	**Yes No** [1] [2] [1] [2] [1] [2]	
Q615	M&E Unit District Province	How were these inconsistencies resolved? a. Province level…… b. District level…… c. Service points level……..		
Q616	M&E Unit	The M&E Unit can demonstrate that regular supervisory site visits have taken place and that data quality has been reviewed.	1. Yes 2. No	
VII - Links with National Reporting System				
Q701	M&E Unit	Are the data reported through a single channel of the	1. Yes	

	Province District Service Point	national reporting system (when applicable).	2. No	
Q702	M&E Unit Province District Service Point	Does the system record information about where the service is delivered (i.e. region, district, ward, facility etc.)?	1. Yes 2. No	→**Skip to Q704**
Q703	M&E Unit Province District Service Point	Are place names recorded using standardized naming conventions?	1. Yes 2. No	
Q704	M&E Unit Province District Service Point	Any comments or observations		

Annex 3.3. Data Analysis Plan

PMTCT Data Quality Assessment

Data analysis plan. March 2016

Study aim and Objectives:

- **The study aim is to:** assess PMTCT data quality at primary healthcare level to national level and associated factors in order to assist with the improvement of the PMTCT data management and reporting.

  Objectives of the study are to: (1) Verify the Accuracy, Completeness, Reliability, Timeliness, Confidentiality, Precision and Integrity of PMTCT programme data (2); assess the capacity of HMIS in managing and reporting PMTCT programme data; (3) assess the possibility of using PMTCT programme data to measure MTCT rates; (4) establish the factors that affect the quality of PMTCT data.

Levels of analysis:

- Collected data will be disaggregated by Province, District, type of Health facility and Location (Rural/Urban).

		Source	
	Indicator	**Tool**	**Question**
	Introduction/Background		
1.1	Description of National Pediatric HIV/AIDS situation in Zambia Brief history of the epidemic and milestones to date		
1.2	Description of the response and milestones in PMTCT		
1.3	Aims and objectives of the study		
2.0	**Socio-Demographic characteristics**		
2.1	Location (Province/District, Rural/Urban)	Systems Verification Questionnaire & Record Review Form	**Q002-Q005**
2.2	Type	Systems Verification Questionnaire & Record Review Form	Q005
3.0	**Objective 1:** Verify the Accuracy, Completeness, Reliability, Timeliness, Confidentiality, Precision and Integrity of PMTCT programme data		
3.1	Accuracy	Data Verification Form Systems Assessment Questionnaire	Q102, Q106, Q107, Q201, Q301, Q302 Q101-Q616,
3.2	Completeness	Data Verification Form Systems Assessment Questionnaire	Q101, Q103, Q104, Q107 Q103-Q107, Q201-Q203, Q301-Q302, Q401, Q511-Q512, Q601-Q607, Q612-Q616
3.3	Reliability	Systems Assessment Questionnaire	Q101-Q616
3.4	Timeliness	Data Verification Form Systems Assessment Questionnaire	Q105, Q107, Q101, Q102 Q101-Q102, Q105, Q201-Q203, Q401, Q511-Q512, Q601-Q607, Q612-Q616
3.5	Confidentiality	Systems Assessment Questionnaire	Q105, Q201-Q203, Q608, Q616
3.6	Precision	Systems Assessment Questionnaire	Q103-Q105, Q203, Q510-Q512, Q603-Q607, Q612-Q616, Q701-Q704

3.7	Integrity	Systems Assessment Questionnaire	Q507-Q508, Q511-Q512, Q603-Q607, Q612-Q616
4.0	**Objective 2:** Assess the capacity of HMIS in managing and reporting PMTCT programme data		
4.1	***M&E Capacities, Roles and Responsibilities***	Systems Assessment Questionnaire	Q101-Q108
4.2	Training	Systems Assessment Questionnaire	Q201-Q203
4.3	Indicator Definitions	Systems Assessment Questionnaire	Q301-Q302
4.4	Data Reporting Requirements	Systems Assessment Questionnaire	Q401
4.5	Data collection and reporting forms and tools	Systems Assessment Questionnaire	Q501-Q512
4.6	Data Management processes and data quality controls	Systems Assessment Questionnaire	Q601-Q616
4.7	Links with national reporting system	Systems Assessment Questionnaire	Q701-Q704
5.0	**Objective 3 :** Assess the possibility of using PMTCT programme data to measure MTCT rates		
5.1	Availability and completeness of all indicator source documents for January 2015 to December 2015.	Data Verification Form	Q101-Q107
5.2	Recounting reported Results	Data Verification Form	Q201-Q202
5.3	Cross-check reported results with other data sources	Data Verification Form	Q301-Q303
6.0	**Objective 4 :** Establish the factors that affect the quality of PMTCT data		
6.1	Reasons for discrepancies between the verified and reported data	Data Verification Form	Q202, Q303

Annex 4: Ethical clearance

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

28th February, 2016.

Our Ref: 010-08-15.

Mr. Arthur M. Moonga,
University of Zambia,
School of Medicine,
Department of Public Health,
P.O Box 50110,
Lusaka.

Dear Mr. Moonga,

RE: RESUBMITTED RESEARCH PROPOSAL: **"PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV/AIDS (PMTCT) DATA QUALITY ASSESSMENT (DQA) AND ASSOCIATED FACTORS" (REF. No. 010-08-15)**

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 26th February, 2016. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr. S.H Nzala
VICE-CHAIRPERSON

Date of approval: 28th February, 2016. **Date of expiry:** 27th February, 2017.