

ANTIRETROVIRAL DRUGS LOGISTICS MANAGEMENT AND HIV/AIDS SERVICE DELIVERY IN
BAYLOR-UGANDA SUPPORTED HEALTH FACILITIES IN EASTERN UGANDA

by

HILDA SEKABIRA NAKALEMA BA DPPM

APPROVED:

THESIS CHAIR, DR. SUJA S. RAJAN PHD

ACADEMIC ADVISOR, DR. SUJA S. RAJAN PHD

COMMITTEE MEMBER, DR. ROBERT O.
MORGAN PHD

COMMITTEE MEMBER, DR. SHERYL MCCURDY
PHD

COPYRIGHT

By

HILDA SEKABIRA NAKALEMA BA DPPM MPH

2015

DEDICATION

To My Mum Robinah Sekabira

ANTIRETROVIRAL DRUGS LOGISTICS MANAGEMENT AND HIV/AIDS SERVICE DELIVERY IN
BAYLOR-UGANDA SUPPORTED HEALTH FACILITIES IN EASTERN UGANDA

by

HILDA SEKABIRA NAKALEMA BA DPPM

Presented to the Faculty of The University of Texas

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS
SCHOOL OF PUBLIC HEALTH
Houston, Texas
August, 2015

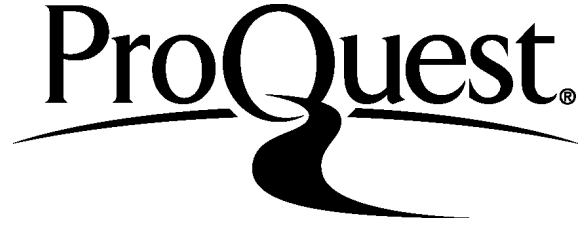
ProQuest Number: 1604125

All rights reserved

INFORMATION TO ALL USERS

The quality of this reproduction is dependent upon the quality of the copy submitted.

In the unlikely event that the author did not send a complete manuscript and there are missing pages, these will be noted. Also, if material had to be removed, a note will indicate the deletion.



ProQuest 1604125

Published by ProQuest LLC (2015). Copyright of the Dissertation is held by the Author.

All rights reserved.

This work is protected against unauthorized copying under Title 17, United States Code
Microform Edition © ProQuest LLC.

ProQuest LLC.
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106 - 1346

ACKNOWLEDGEMENTS

This study was made possible through funding from NIH in collaboration with the Baylor International Pediatric AIDS Initiative (BIPAI). I am grateful to Dr. Mark Kline for giving me the opportunity to receive this scholarship. I am grateful to the American government, NIH, Baylor College of Medicine and the American people.

I would like to thank Dr. Suja S. Rajan for her support and guidance for the past 2 years. Without her support I do not know how I would have completed this work. I thank my committee members, Dr. Robert O. Morgan and Dr. Sheryl McCurdy for their time and counsel.

I thank the staff at BIPAI who made sure my stay in the US went well. Tina Burley and Bridgette Naik made sure I had a place to stay and funds for my upkeep. I also thank Dr. Susan Gillespie for her support and guidance. Lastly I thank my Mum and siblings for their love and support as I worked on this document.

ANTIRETROVIRAL DRUGS LOGISTICS MANAGEMENT AND HIV/AIDS SERVICE DELIVERY IN
BAYLOR-UGANDA SUPPORTED HEALTH FACILITIES IN EASTERN UGANDA

Hilda Sekabira Nakalema BA DPPM MPH
The University of Texas
School of Public Health, 2015

Thesis Chair: DR. SUJA S. RAJAN PHD

INTRODUCTION: The number of people receiving antiretroviral treatment (ART) continues to grow as the global effort to fight HIV/AIDS continues to overcome barriers to ART and ensure that drugs are available to those infected with the virus. As part of its systems strengthening program, Baylor-Uganda provided technical support in ARV logistics management to health facilities. This improved service delivery and ensured HIV-positive pregnant women and exposed infants got the drugs they needed to survive.

RESEARCH QUESTIONS: The study sought to answer the questions: Can an intervention effectiveness study on the ARV logistics management program and HIV/AIDS management services be done? What sources of data and key personnel are available to conduct such a study? How does the ARV logistics management program affect starting ART for mothers and exposed infants? How does the program impact reporting and ordering of HIV commodities from the national supply chain agencies?

STUDY DESIGN: This was a feasibility/pilot study to estimate the parameters needed to design a larger intervention effectiveness study and determine whether the research questions

could be answered. The study was conducted among 25 Baylor – Uganda supported health facilities in eastern Uganda.

RESULTS: Improvement in the ARV logistics management at the health facilities was reported. The number of HFs submitting complete and correct order forms to NMS has increased. This has in turn increased the number of HIV positive pregnant women and exposed infants started on ART although not all of them are started as required under the new treatment guidelines.

CONCLUSIONS: Although there are still areas that need improvement in ARV logistics management, improvements have been observed in the supported health facilities including timely submission of order forms, and increased number of HIV positive pregnant women and exposed infants started on ART. A larger study involving patient-level data would provide greater insights into the impact of this program.

TABLE OF CONTENTS

| | |
|--|-----|
| List of Tables | i |
| List of Figures | ii |
| List of Appendices | iii |
| BACKGROUND | 1 |
| Global Situation..... | 1 |
| National Situation | 2 |
| ART for HIV positive pregnant women and Exposed infants..... | 3 |
| Association between ARV Logistics Management and HIV/AIDS service delivery..... | 4 |
| Healthcare Service Delivery System in Uganda | 5 |
| Supply Chain System in Uganda..... | 5 |
| Baylor College of Medicine Children’s Foundation-Uganda (Baylor-Uganda) | 9 |
| PUBLIC HEALTH SIGNIFICANCE AND CONTRIBUTION OF THE CURRENT STUDY | 12 |
| RESEARCH OBJECTIVES | 14 |
| METHODS:..... | 16 |
| Study Design..... | 16 |
| Study Setting | 16 |
| Study Population..... | 16 |
| Data Collection..... | 17 |
| Data Analysis..... | 17 |
| Human Subjects, Animal Subjects, and/or Safety Considerations | 20 |
| RESULTS..... | 21 |
| DISCUSSION..... | 40 |
| CONCLUSION..... | 52 |
| Appendices..... | 54 |
| References | 71 |

LIST OF TABLES

| | |
|--|----|
| Table 1: Number of health facilities surveyed | 21 |
| Table 2: Patient population and ARV training characteristics | 24 |
| Table 3: Type and number of healthcare workers by cadre in the entire health facility and in the HIV clinic..... | 26 |
| Table 4: Number of healthcare workers trained in ARV logistic management..... | 28 |
| Table 5: Number of healthcare workers trained by type of training..... | 28 |
| Table 6: Responses to the interview questions (n=21) | 29 |
| Table 7: Challenges faced by HFs and proposed recommendations..... | 30 |
| Table 8: Health facilities that had complete ARV order forms..... | 31 |
| Table 9: Health facilities that had correct report/order forms | 32 |
| Table 10: Number of health facilities that received supplies from NMS | 32 |
| Table 11: Proportion of Health Facilities that experienced stock-outs..... | 33 |
| Table 12: Number of stock outs that were experienced | 33 |
| Table 13: ARV and OIs drugs that were commonly stocked..... | 34 |
| Table 14: Number of health facilities that received buffer stock from Baylor-Uganda..... | 35 |
| Table 15: Health facilities that had data on testing and starting ART | 35 |
| Table 16: Proportion of pregnant women who were tested and tested positive for HIV | 36 |
| Table 17: Proportion of exposed infants who were tested and tested positive for HIV..... | 38 |

LIST OF FIGURES

| | |
|--|----|
| Figure 1: Evolution of ARV supply chain management in Uganda..... | 6 |
| Figure 2: The current flow chart of supply chain agencies | 7 |
| Figure 3: Baylor-Uganda Project Areas | 10 |
| Figure 4: Factors affecting ARV Logistics Management (n=21) | 30 |
| Figure 5: Number of pregnant women that tested positive and started ART in the pre-intervention period | 37 |
| Figure 6: Number of pregnant women that tested positive and started ART in the post intervention period | 37 |
| Figure 7: Number of exposed infants that tested positive and started ART in the pre-intervention period | 38 |
| Figure 8: Number of exposed infants that tested positive and started ART in the post intervention period | 39 |

LIST OF APPENDICES

| | |
|---|----|
| Appendix 1: Data Collection Tool: Variables and Definitions | 54 |
| Appendix 2: Interview Guide | 64 |
| Appendix 3: Definition of terms..... | 65 |
| Appendix 4: Proposal Approval letter from UTSPH | 67 |
| Appendix 5: Proposal Approval letter from Baylor College of Medicine IRB) | 68 |
| Appendix 6: Proposal Approval letter from Mengo Hospital (local IRB) | 69 |
| Appendix 7: Proposal Approval letter from UNCST | 70 |

BACKGROUND

Global Situation

There are approximately 35 million people currently living with HIV world-wide ¹. Close to 71% of people living with HIV (PLWHA) live in sub-Saharan Africa. Nearly 39 million people have died of AIDS-related causes since the beginning of the epidemic. Although new cases have been reported in all regions of the world, sub-Saharan Africa accounts for almost 70% of the global total of new HIV infections according to World Health Organization (WHO, 2014).

HIV continues to pose a serious health risk for pregnant women and their children in high prevalence settings. Women represent about half of all people living with HIV worldwide, and more than half (58%) in sub-Saharan Africa. HIV is the leading cause of death among women of reproductive age. Vertical transmission occurring during pregnancy, labor, delivery or breast feeding, remains the main mode of HIV infection in children ². According to WHO, at the end of 2013 an estimated 240,000 children (<15years) were newly infected with HIV, and an estimated 3.2 million children were living with HIV globally¹. Infants born to HIV-positive women are at an increased risk of mortality and morbidity in addition to being orphaned at an early age. Without prophylactic treatment, approximately 15–30% of infants born to HIV-positive women will become infected with HIV during gestation and delivery. In addition, 5–15% will become infected through breastfeeding (WHO, 2014). The use of antiretroviral (ARV) drugs during and after pregnancy is a proven intervention to virtually eliminate the risk of HIV transmission to infants, as evidenced in high-income countries where vertical transmission is almost non-existent². Furthermore, studies (²⁻⁶) done in Sub-Saharan countries including Malawi, Tanzania, Botswana,

and South Africa have also shown a reduction in vertical transmission of HIV as a result of these interventions.

National Situation

In Uganda, after more than 10 years of the HIV epidemic, the disease prevalence stagnated at 6.4 %, (down from 18% in the early 1990s). However, the prevalence rate has now risen to 7.3 as of 2010⁷. HIV incidence had increased from 115,775 in 2008 to 130,000 new infections in 2010. In addition, despite expanded access to antiretroviral therapy (ART), coverage of prevention interventions remains low due to inadequacies in the health system, resulting in a major treatment gap. Out of the 540,994 people living with HIV who were eligible for ART in 2010, only about 50% were receiving ARV drugs⁷. This sudden increase in the epidemic, followed by a treatment gap, has raised concerns among stakeholders who have now called for the development of a new HIV/AIDS strategic plan and prevention strategy to address the changing trends. Elimination of transmission from mother to child of HIV (eMTCT) was identified as a key component to ensure that no baby is born with HIV by 2015. This was in line with the 2015 targets and elimination commitments set in the 2011 UN Political Declaration towards achieving Millennium Development Goal (MDGs). In order to reduce mother-to-child HIV transmission, timely ART initiation among HIV positive pregnant women is vital.

To date, more women than men are infected. For example the prevalence among women in age group 15-49 is 7.7% while that of men is 5.6%. Uganda has one of the highest fertility rates in the world (6.7 children per woman), and approximately 91 000 infants are born annually to HIV-positive women⁸. According to the Annual Health Sector Performance Report (MOH, 2013), the percentage of HIV-positive pregnant women who receive ART to reduce the risk of mother-

to-child transmission increased from 50% in 2009 to 96% in 2012. However of these, only 38% received ARV drugs for life (Option B+) under the new WHO HIV treatment guidelines. The previous guidelines had two recommended options A and B for pregnant women who did not need ART. Option A, referred to maternal zidovudine (AZT) prophylaxis, which was given at fourteen weeks of gestation and stopped seven days after delivery. Option B, referred to as maternal triple ARV prophylaxis, was given starting at fourteen weeks of gestation and continued until delivery⁹. In both cases, only breastfeeding mothers would continue with the treatment until one week after all infant exposure to breast milk had ended. The percentage of infants born to HIV-positive women receiving a virological test for HIV within 12 months of birth is 46% while the percentage of eligible adults and children currently receiving ART is 76% (MOH, 2013). While on track, ART coverage is still low to meet the MDGs targets.

ART for HIV positive pregnant women and Exposed infants

Providing ART (treatment as prevention) for people living with HIV improves the individual's health, while reducing the risk of HIV transmission to others. According to WHO, studies have established that ART can reduce the risk of HIV transmission by as much as 96%¹. Thus, revisions were made to the treatment guidelines and scale up efforts began in 2012 to start all HIV positive pregnant women on ART treatment for life (Option B+). In 2013 the WHO published the consolidated simplified treatment guidelines for treating and preventing HIV infection. All pregnant and breastfeeding women living with HIV are to be treated with a simplified, once-daily drug regimen consisting of tenofovir (TDF) + lamivudine (3TC) or emtricitabine (FTC) + efavirenz (EFV)¹⁰. Uganda is currently rolling out this 'treatment as prevention' strategy country-wide. The goal is to reduce mother-to-child transmission to less

than 5%. In spite of these efforts, the country is struggling to ensure a consistent supply of ARV drugs.

According to the HIV/AIDS country progress report 2013, eMTCT service coverage had reached 48% of all health facilities. 93% of pregnant women attending antenatal clinics were tested for HIV between October 2012 and September 2013. A total of 88,792 (71%) out of 123,754 (7.2%) that tested positive for HIV received ARV drugs for eMTCT, including those who were already on ART prior to getting pregnant, and those who were started on Option B+ after testing. However, only 36.7% of the infants born alive to HIV positive mothers received ARVs.

Association between ARV Logistics Management and HIV/AIDS service delivery

An uninterrupted supply of ARV drugs for treatment of HIV/AIDS is a pre-requisite and a challenge for ART programs. Drug stock outs affect uptake, adherence and retention in HIV treatment, in addition to leading to drug resistance. ARV logistics management refers to the management of HIV commodities in a systematic and standardized way by collecting, processing and utilizing timely logistics data to inform quantification, forecasting, ordering, reporting, and accountability of HIV/AIDS commodities¹¹.

Without proper ARV management, HIV programs run the risk of prolonged and frequent stock outs, overstocks and losses which in turn disrupts HIV treatment. Previous studies¹¹⁻¹⁵ have reported a correlation between the availability of ARVs and HIV/AIDS service delivery. Successful scale up of HIV programs depends on consistent availability of required drugs to ensure continuity of care and adherence to treatment regimens.

Healthcare Service Delivery System in Uganda

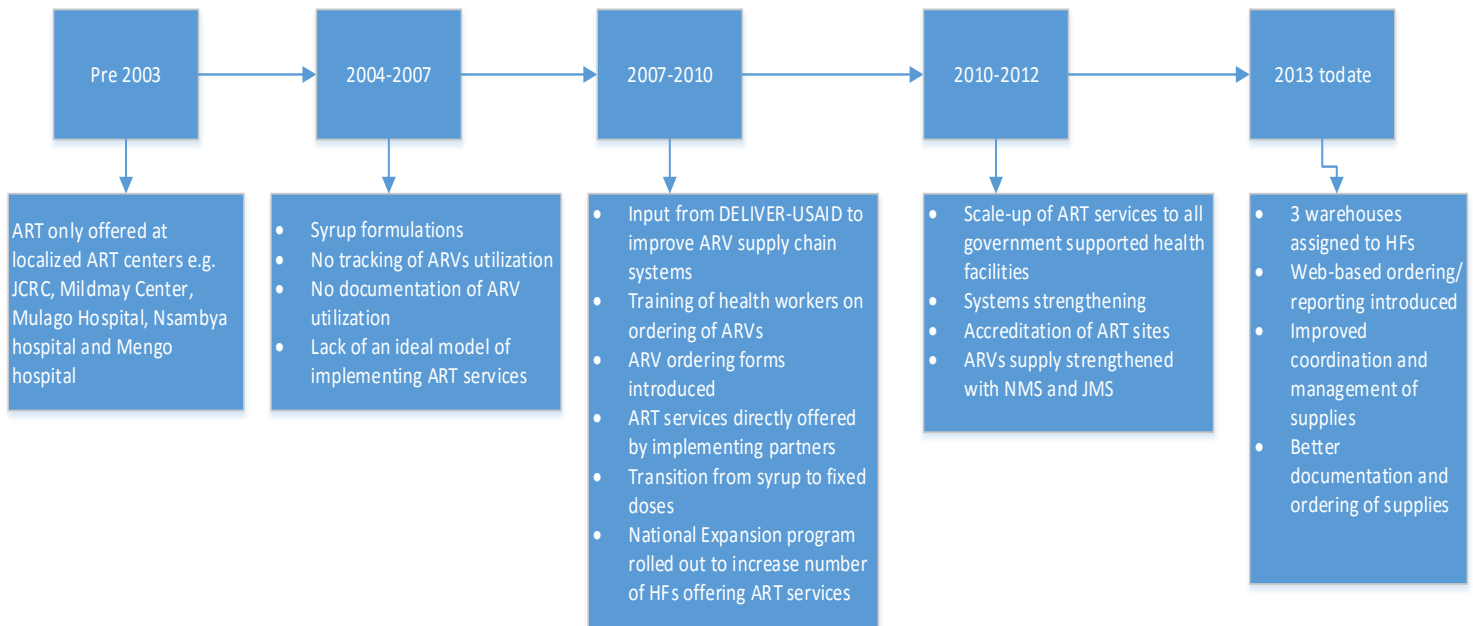
In order to understand the healthcare access issues for ART provision in Uganda, and to discuss the methods to improve ART provision, it is important to first understand the healthcare service delivery system in Uganda. In Uganda, and other African countries, the government provides the majority of healthcare services. The tiered healthcare system includes both the public and private sectors. The public sector comprises the national referral hospitals, regional referral hospitals, general hospitals, lower-level health centers (Level IV – Level II) and Village Health Teams. The private sector comprises the Not-For-Profit (PNFP) and For-Profit healthcare providers (PFP) that follow a similar tiered system like the public sector. The health facilities are located throughout the country and are within 5 kilometers of the majority of the population. HIV/AIDS services are provided by all the health facilities in Uganda from the level of hospitals to HC III. The government is working to roll-out services to HCIIIs to reduce the distance to the nearest ART accredited sites and provide eMTCT services to more pregnant women.

Supply Chain System in Uganda

The supply chain management system for ART in Uganda initially followed a Push & Pull system¹⁶. The upper level health centers (hospitals and HC IVs) ordered medical commodities including HIV drugs based on estimated historical usage and an already set resource envelope (Pull system). On the other hand lower levels facilities (HC III & II) received a fixed set of drugs (Push system) and medical commodities specified under the minimum healthcare package set by the Ministry of Health. However, specific to HIV/AIDS service delivery, HC IIIs are currently mandated to quantify and order HIV commodities, including ARV drugs, following a bimonthly

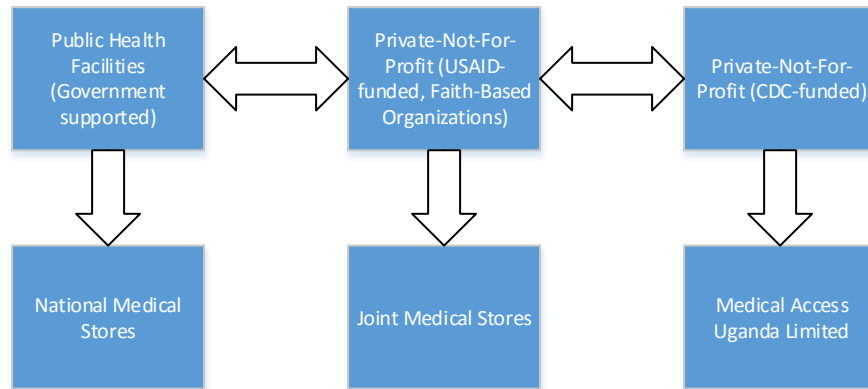
schedule. This was not the situation before changes were made to HIV service delivery. Figure 1 illustrates the evolution of ARV supply chain management and the changes made to the system to address the challenges and ensure ARVs are consistently available.

Figure 1: Evolution of ARV supply chain management in Uganda



There are currently three main warehouses in the supply chain system. These are the intermediaries between manufacturers, importers, distributors, wholesalers of medicines and medical products. These are National Medical Stores (NMS), Joint Medical Stores (JMS) and Medical Access (MA) that cater to the procurement needs of public, PNFP and PFP healthcare providers respectively.

Figure 2: The current flow chart of supply chain agencies



Government-supported health facilities (the main focus of this study) compile usage reports and submit orders to NMS every two months. Hospitals may order more frequently due to high volumes. Order quantities are determined by number of patients treated during the reporting period, in addition to quantities and regimens of drugs dispensed. ARV procurement and supplies runs through standard NMS processes such as bimonthly essential drug delivery as well as parallel processes set up for ARVs. The reporting and ordering of supplies was initially done manually, which in addition to lack of staff trained in logistics management, contributed to the challenges that plagued the supply chain for medicines and medical products. A 2011 health system assessment conducted with USAID funding, reported the lack of a reliable quantification system, problems of poor stock control and poor store management practices. Other challenges were poor dispensing practices, poorly maintained information management tools and records, the lack of harmonization, and the lack of streamlined operations¹⁷. These are some of the challenges plaguing the management of medicines and medical products in Uganda.

In an effort to address the above mentioned challenges there was a push for web-based ordering. This new system is an online ARV and PMTCT medicines reporting and ordering system.

This has helped address delays in reporting which affected the ordering of supplies and led to stock-outs, under- and over-supplies of ARV drugs. The health facility in-charges compile reports, quantify the facility needs and write up an order. The report and order form is then taken to the district logistics focal person who enters the information online and submits the orders to National Medical Stores (NMS).

Whereas at district level, the reporting and ordering is done online, there are still facility-level challenges where paper-based documentation is still in effect. The new system (web-based ordering) is also not without challenges. These include training of healthcare providers, lack of computers and internet services at the health facilities and lack of electricity or power outages in many health facilities, especially upcountry ones.

Treatment outcomes for pregnant women and exposed infants are affected by stock outs and can result in the development of drug resistance. While on the other hand, excess supplies may lead to drug expiration and wasted resources. Literature shows that patients are told to buy drugs (in general) from private pharmacies or drug shops during times of stock-outs at the health facilities¹⁶. Specific to ARVS, during times of stock-outs, health facilities are encouraged to borrow (make negative/positive adjustments) from other health facilities (Annual Health Sector Performance Report Uganda, 2013). Sometimes there is delayed initiation of new patients on ART. This leads to treatment interruptions all of which affect the patient's treatment cycle and eventually the overall health outcomes. Other times patients may be referred to another health facility that has an ART clinic. Whether the patient is able to go to the referred site, is another challenge faced. Furthermore there is no guarantee that the drugs will be available at the referral center or that the patient has transport means to get there.

Baylor College of Medicine Children’s Foundation-Uganda (Baylor-Uganda)

Baylor College of Medicine Children’s Foundation-Uganda (Baylor – Uganda) where the study will be conducted is at the forefront of HIV/AIDS service delivery in Uganda. It is one of the organizations implementing the countrywide roll-out of the new World Health Organization (WHO) treatment guidelines for people living with HIV/AIDS. Uganda, one of the East African countries, has a population of 34.9 million people, who are served by 5229 health facilities (Uganda Bureau of Statistics Statistical Abstract 2014). Over 1500 of these healthcare facilities provide ART services. Baylor – Uganda Centre of Excellence is the largest pediatric HIV/AIDS clinic in Uganda and Africa. It is a not-for-profit, non-governmental organization that provides pediatric and family HIV&AIDS prevention, care and treatment services, health professional training and clinical research. It is part of the Baylor International Pediatric HIV/AIDS Initiative (BIPAI) network. With funding from the US government through the Presidential Emergency Plan for AIDS Relief (PEPFAR), UNICEF and others, the organization has five regional offices. These five regional offices are in in Kampala (Central Uganda), Soroti (Eastern Uganda), Arua (West-Nile), Fort Portal (Rwenzori region) and Moroto (Karamoja). The organization, currently supports 543 health facilities in 30 districts countrywide to improve HIV service delivery in district health facilities and hospitals.

ARV logistics management is one of the focus areas for the organization in order to ensure consistent availability of ARVs and related commodities. The program involves training of health workers (onsite and offsite), mentorship and support supervision, provision of data tools including computers and modems for internet connectivity and provision of a buffer stock in times of low supplies or stock outs. Baylor-Uganda started providing technical support for ARV

logistics management before web-based ordering was introduced and supports health facilities using both manual and web-based systems.

Figure 3: Baylor-Uganda Project Areas



Eastern Uganda

The proposed study will be conducted in eastern Uganda, one of the Baylor-Uganda regional project areas. Baylor-Uganda has been in this region since 2006 and is the main implementing partner on health systems strengthening for comprehensive HIV/AIDS care/treatment services. Baylor-Uganda began by integrating pediatric HIV care and treatment in to existing health systems in 2006. It started with three health facilities in two districts with emphasis on rural underserved health facilities with a high prevalence of HIV/AIDS infections. Over the last 10 years this support has evolved into systems strengthening and has expanded to more than a hundred health facilities in eight districts. The districts are Soroti, Amuria, Kumi, Bukedea, Serere, Ngora, Kaberamaido and Katakwi districts. The 113 supported health facilities comprise both government-funded health facilities and private-not-for-profit health facilities. These include four general hospitals, eleven health center IVs (HCIV), sixty health center IIIs (HCIII) and thirty eight health center IIs (HCII). To support the roll-out of the new WHO treatment guidelines, the organization started training health facilities in ARV logistics management in 2012 and 2013. This was to ensure a consistent supply of ARVs and reduce treatment interruptions, if any, that would affect health outcomes of pregnant women and exposed infants.

PUBLIC HEALTH SIGNIFICANCE AND CONTRIBUTION OF THE CURRENT STUDY

HIV/AIDS is still a serious public health threat in Sub-Saharan Africa and Uganda. The number of people receiving ART continues to grow. This is a result of the continued global effort to fight HIV/AIDS, overcome barriers to ART and ensure that drugs are available to those infected with the virus. The WHO reported an increase from 10 million in 2012 to 12 million people receiving ARVs for treatment by the end of 2013 in low and middle income countries¹. Maintaining uninterrupted supplies of ARV drugs and preventing stock-outs is still a major challenge. Uganda, like other developing countries, has struggled to ensure an adequate and consistent supply of ARVs. The global HIV agencies have reported this as threat to achieving the MDG of eliminating HIV among children and reduce maternal death. Drug stock outs discourage treatment uptake, weaken adherence and hinder program effectiveness. They also lead to delays in starting ART for HIV positive pregnant women thereby exposing the babies to HIV infection. Stock outs also affect reduction of HIV infection in the population as a whole.

Several studies¹⁶⁻²⁰ have been conducted on ARV procurement and supply chain management in sub-Saharan Africa. However in Uganda, research in this area is still limited. Most of the available literature^{8, 21-23} in Uganda is on the efficacy of the treatment regimens on the prevention of mother-to-child transmission of HIV. Baylor-Uganda has also conducted several HIV-related studies, both clinical and operational^{22, 24, 25}. Furthermore Uganda, like other developing countries, is constrained by the availability of reliable data sources for research. It is important therefore to conduct a feasibility/pilot study to understand and estimate the parameters needed to design a larger study²⁶.

This feasibility/pilot study will be the first of its kind at Baylor-Uganda – no intervention effectiveness studies specific to the ARV logistics management program have been conducted. In addition, it will provide a foundation for future research, offering information needed to run formal tests and determine whether data on important variables can be collected. This study will also provide the effect size needed to estimate the sample size for a larger intervention effectiveness study which has a very high public health significance. The hope is that study findings will inform planning and decision making processes for Baylor-Uganda to consolidate and sustain the improvements made in HIV service delivery. It is also hoped the findings will contribute to knowledge on ARV logistics management in the organization and be a source of information for policy makers at the national level to improve HIV/AIDS service delivery in the country.

RESEARCH OBJECTIVES

As the number of people receiving ART continues to grow, the need to strengthen supply chain systems also grows. An inconsistent supply of drugs can lead to treatment disruptions, discourage treatment uptake, weaken adherence and hinder program effectiveness. It may subsequently cause drug resistance among patients and fail to reduce HIV transmission in the population. Uganda as a country still struggles with ensuring that ARV drugs and related commodities are available in the health facilities at the right time and in the right quantities.

As part of its systems strengthening program, Baylor-Uganda provided technical support in ARV logistics management to more than 400 supported health facilities. This effort was aimed at improving service delivery and ensuring HIV-positive pregnant women and exposed infants got the drugs they needed to survive. The performance of the health facilities also impacted the organization's goals and targets and had implications on its funding. Despite the interventions, there were still challenges with the management of ARV logistics including availability of data.

The proposed study sought to assess the feasibility of evaluating the impact of the ARV logistics management program and provide feedback for future interventions in Baylor-Uganda supported health facilities. The study also involved collection of pilot data to assess and estimate the impact of the ARV logistics management program for a small sample of health facilities.

Research Objectives

The study aimed to answer the general questions: Can an intervention effectiveness study on the ARV logistics management program and HIV/AIDS management services be done? What sources of data and key personnel are available to conduct such a study? How did the ARV logistics

management program affect starting ART for mothers and exposed infants? How did the program impact reporting and ordering of HIV commodities from the national supply chain agencies?

Specific objectives:

The specific objectives were:

1. To assess the availability and quality of documents, key informants and data sources on ARV logistics in Baylor-Uganda supported health facilities in the eastern region.
2. To describe and examine factors affecting ARV logistics management in Baylor-Uganda supported health facilities in the eastern region.
3. To assess the effect of the ARV logistics management program on submission of complete and correct ARV order forms in Baylor-Uganda supported health facilities in the eastern region.
4. To assess the effect of the ARV logistics management program on starting ART treatment for HIV-positive pregnant women and exposed infants in Baylor-Uganda supported health facilities in the eastern region.

METHODS:

Study Design

The proposed study design was a feasibility/pilot study to estimate the parameters needed to design a larger intervention effectiveness study and determine whether examining the listed study objectives could be done. In line with previous studies, this study tested the processes, resources, management and scientific basis of the planned study²⁶. The researcher reviewed pre-existing data and conducted key informant interviews. A single group time difference method was used to analyze data a year before the program initiation (pre-period) and compared that with data a year after the program initiation (post period). The researcher determined the date of initiation of the ARV logistics program in each health facility. Data on all variables was collected for 12 months, which ended thirty days prior to the initiation date (pre-period) and was compared to the 12 months data collected thirty days after the initiation date (post period). This included health facility characteristics, number of HIV-positive pregnant women and exposed infants started on ART, and health facility report and order forms.

Study Setting

This study was conducted among twenty five (25) health facilities supported by Baylor-Uganda in the eastern region. These included hospitals, health center IVs and health center IIIs that are both government-funded and private-not-for-profit health facilities.

Study Population

This study examined twenty five health facilities and key informant interviews. The researcher used a convenience sample of 25 health facilities that was stratified into the three levels of hospitals, HC IVs and HC IIIs. The sample included 4 hospitals, 11 Health Centre IVs and

10 HC IIIs. Only the facilities that had been accredited to provide ART services were included in the study.

Data Collection

Facility-level data was collected from existing data that was collected by Baylor-Uganda staff. Data on all the variables (see Appendix 1) was collected for each health facility for the pre and post period. The data included descriptive health facility characteristics, information on ARV logistics reporting and ordering, and the number of HIV-positive pregnant women and exposed infants started on ART treatment. Key informant interviews among a select sample of the health facilities, district health officials and Baylor-Uganda technical staff were also conducted to understand the current status of the program, challenges and suggestions.

Data Analysis

The data was organized in a spreadsheet and analyzed using Excel and STATA software. Basic descriptive statistics such as frequencies and t-tests were used to analyze the data and make comparisons before the intervention and the current situation. Comparisons among the different level health facilities were made. Relationships between variables were explored and factors affecting the ARV logistics management at health facility level were identified. Finally, responses from key informant interviews were summarized.

Each of the objectives were analyzed as follows:

- 1. To assess the availability and quality of documents, key informants and data sources on ARV logistics in Baylor-Uganda supported health facilities in the eastern region.**

Data on important parameters for designing a future study were collected. The focus was on answering the following questions:

1. Who were the right people to talk to about the challenges faced in implementing the ARV logistics management program, future steps and recommendations?
2. Did records exist at both pre and post time periods to capture clinic-level descriptive information (e.g. type of facility, geographical location of health facility, type of staffing, staffing numbers, and patient volume)?
3. Did records and forms exist at both the pre and post time periods to capture outcome variables such as proportion of pregnant women and children treated, degree of completeness and correctness of the report/order forms?
4. Did the records/forms/other sources of information vary between pre and post period?
5. Could the researcher successfully determine the starting point/date of the ARV logistic management intervention in each clinic/facility?
6. Was the initiation of training of at least one person in each clinic/facility the best indicator for intervention initiation?
7. What was the effect size for each of the outcomes mentioned in the last two objectives for the data collected during the feasibility/pilot study?

In addition to answering the above questions, the researcher sought to determine whether examining the three objectives listed below could be done.

- 2. To describe and examine the factors affecting logistics management in Baylor-Uganda supported health facilities in the eastern region**

Data on the descriptive characteristics of the health facilities was collected. These included the type, staffing, location, and size of the health facility. In addition, information on training dates, duration of mentorship and technical support (in months) was obtained. This also included the number and cadre of staff trained. The Baylor-Uganda technical support team and a sample of health facility in-charges were interviewed. Challenges that the health facilities were facing with the logistic management program were identified. Future steps and recommendations were also obtained and these will be used to inform future ARV logistics systems strengthening programs. A question guide (see Appendix 2) was used for the interviews in addition to reviewing the mentorship and support supervision reports.

3. To assess the effect of the logistics management program on submission of complete and correct ARV order forms in Baylor-Uganda supported health facilities in the eastern region.

Copies of bimonthly orders vis-à-vis the ordering schedule to assess timeliness of report and order forms were reviewed. Health facilities submit reports and order forms following a schedule that is provided by the supply chain agency at the beginning of each fiscal year. The forms were assessed for completeness and correctness. A form was considered complete and correct if all the parameters relevant to the health facility were filled, and if when compared, all parts of reporting and ordering tallied. Data on the supplies received from NMS, stock outs and specific drugs that were stocked out were also analyzed for improvements in stock supplies and management in general. This data was compared to the number of pregnant women and exposed infants initiated on ART to identify trends, if any.

4. To assess the effect of logistics management program on starting ART treatment for HIV-positive pregnant women and exposed infants in Baylor-Uganda supported health facilities in the eastern region

To answer this question quantitative health facility-level data on HIV-positive pregnant women and exposed infants identified and started on treatment was analyzed. This data was abstracted from existing monthly and quarterly reports that are submitted to Baylor-Uganda and Ministry of Health. The data was not limited to number of patients tested for HIV, number of patients that tested positive and the number of patients started on ART according to the new ART guidelines. It also included common ARV regimens used and OI drugs dispensed to the patients. Rates and trends in starting ART treatment in supported health facilities were analyzed. We sought to examine the relationship between the treatment numbers and periods of stock-outs or low supplies for the study population.

Human Subjects, Animal Subjects, and/or Safety Considerations

Permission was sought from the University of Texas Health Science Center at Houston Institutional Review Board, Baylor College of Medicine Institutional Review Board, Uganda National Council of Science and Technology, Mengo Hospital Research Committee (local IRB). Permission was also be sought from the management at Baylor-Uganda. There was no direct contact with patients nor will the names of the health facilities involved be made public. The dataset was encrypted and stored securely. Upon completion of the study and publication of the results, all data capture tools and related documents will be disposed of in accordance with the policies and procedures of Baylor-Uganda and University of Texas Health Science Center at Houston.

RESULTS

Twenty five health facilities in Eastern Uganda were evaluated. Twenty-four out of 25 health facilities had data on most of the variables in the data collection tool. One health facility did not have data at all. These results are based on the 24 health facilities that had data.

Table 1: Number of health facilities surveyed

| Type of health facility | Number surveyed | Had records | Did not have records |
|--------------------------------|------------------------|--------------------|-----------------------------|
| Hospital | 4 | 3 | 1 |
| HC IV | 11 | 11 | 0 |
| HC III | 10 | 10 | 0 |
| Total | 25 | 24 | 1 |

AVAILABILITY AND QUALITY OF DOCUMENTS, KEY INFORMANTS AND DATA SOURCES

At organization level, the right people to talk to about the challenges faced in implementing the ARV logistics management program, future steps and recommendations are the Baylor-Uganda regional and cluster medical logistics officers, the pharmacy manager and coordinator. At district level these include the district stores assistants, district biostatisticians and medicine supervisors. At the health facility, health facility in-charges, ART clinic in-charges, midwives, stores assistants and dispensers would have the information needed for this program.

All the respondent health facilities captured clinic level descriptive information in the monthly and quarterly Health Management Information System (HMIS) reports. These records exist for both the pre and post intervention periods. These include type of facility, geographical location, staffing numbers and patient volumes among others. These reports are submitted to the district and the Ministry of Health on a monthly and quarterly basis. Manual records exist for the period prior to 2013. In 2013 the district health information system (DHIS 2) was introduced and web-

based reporting was rolled out at district level. This online database however has data for more recent years. On the other hand, records that capture outcome variables such as proportion of pregnant women and children treated, completeness of order forms could not be easily found especially for the period 2010 to 2012. The records had either been misplaced or there were no copies at the health facility. These records may be available at the district, MOH and NMS but at the health facilities, storage of older records seems to be a challenge.

There is variation in the records and sources of information for both the pre and post intervention periods. The ARV ordering forms have been revised four times in the last 10 years, to remove idle items like D4T which is no longer on the essential medicines list. New medicines and regimens have also been added. The ART and PMTCT registers, appointment books, stock cards, to mention a few, have also been revised in line with new treatment guidelines. With the new revisions, some of the older records could not be found. Also there is attrition and regular transfers of healthcare workers. Therefore finding a key informant at facility level was a challenge. This is further compounded by poor storage of records.

It is assumed that training of a healthcare worker is the start point of this program. After the training, subsequent mentorship and support supervision visits, the healthcare worker would pass on the knowledge and skills to others in the facility. This would in turn improve logistics management at the facility, not just for ARVs but for other medical commodities as well. This was affected, however, by the choice of trainee and staff attrition.

Although training dates for each of the health facilities in the study were successfully determined, the start point of the program in all of them could not be determined. Baylor-Uganda had started supporting them in ARV logistics before the training was conducted. The organization also conducted mobile HIV clinics in some of the HFs that had not been accredited and managed the ARVs for those clinics.

Another assumption was that the trainees were able to compile report/order forms correctly, completely and on time, in addition to monitoring stock levels and quantify correctly. Therefore initiation of training of at least one person in a health facility was considered the best indicator. This is not so because of the challenges mentioned in the previous paragraph.

FACTORS AFFECTING ARV LOGISTICS MANAGEMENT

Health Facility Characteristics

The researcher collected data on descriptive characteristics of 24 health facilities as summarized in Table 2. The target patient population ranged from 9231 to 38200¹.

Average target population for the HIV clinic was

| Type | Target Population | Patient Enrolled |
|-------------|--------------------------|-------------------------|
| • Hospitals | 1379 | 3561 - 3955 |
| • HCIVs | 1067 | 831 - 1231 |
| • HC IIIs | 1073 | 134 - 221 |

¹ Based on 2002 Population Census projections

The number of patients enrolled in the HIV clinic increased in the post intervention period. Staff from the supported facilities were trained in August 2011, November 2012 and September 2013. Baylor-Uganda has supported these facilities in ARV logistics management for an average of 37.4 months.

Table 2: Patient population and ARV training characteristics

| Facility Name | District | Target Population | | Target Population HIV clinic | | Patients enrolled | | Date of ARV training | Type of ARV training ² | Duration of ARV logistics mgmt. support (months) | Received mentors hip visits | Received Technical Support Supervision visits |
|-----------------------|-------------|-------------------|----------------|------------------------------|---------------|-------------------|---------------|----------------------|-----------------------------------|--|-----------------------------|---|
| | | Pre | Post | Pre | Post | Pre | Post | | | | | |
| Hospitals | | | | | | | | | | | | |
| Lwala | Kaberamaido | | 14521 | | 770 | 1750 | 2300 | 08/08/11 | M | 47 | Yes | Yes |
| Katakwi | Katakwi | 24500 | 28525 | 1298 | 1512 | 5768 | 6079 | 09/02/13 | M&W | 34 | Yes | Yes |
| Atatur | Kumi | 33500 | 35006 | 1776 | 1855 | 3167 | 3487 | 09/02/13 | M&W | 34 | Yes | Yes |
| Hosp Average | | | 26017.3 | | 1379.0 | 3561.7 | 3955.3 | | | | | |
| HC IV | | | | | | | | | | | | |
| Kapelebyong | Amuria | | 22100 | | 1643 | 132 | 615 | 08/08/11 | M&W | 47 | Yes | Yes |
| Amuria | Amuria | | 11900 | | 631 | 1494 | 1773 | 09/02/13 | M&W | 34 | Yes | Yes |
| Bukedea | Bukedea | | 38200 | | 1643 | 452 | 1343 | 08/08/11 | M&W | 47 | Yes | Yes |
| Kaberamaido | Kaberamaido | | 16814 | | 891 | 3775 | 4257 | 08/08/11 | M&W | 47 | Yes | Yes |
| Toroma | Katakwi | | 15200 | | 805 | 464 | 706 | 11/19/12 | M&W | 31 | Yes | Yes |
| Kumi | Kumi | 35800 | 36447 | 1897 | 1932 | 466 | 758 | 09/02/13 | M&W | 34 | Yes | Yes |
| Ngora | Ngora | | 20109 | | 1066 | 100 | 165 | 09/02/13 | M&W | 34 | Yes | Yes |
| Apapai | Serere | | 15852 | | 840 | 162 | 366 | 08/08/11 | M&W | 47 | Yes | Yes |
| Serere | Serere | | 24466 | | 1297 | 1861 | 2790 | 09/02/13 | M&W | 34 | Yes | Yes |
| Princess Diana | Soroti | | 9557 | | 507 | 167 | 545 | 08/08/11 | M&W | 47 | Yes | Yes |
| Tiriri | Soroti | | 9231 | | 489 | 68 | 231 | 08/08/11 | M&W | 47 | Yes | Yes |
| HC IV Average | | | 19988.7 | | 1067.6 | 831.0 | 1231.7 | | | | | |
| HC III | | | | | | | | | | | | |
| Wera | Amuria | | 38200 | | 2025 | 132 | 222 | 09/02/13 | M&W | 34 | Yes | Yes |
| Kabarwa | Bukedea | | 17200 | | 740 | 107 | 250 | 09/02/13 | W | 34 | Yes | Yes |
| Kidongole | Bukedea | 25900 | 26357 | 1113 | 1133 | 33 | 63 | 09/02/13 | M&W | 34 | Yes | Yes |
| Ochero | Kaberamaido | | 21855 | | 1158 | 429 | 547 | 09/02/13 | M&W | 34 | Yes | Yes |
| Kapujan | Katakwi | 25900 | 26357 | 754 | 779 | 76 | 119 | 09/02/13 | M&W | 34 | Yes | Yes |
| Nyero | Kumi | | 14003 | | 742 | 209 | 300 | 11/19/12 | M&W | 31 | Yes | Yes |
| Kobwin | Ngora | | 20021 | | 861 | 113 | 201 | 11/19/12 | M&W | 31 | Yes | Yes |
| Pingire | Serere | | 27476 | | 1456 | 205 | 311 | 09/02/13 | M&W | 34 | Yes | Yes |
| Tubur | Soroti | | 25353 | | 1334 | 18 | 86 | 09/02/13 | M&W | 34 | Yes | Yes |
| Soroti | Soroti | | 9557 | | 507 | 18 | 111 | 09/02/13 | M&W | 34 | Yes | Yes |
| HC III Average | | | 22637.9 | | 1073.5 | 134 | 221 | | | | | |

The health facilities have more than 70% of the required staff. These are listed by cadre in Table 3. However the HC IVs and HC IIIs reported more staff than are required in the staffing norms.

² M refers to manual logistics training. W refers to web-based logistics training

| Type | Approved | Staff levels |
|------------|----------|-----------------------------------|
| • Hospital | 162 | 120 healthcare workers (74.07%) |
| • HC IV | 41 | 56.3 healthcare workers (148.09%) |
| • HC III | 15 | 23.8 healthcare workers (158.67%) |

The number of medical officers in the hospitals on average is 18.6% (pre-period) and 28.6% (post period), which is less than the seven (7) that are required. The HC IVs are missing key staff like medical officers. Only 36.4% HCIVs had medical officers in the pre-period and 54.5% had medical doctors in the post period.

Regarding the HIV clinic, staff are allocated to the clinic on a rotational basis. None of the facilities surveyed had specific staff allocated to the HIV clinic only. They have other roles and only serve in the HIV clinic on designated clinic days. The minimum staff required to run the clinic include a clinician (medical officer or clinical officer), a nurse or midwife, laboratory personnel and someone to dispense drugs.

Table 3: Type and number of healthcare workers by cadre in the entire health facility and in the HIV clinic

| | Total Number of health workers in the HF | | | | | | Number of health workers in the HIV clinic | | | | | |
|----------------------------------|--|------------|--------------|-----------|----------------|-----------|--|----------|--------------|-----------|----------------|----------|
| | Hospital (n=3) (Number, Average) | | HC IV (n=11) | | HC IIII (n=10) | | Hospital (n=3) | | HC IV (n=11) | | HC IIII (n=10) | |
| | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post |
| <i>Medical officer</i> | 4 (1.33) | 6 (2.00) | 5 (0.45) | 8 (0.73) | | | 3(1.0) | 3(1.0) | 5(0.45) | 6(0.55) | | |
| <i>Dental Officer</i> | 2(0.67) | 3 (1.00) | 2 (0.18) | 5 (0.45) | | | | | | | | |
| <i>Pharmacist</i> | 1 (0.33) | 2 (0.67) | | | | | 1 (0.33) | 1 (0.33) | | | | |
| <i>Dispenser</i> | 2 (0.67) | 2 (0.67) | 1 (0.09) | 2 (0.18) | | | 2 (0.67) | 2 (0.67) | 1 (0.09) | 2(0.18) | | |
| <i>Orthopedic officer</i> | 2 (0.67) | 1 (0.33) | | | | | | | | | | |
| <i>Anesthetic officers</i> | 4 (1.33) | 5 (1.67) | 1 (0.09) | 1 (0.09) | | | | | | | | |
| <i>Clinical Officer</i> | 11 (3.67) | 18 (6.00) | 29 (2.64) | 29 (2.64) | 13 (1.30) | 16 (1.60) | 3(1.0) | 3(1.0) | 10 (0.91) | 11(1.00) | 10(1.00) | 10(1.00) |
| <i>Nursing Officer</i> | 12 (4.00) | 16 (5.33) | 26 (2.36) | 34 (3.09) | 10 (1.00) | 12 (1.20) | 3(1.0) | 3(1.0) | 11(1.00) | 10 (0.91) | 9 (0.90) | 9 (0.90) |
| <i>Nurse</i> | 38 (12.67) | 38 (12.67) | 64 (5.82) | 78 (7.09) | 24 (2.40) | 23 (2.30) | 3(1.0) | 3(1.0) | 11(1.00) | 11(1.00) | 10(1.00) | 10(1.00) |
| <i>Midwives</i> | 25 (8.33) | 24 (8.00) | 38 (3.45) | 45 (4.09) | 18 (1.80) | 18 (1.80) | 3(1.0) | 3(1.0) | 10 (0.91) | 10 (0.91) | 9 (0.90) | 10(1.00) |
| <i>Nursing assistant</i> | 39 (13.00) | 39 (13.00) | 36 (3.27) | 33 (3.00) | 21 (2.10) | 14 (1.40) | 3(1.0) | 3(1.0) | 11(1.00) | 11(1.00) | 10(1.00) | 10(1.00) |
| <i>Lab Technologist</i> | 0(0.00) | 2(0.67) | 0(0.00) | 1(0.09) | | | 0(0.00) | 0(0.00) | 0(0.00) | 0(0.00) | | |
| <i>Lab technician</i> | 4(1.33) | 6(2.00) | 13 (1.18) | 12 (1.09) | 6 (0.60) | 9 (0.90) | 2(0.67) | 2(0.67) | 9 (0.82) | 9 (0.82) | 6 (0.60) | 8 (0.80) |
| <i>Lab assistant</i> | 5(1.67) | 4(1.33) | 19 (1.73) | 19 (1.73) | 9 (0.90) | 8 (0.80) | 3 (1.00) | 3 (1.00) | 10 (0.91) | 11 (1.00) | 9 (0.90) | 8 (0.80) |
| <i>Anesthetic assistant</i> | 1(0.33) | 2(0.67) | 4 (0.36) | 5 (0.45) | | | | | | | | |
| <i>Theatre assistant</i> | 2(0.67) | 1(0.33) | 7 (0.64) | 8 (0.73) | | | | | | | | |
| <i>Cold chain assistant</i> | | | | 3 (0.27) | | | | | | | | |
| <i>Health educator</i> | 3(1.00) | 2(0.67) | 4 (0.36) | 5 (0.45) | | | | | | | | |
| <i>Health inspector</i> | 4(1.33) | 4(1.33) | 10 (0.91) | 10 (0.91) | | | | | | | | |
| <i>Health assistant</i> | 3(1.00) | 3(1.00) | 7 (0.64) | 8 (0.73) | 9 (0.90) | 9 (0.90) | | | | | | |
| <i>Stores assistant</i> | 3(1.00) | 3(1.00) | 6 (0.55) | 9 (0.82) | | | | | | | | |
| <i>Medical records assistant</i> | 6 (2.00) | 8 (2.70) | 14 (1.21) | 18 (1.64) | 9 (0.90) | 10 (1.00) | 3 (1.00) | 3 (1.00) | 9 (0.82) | 11 (1.00) | 8 (0.80) | 9 (0.90) |

Baylor-Uganda trained healthcare workers from each facility in ARV logistics management (see Tables 4&5). This was either manual or web-based ordering or both. All HFs have been trained in web-based ordering which was rolled out in 2013 for all HFs to use. A total of 44 healthcare workers were trained in manual ARV logistics management and 39 health care workers were trained in web-based reporting and ordering of ARVs. Laboratory assistants, stores assistants and records assistants were the biggest number of staff that were trained.

Table 4: Number of healthcare workers trained in ARV logistic management

| | Medical officer | Pharmacist | Dispenser | Clinical Officer | Nursing Officer | Nurse | Midwives | Nursing assistants | Lab Technologist | Lab technician | Lab assistant | Stores Assistant | MRA |
|-----------------------|--|------------|-----------|------------------|-----------------|-------|----------|--------------------|------------------|----------------|---------------|------------------|-----|
| Facility Type | Number of health workers trained in ARV logistics by Cadre | | | | | | | | | | | | |
| <i>Hospital (n=3)</i> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 2 | 1 | 0 |
| <i>HC IV (n=11)</i> | 0 | | 2 | 3 | 3 | 0 | 0 | 0 | 0 | 2 | 3 | 7 | 5 |
| <i>HC IIII (n=10)</i> | | | | 0 | 2 | 2 | 1 | 1 | 0 | 3 | 5 | 0 | 0 |
| | Number of health workers trained in web based ordering by cadre | | | | | | | | | | | | |
| <i>Hospital (n=3)</i> | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| <i>HC IV (n=11)</i> | 0 | | 2 | 1 | 2 | | 0 | 0 | 0 | 2 | 3 | 7 | 6 |
| <i>HC IIII (n=10)</i> | | | | 2 | 1 | 0 | 1 | 1 | 0 | 1 | 5 | 0 | 1 |

Table 5: Number of healthcare workers trained by type of training

| Cadre | Number of staff trained (%) | |
|-----------------------|-----------------------------|-------------------|
| | Manual (n =44) | Web – based(n=39) |
| Clinical Officer | 3 (6.82%) | 4 (10.26%) |
| Nursing Officer | 5 (11.36%) | 3 (7.69%) |
| Nurse | 2 (4.55%) | 0 (0.00%) |
| Midwife | 1 (2.27%) | 1 (2.56%) |
| Nursing Assistant | 2 (4.55%) | 1 (2.56%) |
| Dispenser | 2 (4.55%) | 2 (5.13%) |
| Laboratory Technician | 6 (13.64%) | 4 (10.26%) |
| Laboratory Assistant | 10 (22.73%) | 8 (20.51%) |
| Stores Assistant | 8 (18.18%) | 8 (20.51%) |
| Records Assistant | 5 (11.36%) | 8 (20.51%) |

Thirty one (31) key informants were also interviewed. These included the Baylor-Uganda Pharmacy manager, the Regional Medical Logistics Officer, health facility In-Charges, stores assistants and health workers in charge of stores at the surveyed health facilities. Table 6 gives a summary of the responses to the questions in Appendix 2.

Table 6: Responses to the interview questions (n=21)

| Question | Hospital | | HC IV | | HC III | |
|---|------------------------|--|------------------------|--|------------------------|--|
| | Total number responded | Total number with affirmative response (%) | Total number responded | Total number with affirmative response (%) | Total number responded | Total number with affirmative response (%) |
| <i>Are health facilities submitting orders on time</i> | 3 | 3 (100%) | 10 | 10 (100%) | 8 | 8 (100%) |
| <i>Are health facilities receiving orders as ordered</i> | 3 | 1 (33%) | 10 | 3 (30%) | 8 | 4 (50%) |
| <i>Did health facilities report a stock-out of ARVS in the past 1 year</i> | 3 | 1 (33%) | 10 | 5 (50%) | 8 | 6 (75%) |
| <i>Did stock outs affect treatment for pregnant women and exposed infants</i> | 3 | 0 (0%) | 10 | 1 (10%) | 8 | 4(50%) |

- All 21 health facilities that responded to the questions are submitting order forms on time.
- Only 8 (38 %) of the health facilities reported that they received supplies as ordered.
- More than half (57%) of the health facilities experienced a stock out of at least one ARV drug in the last one year.
- Five (23.8%) health facilities reported that the stock out affected treatment of HIV positive pregnant women and their exposed infants. Sixteen health facilities borrowed ARVs from other health facilities to cover the drug shortages.

The factors that affect ARV logistics management in the Baylor-Uganda supported health facilities were examined. These are summarized in Figure 4 and include incorrect quantification of drugs, supplies that were not delivered as ordered, delayed deliveries and shortage of healthcare workers to mention a few.

Figure 4: Factors affecting ARV Logistics Management (n=21)

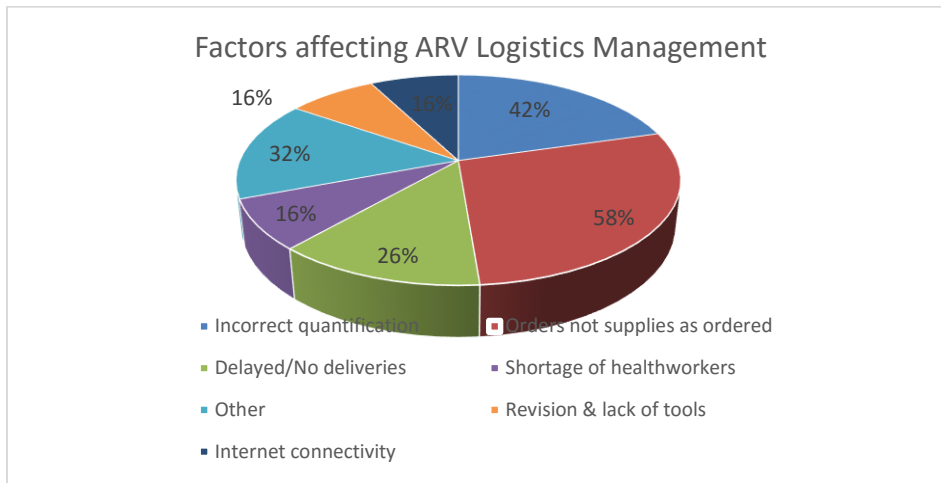


Table 7 shows the future steps and recommendations given by the respondents that can be used to inform future programs.

Table 7: Challenges faced by HFs and proposed recommendations

| Challenges | # of HFs (%) | Recommendations |
|--|--------------------------|---|
| Supplies are not delivered by NMS as ordered | Reported by 11 HFs (58%) | <ul style="list-style-type: none"> NMS should ensure that supplies delivered tally with the order form |
| Incorrect quantification | Reported 8 HFs (42%) | <ul style="list-style-type: none"> Train more healthcare workers in ARV logistics Train district biostatisticians to crosscheck that reports and orders tally and are correct |
| Delayed/Supplies not delivered | Reported by 5 HFs (58%) | <ul style="list-style-type: none"> NMS should endeavor to deliver supplies as per schedule |
| Shortage of healthcare workers | Reported by 3 HFs (16%) | <ul style="list-style-type: none"> Recruit and train stores assistants in ARV ordering and quantification |
| Revision/lack of tools | Reported by 3 HFs (16%) | <ul style="list-style-type: none"> Provide the revised tools and train staff to use them |
| Lack of internet connectivity | Reported by 3 HFs (16%) | <ul style="list-style-type: none"> Provide modems to healthcare workers that are involved in ordering of supplies |

| Challenges | # of HFs (%) | Recommendations |
|---|-------------------------|--|
| Other (lack of communication, data entry mistakes, expired drugs, inadequate storage) | Reported by 6 HFs (32%) | <ul style="list-style-type: none"> • Provide HWs access to the WAOS • Improve communication among dispensing points, stores and records personnel at the time of ordering • Continuous mentorship and technical support supervision • Construct stores |

SUBMISSION OF COMPLETE AND CORRECT ARV ORDER FORMS

ARV reports and order forms for 24 health facilities were reviewed. For some health facilities whose pre-intervention period was earlier than 2012, the forms were not available. Some HC IIIs that were accredited to offer ART services in 2013 did not have ARV order forms because they had not started offering ART services. HIV positive mothers and infants were referred to the nearest accredited site for ART.

The number of HFs that submitted order forms to NMS increased in the post period. However not all the health facilities that submitted forms were able to complete them as required (i.e. all the relevant information had been filled).

Table 8: Health facilities that had complete ARV order forms

| Reporting Period | Number of Health facilities that had complete order forms | | | | df | T-test | P-Value |
|--------------------|---|-------------------|--------------------------|--------------------|------------|---------------|--------------|
| | Pre-intervention | | Post intervention | | | | |
| | Total # orders submitted | Complete | Total # orders submitted | Complete | | | |
| Reporting period 1 | 7 | 2 (0.286) | 23 | 15 (0.652) | 28 | -1.743 | 0.092 |
| Reporting period 2 | 9 | 4 (0.444) | 23 | 19 (0.826) | 30 | -2.262 | 0.031 |
| Reporting period 3 | 13 | 5 (0.385) | 23 | 20 (0.869) | 34 | -3.417 | 0.002 |
| Reporting period 4 | 6 | 3 (0.5) | 21 | 21 (1) | 25 | -4.409 | 0.0002 |
| Reporting period 5 | 15 | 8 (0.533) | 23 | 19 (0.826) | 36 | -1.995 | 0.054 |
| Reporting period 6 | 11 | 6 (0.545) | 22 | 17 (0.772) | 31 | -1.335 | 0.192 |
| Total | 61 | 28 (0.459) | 135 | 111 (0.822) | 194 | -5.552 | 0.000 |

There was a significant difference between the pre and post period for reporting periods 3 ($t=3.417$, $p = 0.002$) and 4 ($t=-4.409$, $p = 0.0002$).

Table 9 shows the HFs that submitted correct forms. That is all the different parts of reporting and ordering tallied together.

Table 9: Health facilities that had correct report/order forms

| Reporting Period | Number of HFs who had correct report/order forms | | | | df | T-test | P-Value |
|--------------------|--|-------------------|--------------------------|-------------------|------------|---------------|--------------|
| | Pre-intervention | | Post intervention | | | | |
| | Total # orders submitted | Correct | Total # orders submitted | Correct | | | |
| Reporting period 1 | 7 | 1 (0.143) | 23 | 16 (0.696) | 28 | -2.832 | 0.236 |
| Reporting period 2 | 9 | 5 (0.556) | 22 | 17 (0.773) | 29 | -1.198 | 0.241 |
| Reporting period 3 | 13 | 6 (0.462) | 22 | 19 (0.864) | 33 | -2.737 | 0.0099 |
| Reporting period 4 | 6 | 1 (0.167) | 21 | 19 (0.905) | 25 | -4.904 | 0.0000 |
| Reporting period 5 | 15 | 9 (0.600) | 23 | 18 (0.783) | 36 | -1.204 | 0.236 |
| Reporting period 6 | 11 | 6 (0.545) | 22 | 17 (0.773) | 31 | -1.335 | 0.1917 |
| Total | 61 | 28 (0.459) | 133 | 106(0.796) | 192 | -5.001 | 0.000 |

There was a significant difference between the pre and post period for reporting periods 3 ($t=-2.737$, $p = 0.009$) and 4 ($t=-4.904$, $p = 0.000$).

Table 10: Number of health facilities that received supplies from NMS

| Reporting Period | Number of HFs that received supplies from NMS | | | |
|--------------------|---|-------------------|--------------------|-------------------|
| | Pre-intervention | | Post intervention | |
| | # Orders submitted | # Orders received | # Orders submitted | # Orders received |
| Reporting period 1 | 5 | 5 (1.00) | 19 | 13 (0.68) |
| Reporting period 2 | 7 | 10 (1.43)* | 21 | 19 (0.90) |
| Reporting period 3 | 11 | 11 (1.00) | 20 | 21 (1.05)* |
| Reporting period 4 | 5 | 8 (1.60)* | 17 | 17 (1.00) |
| Reporting period 5 | 12 | 11 (0.92) | 21 | 24 (1.14)* |
| Reporting period 6 | 7 | 7 (1.00) | 17 | 21 (1.24)* |
| Total | 47 | 52(1.106) | 115 | 115(1.000) |

Some health facilities received supplies from NMS even though they did not submit orders for that reporting period. On average more than 50% of the health facilities that submitted orders to NMS received supplies.

ARVS & OIs stock outs

A number of ARVs and opportunistic infections (OIs) medicines were stocked out during both the pre and post intervention periods.

Table 11: Proportion of Health Facilities that experienced stock-outs

| Reporting Period | Proportion of HFs experienced a stock out of at least one ARV and/or OI drug | | | | |
|--------------------|--|--------------------------|----|---------|---------|
| | Pre-intervention (n=24) | Post intervention (n=24) | df | t test | p-value |
| Reporting period 1 | 2 (0.083) | 10 (0.417) | 46 | -2.828 | 0.007 |
| Reporting period 2 | 0 (0.000) | 8 (0.333) | 46 | -3.391 | 0.001 |
| Reporting period 3 | 1 (0.042) | 7 (0.262) | 46 | -2.415 | 0.019 |
| Reporting period 4 | 0 (0.000) | 5 (0.208) | 46 | -2.460 | 0.018 |
| Reporting period 5 | 4 (0.167) | 8 (0.333) | 46 | -1.3301 | 0.190 |
| Reporting period 6 | 2 (0.083) | 7 (0.292) | 46 | -1.878 | 0.067 |
| Total | 9 (0.063) | 45 (0.313) | | | |

On average more health facilities experienced stock outs of at least one ARV/OI drug during the post period compared to the pre period. The difference was significant for reporting periods 1 to 4 ($p < 0.05$).

Table 12: Number of stock outs that were experienced

| Reporting Period | Number of stock outs that were experienced | | | |
|--------------------|--|-------------------|---------------------|-------------------|
| | Pre-intervention | | Post intervention | |
| | HFs with stock outs | # Stock out | HFs with stock outs | # Stock out |
| Reporting period 1 | 2 | 3 (1.500) | 10 | 10 (1.000) |
| Reporting period 2 | 0 | 0 (0.000) | 8 | 8 (1.000) |
| Reporting period 3 | 1 | 1 (1.000) | 7 | 8 (1.143) |
| Reporting period 4 | 0 | 0 (0.000) | 5 | 6 (1.200) |
| Reporting period 5 | 4 | 4 (1.000) | 8 | 10 (1.250) |
| Reporting period 6 | 2 | 2 (1.000) | 7 | 7 (1.000) |
| Total | 9 | 10 (1.111) | 45 | 49 (1.089) |

Of the health facilities that reported a stock out of ARVs/OI drugs, 4 HF's had stock outs more than once in a reporting period. The triple dose combination of Zidovudine, Lamivudine and Niverapine (AZT/3TC/NVP) was the frequently stocked out (see Table 13) drug for both the pre and post intervention periods. The stock outs were reported for both adult and pediatric formulations.

Table 13: ARV and OIs drugs that were commonly stocked

| | ARV drugs and OIs that were commonly stocked | | | | | | | |
|------------------|---|---|---|---|--|--|--|--|
| | Pre-intervention | | Post intervention | | Pre-intervention | | Post intervention | |
| | Total # HF's that reported stock outs of ARVs | Facilities stocked out on specific ARVs | Total # HF's that reported stock outs of ARVs | Facilities stocked out on specific ARVs | Total # HF's that reported stock outs of OIs | Facilities stocked out on specific OIs | Total # HF's that reported stock outs of OIs | Facilities stocked out on specific OIs |
| AZT/3TC/NVP | 8 | 6 (0.75) | 20 | 12 (0.60) | | | | |
| AZT/3TC | 8 | | 20 | 7 (0.35) | | | | |
| TDF/3TC/EFV | 8 | | 20 | 3 (0.15) | | | | |
| TDF/3TC | 8 | 1 (0.13) | 20 | 7 (0.35) | | | | |
| ABC/3TC | 8 | 1 (0.13) | 20 | 8 (0.40) | | | | |
| D4T/3TC/NVP | 8 | 1 (0.13) | 20 | | | | | |
| AZT/3TC/EFV | 8 | 1 (0.13) | 20 | | | | | |
| Efavirence | 8 | | 20 | 2 (0.10) | | | | |
| Niverapine syrup | 8 | | 20 | 5 (0.25) | | | | |
| Lopinavir | 8 | | 20 | 3 (0.15) | | | | |
| Atanavir | 8 | | 20 | 3 (0.15) | | | | |
| Cotrimoxazole | | | | | 3 | 3 (1.00) | 15 | 11 (0.73) |
| Fluconazole | | | | | 3 | | 15 | 11 (0.73) |
| Dapsone | | | | | 3 | | 15 | 3 (0.20) |

The number of HF's that experienced stock outs increased in the post period as more HF's started offering ART services.

Buffer stocks

Baylor-Uganda supported a number of health facilities with buffer stocks of ARVS and OI drugs during times of stock outs, low stock and/or before a health facility was accredited to offer ART services.

Table 14: Number of health facilities that received buffer stock from Baylor-Uganda

| | Pre-intervention | | Post intervention | |
|--------------------|------------------------------|--------------------------|------------------------------|--------------------------|
| | # HFs received buffer (n=24) | # buffer stocks received | # HFs received buffer (n=24) | # buffer stocks received |
| Reporting period 1 | 5 (.0208) | 7 (1.400) | 4 (0.167) | 5 (1.250) |
| Reporting period 2 | 6 (0.250) | 8 (1.333) | 2 (0.083) | 2 (1.000) |
| Reporting period 3 | 6 (0.250) | 6 (1.000) | 0 (0.000) | 0 (0.000) |
| Reporting period 4 | 5 (.0208) | 5 (1.000) | 3 (0.125) | 3 (1.000) |
| Reporting period 5 | 11 (0.458) | 12 (1.091) | 4 (0.167) | 5 (1.250) |
| Reporting period 6 | 3 (0.125) | 3 (1.000) | 4 (0.167) | 6 (1.500) |
| Total | 36(0.250) | 41(1.139) | 17(0.118) | 21(1.235) |

STARTING ART TREATMENT FOR HIV POSITIVE PREGNANT WOMEN AND EXPOSED INFANTS

Table 15 shows the number of health facilities that had records on the number of pregnant women that were tested for HIV and started ART in both the pre and post periods.

Table 15: Health facilities that had data on testing and starting ART

| Month | <i>Number of Health Facilities that had data on women and infants tested, tested positive and started ART</i> | | | | | | | | | | | |
|-------|---|------|-------------------------|------|----------------------|------|-----------------|------|---------------------------|------|------------------------|------|
| | #Women tested | | #Women testing positive | | # Women starting ART | | #Infants tested | | #Infants testing positive | | # Infants starting ART | |
| | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post |
| 1 | 17 | 23 | 17 | 23 | 11 | 23 | 16 | 23 | 16 | 23 | 16 | 23 |
| 2 | 17 | 23 | 17 | 23 | 11 | 22 | 16 | 23 | 16 | 23 | 16 | 23 |
| 3 | 18 | 23 | 18 | 23 | 12 | 22 | 17 | 23 | 17 | 23 | 17 | 23 |
| 4 | 18 | 23 | 18 | 23 | 12 | 23 | 17 | 23 | 17 | 23 | 17 | 23 |
| 5 | 18 | 24 | 18 | 24 | 12 | 23 | 17 | 24 | 17 | 24 | 17 | 24 |
| 6 | 18 | 24 | 18 | 24 | 12 | 23 | 17 | 24 | 17 | 24 | 17 | 24 |
| 7 | 19 | 24 | 19 | 24 | 13 | 23 | 18 | 24 | 17 | 24 | 18 | 24 |
| 8 | 19 | 24 | 19 | 24 | 13 | 23 | 18 | 24 | 17 | 24 | 18 | 24 |
| 9 | 19 | 24 | 19 | 24 | 13 | 23 | 18 | 24 | 17 | 24 | 18 | 24 |
| 10 | 21 | 24 | 21 | 24 | 15 | 23 | 21 | 24 | 21 | 24 | 21 | 24 |
| 11 | 21 | 24 | 21 | 24 | 17 | 23 | 21 | 24 | 21 | 24 | 21 | 24 |
| 12 | 21 | 24 | 21 | 24 | 17 | 23 | 21 | 24 | 21 | 24 | 21 | 24 |

Table 16: Proportion of pregnant women who were tested and tested positive for HIV

| | Pre | | | Post | | |
|--------------|--------------|------------|--------------|--------------|------------|--------------|
| | Tested | Positive | Percent | Tested | Positive | Percent |
| 1 | 1019 | 22 | 2.16% | 2091 | 34 | 1.63% |
| 2 | 1355 | 29 | 2.14% | 2026 | 31 | 1.53% |
| 3 | 1611 | 27 | 1.68% | 2280 | 31 | 1.36% |
| 4 | 1875 | 36 | 1.92% | 1930 | 37 | 1.92% |
| 5 | 1802 | 38 | 2.11% | 2072 | 35 | 1.69% |
| 6 | 1571 | 41 | 2.61% | 2310 | 20 | 0.87% |
| 7 | 2170 | 31 | 1.43% | 1823 | 23 | 1.26% |
| 8 | 1658 | 41 | 2.47% | 1824 | 23 | 1.26% |
| 9 | 1803 | 50 | 2.77% | 2199 | 32 | 1.46% |
| 10 | 1969 | 47 | 2.39% | 2502 | 40 | 1.60% |
| 11 | 2419 | 45 | 1.86% | 2082 | 28 | 1.34% |
| 12 | 2620 | 49 | 1.87% | 2352 | 26 | 1.11% |
| Total | 21872 | 456 | 2.08% | 25491 | 360 | 1.41% |

There was a reduction in the proportion of pregnant women that tested positive in the post period compared to the pre period. However the number of positive pregnant women starting ART in the pre-period (Figure 5) is lower than those that started ART in the post-period (Figure 6).

Figure 5: Number of pregnant women that tested positive and started ART in the pre-intervention period

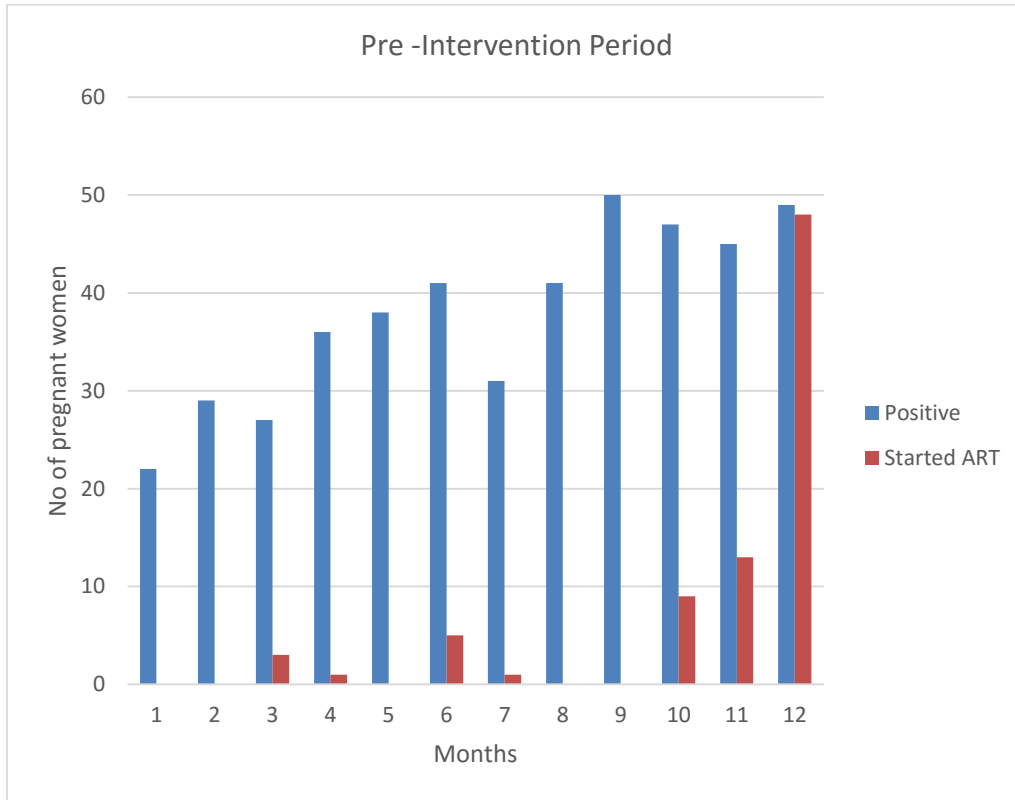


Figure 6: Number of pregnant women that tested positive and started ART in the post intervention period

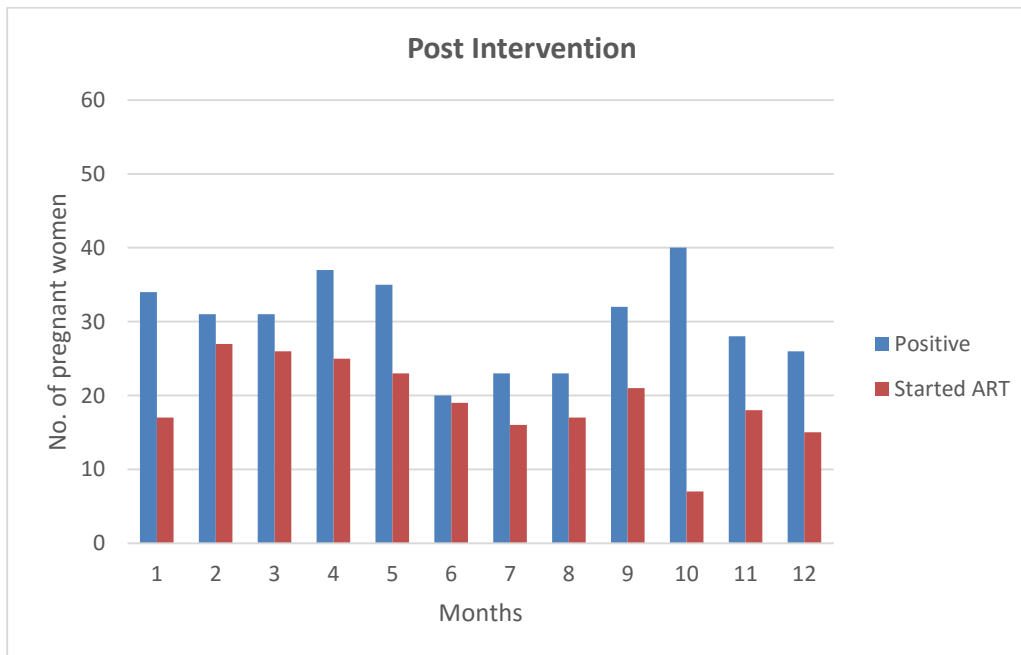


Table 17: Proportion of exposed infants who were tested and tested positive for HIV

| | Pre | | | Post | | |
|---------------|------------|-----------|--------------|------------|-----------|--------------|
| | Tested | Positive | Percent | Tested | Positive | Percent |
| 1 | 33 | 4 | 12.12% | 32 | 2 | 6.25% |
| 2 | 37 | 4 | 10.81% | 35 | 1 | 2.86% |
| 3 | 37 | 2 | 5.41% | 49 | 6 | 12.24% |
| 4 | 45 | 4 | 8.89% | 40 | 6 | 15.00% |
| 5 | 30 | 3 | 10.00% | 70 | 5 | 7.14% |
| 6 | 30 | 3 | 10.00% | 51 | 4 | 7.84% |
| 7 | 47 | 5 | 10.64% | 81 | 7 | 8.64% |
| 8 | 33 | 1 | 3.03% | 38 | 2 | 5.26% |
| 9 | 47 | 5 | 10.64% | 56 | 5 | 8.93% |
| 10 | 69 | 8 | 11.59% | 66 | 10 | 15.15% |
| 11 | 94 | 7 | 7.45% | 61 | 2 | 3.28% |
| 12 | 78 | 6 | 7.69% | 49 | 2 | 4.08% |
| Totals | 580 | 52 | 8.97% | 628 | 52 | 8.28% |

A reduction in the number of exposed infants testing positive was also observed in the post period compared to the pre-period except for months 3, 4, 8 and 10. However not all infants that tested positive were started on ART (Figure 7 & 8).

Figure 7: Number of exposed infants that tested positive and started ART in the pre-intervention period

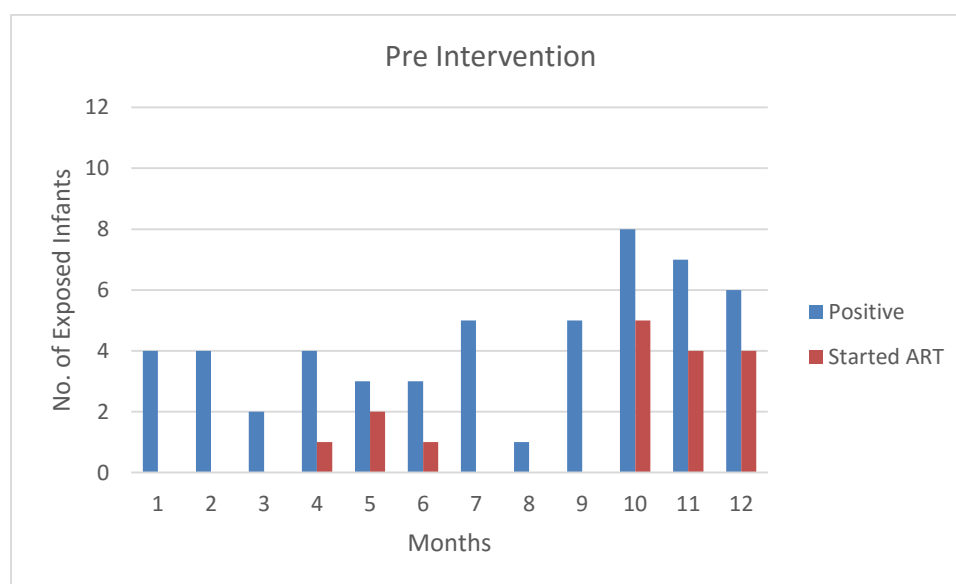
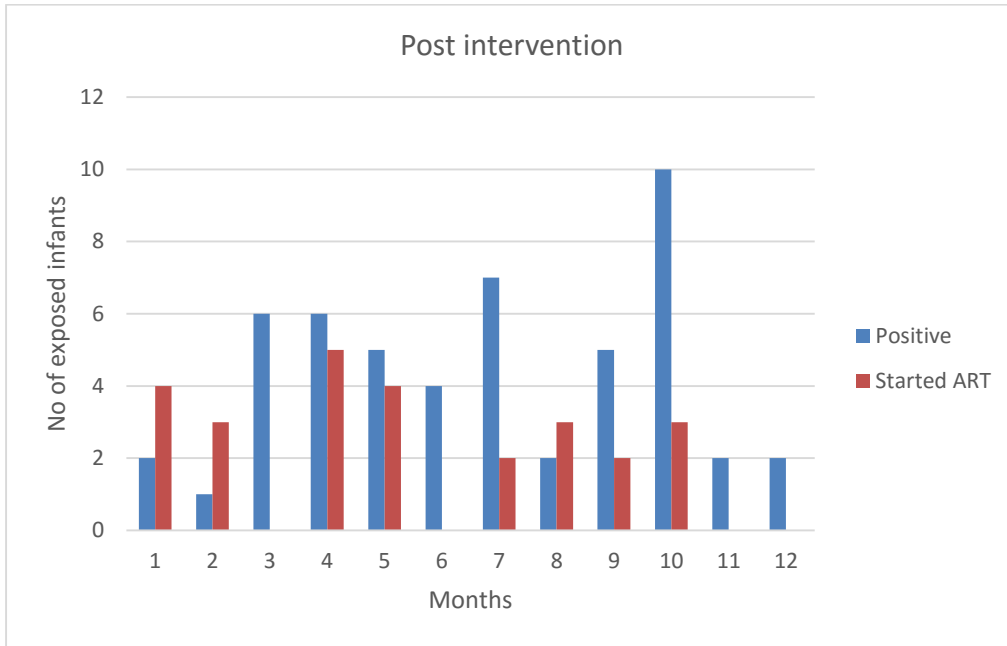


Figure 8: Number of exposed infants that tested positive and started ART in the post intervention period



DISCUSSION

This study sought to answer the question could an intervention effectiveness study on the ARV logistics management program be done in Uganda. The study was carried among Baylor-Uganda supported Health facilities in eastern Uganda. This involved analyzing existing data, reviewing documents and reports, in addition to conducting key informant interviews.

AVAILABILITY AND QUALITY OF DOCUMENTS, KEY INFORMANTS AND DATA SOURCES

Key informants

Each of the recommended people to talk to have different roles in relation to ARV logistics management. The district stores assistants supervise health facilities and help ensure supplies are available in all the HFs. The district biostatistician compiles reports and orders, submits them to NMS and avails copies of the order forms to the health facilities. In many instances copies of the order forms are not picked up from the district office and the health facilities end up with no record of what was ordered. The medicines supervisors offer technical support, monitor medicines stocks, and help with medicine management that is storage, dispensing and quality control. At the health facility, the midwives, ART clinic in-charges, health facility in-charges, stores assistants and dispensers are all involved in reporting and ordering of ARVs. The main challenge is that the different end-users do not cooperate in compiling the final order form that is submitted to NMS.

Availability and quality of documents

Obtaining pre-intervention HIV treatment data especially for the period 2010 – 2012 was a problem. Some of the health facilities had records on women that tested positive and started

ART, and others did not have. For the health facilities that were accredited starting late 2012, the older PMTCT report forms used to capture data on HIV positive pregnant women accreditation were not available. The new PMTCT addendum form captures data starting in 2013. Prior to 2012 HIV/AIDS summary data was captured manually in the HMIS report form, a copy of which was submitted to the district biostatistician. The biostatistician then submitted copies of the reports to the Ministry of Health. In 2012 the online District Health Information System (DHIS2) was rolled out and now data is entered directly into the HMIS system by the district biostatistician. Therefore for a researcher to access data prior to 2012, he/she would have to manually sort through old registers and HMIS records at the health facilities.

Whereas the HMIS reports were available, some of the HIV-specific registers and reports that had detailed information on numbers tested and treated, were not available. Furthermore, sites that were supported by The AIDS Support Organization (TASO) do not have data on ART patients that were enrolled into care by TASO. TASO only handed over the Pre-ART patients who are all transfer-ins in the pre –ART register. There are no previous patient charts for these patients. In the post intervention period, more specifically after 2012, it is much easier to access the data in an online database at the district, Ministry of Health or an implementing organization. However the data available at organizational level is tailored to the interests and objectives on the organization.

Report/Order Forms

Regarding the ordering for ARVs, the ARV and PMTCT medicines reporting and ordering system, code named 'WAOS' (Web-based ARV/PMTCT Ordering/Reporting System) was introduced in

2013. It is easy to access data from the system since the implementing organizations have access to it. The organizations are able to monitor stocks and track supplies to better support the health facilities within their jurisdictions and track over stocks and low stocks and help districts reallocate ARVs so that they do not expire in the facility stores.

The ARV report/order form is constantly being revised to take into account the changing treatment guidelines. This is very confusing to the HFs. Before the health workers are conversant with using one form, it is revised. Often times the health workers are not trained on using the revised form because the form is delivered at the health facility with the supplies from NMS. The 2014 form that is currently being rolled out is not available in all HFs. A copy of the online form that is being used is not available in some health facilities that do not have computers and/or internet access. Furthermore, the health workers have to constantly be trained on using the new forms. In many cases the people in charge of ordering are not the ones that are trained.

This is further complicated by the constant staff transfers, staff on study leave and the shortage of healthcare workers in general. The Baylor-Uganda Regional Medical Logistics Officer reported that there is always a different person in charge of ordering at some health facilities. This was and will be a challenge for future studies if there is not staff that was in the HFs long enough to give information about the program being studied.

As discussed above, Baylor-Uganda assumes that training at least one healthcare worker in a HF is would translate into improved management of ARVs and other medical commodities. However

this is not the case because the information does not trickle down to the other health workers in the HFs. In some cases trainees were transferred immediately after the training. In other cases, knowledge and skills were not passed down due to personality-related issues or the authority structure within the HF. The greatest number of staff trained in ARV logistics are Laboratory Assistants, Store Assistants and Medical Records Assistants.

FACTORS AFFECTING ARV LOGISTICS MANAGEMENT

A number of factors that affected ARV logistics management were reported by the HFs. These ranged from staffing shortages, incorrect quantification, orders not being supplied as ordered, delayed or no deliveries, and revision of tools, among others.

Patient population

All district health local governments have set population targets for health service delivery. All health facilities display and report these targets in the HMIS. However only 4 HFs had records of these population targets for the pre-period. Based on the population projections, the number of people that were tested for HIV and started ART increased in the period under study. As more HFs were accredited to provide ART services closer to the community, the number of patients enrolled in the HIV clinic increased. This supports the literature that the number of people receiving ART continues to grow as a result of continued global efforts to overcome barriers to ART. The increasing numbers of patients had implications on the management of ARVs and efforts were made to enable healthcare workers provide ART without treatment disruptions. This was done through training in ARV logistics management, mentorship and support supervision in addition to providing data tools and drugs to kick start the newly accredited HFs.

Health facility staffing levels and ARV training

With regards to staffing levels, the HFs seem to be adequately staffed as evidenced by the study findings. On the other hand they still reported staffing challenges. These problems stemmed from staff who were away on study leave, whose positions were not filled and the rampant transfers. In addition, the HC IIIs did not have stores assistants and supplies were handled by a staff member who was allocated that duty by the facility in-charge. However when it came to training, the person in charge of the stores may not have been the person who was trained. Study findings also showed that the HF In-charges (Clinical Officers or Nursing Officers) are the least number of cadres that were trained in ARV logistics management. These are the people responsible for submitting and signing off on the report/order forms that go to NMS.

Reporting and Ordering

Reporting and ordering at the health facility level was fragmented. There was poor communication between the units that provided the information needed to report and order for ARVs. There were no inter-unit/departmental meetings to reconcile all parts of the order form before it was submitted to NMS. Each of the units compiled its own reports and submitted them to the facility I/C who compiled the final one that was submitted. In many cases it was the HF I/C who compiled the final order form and submitted it to district biostatistician. The study also found that copies of the order forms were not available in the stores. The stores assistants or the person in charge of the stores in many cases did not know what had been ordered. They only saw

what was delivered by NMS. There was no mechanism to cross check what was delivered against what was ordered.

Incorrect quantification

The regional MLO also reported that some records assistants/stores I/Cs did not know the sources of data from which to extract the information needed to make accurate reports and orders. This in turn affected the quantification of drugs. Incorrect quantification was a challenge reported by almost 50% of the HFs. If the quantification is wrong, the risk of over stocks or stock outs is increased, a fact that is supported by previous research³². This also leads to drugs expiring in the health facilities' stores, a challenge that health workers are working hard to address. The online tracking system to which Baylor-Uganda has access, showed that all the 24 health facilities had both over stocks and low stocks of certain ARV formulations. The regional logistics officer and the pharmacy manager both confirmed that this was a challenge that needed to be addressed. Continuous technical support and mentorship would help HFs report and order correct quantities.

Supplies are not delivered as ordered

The health facilities are submitting the order forms according to scheduled deadlines. However the health facilities reported they received less or more than what was ordered, experienced delays in deliveries or no deliveries were made in some reporting cycles. The respondents also reported that NMS still pushes drugs that they do not need and some drugs had a short shelf life. One HF reported the pediatric AZT/3TC supplied had a short shelf life. This led to drugs expiring

in the stores. Some of the regimens were supplied less than what was ordered and others more than was ordered. One HF reported it received huge supplies of Ritonavir and Lopinavir and low supplies of pediatric ABC/3TC and pediatric AZT/3TC/NVP. Another HF received huge supplies of pediatric ABC/3TC. Redistributing the drugs to other HFs that needed them was not easy even though HFs reported borrowing drugs from other facilities.

SUBMISSION OF COMPLETE AND CORRECT ARV ORDER FORMS

There was an improvement in completing the order forms as well as filling the forms correctly. As reported above, there has been a remarkable improvement. In the pre-intervention period, on average, ten (10) health facilities submitted orders to the NMS in a year. However in the post-intervention period more than 90% of the surveyed health facilities submitted orders to NMS. As reported in the literature, prior to getting ART accreditation, lower HFs (IIIs and IIs) did not order for ARVs from the supply chain agencies since they were under a push system. However with the rolling out ART to lower HFs and revision of treatment guidelines, HC IIIs were allowed to order HIV commodities including ARVs. All the HC IIIs that were surveyed were able to report and order for ARVs especially after July 2013.

On the other hand, the facilities still needed help with reconciling the opening balances to the closing balances. These columns were mixed up many times and did not tally which affected the supplies that were delivered. In addition, inventory management was still a problem because the dispensing logs were not reconciled with the stock cards, nor were the logs used in making the orders. The patient numbers also differed from consumption records. The personnel in charge of

ordering ARVs did not sit with the medical records assistants to reconcile patient numbers to what was in the ART registers. This also affected the estimates for new patients. The area of quantifying for new patients still needs more training and technical support. The HFs therefore reported excesses or low stocks of ARVs because of wrong calculations.

The number of HFs receiving ARVs from NMS increased in the post period. However 58% of the health facilities surveyed still reported delays or no deliveries. The months they experienced delays were June-July when NMS was doing its annual stock taking and during the December - January cycle. Some HFs received 2 deliveries in one cycle as reported in Table 10.

Not all the health facilities had access to WAOS, the system that was rolled out in 2013 to improve the reporting and ordering process. Even though most of the HFs reported using the web-based system, they still compiled the reports manually and submitted them to the district biostatistician who has the access code. The biostatistician then entered the information into the online report-order form and submitted them to NMS. Some of the HFs, though they had computers, did not have modems to connect to the internet. Others reported poor internet connectivity. Many of the HFs still submitted reports close to the deadline.

A number of HFs still experienced stock-outs of certain formulations, for both adult and pediatric formulations. Close to 60% of the health facilities surveyed experienced a stock out of at least one drug in the past one year. More stock outs were reported in the post period compared to pre-period mainly because the number of HFs providing ART and patients starting ART increased.

This supports the literature that the increasing numbers of patients imply that ARV logistics management needs to be strengthened so that adequate supplies are available. The ARVs that were stocked out (see Table 13) included AZT/3TC/NVP, AZT/3TC, TDF/3TC/EFV, TDF/3TC, ABC/3TC and Niverapine syrup, among others.

The stock outs however did not stop treatment of pregnant women and exposed infants per se. The HFs borrowed from other HFs so as not to stop treatment. Five HFs reported that though treatment was affected, it was not completely interrupted. The clinicians either changed the regimens for some of the clients to regimens that were more available or they reduced the amounts dispensed per patient. For example, instead of a month's supply, 1 or 2 weeks' supply was dispensed in the hope that more ARVs were delivered during that time. This had cost implications for the patients since they had to make 2 or more visits instead of one per month. It is surprising to note that it was mainly the HC IVs that were borrowing drugs from lower health units. This implies that either quantification or forecasting was not done correctly or NMS did not supply as ordered.

Among the OIs, dapson, fluconazole and cotrimoxazole were the commonly stocked out drugs. Regarding dapson, the quantities needed were small because the number of patients using it was low. It was therefore not regularly supplied by NMS. Not many HFs had it in stock and when they received a patient who had an adverse reaction to cotrimoxazole, there was no other option for that patient.

Buffer supplies were stopped in 2013 and all ARVs supplies were streamlined through national supply agencies (see Figure 2). All funding for ARV drugs is channeled through the three warehouses – NMS, JMS and MAUL. All HFs then submitted orders to the respective warehouse. During times of stock outs the health facilities borrowed from or referred the affected patient to another HF because Baylor- Uganda could no longer provide buffer supplies of ARVs.

It should also be noted that HC IIs are not yet authorized to order for HIV commodities from NMS, yet they have HIV clinics and some of them are high-volume clinics. They borrowed ARVs from HCIIIs and HC IVs. This will eventually affect the stocks at the higher HCs. Also some of the clients were not willing to travel longer distances to the HCIII that is accredited to offer ART services. This implies that many of the patients in the rural areas may go without treatment unless this is addressed.

STARTING ART TREATMENT FOR HIV POSITIVE PREGNANT WOMEN AND EXPOSED INFANTS

HIV positive pregnant women

Findings from this study show that fewer pregnant women that tested positive for HIV were started on ART in the pre-period compared to the post period. Although all the health facilities surveyed provided PMTCT services, only the hospitals and HC IVs were accredited to offer ART services prior to 2012. Most of the HIV positive pregnant women were given ART prophylaxis which was stopped after cessation of breast feeding. Those that were eligible for ART were referred to the nearest accredited health facility. With the rolling out of new ART treatment guidelines, more health facilities provided ART services and this might account for the increase

in number of HIV positive pregnant women that were started on ART in the post period. In addition, as the number of patients increased, there was need to ensure a consistent supply of ARVs. Healthcare workers needed training in ARV logistics. Therefore this program improved reporting and ordering and ensured a consistent supply of ARVs was available to the increasing number of patients. Findings from the study also show that stock outs did not affect the number of pregnant women that were started on ART.

One can also argue that few HIV positive pregnant women were started on ART during the pre-period because the number of HFs providing ART were few and therefore ARVs were not readily available to the patients that needed them. The increased number of HFs providing ART in the post period led to more patients accessing treatment and thus we see more HIV positive women started on ART. The role of the new treatment guidelines, however, cannot be underscored in requiring that all positive pregnant women be started on ART irrespective of CD4 count or clinical staging.

On the other hand, the factors affecting ARV logistics management cannot be overlooked. If quantification continues to be a challenge and NMS-related issues are not addressed, treatment of pregnant women and exposed infants may be interrupted in the future. This Baylor-Uganda project is ending soon. Experience and research has shown that sustaining the achievements of such projects is a huge challenge faced by many developing countries.

Exposed Infants

Not all the exposed infants identified as needing a DNA-PCR test at 6 weeks, are tested for HIV. Since many of these infants are identified at birth, following up with the mothers to bring them in for the HIV test was a challenge, especially in the pre-intervention period. The data that is reported is for infants that are tested for HIV. Whether or not the infants that were tested in a month were those that had been identified as exposed at birth, could not be determined. Efforts to capture the PMTCT cascade data that would provide this follow-up information are not being utilized.

Despite these challenges, findings from the study show that among the infants that tested positive for HIV, the proportion that started ART improved in the post period. It should however be noted that not all infants that tested positive were started on ART. A number of factors could explain this, one of them being death but these could be explored in future studies.

CONCLUSION

Despite continued global efforts to fight HIV/AIDS, overcome barriers of ART and ensure that drugs are available to those that need them, more interventions are needed to strengthen ARV logistics management. Efforts to strengthen ARV logistics management led to improvements in the quality of report/orders submitted to NMS. Implying that ARVs are available for the increasing number of HIV positive pregnant women and infants that need them. This will eventually contribute to reduction in mother to child transmission of HIV. Health facilities still have problems quantifying the correct amounts of drugs vis-à-vis number of patients, which affects what they report and order. Not all the supplies delivered to the health facilities tally with what is ordered, which has led to low or over stocks of certain ARV regimens. Furthermore, it is still the case that not all HIV positive pregnant women and infants are started on ART as required under the new treatment guidelines.

This feasibility/pilot study was a first step to determine what parameters are needed to conduct future intervention effectiveness studies. The study assessed the impact of the ARV logistics management program and, in addition to addressing the research objectives, provided information on the sources of data and key informants needed for future studies. However, as discussed above, data for the period before 2012 was not easily accessed. One would have to manually review the patient charts to extract the data. The order forms have been revised over time and copies of the older ones could not be found.

The study had some limitations. There were no health facilities to use as a control group since all the supported health facilities had had at least one staff trained in ARV logistics management. A single group-time difference method was used to analyze data pre and post-intervention. Each clinic acted as its own control during the pre-period, and helped assess the effect of the intervention, which was realized during the post-period. A second limitation is that there are other factors affecting HIV service delivery, however this study focused on a single component. Finally, a convenience sample was used, and the small sample size and the different pre and post periods may have led to our inability to adequately assess differences in the pre and post period.

For future studies, a larger sample size should be used and more than one component of HIV service delivery should be studied. Since health facilities were trained at different times, the training dates should be used to determine the pre and post periods. Patient records will have to be reviewed to do an actual difference in difference analysis. The effect size determined from this study can be used to estimate the sample size and help plan for a larger intervention effectiveness study which would have a very high public health significance.

APPENDICES

Appendix 1: Data Collection Tool: Variables and Definitions

| Variable | Definition | |
|---|--|--------------------------|
| Health Facility Characteristics | | |
| 1. Name of Health Facility | | |
| 2. Type of health facility | "0" indicating Hospital "1" indicating HCIV, "2" indicating HCIII | |
| 3. Sub County | | |
| 4. District | "1" Amuria, "2" Bukedea, "3" Kaberamaido, "4" Katakwi, "5" Kumi, "6" Ngora, "7" Serere, "8" Soroti | |
| 5. Target population for health facility | Pre-intervention | Post Intervention |
| | | |
| 6. Target population for HIV/AIDS clinic | Pre-intervention | Post Intervention |
| | | |
| 7. Number or patients enrolled in the HIV/AIDS clinic | Pre-intervention | Post Intervention |
| | | |
| 8. Number of health workers by cadre | Pre-intervention | Post Intervention |
| Medical Officer | | |
| Dental surgeon | | |
| Dental officer | | |
| Pharmacist | | |
| Dispensers | | |
| Orthopedic Officer | | |
| Radiographers | | |
| Anesthetic Officers | | |
| Clinical Officer | | |
| Nursing Officers | | |
| Nurses | | |
| Midwives | | |
| Nursing Assistants | | |
| Laboratory Technologists | | |
| Laboratory Technicians | | |
| Laboratory Assistants | | |
| Anesthetic Assistants | | |
| Physiotherapy | | |
| Theatre Assistants | | |
| Cold chain assistant | | |
| Health Educator | | |
| Health inspectors | | |

| Variable | Definition | |
|--|---|--------------------------|
| Health assistants | | |
| Stores Assistant | | |
| Medical Records Assistant | | |
| 9. Number of health workers in HIV clinic by cadre | Pre-intervention | Post Intervention |
| Medical Officer | | |
| Pharmacist | | |
| Dispensers | | |
| Clinical Officer | | |
| Nursing Officers | | |
| Nurses | | |
| Midwives | | |
| Nursing Assistants | | |
| Laboratory Technologists | | |
| Laboratory Technicians | | |
| Laboratory Assistants | | |
| Health assistants | | |
| Medical Records Assistant | | |
| Training, Mentorship and Support Supervision | | |
| 10. Date of ARV logistics training | | |
| 11. Type of ARV logistics training | "1" Manual, "2" Web-based, "0" Both | |
| 12. How long has the facility had ARV logistics Management support | Number of months the health facility had ARV logistics Management support | |
| 13. Number of health workers trained by cadre | Number | |
| Medical Officer | | |
| Pharmacist | | |
| Dispensers | | |
| Clinical Officer | | |
| Nursing Officers | | |
| Nurses | | |
| Midwives | | |
| Nursing Assistants | | |
| Laboratory Technologists | | |
| Laboratory Technicians | | |
| Laboratory Assistants | | |
| Stores Assistant | | |
| Medical Records Assistant | | |
| 14. Did the HF receive any mentorship visits | "1" Yes, "0" No | |
| 15. Did the HF receive any Technical Support Supervision visits | "1" Yes, "0" No | |
| Starting ART | | |

| Variable | Definition | |
|---|--|--------------------------|
| 16. How many pregnant women were tested for HIV during the month | Number of pregnant women who were tested in that month | |
| | Pre - intervention | Post Intervention |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| 17. How many pregnant women were tested for HIV per quarter | Number of pregnant women who were tested per quarter | |
| | Pre - intervention | Post Intervention |
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| | | |
| 18. How many pregnant women who were tested that month were HIV+ | Number of pregnant women tested HIV-positive in that month | |
| | Pre - intervention | Post Intervention |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| 19. How many pregnant women who were tested per quarter were HIV+ | Number of pregnant women tested HIV-positive per quarter | |
| | Pre - intervention | Post Intervention |

| Variable | Definition | |
|--|--|--------------------------|
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| | | |
| 20. How many pregnant women who were tested positive during the month started ART | Number of pregnant women who tested positive in that month were started on ART | |
| | Pre - intervention | Post Intervention |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| 21. How many pregnant women who were tested positive started ART per quarter | Number of pregnant women who tested positive were started on ART per quarter | |
| | Pre - intervention | Post Intervention |
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| | | |
| 22. How many 6-week old exposed infants were identified as requiring a test during the month | Number of exposed infants who were identified in that month | |
| | Pre - intervention | Post Intervention |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |

| Variable | Definition | |
|--|--|--------------------------|
| September | | |
| October | | |
| November | | |
| December | | |
| 23. How many 6-week old exposed infants were identified as requiring a test per quarter | Number of exposed infants who were identified per quarter | |
| | Pre - intervention | Post Intervention |
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| | | |
| 24. How many identified exposed infants were tested for HIV at 6 weeks during that month | Number of exposed infants who were tested for HIV- in that month | |
| | Pre - intervention | Post Intervention |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| 25. How many identified exposed infants were tested for HIV at 6 weeks per quarter | Number of exposed infants who were tested for HIV per quarter | |
| | Pre - intervention | Post Intervention |
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| | | |
| 26. How many identified exposed infants who were tested at 6 weeks during that month were positive | Number of exposed infants who tested positive that month | |
| | Pre - intervention | Post Intervention |

| Variable | Definition | |
|---|---|--------------------------|
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| 27. How many identified exposed infants who were tested at 6 weeks per quarter were positive | Number of exposed infants who tested positive per quarter | |
| | Pre - intervention | Post Intervention |
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| 28. How many identified exposed infants who tested HIV positive during that month were started on ART that month | Number of infants who tested positive were started on ART in that month | |
| | Pre - intervention | Post Intervention |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| 29. How many identified exposed infants who tested HIV positive during that month were started on ART per quarter | Number of infants who tested positive were started on ART per quarter | |
| | Pre - intervention | Post Intervention |

| Variable | Definition | |
|---|---|--------------------------|
| Quarter 1 | | |
| Quarter 2 | | |
| Quarter 3 | | |
| Quarter 4 | | |
| Reporting and Ordering | | |
| 30. Is the facility implementing web based ordering? | Pre-intervention | Post intervention |
| | "1" Yes, "0" No | "1" Yes, "0" No |
| 31. How many staff were trained in web based ordering | Number of staff trained in web based ordering | |
| 32. How many staff were trained by cadre | Number | |
| Medical Officer | | |
| Pharmacist | | |
| Dispenser | | |
| Clinical Officer | | |
| Nursing Officer | | |
| Nurse | | |
| Midwives | | |
| Nursing Assistant | | |
| Laboratory Technologist | | |
| Laboratory Technician | | |
| Laboratory Assistant | | |
| Stores Assistant | | |
| 33. How many Report/Orders were submitted to NMS | Number of Report/Orders submitted. This will include only those reports that were submitted according to schedule | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 34. Were Report/Orders completely filled | "1" Complete if the form is complete with relevant information, "0" if form is incomplete | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |

| Variable | Definition | |
|--|---|--------------------------|
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 35. Were Report/Orders correctly filled | "1" "Correct" the form is correct if both the report and order sections tally and "0" Incorrect | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 36. How many orders did the health facility receive | Number of orders received from NMS | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 37. Did the health facility have a stock out of one or more required medicines | "1" Yes, "0" No Required medicines refer to ARVs and drugs for opportunistic infections (OI) | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 38. If yes, how many stock outs were experienced | Number of times stock outs were experienced | |
| | Pre - intervention | Post Intervention |

| Variable | Definition | |
|--|--|--------------------------|
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 39. What ARVs were stocked out? | List of ARVs that were stocked out | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 40. What Opportunistic Infections drugs were stocked out | List of OI drugs that were stocked out | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |
| 41. Did HF receive buffer stock from Baylor-Uganda? | "1" Yes, "0" No | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |

| Variable | Definition | |
|--|---|-------------------|
| 42. If yes, how many buffer stocks were received | Number of buffer stocks received from Baylor-Uganda | |
| | Pre - intervention | Post Intervention |
| Reporting period 1 (Date:) | | |
| Reporting period 2 (Date:) | | |
| Reporting period 3 (Date:) | | |
| Reporting period 4 (Date:) | | |
| Reporting period 5 (Date:) | | |
| Reporting period 6 (Date:) | | |
| Reporting period 7 (Date:) | | |
| Reporting period 8 (Date:) | | |

Appendix 2: Interview Guide

1. Are the health facilities submitting report/orders on time? **(1) Yes (2) No**
2. Are the health facilities receiving the orders as ordered? **(1) Yes (2) No**
3. Did any health facility report a stock-out of ARVS in the past 1 year? **(1) Yes (2) No**
4. Did the stock outs affect treatment for pregnant women and exposed infants? **(1) Yes (2) No**
5. What are the main challenges faced by the health facilities regarding ARV drugs logistics management?
6. How can the challenges be addressed?

Appendix 3: Definition of terms

Logistics management: The process of planning, implementing and controlling the efficient, cost effective flow and storage of goods, services from point of origin to point of consumption.

ARV logistics management: The management of HIV commodities in a systematic and standardized way by collecting, processing and utilizing timely logistics data to inform quantification, forecasting, ordering, reporting, and accountability of HIV/AIDS commodities.

HIV Service Delivery: A continuum of healthcare services used in the treatment, care and support of pregnant women and children infected and affected by HIV/AIDS.

PMTCT Option A: Maternal zidovudine (AZT) prophylaxis, given at fourteen weeks of gestation and stopped seven days after delivery.

PMTCT Option B: Maternal triple ARV prophylaxis given starting at fourteen weeks of gestation and continued until delivery

Option B+: Starting pregnant women/lactating women on ART treatment for life ARVs.

Hospital: Also known as general hospitals, these hospitals are intended to serve catchment populations up to 500,000; support all referrals from health centers and lower levels of care; and offer a range of preventive and curative outpatient services, inpatient care, emergency surgery, obstetrics and gynecology, laboratory services, and other general services. District hospitals also provide in-service training, consultation, and research on behalf of community-based health programs at lower levels of care.

Health center IVs: These facilities are intended to serve as the highest non-hospital referral facilities at the sub-district level, or catchment populations around 100,000; and offer basic preventive and curative outpatient services, inpatient care, second-level referral services (e.g., life-saving medical, surgical, and obstetric services such as blood transfusions and caesarean sections), and physical base for district health teams.

Health center IIIs: These facilities are intended to serve catchment areas up to 20,000 (the sub-county level); provide supervision of and referral services to health center IIs under their management; and offer basic preventive and curative outpatient services and inpatient care (largely through general and maternity wards). Many health center IIIs also provide laboratory services.

Health center IIs: These facilities are intended to serve as basic health centers and interfaces to the formal health sector for communities (populations of about 5,000), largely providing only outpatient care at most locations and an additional subset of services in places with poor access to health center IIIs and health center IVs.

Appendix 4: Proposal Approval letter from UTSPH



School of Public Health
Office of Research
Associate Dean for Research

MEMORANDUM

TO: Hilda Sekabira

FROM: Laura Mitchell, PhD
Associate Dean for Research

RE: Thesis Proposal

DATE: May 29, 2015

TITLE: Antiretroviral drugs logistics management and HIV/AIDS service delivery in Baylor-Uganda supported health facilities in Eastern Uganda

Your proposal has been reviewed and approved by the UT School of Public Health Office of Research. Your proposal was determined to be Exempt by the University of Texas Health Science Center at Houston Committee for the Protection of Human Subjects as study # HSC-SPH-15-0362. You may proceed with your research.

Cc: Suja S. Rajan, PhD
Robert O. Morgan, PhD
Sheryl McCurdy, PhD
Anne Baronitis, Student Affairs Office

Appendix 5: Proposal Approval letter from Baylor College of Medicine IRB)



GIVING LIFE TO POSSIBLE

MEMORANDUM

To: SUSAN LANELLE GILLESPIE
From: Miguel Aguirre
CC: File
Date: June 11, 2015
Re: H-37126: ANTIRETROVIRAL DRUGS LOGISTICS MANAGEMENT AND HIV/AIDS SERVICE DELIVERY IN BAYLOR-UGANDA SUPPORTED HEALTH FACILITIES IN EASTERN UGANDA

On **May 19, 2015** your office informed me of the intent to do the following:

The purpose of this study is to evaluate the impact of the ARV logistics management program and provide feedback for future interventions in the Baylor-Uganda supported health facilities. The researcher will review already existing data and conduct key informant interviews. A single group time difference method will be used to analyze data a year before the program initiation (pre-period) and compare that with data a year after the program initiation (post period). The researcher will determine the date of initiation of the ARV logistics program in each health facility. Data on all variables will be collected for 12 months, which will end thirty days prior to the initiation date (pre-period) and will be compared to the 12 months data collected thirty days after the initiation date (post period). This will include health facility characteristics, number of HIV-positive pregnant women and exposed infants started on ART, and health facility report and order forms. The researcher is analyzing facility level programmatic data that has already been reported to the Ministry of Health and development partners, and does not have personal identifiers.

Given the assurances provided above, this memorandum serves as the BCM IRB and the BCM determination that **this activity does not constitute human subjects research**. This is QA activity and not research under 45 CFR 46.102(d). The proposed QA activities are designed solely for internal program evaluation purposes with no external application or generalization. This protocol in BRAIN therefore, does not fall under the regulations for IRB review of human subjects research found at 45 CFR 46.

NOTE TO PI: If the intent changes or at a future date, an opportunity arises to contribute previously collected data gathered in these activities to a new project producing generalizable knowledge, the IRB Office must make the determination of whether the new project constitutes research requiring IRB approval before the data could be released to the new project.

Appendix 6: Proposal Approval letter from Mengo Hospital (local IRB)



MENGO HOSPITAL

FOUNDED ON 22 FEBRUARY 1897

MENGO HOSPITAL RESEARCH ETHICS COMMITTEE

P.O. BOX 7161, KAMPALA

P.O.,Box 7161, Kampala, Uganda
Tel: +256-414-270222/3
Direct: +256-312-307106
Fax: 256-414-340466
Email: medicaldirector@mengo-hospital.org
Website: www.mengo-hospital.org

Our Ref: MH 2430

Your Ref: 2 July 2015

Hilda Nakalema Sekabira
Principal investigator
Baylor Uganda

RE: Antiretroviral Drugs logistics management and HIV/AIDS service delivery in Baylor-Uganda Supported health facilities in Eastern Uganda. (694/05-15)

This is to inform you that the Mengo Hospital Research Ethics Committee (MHREC) has approved the above research study. The approval period is from 2nd July 2015 to 2nd July 2016. Your study number is 694/05-15. Please be sure to reference either this number in any correspondence with the MHREC.

Continued approval is conditional upon your compliance with the following requirements:

- 1) A copy of the **Informed Consent Document**. Approved as of 2/07/15, is enclosed. No other consent form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each member must be given a copy of the signed consent form.
- 2) All protocol amendments and changes to approved research must be submitted to the MHREC and not be implemented until approved by the MHREC except where necessary to eliminate apparent immediate hazards to the study subjects.
- 3) Significant changes to the study site and significant deviations from the research protocol and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research must be promptly reported to the MHREC.
- 4) All deaths, life threatening problems or serious or unexpected adverse events, *whether related to the study article or not*, must be reported to the MHREC in a timely manner as specified in the National Guidelines for Research Involving Humans as Research Participants.
- 5) Please complete and submit reports to the MHREC as follows:
 - a) Renewal of the study-complete and return the Continuing Review Report- Renewal Request (Form 404A) at least 8 weeks prior to the expiration of the approval period. The study cannot continue after **2nd July 2016** until re-approved by the MHREC.
 - b) Completion, termination, or if renewing the projects –send the report upon completion of the study.

Please call the chairman if you have any questions about the terms of this approval. Enclosed is the approved informed consent document dated 2nd July 2015.

NB: Final approval is to be granted by the Uganda National Council for Science and Technology

Yours Sincerely,

for Dr. Namulema,

Prof. Kawooya G. Michael
Chairman (MHREC)



Appendix 7: Proposal Approval letter from UNCST



Uganda National Council for Science and Technology (Established by Act of Parliament of the Republic of Uganda)

Our Ref: SS 3837

11th August 2015

Hilda Nakalembe Sekabira
Baylor College of Medicine Children's foundation
Mulago Hospital
Kampala

Re: Research Approval: Antiretroviral drugs logistics Management and HIV/AIDS Service delivery in Baylor – Uganda Supported Health Facilities in Eastern Uganda

I am pleased to inform you that on **15/07/2015**, the Uganda National Council for Science and Technology (UNCST) approved the above referenced research project. The Approval of the research project is for the period of **15/07/2015 to 15/03/2016**.

Your research registration number with the UNCST is **SS 3837**. Please, cite this number in all your future correspondences with UNCST in respect of the above research project.

As Principal Investigator of the research project, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the research protocol or the consent form (where applicable) must be submitted to the designated local Institutional Review Committee (IRC) or Lead Agency for re-review and approval **prior** to the activation of the changes. UNCST must be notified of the approved changes within five working days.
3. For clinical trials, all serious adverse events must be reported promptly to the designated local IRC for review with copies to the National Drug Authority.
4. Unanticipated problems involving risks to research subjects/participants or other must be reported promptly to the UNCST. New information that becomes available which could change the risk/benefit ratio must be submitted promptly for UNCST review.
5. Only approved study procedures are to be implemented. The UNCST may conduct impromptu audits of all study records.
6. A progress report must be submitted electronically to UNCST within four weeks after every 12 months. Failure to do so may result in termination of the research project.

Below is a list of documents approved with this application:

| | Document Title | Language | Version | Version Date |
|----|-------------------|----------|---------|--------------|
| 1. | Research Proposal | English | N/A | N/A |
| 2. | Consent documents | English | N/A | N/A |

Yours sincerely,


Hellen N. Opolot
for: Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

LOCATION/CORRESPONDENCE

Plot 6 Kimera Road, Ntinda
P. O. Box 6884
KAMPALA, UGANDA

COMMUNICATION

TEL: (256) 414 705500
FAX: (256) 414-234579
EMAIL: info@uncst.go.ug
WEBSITE: <http://www.uncst.go.ug>

REFERENCES

1. World Health Organization. Global update on the health sector response to HIV, 2014. 2014.
2. Fasawe O, Avila C, Shaffer N, Schouten E, Chimbwandira F, Hoos D, Nakakeeto O, De Lay P. Cost-effectiveness analysis of option B for HIV prevention and treatment of mothers and children in malawi. PloS One 2013;8(3):e57778.
3. Marseille E, Kahn JG, Saba J. Cost-effectiveness of antiviral drug therapy to reduce mother-to-child HIV transmission in sub-Saharan africa. AIDS 1998;12(8):939-48.
4. O'Brien L, Shaffer N, Sangrujee N, Abimbola TO. The incremental cost of switching from option B to option B for the prevention of mother-to-child transmission of HIV. Bull World Health Organ 2014;92(3):162-70.
5. Robberstad B, Evjen-Olsen B. Preventing mother to child transmission of HIV with highly active antiretroviral treatment in tanzania--a prospective cost-effectiveness study. J Acquir Immune Defic Syndr 2010 Nov;55(3):397-403.
6. Ross JS, Labbok MH. Modeling the effects of different infant feeding strategies on infant survival and mother-to-child transmission of HIV. Am J Public Health 2004 Jul;94(7):1174-80.
7. Uganda Ministry of Health and ICF International. 2011 uganda AIDS indicator survey: Key findings. 2012.
8. Kuznik A, Lamorde M, Hermans S, Castelnovo B, Auerbach B, Semeere A, Sempa J, Ssenono M, Ssewankambo F, Manabe YC. Evaluating the cost-effectiveness of combination antiretroviral therapy for the prevention of mother-to-child transmission of HIV in uganda. Bull World Health Organ 2012;90(8):595-603.
9. World Health Organization. Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: Recommendations for a public health approach- 2010 version. World Health Organization; 2010. .

10. World Health Organization. March 2014 supplement to the 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach. 2014.
11. Desale A, Taye B, Belay G, Nigatu A. Assessment of laboratory logistics management information system practice for HIV/AIDS and tuberculosis laboratory commodities in selected public health facilities in addis ababa, ethiopia. The Pan African Medical Journal 2013;15:46.
12. Hirnschall G, Harries AD, Easterbrook PJ, Doherty MC, Ball A. The next generation of the world health organization's global antiretroviral guidance. J Int AIDS Soc 2013 Jun 30;16:18757.
13. Boyer S, Clerc I, Bonono C, Marcellin F, Bilé P, Ventelou B. Non-adherence to antiretroviral treatment and unplanned treatment interruption among people living with HIV/AIDS in cameroon: Individual and healthcare supply-related factors. Soc Sci Med 2011;72(8):1383-92.
14. El-Sadr WM, Holmes CB, Mugenyi P, Thirumurthy H, Ellerbrock T, Ferris R, Sanne I, Asiimwe A, Hirnschall G, Nkambule RN, et al. Scale-up of HIV treatment through PEPFAR: A historic public health achievement. J Acquir Immune Defic Syndr 2012 Aug 15;60 Suppl 3:S96-104.
15. Atun R, Bataringaya J. Building a durable response to HIV/AIDS: Implications for health systems. J Acquir Immune Defic Syndr 2011 Aug;57 Suppl 2:S91-5.
16. Windisch R, Waiswa P, Neuhann F, Scheibe F, de Savigny D. Scaling up antiretroviral therapy in uganda: Using supply chain management to appraise health systems strengthening. Globalization and Health 2011;7(1):25-.
17. Ministry of Health, Health Systems 20/20, Makerere University School of Public Health. *Uganda health system assessment 2011*. Kampala, Uganda and Bethesda, MD: Health Systems 20/20 project, Abt Associates Inc; April 2012.
18. Waako PJ, Odoi-adome R, Obua C, Owino E, Tumwikirize W, Ogwal-Okeng J, Anokbonggo WW, Matowe L, Aupont O. Existing capacity to manage pharmaceuticals and related commodities in east africa: An assessment with specific reference to antiretroviral therapy. Hum Resour Health 2009 Mar 9;7:21,4491-7-21.

19. UNICEF W. Evaluation of ARV procurement and supply management systems in west and central africa region. UNICEF Office for West and Central Africa 2008.
20. Overcoming challenges in supply chain management amidst rapid scale up of anti-retroviral services. JOURNAL OF THE INTERNATIONAL AIDS SOCIETY/INT AIDS SOCIETY AVENUE DE FRANCE 23, GENEVA, 1202, SWITZERLAND; 2012. .
21. Kabue MM, Kekitiinwa A, Maganda A, Risser JM, Chan W, Kline MW. Growth in HIV-infected children receiving antiretroviral therapy at a pediatric infectious diseases clinic in uganda. AIDS Patient Care STDS 2008;22(3):245-51.
22. Kekitiinwa A, Asiimwe AR, Kasirye P, Korutaru V, Kitaka S, Maganda A, Madalon M, Graziano FM. Prospective long-term outcomes of a cohort of ugandan children with laboratory monitoring during antiretroviral therapy. Pediatr Infect Dis J 2012 Aug;31(8):e117-25.
23. Jackson JB, Musoke P, Fleming T, Guay LA, Bagenda D, Allen M, Nakabiito C, Sherman J, Bakaki P, Owor M. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in kampala, uganda: 18-month follow-up of the HIVNET 012 randomised trial. The Lancet 2003;362(9387):859-68.
24. Tukei VJ, Asiimwe A, Maganda A, Atugonza R, Sebuliba I, Bakeera-Kitaka S, Musoke P, Kalyesubula I, Kekitiinwa A. Safety and tolerability of antiretroviral therapy among HIV-infected children and adolescents in uganda. J Acquir Immune Defic Syndr 2012 Mar 1;59(3):274-80.
25. Namukwaya Z, Mudiope P, Kekitiinwa A, Musoke P, Matovu J, Kayma S, Salmond W, Bitarakwate E, Mubiru M, Maganda A, et al. The impact of maternal highly active antiretroviral therapy and short-course combination antiretrovirals for prevention of mother-to-child transmission on early infant infection rates at the mulago national referral hospital in kampala, uganda, january 2007 to may 2009. J Acquir Immune Defic Syndr 2011 Jan 1;56(1):69-75.
26. Tickle-Degnen L. Nuts and bolts of conducting feasibility studies. American Journal of Occupational Therapy 2013;67(2):171-6.
27. Ministry of Health, Uganda, 2013 Annual Health Sector Performance Report Uganda.
28. Baylor Uganda, 2014 Annual Report 2013 - 2014

29. Ministry of Health et al., (2012). Uganda AIDS Indicator Survey 2011. Kampala: Government of Uganda.
30. Ministry of Health. (2009). Health Sector Strategic Plan III 2010/2015. Government of Uganda
31. Uganda AIDS Commission. (2011). The National HIV Prevention Strategy for Uganda: 2011-15; “.....Expanding and Doing HIV Prevention Better....” Vol. 2. Kampala. Ministry of Health.
32. Uganda AIDS Commission. (2011). The National Strategic Plan 2011/12-2014/15. Government of Uganda.
31. Uganda AIDS Commission. (2014). Uganda HIV and AIDS Country Progress Report; 2013. Government of Uganda.
32. Schouten, E. J., Jahn, A., Ben-Smith, A., Makombe, S. D., Harries, A. D., Aboagye-Nyame, F., & Chimbwandira, F. (2011). Antiretroviral drug supply challenges in the era of scaling up ART in Malawi. *Journal of the International AIDS Society*, 14(Suppl 1), S4.