Improving Viral Load Monitoring Coverage Using a Quality Improvement Approach in Blantyre Malawi

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

Angella Joy Kamwendo

Student Number: 1896506

A research report submitted to the Faculty of Health Sciences, University of Witwatersrand-School of Public Health, in partial fulfilment of the requirements for the *Master of Science (MSc)* degree in Epidemiology – Implementation Science.

30th August, 2021

Declaration

I, **Angella Joy Kamwendo**, declare that this research is my own work. It is being submitted for the degree of Master of Science Epidemiology- Implementation Science to the faculty of Health Sciences at the University of Witwatersrand School of Public Health, Johannesburg. This work has not been submitted before in part or in full for any degree or examination at this or any other university.

Angella Joy Kamwendo

30th August, 2021

Dedication

I dedicate this work to my daughter *Langa Alexis*, my late dad *Edward Kamwendo* and my late mum *Dalitso Matuta Kamwendo*. Special appreciation to *Melody Sakala*, *Edward Dzimphonje*, my family and friends for the amazing support. God bless you.

ABSTRACT

Background: Viral load (VL) testing coverage in individuals with HIV remains low particularly in resource limited countries despite recommendation by World Health Organization, and Malawi is no exception. A quality improvement (QI) approach was used to improve VL testing coverage from 27% to a target of 80% at an urban health facility in Malawi.

Methods: A QI study employing a time-series quasi-experimental design with no comparison group was conducted at Chilomoni health centre in Blantyre from April 2020 to July 2020. A retrospective record review of 257 patient records from 8 weeks before the study was conducted to determine baseline VL testing coverage. Root cause identification and prioritization of low VL testing coverage was done using fish-bone tool and Pareto-chart respectively by healthcare providers. Change ideas were identified and prioritized using an effort-impact matrix by healthcare providers. Two change ideas; *re-orienting ART providers on VL test order in EMR* and *dedicated ART provider to serve VL tested patients* were implemented and tested in 5 Plan-Do-Study-Act (PDSA) cycles from the Model for Improvement (MFI), each lasting one week. The latter was tested, and adapted in 3 cycles, and eventually adopted for monitoring for another 5 weeks. VL testing coverage was tracked throughout the study using run charts and p-charts. Segmented regression analysis was also done to assess significance of the change in outcome.

Results: VL testing coverage increased from 27% to 81% in the post-intervention period, with children aged up to 17 years experiencing the lowest VL testing coverage. A significant overall increase in the outcome was observed after implementation of interventions in the post

intervention period (IRR 7.026; 95% confidence interval (CI) 1.484-33.263; P < 0. 014). However, change in children was insignificant.

Conclusion: The MFI as a QI approach improved VL testing coverage through implementation of contextualized change ideas, although the results suggest children need tailored interventions. Future research should focus on evaluating sustainability of improved VL testing coverage at the health facility and assessing barriers to VL testing among children.

Keywords: HIV, Viral load testing coverage, Quality Improvement, Model for Improvement

Acknowledgement

Firstly, I would like to thank God Almighty for His many blessings and relentless love always.

I would also like to thank my supervisors; *Dr Juliana Kagura* and *Professor Mina Hosseinipour* for their guidance and amazing support throughout my research journey. My sincere gratitude also goes to Malawi HIV implementation research scientist training (M-HIRST) program (Fogarty D43TW010060) for the financial support throughout my studies, Lecturers at the University of Witwatersrand School of Public Health and to the participants for their contribution towards the research.

Finally, special thanks to my classmates *Jennifer Galenda Nagudi* and *Wuraola Aduke*. You kept me sane.

Contents

LIST OF FIGURES

LIST OF TABLES

LIST OF ACRONYMS

AIDS	**Acquired Immune Deficiency Syndrome**
ART	**Antiretroviral Therapy**
CD4	**Cluster Differentiation 4**
CDC	**Centre for Disease Control**
DAI	**Diagnostics Access Initiative**
DBS	**Dried Blood Spots**
DPS	**Dried Plasma Spots**
DRC	**Democratic Republic of Congo**
DSS	**Dried Serum Spots**
HIV	**Human Immunodeficiency Syndrome**
MFI	**Model for Improvement**
MSF	**Medecines San Frontieres**
PEPFAR	**President's Emergency Plan for AIDS Relief**
PDSA	**Plan Do Study Act**
QI	**Quality Improvement**
UNAIDS	**Joint United Nations Program on HIV/AIDS**
VL	**Viral Load**

1.0. CHAPTER ONE: INTRODUCTION

This chapter gives a background on HIV/AIDS, the UNAIDS targets and how they link to VL testing. The chapter also puts into perspective the importance of viral load testing, the gap that exists in research, including what has been done already, the need for quality improvement methods in the viral load continuum and the framework used in the study. The chapter ends with the objectives of this study.

1.1. Background

HIV/AIDS remains the primary cause of death for nearly one million people worldwide every year, despite decreases in HIV- related mortality since 2004 (1,2). Globally, 37.9 million people were living with HIV in 2018 and 54% of these people were from Sub-Saharan Africa, particularly the Eastern and Southern region (3,4). According to 2018 WHO updates, 1.7 million people were newly infected with HIV and 770, 000 HIV-related deaths occurred in that year worldwide (5). Among the newly HIV-infected individuals and HIV-related deaths, 800, 000 individuals and 310, 000 individuals respectively were from Eastern and Southern Africa alone (6).

In order to complement SDG number three's agenda of ending the HIV/AIDS epidemic by 2030, the UNAIDS set out 90-90-90[1] targets to be achieved by 2020 and 95-95-95[2] targets to be achieved by 2030 (2). The implication of the 90-90-90 targets set by UNAIDS is the reduction of HIV incidences and mortality by 75% by year 2020 and 95-95-95 targets, by 90% by year 2030 (2). Success of eliminating HIV/AIDS as a public health concern lies in a 90 percent reduction in new HIV infections and deaths from HIV related illnesses by 2030 (4). This impact can only be realized upon achieving suppressed viral loads among individuals on ART (third 90 UNAIDS target) according to the HIV cascade (7). It is therefore imperative that among other tools, interventions and implementation strategies, HIV diagnostic tests for viral load (VL) are being carried out on individuals on ART if HIV/AIDS is going to be eradicated.

[1] 90% of individuals who are HIV positive know their status: 90% of those who are HIV positive are on ART: 90% of those on ART are virally suppressed

[2] 95% of individuals who are HIV positive know their status: 95% of those who are HIV positive are on ART: 95% of those on ART are virally suppressed

The World Health Organization (WHO) recommends viral load (VL) testing as means of monitoring the response of clients with HIV to Antiretroviral Therapy (ART) and the scale up of routine VL testing in resource limited countries(8). On the same note, WHO also recommends that VL testing should be conducted 6 months after initiation of ART, which can be conducted again at 12 months after initiation and thereafter routinely once every 12 months, or if there is suspected failure of ART treatment (Targeted testing) (8,9). Viral load testing assists in early detection of ART failure, prevents unnecessary switches to other regimens thereby reducing ART drug resistance and enables health service providers to take early action in the management of HIV clients who have portrayed signs of ART failure (10). This, in turn, is important for maintaining and sustaining a suppressed viral load in individuals on ART thereby reducing transmission and realizing better patient outcomes (11).

Globally, significant progress has been made towards the 90-90-90 targets: 79% of the people living with HIV know their HIV status, 78% of those who know their HIV status are on ART and 86% of individuals on ART are virally suppressed (12). However, in many parts of the world VL testing coverage is still low with resource limited countries experiencing the most challenges (13). In Malawi, VL testing for individuals on ART was launched in August 2012 and has been a priority of the ministry of health in the country (14). With regards to the UNAIDS 90-90-90 targets, Malawi has made substantial progress in achieving the target despite having one of the highest HIV prevalence rates (10.6%): 90% of individuals who are HIV positive know their status, 87% of those who know they are HIV positive are on ART and 89% of individuals on ART are virally suppressed (15,16).

1.2. Problem Statement

Malawi faces challenges of low VL testing coverage despite having a policy in place and financial support for HIV services. Viral load testing coverage is defined as the proportion of people who have been on ART for 6 months or more, received a VL test and have the result documented in their medical record (17). Low coverage on VL testing has implications on the Malawi government's ability to maintain and sustain suppressed viral loads among individuals with HIV hence continued transmission and poor patient outcomes.

A study conducted by Lecher and colleagues in 2014 showed VL testing coverage in Malawi was at 11% (18). In 2015 and 2016, coverage remained constant at 19% (13). In 2018, VL testing coverage ranged from 15% to 54% across 27 districts in Malawi, with only 2 districts having coverage above 40% (19). This is below the 70% VL testing coverage target for 2018 set by the Ministry of Health in the country (14). General factors such as transportation, laboratory equipment, affecting VL testing coverage in resource limited countries have been established (20,21). However, a gap exists in contextual factors specific to a site or health facility that affect viral load testing coverage, as well as simple methods for developing context specific and tailored solutions at these facilities. Such a gap can be covered using quality improvement (QI) as it allows for systematic changes and rapid tests of tailored interventions (22).

1.3. Justification

Viral load testing has been highly recommended by WHO because of its ability to detect VL failure early (23). Studies have shown that VL testing using DBS is feasible in resource limited countries, including Malawi (24,25). In addition, a few studies that have been conducted so far have also shown it is possible to improve VL testing using quality QI methods (26,27). However, QI studies aimed at improving VL testing conducted in Sub-Saharan were executed in health facilities receiving special financial and technical support for systems strengthening through donor funded projects. In Malawi for instance, the study was conducted by an NGO through a PEPFAR funded project and included intesive mentorship visits by staff from the NGO to ensure adherence to VL testing guidelines. In this regard, methods and results from such QI studies might not be generalizable to health facilities that do not have special networks or support for HIV services or systems strengthening (26). In addition, but also very important, the use of a QI framework that guides the process of implementation of such studies was lacking.

It was therefore in the interests of this study that a quality improvement approach using the Model for Improvement (MFI) framework, be used to improve VL testing coverage at a health facility in Blantyre. To the best of our knowledge, the MFI framework has not been used in a QI study aimed at improving VL testing coverage in Malawi. The methods of this study can be replicated to improve VL testing coverage in other health facilities hence helping Malawi to achieve its VL testing coverage target. In addition, results of this study will help inform policy

makers to promote the systematic use of QI methodologies in the VL monitoring continuum for better patient outcomes in other facilities experiencing low VL monitoring coverage.

1.4. Research Question

Can quality improvement approaches using the MFI framework be used to improve viral load testing coverage at Chilomoni Health Centre in Blantyre, Malawi from 27% to 80% between April 2020 to July 2020?

1.5. Aim

To improve viral load testing coverage at Chilomoni health center in Blantyre, Malawi from 27% to 80% between April 2020 to July 2020 using the Model for Improvement as a quality improvement approach.

1.6. Objectives

- To establish baseline viral load testing coverage at Chilomoni health center in Blantyre, Malawi
- To identify root causes for low VL coverage at Chilomoni health center in Blantyre, Malawi
- To identify and test possible solutions or change ideas towards improving VL at Chilomoni health center in Blantyre, Malawi
- To monitor and evaluate the effect of QI approaches on improving the VL coverage at Chilomoni health center in Blantyre, Malawi

1.7. Literature review

1.7.1. Viral Load Testing

Viral load testing is considered the gold standard for observing the effect of ART treatment in individuals who are HIV infected. It involves taking blood samples that are tested for particles or copies of the HIV virus and using the results to guide decision making: a low viral load of less than 1000 copies per millilitre (ml) of blood implies treatment is effective (28). When one is on ART treatment, the goal is to have an undetectable viral load.

In situations where routine VL testing is not available, WHO used to recommend that CD4 count coupled with clinical symptoms monitoring be used instead (9,28). A systematic review assessing the performance of immunologic criteria and virologic criteria in diagnosing virologic failure suggests that using VL monitoring is more suitable (29). Different studies have showed that clinical and immunological criteria are less sensitive and have a low positive predictive value for virological failure hence late indication of treatment failure (29–33). This eventually became the main rationale for WHO to recommend VL testing, unlike other monitoring strategies. In Malawi, CD4 counting was dropped entirely as means of ART treatment monitoring (18).

1.7.2. Feasibility of Viral Load Testing in Malawi

Viral load testing can be conducted using different specimens. Using plasma for VL testing is considered the most appropriate approach as it allows a lower limit of detection of viral replication. However, the majority of HIV infections occur in resource limited countries like Malawi and use of plasma is not feasible due to transportation issues, separating the plasma from blood, storage issues as well as laboratory infrastructure that are expensive (34,35).

An alternative to plasma is Dried Blood Spots (DBS), Dried Plasma Spots (DPS) and Dried Serum Spots (DSS). WHO accepts DBS as a sample alternative choice for plasma to increase routine VL testing (36). Systematic reviews have shown that use of DBS for VL monitoring in resource limited countries is feasible and a reliable replacement for plasma in both adult and paediatric populations; DBS produced the same results as plasma(37,38). However, success is dependent on correct methods of specimen preparation, storage and transportation, including the correct specimen volume. Studies conducted in various resource limited countries including Malawi

continued to show DBS is feasible and effective and can be used to promote scale up of VL monitoring by using centralized laboratories (24,25,39,40). Feasibility of DBS in resource limited countries is possible due to its ease of preparation, ease of transportation to central laboratories, and requires less intense training (36,41).

Although DBS is an acceptable alternative for plasma, it has several disadvantages. These include less sensitivity due to spot volume, existence of proviral DNA (inactive form of the HIV virus) in DBS which may lead to overestimation of VL and the potential for decreased efficiency of DBS due to subjection of the specimen to different humidity and temperatures during transportation to central laboratory (35,37,41).

On the same note, despite DBS being the best alternative sample in resource limited countries, plasma can also be utilized if near Point of Care or true Point of Care platforms are available. POC platforms are simpler to use, do not require complex human resource skills, require less infrastructure than conventional laboratory platforms and are convenient for contexts where sample transportation is not feasible or is problematic (42,43). The most commonly used POC approved by WHO is Xpert HIV-1. A systematic review and a clinical meta-analysis on Xpert HIV-1 portrayed that it is comparable to other laboratory-based assays with regards to accuracy and has high specificity and sensitivity for VL thresholds of less than 1000copies/ml (44,45). Xpert HIV-1 is a reliable alternative and is feasible in rural and resource limited settings. The assay has also helped to improve VL coverage and reduced turnaround time(TAT) (46–48). However, constant and reliable source of power is required to avoid assay failure when considering Xpert HIV-1 for broader implementation (48). In addition, Xpert HIV-1 had a 20 percent chance of misclassifying suppressed individuals as unsuppressed when a treatment failure of detectable (more than 1000copies/ml) was used and that it slightly overestimates the amount of viral load (45,47). Further context-specific implementation research is also needed to explore acceptability and feasibility of Xpert HIV-1 as well as its cost effectiveness in comparison to other laboratory-based assays, and the impact it has on patient outcomes (44,45).

1.7.3. Barriers and Facilitators of Viral Load Testing

Despite VL testing being feasible in resource limited countries, barriers and facilitators to VL testing exist in such settings. Prior to WHO's recommendation for routine VL monitoring in 2012, it was established that the cost of VL tests and laboratory equipment, as well as the complexity of the procedure itself were the major barriers to VL testing (49). Further review by the same authors in 2016 as they set out to describe challenges and opportunities in the scale up of VL monitoring in resource limited countries indicated as challenges; high costs for VL tests (including reagents and consumables), poor adherence to WHO VL monitoring guidelines, weak laboratory and transport systems, low levels of training and quality assurance, lack of awareness by patients and clinicians on the importance of VL monitoring and lack of demand creation for VL testing services (50). As can be noted, barriers described in both papers could be addressed better as an initiative from national or policy level and are common to any resource limited country. In a study conducted in Malawi, Rustein and colleagues also found that other barriers included inadequate human resource, poor training and delayed results (20). Results from both studies were in concordance with survey results produced by MSF as the organization was evaluating scale up of a VL monitoring program in selected sites of Lesotho, Malawi, Swaziland, Mozambique, DRC, Uganda and Zimbabwe. Barriers identified by MSF were similar and also included missed opportunities in identifying individuals due for VL testing as a barrier (21).

On the other hand, task shifting, perceived benefits of VL testing by health providers, recruiting a VL focal person and creating demand for VL testing were the identified facilitators to VL testing (20,21). Increasing country's bargaining power to minimize costs; training; investing in transport, laboratory tools and reporting tools; as well as using DBS and pooled VL testing were also among the mentioned facilitators to VL monitoring(49,50). Diagnostics Access Initiative (DAI- includes PEPFAR. WHO, UNAIDS, CDC, among others) was also launched to address cost and laboratory capacity barriers, from which Malawi also benefits from (13). DAI collaborates with manufactures and suppliers of VL reagents, provides technical expertise and builds capacity.

In Malawi, HIV Diagnostic Assistants (HDAs) were introduced and deployed by the Department of HIV/AIDS (DHA) and their responsibilities besides HIV testing and counselling included sample collection for viral load testing, among others. An assessment on the impact of this cadre from

October 2013 to October 2017 showed that infants receiving DNA-PCR (a form of VL test but used as an HIV test in exposed children less than 18 months) by age two months increased from less than 40% to above 75%. HDAs did not just improve DNA-PCR, HIV testing and syphilis testing in pregnant women also improved (51). The study however, did not evaluate how HDAs improved VL testing in general. Further studies are needed to evaluate the impact of HDAs on VL testing as this cadre could be an important facilitator.

While a myriad of factors that hinder or facilitate VL testing have been identified, it is also important for health care providers to be able to identify missed opportunities and gaps in their settings of service delivery, regardless of high-level barriers that may exist within the health care system. This is important for the development of customized interventions for their setting that will help health care providers improve service delivery, reach more patients leading to improved health outcomes (52).

1.7.4. Improving Viral Load Testing using Quality Improvement Methods

Quality improvement is the continued use of health and program data with the aim of improving service systems and processes thereby leading to better patient outcomes (53,54). In public health, there is a need for deliberate efforts that target health systems to improve program effectiveness and service delivery. Improving VL monitoring involves viewing viral load monitoring as a continuum with a series of processes. These processes include identifying eligible clients and collecting a blood sample for VL testing, transportation of blood samples to a laboratory, receipt of results by health care providers and clients, and using the results for decision making (12). Every process must undergo scrutiny and bottlenecks with the process identified and addressed if VL monitoring is to be improved.

Over the years, a few QI studies aimed at improving VL testing have been conducted in Africa (18,26,55). Results of all studies have shown substantial improvement in one or more of the processes in the VL continuum. For instance, a QI study conducted in Limpopo, South Africa by Kekana and colleagues aimed at improving VL testing coverage used stickers to determine if patients were due for VL testing as a change idea. The result was improved VL testing coverage in all sites of focus during the study (56). A similar study conducted in Malawi by Hubbard et al with different change ideas resulted in an improvement in VL testing (26). Change ideas in this

study included provision of resources for a VL focal person, patient focused education materials and VL standard operating procedures and flow charts. Regardless of the difference in change ideas and methods, QI approaches were used in both studies to improve VL testing coverage. However, neither study used a QI framework, nor was there a mention of how changes were identified. In addition, in both studies health facilities were receiving support from external entities hence results from these studies may not be representative of other facilities that do not receive such support. In a slightly different study conducted in Kwazulu Natal South Africa, identifying a focal person for VL services at all sites resulted in improved VL monitoring and recognition of treatment failure (55). The strategy used in this study was one of the recommended strategies in the MSF report for improving VL testing (21). As can be evidenced by the studies above, QI efforts have proven to bring about some level improvement in the VL continuum.

1.7.5. Conceptual Framework

The MFI was developed by Associates in Process Improvement and is a framework used to guide the process of identifying, prioritizing, testing and introducing change ideas with the aim of improving systems (58). It is conceptually simpler and easier to use unlike other QI frameworks like Six sigma and Lean, although fidelity is of great importance (59). A change idea is an intervention that is identified, developed, and implemented through iterative series of steps to check if it brings about improvement. The MFI uses the PDSA cycle to test prioritized change ideas. During the study, the 3 guiding questions in the framework were used to guide the process of setting an aim, identifying process and outcome variables and identifying change ideas/interventions. The Plan-Do-Study-Act (PDSA) cycle from the framework was used to guide the testing and review of change ideas/interventions.

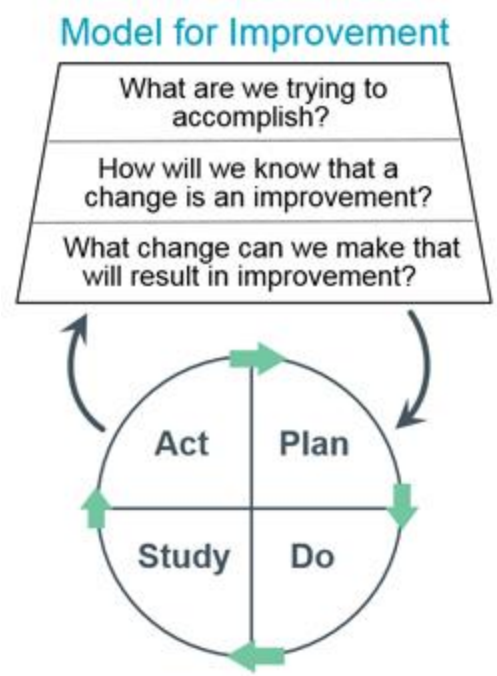


Figure 1: Model for Improvement Framework (Adapted from Langley, G. J., et al (2009): The Improvement Guide: A Practical Approach to Enhancing Organizational Performance, *2nd ed.)*

References

1. Roth GA, Abate D, Abate KH, Abay SM, Abbafati C, Abbasi N, et al. Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018 Nov 10;392(10159):1736–88.
2. Disease GB of, Collaborators 2017 HIV. Global , regional , and national incidence , prevalence , and mortality of HIV , 1980 – 2017 , and forecasts to 2030 , for 195 countries and territories : a systematic analysis for the Global Burden of Diseases , Injuries , and Risk Factors Study 2017. 2019;6(December):831–59.
3. UNAIDS. Global AIDS update : Communities at the centre. 2019.
4. UNAIDS data 2018. Geneva, Switzerland; 2018.
5. WHO. Summary of global HIV epidemic (2018) [Internet]. [cited 2020 Feb 4]. Available from: https://www.who.int/hiv/data/2018_summary-global-hiv-epi.png?ua=1
6. HIV and AIDS in East and Southern Africa regional overview | Avert [Internet]. [cited 2020 Feb 26]. Available from: https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview
7. WHO. Considerations for developing a monitoring and evaluation framework for viral load testing. 2019.
8. World Health Organization. March 2014 Supplement on the use of antiretroviral drugs for treating and preventing HIV infection. 2014;(March):130. Available from: https://apps.who.int/iris/bitstream/handle/10665/104264/9789241506830_eng.pdf?sequence=1
9. World Health Organization. What's New in HIV Treatment Fact Sheet. Fact Sheet [Internet]. 2015;(November):1–2. Available from: apps.who.int/iris/bitstream/handle/10665/204347/WHO_HIV_2015.44_eng.pdf;jsessionid=5E3029A29857C8AB0BF282AFDF33839A?sequence=1
10. Sigaloff KCE, Hamers RL, Wallis CL, Kityo C, Siwale M, Conradie F, et al. Unnecessary ART Regimen Switches and Accumulation of HIV-1 Drug-Resistance Mutations : Two Arguments for Viral Load Monitoring in sub-Saharan Africa. 2011;58(12454):12454.
11. Killingo BM, Taro TB, Mosime WN. Community-driven demand creation for the use of routine viral load testing: A model to scale up routine viral load testing. J Int AIDS Soc. 2017;20:4–8.
12. Global HIV and AIDS statistics | Avert [Internet]. [cited 2020 Feb 26]. Available from: https://www.avert.org/global-hiv-and-aids-statistics
13. Lecher S, Williams J, Fonjungo PN, Kim AA, Ellenberger D, Zhang G, et al. Progress with Scale-Up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries, January 2015–June 2016. MMWR Morb Mortal Wkly Rep. 2016;65(47):1332–5.
14. MoH Malawi. Ministry of Health HIV viral load scale Up implementation plan [Internet]. 2015. Available from: aidsfree.usaid.gov/sites/default/files/malawi_vl_scaleup.pdf
15. UNAIDS. Malawi factsheet | 2018 HIV testing and treatment cascade people living with HIV

[Internet]. 2018. Available from: https://www.unaids.org/en/regionscountries/countries/malawi

16. Malawi Ministry of Health. Malawi Population-Based HIV Impact Assessment (MPHIA) 2015-2016: Final Report. 2018.

17. World Health Organization. Considerations for Developing a Monitoring and Evaluation Framework for Viral Load Testing. 2019;(April):1–56. Available from: https://www.who.int/hiv/pub/surveillance/monitoring-framework-hiv-viral-load-testing.pdf?ua=1

18. Lecher S, Ellenberger D, Kim AA, Fonjungo PN, Agolory S, Borget MY, et al. Scale-up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries. MMWR Morb Mortal Wkly Rep. 2015;64(46):1287–90.

19. PEPFAR. Malawi Country Operational Plan (COP) 2018 Strategic Direction. 2018; Available from: https://www.pepfar.gov/documents/organization/285860.pdf

20. Rutstein SE, Golin CE, Wheeler SB, Kamwendo D, Hosseinipour MC, Weinberger M, et al. On the front line of HIV virological monitoring: Barriers and facilitators from a provider perspective in resource-limited settings. AIDS Care - Psychol Socio-Medical Asp AIDS/HIV. 2016;28(1):1–10.

21. Médecins Sans Frontières. Making viral load routine: Successes and challenges in the implementation of routine HIV viral load monitoring [Internet]. UNITAID report. 2016. Available from: aidsfree.usaid.gov/sites/default/files/making_vlprogstrat.pdf

22. Kurowski EM, Schondelmeyer AC, Brown C, Dandoy CE, Hanke SJ, Cooley HLT. A practical guide to conducting quality improvement in the health care setting. Curr Treat Options Peds. 2015;380–92.

23. UNAIDS. Knowledge is Power [Internet]. Joint United Nations Programme on HIV/AIDS (UNAIDS). 2018. Available from: http://www.unaids.org/sites/default/files/media_asset/jc2940_knowledge-is-power-report_en.pdf

24. Boillot F, Serrano A, Muwonga J, Kabuayi J, Kambale A, Mutaka F. Implementation and Operational Research: Programmatic Feasibility of Dried Blood Spots for the Virological Follow-up of Patients on Antiretroviral Treatment in Nord Kivu, Democratic Republic of the Congo. J Acquir Immune Defic Syndr [Internet]. 2016;71(1):e9–15. Available from: http://journals.lww.com/jaids/pages/default.aspx%0Ahttp://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emexa&NEWS=N&AN=606468742

25. Rutstein SE, Hosseinipour MC, Kamwendo D, Soko A, Mkandawire M, Biddle AK, et al. Dried blood spots for viral load monitoring in malawi: Feasible and effective. PLoS One. 2015;10(4):1–17.

26. Hubbard J, Kakwesa G, Nyirenda M, Mwambene J, Bardon A, Balakasi K, et al. Towards the third 90: improving viral load testing with a simple quality improvement program in health facilities in Malawi. Int Health [Internet]. 2019;11(3):215–20. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6676971/pdf/ihy083.pdf

27. Tumwikirize J, Nakanwagi F, Kisamba H, Karamagi E, Rahimzai M. Improving viral load monitoring at health facilities providing HIV care : Tested changes and guidance from Uganda. 2017;(January).

28. UNAIDS. The need for routine viral load testing [Internet]. 2016. Available from: https://www.unaids.org/sites/default/files/media_asset/JC2845_en.pdf

29. Rutherford GW, Anglemyer A, Easterbrook PJ, Horvath T, Vitoria M, Penazzato M, et al. Predicting treatment failure in adults and children on antiretroviral therapy : a systematic review of the performance characteristics of the 2010 WHO immunologic and clinical criteria for virologic failure. 2014;

30. Reynoids SJ, Nakigozi G, Newell K, Ndyanabo A, Galiwongo R, Boaz I, et al. Failure of immunologic criteria to appropriately identify antiretroviral treatment failure in Uganda. AIDS. 2009 Mar 27;23(6):697–700.

31. Mee P, Fielding KL, Charalambous S, Churchyard GJ, Grant AD. Evaluation of the WHO criteria for antiretroviral treatment failure among adults in South Africa. AIDS. 2008;22(15):1971–7.

32. Keiser O, MacPhail P, Boulle A, Wood R, Schechter M, Dabis F, et al. Accuracy of WHO CD4 cell count criteria for virological failure of antiretroviral therapy. Trop Med Int Heal. 2009 Oct;14(10):1220–5.

33. Chaiwarith R, Wachirakaphan C, Kotarathititum W, Praparatanaphan J, Sirisanthana T, Supparatpinyo K. Sensitivity and specificity of using CD4+ measurement and clinical evaluation to determine antiretroviral treatment failure in Thailand. [cited 2020 Mar 9]; Available from: http://intl.elsevierhealth.com/journals/ijid

34. Steinmetzer K, Seidel T, Stallmach A, Ermantraut E. HIV load testing with small samples of whole blood. J Clin Microbiol. 2010;48(8):2786–92.

35. Silvia GJB, Neil T. P, Michael J, James B, and García-Lerma. Dried blood spots for HIV-1 drug resistance and viral load testing: A review of current knowledge and WHO efforts for global HIV drug resistance surveillance. AIDS Rev. 2010;12(4):195–208.

36. Rodriguez-Auad JP, Rojas-Montes O, Maldonado-Rodriguez A, Alvarez-Muñoz MT, Muñoz O, Torres-Ibarra R, et al. Use of Dried Plasma Spots for HIV-1 Viral Load Determination and Drug Resistance Genotyping in Mexican Patients. Biomed Res Int. 2015;2015.

37. Bertagnolio S, Testing VL. Dried blood spots for HIV-1 Drug Resistance and Viral Load Testing : A Review of Current Knowledge and WHO Efforts for Global HIV Drug Resistance Surveillance. 2010;195–208.

38. Smit PW, Sollis KA, Fiscus S, Ford N, Vitoria M, Essajee S, et al. Systematic review of the use of dried blood spots for monitoring HIV viral load and for early infant diagnosis. PLoS One. 2014;9(3):1–8.

39. Monleau M, Aghokeng AF, Eymard-duvernay S, Dagnra A, Kania D. Field Evaluation of Dried Blood Spots for Routine HIV-1 Viral Load and Drug Resistance Monitoring in Patients Receiving Antiretroviral Therapy in Africa and Asia. 2014;52(2):578–86.

40. Johannessen A, Petersen MH, Lövgaarden G, Naman E, Ormaasen V. Original article HIV type-1 drug resistance testing on dried blood spots is feasible and reliable in patients who fail antiretroviral therapy in rural Tanzania. 2010;1009:1003–9.

41. García-Lerma JG, McNulty A, Jennings C, Huang D, Heneine W, Bremer JW. Rapid decline in the efficiency of HIV drug resistance genotyping from dried blood spots (DBS) and dried plasma spots

(DPS) stored at 37°C and high humidity. J Antimicrob Chemother. 2009;64(1):33–6.

42. MSF. MAKING VIRAL LOAD ROUTINE. Successes and challenges in the implementation of routine HIV viral load monitoring. PART 2: THE VIRAL LOAD LABORATORY (2016) [Internet]. [cited 2020 Mar 9]. Available from: www.msfaccess.org/makingviralloadroutine

43. Rubio-Garrido M, Ndarabu A, Reina G, Barquín D, Fernández-Alonso M, Carlos S, et al. Utility Of POC Xpert HIV-1 Tests For Detection-Quantification Of Complex HIV Recombinants Using Dried Blood Spots From Kinshasa, D. R. Congo. Sci Rep. 2019 Dec 1;9(1).

44. Nash M, Huddart S, Badar S, Baliga S, Saravu K, Paia M. Performance of the xpert HIV-1 viral load assay: A systematic review and meta-analysis. J Clin Microbiol. 2018 Apr 1;56(4).

45. Sacks JA, Fong Y, Gonzalez MP, Andreotti M, Baliga S, Garrett N, et al. Performance of Cepheid Xpert HIV-1 viral load plasma assay to accurately detect treatment failure. AIDS [Internet]. 2019 Oct 1 [cited 2020 Mar 10];33(12):1881–9. Available from: http://journals.lww.com/00002030-201910010-00008

46. Garrett NJ, Drain PK, Werner L, Samsunder N, Abdool Karim SS. Diagnostic accuracy of the point-of-care xpert HIV-1 viral load assay in a south african HIV clinic. Vol. 72, Journal of Acquired Immune Deficiency Syndromes. Lippincott Williams and Wilkins; 2016. p. e45–8.

47. Moyo S, Mohammed T, Wirth KE, Prague M, Bennett K, Holme MP, et al. Point-of-care Cepheid Xpert HIV-1 viral load test in rural African communities is feasible and reliable. J Clin Microbiol. 2016 Dec 1;54(12):3050–5.

48. Villa G, Abdullahi A, Owusu D, Smith C, Azumah M, Sayeed L, et al. Determining virological suppression and resuppression by point-of-care viral load testing in a HIV care setting in sub-Saharan Africa. EClinicalMedicine. 2020 Jan 1;18.

49. Roberts T, Bygrave H, Fajardo E, Ford N. Challenges and opportunities for the implementation of virological testing in resource-limited settings. J Int AIDS Soc. 2012;15(2):1–7.

50. Roberts T, Cohn J, Bonner K, Hargreaves S. Scale-up of Routine Viral Load Testing in Resource-Poor Settings: Current and Future Implementation Challenges. Clin Infect Dis. 2016;62(8):1043–8.

51. Flick RJ, Simon KR, Nyirenda R, Namachapa K, Hosseinipour MC, Schooley A, et al. The HIV diagnostic assistant: Early findings from a novel HIV testing cadre in Malawi. AIDS. 2019 Jun 1;33(7):1215–24.

52. Kassaid G, Doughertyid G, Madevu-Matson C, Egesimba G, Sartie K, Akinjeji A, et al. Improving inpatient provider-initiated HIV testing and counseling in Sierra Leone. [cited 2020 Sep 15]; Available from: https://doi.org/10.1371/journal.pone.0236358

53. World Health Organizaton. Operations Manual for Delivery of HIV Prevention, Care and Treatment at Primary Health Centres in High-Prevalence, Resource-Constrained Settings. Who [Internet]. 2008;264–81. Available from: who.int/hiv/pub/imai/om.pdf

54. Batalden PB, Davidoff F. What is “quality improvement” and how can it transform healthcare? Qual Saf Heal Care. 2007;16(1):2–3.

55. Sunpath H, Hatlen TJ, Naidu KK, Msimango P, Adams RN, Moosa MS, et al. Targeting the third “90”:introducing the viral load champion. Public Heal action [Internet]. 2018;I(4):225–31.

Available from: http://dx.doi.org/10.5588/pha.18.0063

56. Kekana MM, Railton J, Chb MB, Med DHI V. Quality improvement of the viral load programme in Mopani District , Limpopo Province. 2016;(December):35–9.

57. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. BMJ Qual Saf. 2014;23(4):290–8.

58. Langley GJ. The improvement guide a practical approach to enhancing organizational performance. 2nd ed. Langley GJ, editor. San Francisco, California: Jossey-Bass; 2009.

59. Reed JE, Card AJ. The problem with plan-do-study-act cycles. BMJ Qual Saf. 2016;25(3):147–52.

2.0. CHAPTER TWO: MANUSCRIPT

This chapter contains the manuscript which was written and submitted to PLoS ONE journal. The chapter begins with a declaration and is followed by the main manuscript. The manuscript details how the study was conducted, gives an account of the results and discusses findings. Parts of the methodology and discussion are also given after the manuscript to provide more clarity.

Declaration

I, **Angella Joy Kamwendo**, declare that this research is my own work. It is being submitted for the degree of Master of Science Epidemiology- Implementation Science to the faculty of Health Sciences at the University of Witwatersrand School of Public Health, Johannesburg. This work has not been submitted before in part or in full for any degree or examination at this or any other university.

Angella Joy Kamwendo

30th August, 2021

Full title: Improving viral load testing using a quality improvement approach in Blantyre, Malawi

Short title: Quality improvement and viral load testing

Angella J Kamwendo [1], Mina C Hosseinipour [2 3], Juliana Kagura [1]

[1] School of Public Health, University of Witwatersrand, Johannesburg, South Africa

[2] University of North Carolina Project, Lilongwe, Malawi

[3] School of Medicine, University of North Carolina School of Medicine, Chapel Hill, USA

*Angella Joy Kamwendo

joykamwendo@gmail.com /1896506@students.wits.ac.za (AJK)

Abstract

Background: Viral load (VL) testing coverage remains low particularly in resource limited countries despite recommendation by World Health Organization, and Malawi is no exception. A quality improvement (QI) approach was used to improve VL testing coverage from 27% to a target of 80% at an urban health facility in Malawi.

Methods: A QI study employing a time-series quasi-experimental design with no comparison group was conducted at Chilomoni health centre in Blantyre from April 2020 to July 2020. A retrospective record review of 257 patient records from 8 weeks before the study was conducted to determine baseline VL testing coverage. Root cause identification and prioritization of low VL testing coverage was done using fish-bone tool and Pareto-chart respectively by healthcare providers. Change ideas were identified and prioritized using an effort-impact matrix by healthcare providers. Two interventions were implemented and tested in 5 Plan-Do-Study-Act cycles from the Model for Improvement, each lasting one week. The latter intervention was tested, and adapted in 3 cycles, and eventually adopted for monitoring for another 5 weeks. VL testing coverage was tracked throughout the study using run charts and p-charts. Segmented regression analysis was also done to assess significance of the change in outcome.

Results: VL testing coverage increased from 27% to 81% in the post-intervention period, with children experiencing the lowest VL testing coverage. A significant overall increase in the outcome was observed after implementation of interventions in the post intervention period (IRR 7.026; 95% (CI) 1.484-33.263; P < 0. 014). However, change in children was insignificant.

Conclusion: The MFI as a QI approach improved VL testing coverage through implementation of contextualized change ideas. Results however also suggest children need tailored

interventions. Future research should focus on evaluating sustainability of improved VL testing coverage at the health facility and assessing barriers to VL testing among children.

Keywords: HIV, Viral load testing coverage, Quality Improvement, Model for Improvement

Introduction

The World Health Organization (WHO) recommends viral load (VL) testing as means of monitoring the response of clients with HIV to Antiretroviral Therapy (ART) and the scale up of routine viral load testing in resource limited countries[1]. Viral load testing assists in early detection of ART failure, prevent unnecessary switches to other regimens thereby reducing ART drug resistance and enables health service providers to take early action in the management of HIV clients who have portrayed signs of ART failure [2]. This, in turn is important for maintaining and sustaining a suppressed viral load in individuals on ART thereby reducing transmission and realizing better patient outcomes [3]. A 90 percent reduction in new HIV infections and deaths from HIV related illnesses is the key to eliminating HIV/AIDS as a public health concern [4]. This impact can only be realized upon achieving suppressed viral loads among individuals on ART according to the HIV cascade, hence the need to capitalize on VL testing [5]. Regardless of the recommendation by WHO, VL testing coverage is still low in many parts of the world, with resource limited countries experiencing the most challenges [6].

In Malawi, VL testing for individuals on ART was launched in August 2012 and has been a priority of the Ministry of Health in the country [7]. However, Malawi faces challenges of low VL testing coverage (19%) despite having a policy in place and financial support for HIV services [6,7]. In 2018, VL testing coverage ranged from 15% to 54% across 27 districts in Malawi, with only 2 districts having coverage above 40% [8]. This is below the 70% VL testing coverage target for 2018 set by the Ministry of Health in the country [7]. Low coverage on VL testing has implications on the Malawi government's ability to maintain and sustain suppressed viral loads among individuals with HIV hence continued transmission and poor

patient outcomes. General factors such as transportation and laboratory equipment, affecting VL testing coverage and common to resource limited countries have already been established [9,10]. However, there exists a gap in contextual factors specific to a site or health facility that affect VL testing coverage, as well as simple methods for developing context specific and tailored solutions at these facilities using a QI framework. Such a gap can be covered using quality improvement (QI) as it allows for systematic changes and rapid tests of tailored interventions [11].

At Chilomoni health centre in Blantyre Malawi, substantial proportion of patients had missed VL tests that were due. In April 2020, VL testing coverage for pregnant and lactating women as well children were pegged at 27%. We therefore set out to improve VL testing coverage at the health facility using the Model for Improvement (MIF) framework. Specifically, we explored the factors affecting VL testing coverage at the health facility, identified change ideas and tracked the outcome measure throughout the study. In this paper, we describe the methods used to develop interventions and components of the interventions that brought about change in the VL testing coverage at the health facility.

Materials and methods

Study design

We conducted a QI study utilizing a time series (AB) quasi-experimental study design with no comparison group from April 2020 to July 2020 at Chilomoni Health Centre ART clinic in Blantyre, Malawi. The study design was employed to allow continuous monitoring of the outcome at different time points, from baseline to the end of the study [12].

Study site

Chilomoni health centre is government owned and recognized as an urban health facility. The ART clinic at the health centre was established in 2006 and serves 4400 individuals on ART. It is located at latitude 15°46'14.9" in the South and longitude -34°58'54.9" in the East in Blantyre city. Blantyre city is situated in the southern region of Malawi and has one of the highest HIV prevalence, 17.7% [13]. In addition, Blantyre has a VL monitoring coverage between 25 and 30 %, and is among the lowest performing districts in the country [14].

Study population

We initially planned to include patient records of all individuals who were HIV positive, had been on ART for 6 months or more, and were due for a VL test from 8 weeks prior to the study and during the study period. However, due to COVID-19, the Malawi Ministry of Health issued new HIV services guidelines which stipulated that routine VL testing for the general population was put on hold. The service was only available to pregnant and lactating women, children and those in need of targeted testing [15]. Therefore, the study only included pregnant and lactating women as well as children and excluded those in need of targeted testing as identification of this group requires extra attention and would require its own set of interventions. Their records were used to measure VL testing coverage at baseline and throughout the rest of the study.

The study also included health care providers who were key in the process of VL testing at the ART clinic in order to investigate factors affecting VL testing coverage and development of a change ideas. These health care providers included clinicians, nurses, Expert Clients, clerks and Health Surveillance Assistants (HSAs).

Sample procedure

For the VL testing coverage component, all 428 records belonging to individuals (pregnant and lactating women and children) due for a routine VL test during the study, including the baseline period were included in the study. This was done in order to get precise VL testing coverage results, but also because of the shrinkage of the study population due to COVID-19 HIV service delivery guidelines.

On the other hand, purposive sampling was used to determine health care providers to be included in the study for investigation of factors affecting VL testing coverage at the health facility and development of change ideas. Only those health care providers who were directly involved in the VL testing process at the ART clinic were involved in the study. A total of 15 health care providers were used for this exercise. Purposive sampling was also used to determine the health facility where the study would take place; expert guidance was sought from the Blantyre District Health Office.

The viral load testing process and measures

In this study, we sought to improve VL testing during ART clinic days. At Chilomoni Health Centre, the initial process of VL testing started with health talks at the waiting area and topics such as viral load testing were covered. At the waiting area, patients underwent VL test eligibility screening done by any available health care provider. From the waiting area, the patient went to the reception to collect their ART card and to get their vitals such as weight and height checked. The patient would then go back to the waiting area or the ART provider's office for consultation and medication. If the patient was found eligible for a VL test at the waiting area or in the ART providers office, the patient was sent to the VL testing room for a

sample to be drawn and then proceed with all other activities at the ART clinic. If the patient is a Mother-Infant pair (MIP), the pair would first go to the Exposed Infants Diagnosis (EID) desk for consultation and medication for the infant, after which the mother would go to the waiting area to proceed with all other processes.

To track improvement of the process, the outcome that was being tracked during the study was VL testing coverage. For purposes of this study, it was defined as the proportion of individuals who had been on ART for 6 months or more and were due for a VL test, whose sample for a VL test was collected, and their names had been documented in the VL testing register regardless of whether they received a result or not. The number of people in the VL register (numerator) was compared to the number of people who have been on ART for 6 months or more and were due for a VL test (denominator) during the study period. The VL register was the only source of complete VL testing data, unlike Electronic Medical Records (EMR).

Apart from the outcome measure, we also collected data on process and balancing measures throughout the study (**Table 1**). This was done in order to ensure change ideas were being implemented as planned and consequences of implementing the change ideas on other parts of the system were being tracked. Data on process and balancing measures were collected and reviewed on weekly basis with the testing of each change idea. The outcome was measured throughout the study.

Table 1: Change Ideas, Process and Balancing Measures

Change Idea	Process Measures	Balancing Measures
Re-orienting ART providers on VL test order in EMR	Proportion of ART providers oriented on ART clinic day Proportion of VL tests ordered in EMR	Proportion of VL tests ordered in EMR but patient did not receive a VL test
Dedicated ART provider to serve VL test patients i.e. ordering VL tests in EMR	Proportion of patients who were eligible for a VL test and had their health passport held at the reception, received a VL test. Proportion of VL tests ordered in EMR	Proportion of VL tests ordered in EMR but patient did not receive a VL test

Data collection

Data collection during the study was conducted in 2 phases:

Phase I

This phase comprised of the following steps:

Step 1: Baseline assessment

Since the health facility already had a QI team, 3 QI team representatives were assigned by the health facility In-charge to work in this project: a Data Clerk, VL focal person and nurse. During the baseline assessment, a retrospective record review of pregnant and lactating women as well as children who were due for a VL test from 17th February 2020 to 11th April

2020 (8 weeks) was conducted. Records were taken from the ART attendance register and from an electronic medical record (EMR) system. These records were compared to records in the VL register and/or the EMR to check if individuals who were due had a sample collected for a VL test. Data from records was extracted by the investigator and data clerk into Microsoft Excel. Overall baseline VL coverage at the health facility was 27%; among women and lactating women 34% and 11% among children. The target was to get to 80%, motivated by the national target.

Step 2: Root-cause analysis and prioritization

A root cause analysis of factors that have led to low VL coverage at Chilomoni health centre were established using a fishbone diagram by health care providers. A list of guiding questions was developed to ensure an exhaustive analysis, including the use of the 5 'Why' approach (asking 'Why' 5 times) for each mentioned factor [16,17] **(Fig 1**).

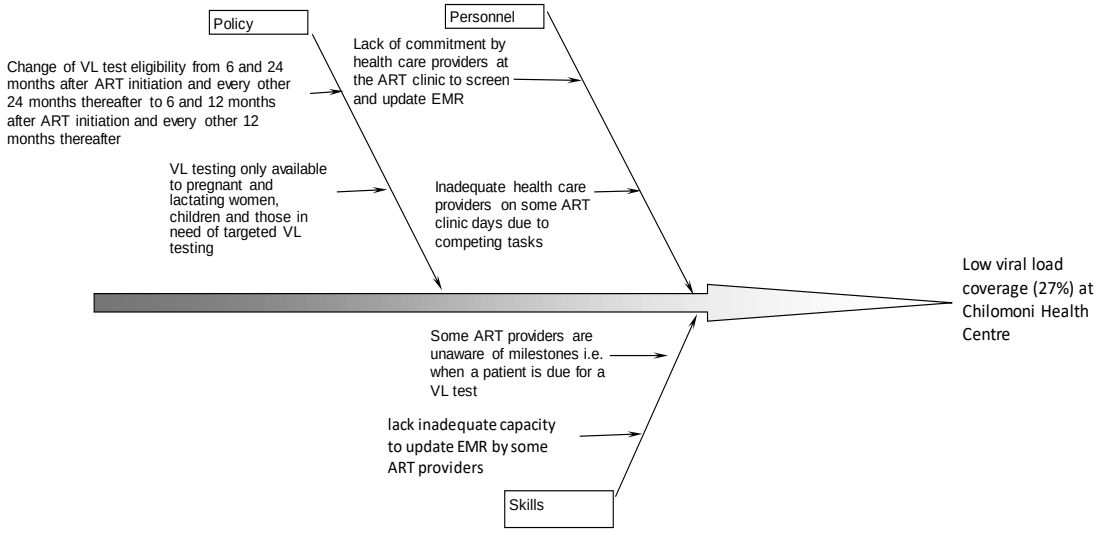


Fig 1: Fishbone Diagram of root causes of low VL testing coverage at Chilomoni Health Centre in Blantyre

Factors that affect VL testing coverage at the health facility were prioritized using a pareto chart **(Fig 2).** This allowed for the easy determination of factors with the highest priority and to guide the development of change ideas. Pareto charts are based on the principle that 80% of the problem is because of 20% of the possible causes, the vital few [16,17]. Factors under 'Policy' from the fishbone diagram were not included in the pareto chart because they were not within the control of the health care providers at the health facility.

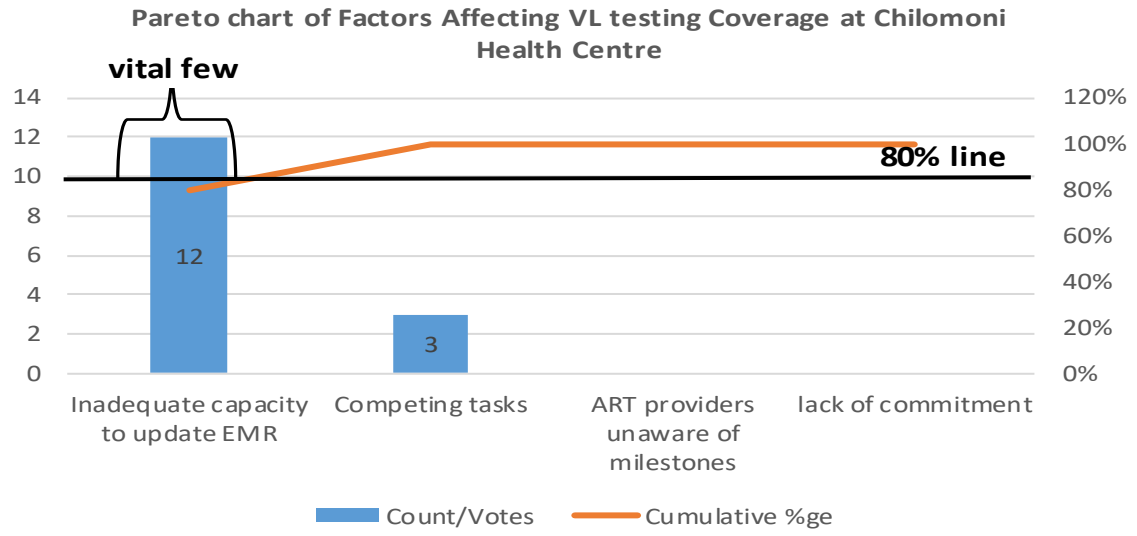


Fig 2: Pareto chart of prioritizing factors affecting low VL coverage at Chilomoni Health Centre in Blantyre

Health care providers voted for factors they perceived highly contributed to the problem of low VL coverage. Updating EMR records was identified as the problem with the highest priority followed by competing tasks that caused inadequate screening.

Step 3: Developing a change idea and prioritization

Possible change ideas that could be implemented were identified by health care providers in a consultative brainstorming session. During the session, health care providers were encouraged to identify change ideas that can be implemented even after control of the COVID-19 situation and delivery of HIV services is back to normal. Health care providers suggested 6 change ideas that could be implemented. Change ideas were prioritized on an effort-impact matrix in order to determine which change idea to implement **(Fig 3)**. The matrix prioritizes change idea(s) based on the effort needed to implement as well as the impact that is cultivated from implementing the change idea [16]. The change ideas requiring the least effort but with high impact were implemented.

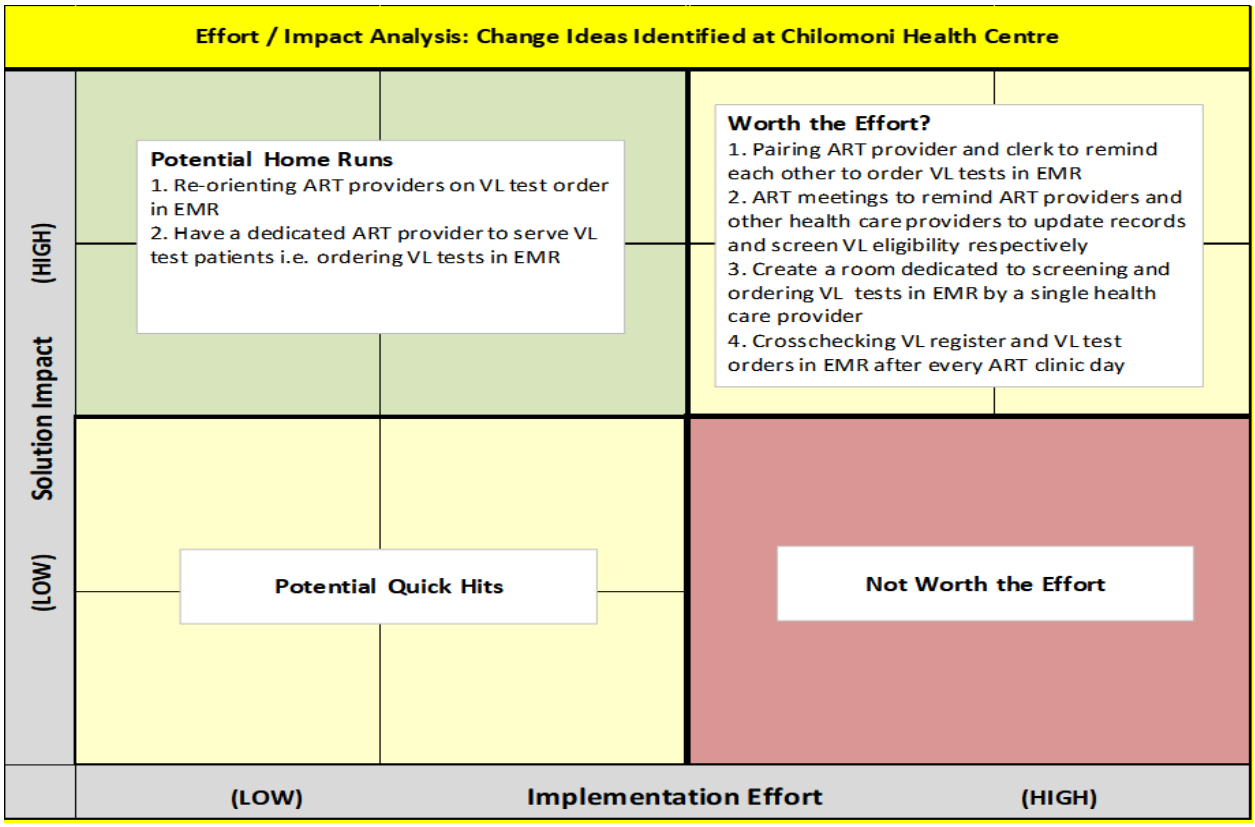


Fig 3: Effort-Impact Matrix of change ideas identified at Chilomoni Health Centre in Blantyre

Phase II

Step 4: Implementation and testing of change ideas (intervention period)

Emanating from the effort-impact matrix, two (2) change ideas were implemented and tested using Plan-Do-Study-Act (PDSA) cycles embedded in the MFI framework (**Table 1**). The PDSA cycle provides a series of steps for planning, executing, analysing and making decisions on a tested change idea. Change ideas were tested in 5 PDSA cycles and with each cycle lasting one week. During each PDSA cycle data on the outcome measure, VL testing coverage, was collected using paper-based forms that were entered in MS Excel. Data on process and balancing measures were also documented.

After each PDSA cycle, the outcome measure and all other related measures were reviewed with the QI team representatives and key health care providers who were present at the ART clinic during the testing of the previous change idea. Key health care providers included ART providers (nurses and clinician), Expert Clients working at the reception, HSAs working in the VL and EID rooms and clerks. It is at these reviews that a decision was made on the previously tested change idea and the next PDSA cycle was planned.

Description of PDSA cycles

PDSA cycle 1: *Re-orienting ART providers on VL test order in EMR*

The VL focal and data clerk reoriented ART providers present on that ART clinic day on how to order a VL test in EMR 15 minutes prior to start of the ART clinic.

PDSA cycle 2: *Re-orienting ART providers on VL test order in EMR adapted*

The same change idea from the first PDSA cycle was implemented. However, the VL focal appointed a team leader who was responsible for assigning responsibilities to health care providers present at the ART clinic, including screening for VL eligibility. A different set of health care providers worked on each ART clinic day.

PDSA cycle 3: *Dedicated ART provider to serve VL tested patients*

One ART provider was responsible for serving patients who had received a VL test. The designated ART provider sat in the office nearest to the VL test room on that clinic day. All patients including MIPs were asked to go through the reception for screening before accessing any service at the ART clinic, including EID services. Health passports of eligible patients were held at the reception and forwarded to the VL testing room. After the VL test, health passports and patients were forwarded to the dedicated ART providers' office. Receipt of VL test was documented in the patients' health passport.

PDSA cycle 4: *Dedicated ART provider to serve VL tested patients adapted*

The same change idea from PDSA 3 was adapted in PDSA 4 to include a VL screening and VL testing roster. Predetermination of health care providers responsible for VL eligibility screening and collecting samples for VL testing was done to promote planning and ensure these core components had dedicated people who knew and had prepared for their task on that ART clinic day.

PDSA cycle 5: *Dedicated ART provider to serve VL tested patients adapted*

The change idea in PDSA 4 was modified in PDSA 5 to include a hardcover that was used by the health care provider responsible for screening to document ART numbers of screened patients and last VL test dates. This was particularly for those patients whose previous ART printed sticker did not show VL test results. This change idea was eventually adopted for use.

Step 5: Monitoring of performance of outcome measure after PDSA cycles (Post-intervention period)

After a change idea was adopted as the new way of operation, PDSA cycles were stopped and performance monitoring of the VL testing coverage continued. This was done to determine if continued implementation of the adopted change idea would bring about the same changes and whether the change idea was sustainable. Monitoring performance of the outcome measure after PDSA cycles lasted 5 weeks and no weekly reviews were done during this period. However, a presentation on the entire QI project was made at the health facility, including the monitoring period data.

Data analysis, documentation and dissemination

Data on individuals due for a VL test regardless of whether they got a VL test or not was imported from Microsoft Excel to STATA for descriptive statistics and bivariate analysis. Segmented regression analysis was also done to assess the significance of change in VL testing coverage at baseline and post-intervention period. We checked for autocorrelation and seasonality, as well as allowed for overdispersion. A standardized population was not used as there were no potential changes over time[18]. Data points during the intervention period were removed during the segmented regression analysis to model out effects of multiperiod interventions which imply PDSA cycles in this study [19].

Run charts and statistical process control (SPC) methods particularly Proportion charts (P-charts), were also used to analyse and review the performance of the outcome measure on a weekly basis throughout the study period.

Ethical consideration

Prior to the start of the study, administrative permission was obtained from the Blantyre District Health Office. Ethical clearance was also obtained from the Human Research Ethics

Committee (HREC) of University of the Witwatersrand (Protocol No.: M1911158) in South Africa and from the National Health Sciences Research Committee (NHSRC) in Malawi (Protocol No.: 20/01/2455).

Written consent was obtained from health care providers and patients whose records were used for the prospective record review. For children, consent was taken from their parents and guardians. For children aged 7 to 17 years, consent was also taken form the children themselves. Names and identifiable data of patients were not documented and data was password protected.

Results

Overall, 803 records were identified. However, 428 records belonging to 370 pregnant and lacting women as well as children were reviewed during the study from baseline to the end. Some patients visited the ART clinic twice during the study; at baseline and during the intervention or post-intervention period hence they had more records than other patients. However, each visit was treated as a unique record during weekly tabulations of VL testing coverage.

Generally, more individuals came to the ART clinic at baseline (55%) than during the post intervention period ***(Table 2)***. In addition, there were fewer children than pregnant and lactating women that came through to the ART clinic at baseline and post-intervention. On a related note, age group and particant type were highly associated with receiving a VL test at baseline ($\chi2=14.1515(p=0.001)$ and $\chi2=14.0504(p=0.000)$ respectively).

289 *Table 2 Characteristics of study participants during baseline and post-intervention*

Characteristic	*Viral load test*							
	Baseline				**Post-Intervention**			
	Yes [n=69(34%)]	**No [n=134(66%)]**	**Total [n=203(100%)]**	**Test Statistic (p-value)**	**Yes [n=61(83.56%)]**	**No [n=12(16.44%)]**	**Total [n=73(100%)]**	**Test Statistic (p-value)**
Age-Group				χ2=14.1515(p=0.001)				χ2=0.8172(p=0.665)
Less than 14years	8(14.81%)	46(85.19%)	54(100%)		13(86.67%)	2(13.33)	15(100%)	
15-17years	2(20%)	8(80%)	10(100%)		3(100%)	0(0%)	3(100%)	
18years and older	59(42.45%)	80(57.55%)	139(100%)		45(81.82%)	10(18.18%)	55(100%)	
Sex				χ2=2.565(p=0.109)				χ2=0.5090(p=0.476)
Male	9(23.08%)	30(76.92%)	39(100%)		10(90.1%)	1(9.09%)	11(100%)	
Female	60(36.59%)	104(63.41%)	164(100%)		51(82.26%)	11(17.74%)	62(100%)	
Participant Type				χ2=14.0504(p=0.000)				χ2=0.4936(p=0.482)
Child	10(15.63%)	54(84.38%)	64(100%)		16(88.89%)	2(11.112%)	18(100%)	
Pregnant and/or lactating mother	59(42.45%)	80(57.55%)	139(100%)		45(81.82%)	10(18.18%)	55(100%)	

290

Overall, VL testing coverage improved from 27% during the baseline period to 81% in the post intervention period. Change ideas in the intervention period were implemented and tested from week 9 to week 13 in which an upward trend was observed (**Fig 5**).

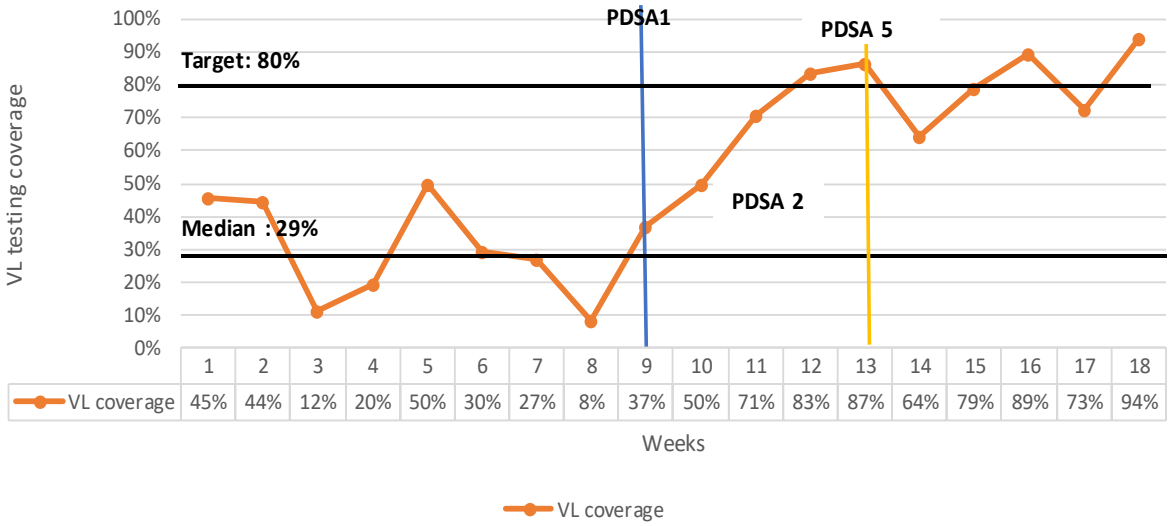


Fig 4: Run chart of VL testing coverage at Chilomoni Health Center in Blantyre

The first change idea was implemented at week 9 (PDSA 1) and adapted at week 10 as it was observed that there was inadequate capacity to make VL test orders in EMR. In addition, screening for VL test eligibility was also inadequate. However, the change idea was abandoned all together after review of PDSA 2 at week 10; low proportions of VL tests were made in the EMR (50%) and 29% of the VL tests ordered in EMR were made without collection of a blood sample. This was particularly so for individuals who were discovered to be due for a VL test in the ART providers office and were sent to the VL testing room for sample collection after they had already received their medication. The ART provider would order a VL test in EMR but patients never made it to the VL testing room.

The new change idea implemented at week 11 (PDSA cycle 3) emphasized on intensified screening at the ART clinic reception, rather than the waiting area. There were no incorrect lab orders made in EMR in this PDSA cycle and 95% of the VL tests conducted were ordered in EMR. The health facility was able to hit the 80% target at weeks 12 and 13 (PDSA cycles 4 and 5) and all VL tests conducted were ordered in EMR, with no incorrect orders being made in the system. PDSA 4 and 5 were an adaptation of the change idea in PDSA 3 after it was observed that identifying people responsible for screening and and collecting samples for VL testing on an ART clinic day was a challenge and delayed service delivery, and some VL test records in the EMR were not up to date. The *ART provider dedicated to serve VL tested patients* change idea was adopted after PDSA 5 and was implemented throughout the post-intervention phase.

Monitoring of the outcome in the post-intervention phase started at week 14. Coverage of VL testing dropped at weeks 14 and 17, with the highest VL testing coverage being recorded at week 18 (the final week) at 94%. Special cause variations were also observed during the post intervention phase (weeks 16 and 18); VL testing was above the upper control limit (UCL) (**Fig 5**).

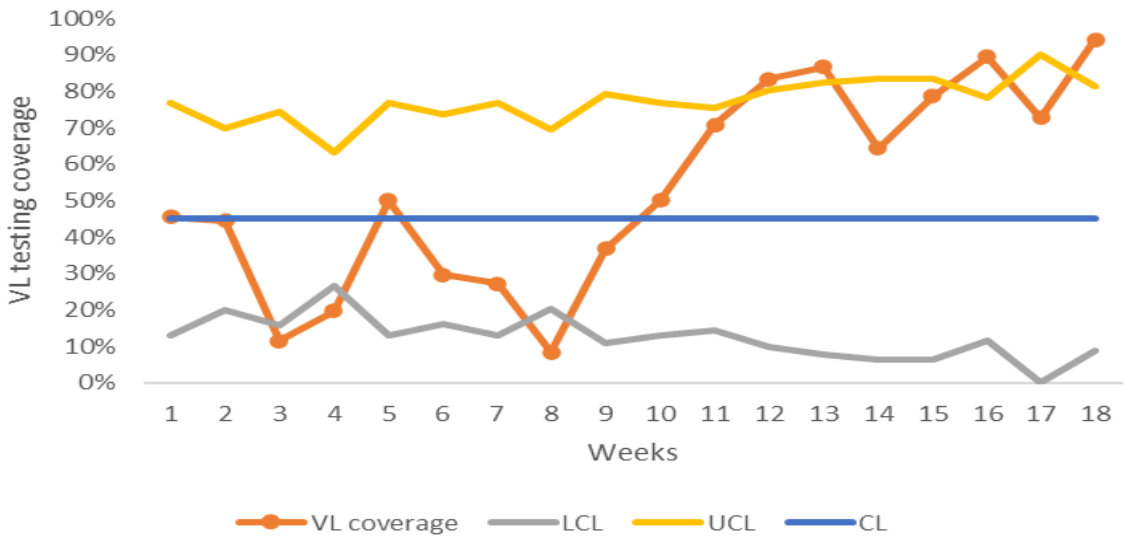


Fig 5: P-Chart of VL testing coverage at Chilomoni Health Center with Upper and Lower Control Limit

These can be attributed to the change idea that was being implemented [20]. The special cause variations at weeks 12 and 13 in the intervention phase were also caused by the same adopted change idea. Reasons for special cause variations observed during the during baseline at weeks 12, 13, 16 and 18 could not be identified due to restrospective data collection.

Evidence from the segmented regression analysis also suggests there was an overall significant increase in VL testing coverage after implementation of the change ideas in the post intervention period (IRR 7.026; 95% confidence interval (CI) 1.484-33.263; P < 0. 014), despite no signficance in the change in VL testing coverage from week to week (IRR 0.929; 95% confidence interval (CI) 0.819-1.054; P < 0. 255). However, the increase in VL testing coverage in the post-intervention period among children was not significant (IRR 4.840; 95% confidence interval (CI) 0.406-57.681; P < 0. 212), unlike the increase that was observed among the pregnant and lactating women (IRR 6.929; 95% confidence interval (CI) 1.494-32.119; P < 0. 013). The regression results suggest the interventions were not as effective on the child population.

Discussion

Our study set out to improve VL testing coverage at Chilomoni health centre using a QI approach, particularly using the MFI. Overall, VL testing coverage improved by 3 times in the post-intervention period. Implementation of the adopted change idea that was identified and tested through utilization of the MFI model brought about significant improvement in VL testing coverage among pregnant and lactating women in the post intervention period. On the other hand, the results suggest the need to develop interventions specific for children in order to

improve VL testing coverage as evidenced by the insignificant change of the outcome in the post-intervention period.

Although there was a steady increase in the outcome during the intervention period, shortage of staff caused fluctuations in VL testing coverage particularly in the post intervention period. Shortage of staff was identified as the utmost facility-specific barrier to VL monitoring in another study conducted in Malawi [21]. The situation in our study was further exacerbated by the report of the first COVID-19 case at the health facility during the last PDSA cycle which resulted in immediate quarantine of some health care providers from the ART clinic hence a reduction in staff. Inadequate staffing in our study was also caused by competing tasks; health care providers were attending a TB training, while others were supporting the COVID-19 quarantine centre in the district and some were still in quarantine. Staffing is therefore a critical factor in cultivating wins in the VL testing process.

Similar to the baseline VL testing coverage in our study, Blantyre district's VL testing coverage was reported to be between 25% and 30% in 2019 [14]. Causes of low VL testing coverage established in this study through fish bone analysis; in adequate capacity by ART providers to update EMRs, competing tasks, ART providers being unaware of milestones and lack of commitment, also agree with other study findings conducted in other limited resource countries, including Malawi. For instance, inadequate documention of samples collected for VL tests, clinical knowledge gaps and shortage of staff that led to overwhelming responsibilities were identified as barriers to VL testing in Malawi [22,23]. In our study, the most prominent factors were inadequate capacity by ART providers to update EMRs and competing tasks. As such, all change

362 ideas implemented from the second PDSA to the last cycle aimed at addressing these factors as
363 a package.

364 Emphasis in the first implemented change idea was reorienting ART providers, an informal
365 method of training, and screening of VL test eligibility. Training of health care providers has the
366 ability to improve willingness to use Electronic Health Records (EHR) systems as well as effective
367 use of the system, including using advanced features in EHR like order tests [24]. However, in our
368 study training did not bring about substantial change as would have been anticipated. This can
369 be attributed to the informal nature of the orientation itself but also time taken to conduct the
370 exercise. The second change idea was more complex. Deciding to have the reception as the
371 starting point for all patients visiting the ART clinic made screening efficient and identification of
372 VL eligible patients easier. In addition, escorting patients eligible for VL testing to the VL room
373 while holding on to their health passports ensured that the patients made it to the VL room, a
374 sample for VL testing was collected and documented in their health passport. Accompanying HIV
375 positive pregnant mothers with low CD4 count by ANC clinic staff to the Highly Active
376 Antiretroviral Therapy (HAART) clinic led to improved access to HAART in ANC clinics from 10%
377 to 25 % in primary care sites in Cape Metro Subdistrict, South Africa [25]. A dedicated ART
378 provider situated in a room next to the VL room also enabled the ART provider to remember to
379 update VL test orders in EMR hence all VL tests were reflected in the system.

380 Contexts in which structures and guidelines for QI are already existent provide a conducive
381 environment for implementing QI projects [26]. The existence of a QI team and knowledge of QI
382 at the health facility was an important enabler in this project. Other facilitators in our study
383 included committed health care providers to the QI project, good data collection and extraction

of records and local leadership buy-in. Good communication and review of VL testing coverage with relevant health care providers was also another facilitator. On the other hand, COVID-19 was a barrier as it slowed down processes and affected the study population. An unreliable data system at the health facility was also another barrier although this was dealt with through a catchup data entry exercise of all VL testing data. The existence of a reliable data system that is functional, up to date and allows easy extraction of data can not be emphasized enough if a QI intervention of this nature is to succeed as this is the source of all the evidence of whether progress is being made or not.

One of the limitations of our study was that the study duration was short. As a result, there was inadequate time to assess sustainability of improved VL testing coverage due to the adopted and implemented change idea. External validity of the change ideas implemented in this study is uncertain as these were specific to Chilomoni health center and its problems. Nevertheless, other health facilities are encouraged to employ the methods and components of interventions that apply to their setting. On a related note, our study expected to have a larger sample size than what was realized. Sample size was affected by change in HIV service delivery guidelines because of COVID-19; VL testing was only available to certain groups of individuals. On the other hand, strengths of the study included using local data and expert opinion as well as available resources and structures. There was no creation of parallel structures just to cater for the QI study. This helped to promote a sense of ownership and commitment from health care providers. It also assisted in minimizing costs that come with introducing new structures in a system [27]. Use of the MFI as a guiding framework will also allow comparison of our study methodology and results with other studies.

Conclusion and recommendations

Our study experience demonstrates that VL testing coverage can be improved using a QI approach, particularly using the MFI framework. We recommend the use of QI approaches in improving VL testing coverage, and the VL continuum as a whole in order to improve service delivery. On a different note, there is need for investment by government through the Ministry of Health in reliable and efficient electronic data systems that enable health care providers easily access complete and rich data for monitoring indicators, as well as implementation of QI interventions. Iinvestments in electronic data systems would allow health care providers to be able to easily extract data and monitor progress without having to go through the tedious process of reviewing all individual patient records just to determine VL test eligibility for instance. The appointment calendar in the ART EMR system in Malawi provides a list of names of individuals coming to the ART clinic on any particular date, including their age, sex and date of ART initiation. We suggest including VL test eligibility data on this appointment list in EMR to improve screening and data extraction processes hence improving VL testing coverage. Continued success and improvement will be dependent on the QI leadership as well as commitment of health care providers.

Further research is needed to evaluate sustainability of the improved VL testing coverage at the health facility, including an assessment on patient related factors that affect VL testing coverage with a focus on the paediatric population and application of quality improvement efforts to improve their VL testing coverage. It would also be vital to assess the impact of change in policy

from VL testing every two years after the first initial VL test to annually, including the new guidelines for VL testing amid COVID-19.

Acknowledgements

We would like to thank the University of Witwatersrand and UNC project in Lilongwe for their support during research. We would also like to thank the Blantyre District Health Office for allowing us access to their health facility including its data, as well as Chilomoni Health Centre for all their support.

References

1. World Health Organization. March 2014 Supplement on the use of antiretroviral drugs for treating and preventing HIV infection. 2014; 130. Available: https://apps.who.int/iris/bitstream/handle/10665/104264/9789241506830_eng.pdf?sequence=1

2. Sigaloff KCE, Hamers RL, Wallis CL, Kityo C, Siwale M, Conradie F, et al. Unnecessary ART Regimen Switches and Accumulation of HIV-1 Drug-Resistance Mutations : Two Arguments for Viral Load Monitoring in sub-Saharan Africa. 2011;58: 12454.

3. Killingo BM, Taro TB, Mosime WN. Community-driven demand creation for the use of routine viral load testing: A model to scale up routine viral load testing. J Int AIDS Soc. 2017;20: 4–8. doi:10.1002/jia2.25009

4. UNAIDS data 2018. Geneva, Switzerland; 2018.

5. WHO. Considerations for developing a monitoring and evaluation framework for viral load

testing. 2019.

6. Lecher S, Williams J, Fonjungo PN, Kim AA, Ellenberger D, Zhang G, et al. Progress with Scale-Up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries, January 2015–June 2016. MMWR Morb Mortal Wkly Rep. 2016;65: 1332–1335. doi:10.15585/mmwr.mm6547a2

7. MoH Malawi. Ministry of Health HIV viral load scale Up implementation plan. 2015. Available: aidsfree.usaid.gov/sites/default/files/malawi_vl_scaleup.pdf

8. PEPFAR. Malawi Country Operational Plan (COP) 2018 Strategic Direction. 2018. Available: https://www.pepfar.gov/documents/organization/285860.pdf

9. Rutstein SE, Golin CE, Wheeler SB, Kamwendo D, Hosseinipour MC, Weinberger M, et al. On the front line of HIV virological monitoring: Barriers and facilitators from a provider perspective in resource-limited settings. AIDS Care - Psychol Socio-Medical Asp AIDS/HIV. 2016;28: 1–10. doi:10.1080/09540121.2015.1058896

10. Médecins Sans Frontières. Making viral load routine: Successes and challenges in the implementation of routine HIV viral load monitoring. UNITAID Rep. 2016. Available: aidsfree.usaid.gov/sites/default/files/making_vlprogstrat.pdf

11. Kurowski EM, Schondelmeyer AC, Brown C, Dandoy CE, Hanke SJ, Cooley HLT. A practical guide to conducting quality improvement in the health care setting. Curr Treat Options Peds. 2015; 380–392. doi:10.1007/s40746-015-0027-3

12. Speroff T, O'Connor GT. Study designs for PDSA quality improvement research. Qual Manag Health Care. 2004;13: 17–32. doi:10.1097/00019514-200401000-00002

13. Malawi Ministry of Health. Malawi Population-Based HIV Impact Assessment (MPHIA) 2015-2016: Final Report. 2018.

14. USAID- PEPFAR. Malawi Country Operational Plan COP 2019. 2019 Apr. Available: http://www.croiconference.org/sessions/effect-tb-screening-and-retention-interventions-early-art-mortality-botswana

15. Malawi Ministry of Health. Ministry of Health: COVID-19 Guidance for HIV Services. 2020. Available: https://www.differentiatedcare.org/Portals/0/adam/Content/dGLU8P8dhkOEMHjU8ZRqiA/File/Malawi_Guidance on HIV services with COVID-19Edition 2version 2.pdf

16. Langley GJ. The improvement guide a practical approach to enhancing organizational performance. 2nd ed. Langley GJ, editor. San Francisco, California: Jossey-Bass; 2009.

17. Harel Z, Silver SA, McQuillan RF, Weizman A V., Thomas A, Chertow GM, et al. How to Diagnose Solutions to a Quality of Care Problem. Clin J Am Soc Nephrol. 2016;11: 901. doi:10.2215/CJN.11481015

18. Bernal JL, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial. Int J Epidemiol. 2017;46: 348–355. doi:10.1093/IJE/DYW098

19. Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther. 2002;27: 299–309. doi:10.1046/J.1365-2710.2002.00430.X

20. Crisóstomo Portela M, Pronovost PJ, Woodcock T, Carter P, Dixon-Woods M, Margareth D, et al. How to study improvement interventions: a brief overview of possible study types. [cited 11 Sep 2020]. doi:10.1136/bmjqs-2014-003620

21. Roth GA, Abate D, Abate KH, Abay SM, Abbafati C, Abbasi N, et al. Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980–2017: a

systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392: 1736–1788. doi:10.1016/S0140-6736(18)32203-7

22. Lecher S, Ellenberger D, Kim AA, Fonjungo PN, Agolory S, Borget MY, et al. Scale-up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries. MMWR Morb Mortal Wkly Rep. 2015;64: 1287–1290. doi:10.15585/mmwr.mm6446a3

23. Hubbard J, Kakwesa G, Nyirenda M, Mwambene J, Bardon A, Balakasi K, et al. Towards the third 90: improving viral load testing with a simple quality improvement program in health facilities in Malawi. Int Health. 2019;11: 215–220. doi:10.1093/inthealth/ihy083

24. Bredfeldt CE, Awad EB, Joseph K, Snyder MH. Training providers: Beyond the basics of electronic health records. BMC Health Serv Res. 2013;13: 503. doi:10.1186/1472-6963-13-503

25. Youngleson MS, Nkurunziza P, Jennings K, Arendse J, Mate KS, Barker P. Improving a Mother to Child HIV Transmission Programme through Health System Redesign: Quality Improvement, Protocol Adjustment and Resource Addition. Marais B, editor. PLoS One. 2010;5: e13891. doi:10.1371/journal.pone.0013891

26. Kassaid G, Doughertyid G, Madevu-Matson C, Egesimba G, Sartie K, Akinjeji A, et al. Improving inpatient provider-initiated HIV testing and counseling in Sierra Leone. [cited 15 Sep 2020]. doi:10.1371/journal.pone.0236358

27. Twum-Danso NAY, Akanlu GB, Osafo E, Sodzi-Tettey S, Boadu RO, Atinbire S, et al. A nationwide quality improvement project to accelerate Ghana's progress toward millennium development goal four: Design and implementation progress. Int J Qual Heal Care. 2012;24: 601–611. doi:10.1093/intqhc/mzs060

EXTENDED METHODOLOGY

This chapter gives an extended description of the methods that were not adequately described in the manuscript. Specifically, the section describes the process of VL testing at Chilomoni health centre and measures in detail. The chapter concludes with a detailed explanation of what was entailed in each of the PDSA steps as used in this study. All other sections were thoroughly described in the manuscript.

The Process and Measures

Quality improvement seeks to improve services being provided and a service where QI is being applied for improvement is called a Process. In this study, the process being improved was viral load testing during ART clinic days.

The Viral Load Testing Process at Chilomoni Health Centre

At Chilomoni Health Centre, the initial process of VL testing started with health talks at the waiting area. Topics covered during the health talk included what viral load is and how often one should receive a VL test, taking ART and possible side effects, including COVID-19 safety measures after the first COVID-19 case was identified in Malawi. From the waiting area, the patient went into the reception to collect their ART card and to get their vitals such as weight and height checked. The patient would then go back to the waiting area or the ART provider's office for consultation and medication. Prior to consultation, if the patient is found to be due for a VL test at the waiting area where health passport books were checked, or in the ART providers office, the patient was sent to the VL testing room for a sample to be drawn and then proceed with all other activities at the ART clinic.

If the patient is a Mother-Infant pair, the pair would first go to the EID desk for consultation and medication for the infant, after which the mother would go to the waiting to be screened for VL eligibility, but also to get an ART card at the reception. The mother would also get vitals checked at the reception. If the mother is found to be due for a VL test, the mother was sent to the VL room, which is in the same room where the EID desk is at the health facility. The mother-infant pair would then go through the rest of the steps at the ART clinic. The figure below depicts the VL testing process at Chilomoni health centre before implementing change ideas:

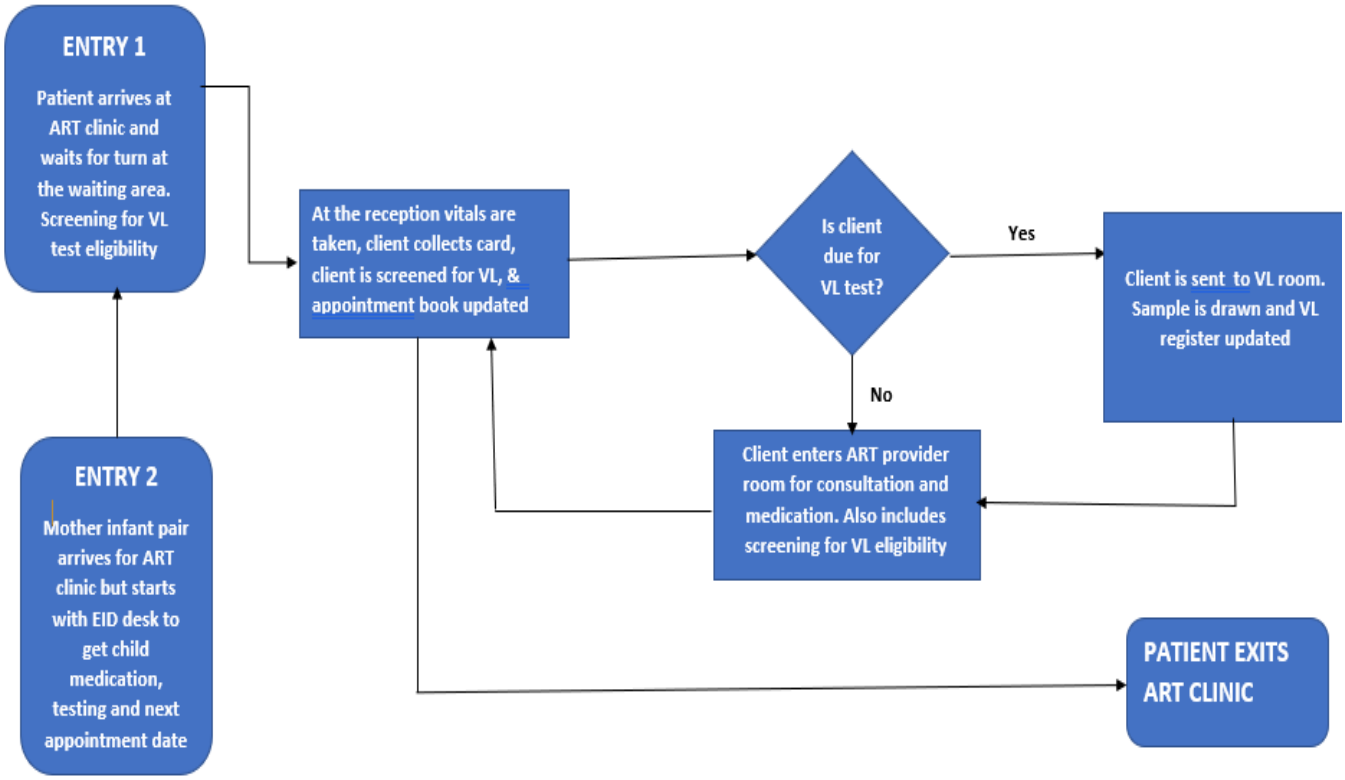


Figure 2: Viral load testing process at Chilomoni health center

Outcome, Process and Balancing Measures

As a QI project is being conducted, it is important to have a set of variables on which data will be collected in order to keep track of the QI intervention. These are called Measures in QI and they are categorized into three: Outcome, Process and Balancing Measures.

Outcome measure is the main goal that is to be achieved by the QI intervention(1). In the study, the outcome measure was VL testing coverage. For the purposes of this study, VL testing coverage is defined as the proportion of individuals who have been on ART for 6

months or more, were due for a VL test and received a VL test, and have been documented in the VL testing register regardless of whether they received a result or not. Calculations for this measure involve:

Numerator: Number of individuals who have been on ART for 6 months or more, were due for a VL test and had a VL test and are documented in the VL register regardless of whether they received a result or not.

Denominator: Number of individuals who have been on ART for 6 months or more and are due for a VL test at the facility during that period.

Process measures are associated with the change idea and help to keep track of the key steps in the implementation of the change idea (2). Process measures for each change idea were determined before implementation and testing of the change idea by the Primary Investigator (PI) and representatives from the QI team. Overall, the study had 3 process measures:

Proportion of ART providers re-oriented on ART clinic day. This was defined as the proportion of ART providers present who received orientation on how to order VL tests in EMR by the Data clerk on that ART clinic day. Reorientation took utmost 10 minutes.

Numerator: Number of ART providers present on ART clinic day

Denominator: Number of ART providers re-oriented on how to order VL tests in EMR by Data clerk on that ART clinic day

Proportion of VL tests ordered in EMR defined as the proportion of VL tests available in VL register that have been ordered in the EMR

Numerator: Number of VL tests ordered in EMR

Denominator: Number of VL tests documented in VL register

Proportion of individuals who were eligible for a VL test and had their health passport held at the reception, received a VL test. This measure was defined as proportion of individuals who were eligible for a VL test after being screened at the reception, had their health passports held and forwarded to the VL room for VL testing.

Numerator: Number of individuals who were identified as eligible for a VL test, had their health passports held at the reception and then forwarded to the VL room for testing

Denominator: Number of individuals who actually received a VL test as documented in the VL register

Balancing measures are measures that aim to track unintended consequences to other parts of the system due to the implementation of the change idea (1). These consequences could either be positive or negative. The balancing measure below was also determined before implementation and testing of change ideas:

Proportion of VL tests ordered in EMR but individual did not receive a VL test. This was defined as the proportion of tests that were in the EMR but the individual did not actually receive a test. It was envisaged that ART providers might order a VL test in EMR for an individual who did not receive a VL test but might have been found eligible by the ART provider.

Numerator: Number VL tests ordered in EMR for individuals who did not receive a VL test

Denominator: Number of all VL tests ordered in EMR

In addition to the measures mentioned above, data on variables described in Appendix I was also collected.

PDSA Cycle Description

Plan

During this step, resources needed to implement the change ideas were identified, including human resource. Responsibilities pertaining to the change idea were assigned to relevant health care providers. In general, this step involved identifying who was responsible for what, where the change would take place and how it will be implemented. Process measures were also identified during this step.

Do

The 'Do' step involved actual implementation of the change idea and collecting data on the outcome, process and balancing measures

Study

During this step, the PI compiled patient record data on the outcome measure in Microsoft Excel. This data was then exported to STATA for basic analysis. The outcome measure was then plotted on the run chart. The run chart was used during review of the outcome measure with 3 QI team representatives and other health care providers from the ART clinic who were present during the test of the change idea. The other health care providers from the ART clinic were included to ensure no issues and/or observations from the last PDSA cycle were missed.

This step also involved a review of what was actually planned against what was implemented, review of measures, as well as establishing what worked and what did not, including possible reasons.

Act

Depending on what was unveiled in the 'Study' step, the change idea was abandoned, adapted or adopted. If there was no change, the change idea was abandoned and another change idea from the list of change ideas was then tested in the next PDSA cycle on priority basis. If the change idea brought about change but needed some alterations, the change idea was adapted and some components were removed or added to the change idea. If the change idea brought about substantial change and the QI team was comfortable with the change that had been attained, the change idea was adopted. Results and actual decisions made for each PDSA cycle are described in the Results section of this report.

Ethical Consideration

Prior to the start of the study, administrative permission was obtained from the Blantyre District Health Office (Appendix III). Thereafter, ethical clearance was obtained from the Human Research Ethics Committee (HREC) of University of the Witwatersrand (Appendix IV), and from the Malawi National Health Sciences Research Committee (NHSRC) (Appendix V).

On a related note, written consent was obtained from health care providers who were involved in the process of identifying problems and change ideas (Appendix VI). Consent was also sought from participants for the prospective record review (Appendix VII).

References

1. Perla RJ, Provost LP, Murray SK. Sampling Considerations for Health Care Improvement. Q Manag Heal Care. 2013;22(1):36–47.

2. Hulscher ME, Laurant MG, Grol RP. Process evaluation on quality improvement interventions. Qual Saf Heal Care [Internet]. 2003;12:40–7. Available from: who.int/hiv/pub/imai/om.pdf

EXTENDED RESULTS

All results have been adequately presented in the manuscript

OVERALL DISCUSSION, CONCLUSION AND RECOMENDATIONS

The aim of the study was to improve VL testing coverage using a QI approach through identification of root causes of low VL testing coverage at Chilomoni health center and implementing and testing identified change ideas as guided by the MFI. The QI approach used in this study involved utilizing small tests of change which eventually led to the improvement of VL testing coverage recorded at baseline, from 27% at baseline to 81% by the end of the study. Implementation of the adopted change idea that was identified and tested brought about significant improvement in VL testing coverage among pregnant and lactating women in the post intervention period. On the other hand, the results suggest the need to develop interventions specific for children in order to improve VL testing coverage as evidenced by the insignificant change of the outcome in the post-intervention period.

This chapter discusses the findings of the study in detail. The chapter first deliberates on the baseline VL coverage and factors affecting VL testing coverage at Chilomoni health center in relation to other literature. The chapter also discusses results of the PDSA cycles, what they imply and what led to success. The chapter concludes with study limitations and recommendations for study results utilization and future research.

Baseline viral load coverage

Viral load testing coverage at Chilomoni health center before implementation of change ideas was at 27%. This was within the range of the VL testing coverage of Blantyre, the district in which the health center is located. Viral load testing coverage in the district is between 25% and 30% (1). Overall, baseline findings of this study revealed that VL testing coverage was low at Chilomoni health center.

Causes of viral load testing coverage at Chilomoni health center

This study established that low VL testing coverage at Chilomoni health center was as a result of inadequate capacity by ART providers to update EMRs, competing tasks, some ART providers were unaware of milestones and lack of commitment. Change in policies was also a contributing factor. However, focus during the study was on factors that health care providers at the health facility had control over.

Inadequate capacity to update EMRs had the highest number of votes, twelve, and a cumulative percentage of 80%, followed by competing tasks which led to inadequate

screening for VL testing. Health workers felt that adequate VL tests were being conducted. Nevertheless, they also felt that most of the tests were not reflected in EMRs due to inadequate capacity of ART providers to make VL test orders in the system. On the other hand, health care providers at the ART clinic also expressed competing tasks caused by staff shortages on some ART clinic days led to low VL testing coverage. This in turn led to inadequate screening for VL test eligibility as health care providers have to toggle two or more duties at once hence missing out on the opportunity to screen and identify individuals in need of a VL test. Inadequate capacity to update EMRs formed the basis for most change ideas as it was thought it to be the leading cause. After the first PDSA cycle it was established that screening was just as much of a major problem as updating VL tests in EMR. Therefore, the subsequent PDSAs after the first PDSA ensured that both issues were tackled as a package in order to address low VL testing coverage at the health facility.

A QI study conducted in Malawi by Hubbard indicated that one of the causes of poor performance for VL testing was inadequate sample documentation(2). A report by MSF also indicated that missed opportunities for identifying patients in need for a VL test (screening) was also a cause for low VL testing coverage (3). This study revealed that factors affecting VL testing coverage established in other studies were still relevant and need continued addressing in order to ensure extensive coverage.

Change ideas and PDSA cycles

Overall, 2 change ideas were implemented in 5 PDSA cycles. Both change ideas were implemented because of the presumed high impact and less effort that would be required for implementation as voted by health care providers. High impact was defined with regards to the change in VL coverage that would be realized after implementation of the change idea. On the other hand, effort was viewed in relation to resources like money, human resource and amount of time it would take to implement the change idea.

The first change idea to be implemented was reorienting ART providers on how to order a test in EMR and this was done in two PDSA cycles. After implementation of the change idea, VL testing coverage improved by 10 points from the overall baseline coverage to 37%. However, during review of the PDSA cycle, it was established that screening was inadequate hence the need to enforce screening in the next PDSA cycle. In the second PDSA, VL testing

coverage improved from 37% to 50% after adapting the change idea implemented in PDSA cycle 1. The adaptation involved a team leader who was responsible for assigning responsibilities: screening and VL testing. Nevertheless, the performance was still not yielding the results the team was looking for hence it was abandoned and the second change idea was implemented and tested.

The second change idea to be implemented was that of a dedicated ART provider. The change idea was implemented in 3 PDSA cycles with the fourth and fifth PDSA cycles being improvements of the third PDSA cycle. It was during the testing of this change idea that the target set by the team was reached.

Emphasis in the first implemented change idea was reorienting ART providers, an informal form of training, and screening of VL test eligibility. Training of health care providers has the ability to improve willingness to use Electronic Health Records (EHR) systems as well as effective use of the system, including using advanced features in EHR like order tests (4). However, in our study training did not bring about substantial change as would have been anticipated. This could be attributed to the informal nature of the orientation itself but also time taken to conduct the orientation. The second change idea was more complex with multiple components. Deciding to have the reception as the starting point for all patients visiting the ART clinic made screening efficient and identification of VL eligible patients easier. Escorting and holding health passports of patients eligible for VL testing to the VL room ensured that a sample for VL testing was collected and documented in their health passport. Accompanying HIV positive pregnant mothers with low CD4 count by ANC clinic staff to the Highly Active Antiretroviral Therapy (HAART) clinic improved access to HAART in ANC clinics from 10% to 25 % in primary care sites in Cape Metro Subdistrict, South Africa (5). A dedicated ART provider situated in a room next to the VL room also enabled the ART provider to remember to update VL test orders in EMR hence all VL tests were reflected in the system.

Overall, during implementation of PDSA cycles, there was steady increase in the VL coverage as an upward trend was noticed. Viral load testing coverage dropped during the first week however and at week 17. During the last PDSA cycle at week 13, the first suspected COVID-19 case was identified. The suspected case came through the ART clinic for a refill and was later confirmed positive. The ART clinic therefore had to be disinfected. This affected operation of the ART clinic as some patients thought the clinic was closed and some health care providers

went into quarantine as they were in direct contact with the COVID-19 patient. At week 17, there was shortage of staff; some health care providers were still in quarantine, others had gone to support the quarantine center in the district and there was also a TB related training going on around the same time.

The special cause variation observed in the P-Chart (Fig 4) at weeks 12 and 13 (PDSA 4 and 5) was a reflection of the change idea being implemented(6). Viral load testing coverage was above the upper control limit. This is also evident during the monitoring period at weeks 16 and 18 as the process and staffing issues returned to normal. Since the special cause variation was a result of the change that was introduced to the process, the change therefore should be maintained.

In summary, the change ideas implemented and tested during the study brought about change; from 27% at baseline to 65% during PDSA cycles and to 81% in the post-intervention/monitoring phase after adoption of the change idea. This is consistent with other studies in which health facilities utilized QI approaches to improve health service provision, including improvements in VL testing coverage (7–11). Average VL testing coverage increased by 200% during the post intervention (monitoring) phase. This is higher than what was evidenced in another QI study aimed at improving VL testing, an average increase of 164% (2). However, it should be noted that in this study, VL testing coverage was tracked weekly and in the other study monthly.

Enablers and barriers to effective implementation of QI interventions

Contexts in which structures and guidelines for QI are already existent are optimal settings for QI projects (10). The existence of a QI team and knowledge of QI at the health facility was an important enabler in this project. Other facilitators included committed health care providers to the QI project, good data collection and extraction of records and local leadership buy-in. Good communication and regular review of VL testing coverage while involving relevant key health care providers was a facilitator (12). On the other hand, COVID-19 was a barrier as it slowed down processes and affected VL testing coverage. A reliable data system at the health facility was also another barrier although this was dealt with partially. The EMR did not allow generation of some basic data like a list of names or ART numbers due for a VL test, even aggregate figures disaggregated by sex, age, and time, including many other basic

functions. There was a lot of backlog VL test results data that had not been entered which could have resulted in other individuals being identified as due for a VL test when they had received a test already. The responsible data personnel was assigned the task of updating records. This exercise was particularly important for patients whose VL test was not ordered at the time of the VL test but their results were ready. The system allowed for entry of results even if the VL test was not ordered. The existence of a reliable data system that is functional, up to date and allows easy extraction of data can not be emphasized enough if a QI intervention of this nature is to succeed as this is the source of all the evidence of whether progress is being made or not.

Strengths and limitations

One of the strengths of this study is the use of local data and local expert opinion from individuals well conversant with issues of VL testing in the district but also at health facility. On a related note, the study utilized resources and structures from the health facility itself and within the capabilities of the health care providers at the facility throughout the study. This assisted in obtaining the necessary buy-in from management both at district level and health facility level. There was also a sense of ownership that was promoted, in addition to the cost-effectiveness as a result of using available resources and using already existent structures, instead of creating parallel structures specifically for the QI study (13).

Using a well-established framework, the MFI, to guide the methodology of the study makes the study methodology and results easy to evaluate and compare with other similar studies. Use of the framework also allowed a comprehensive step by step description of the methodology making it easy for other health facility to follow through and adapt. In addition, the results of this study are generalizable and can be adopted or adapted depending on contextual factors.

On the other hand, the study duration was too short. As a result, there was inadequate time to assess sustainability of improved VL testing coverage due to the adopted and implemented change idea. Although the study included everyone, the study expected to have a bigger sample size than what was realized. Sample size was affected by change in HIV service delivery guidelines because of COVID-19; VL testing was only available a certain group of individuals. Typical of most QI projects, the study did not have a comparison group (10).

Conclusion and Recommendations

Overall, our study results show that VL testing coverage can be improved using small tests of change as a QI approach. It can therefore be concluded that employing QI interventions within the viral load continuum, and the HIV cascade in general can lead to improved health care. However, investment by government and Ministry of health has to be made on reliable electronic data systems that not only collect data for administrative purposes, but also allow for monitoring and QI projects (14). Such investments to data systems would allow health care providers to easily monitor progress without having to go through the tedious process of reviewing all individual patient records, even those that are not eligible for a VL test. The appointment calendar in EMR provides a list of names of individuals coming to the ART clinic on any particular date, including their age, sex and date of ART initiation. Including VL test eligibility data on this appointment list in EMR for instance would greatly improve screening and data extraction processes hence improving VL testing coverage.

Although significant improvement was achieved, it would be ideal to assess the impact of our intervention as well as sustainability in maintaining improved VL testing coverage. On the same note, it would also be important to establish patient related factors that affect utilization of VL testing services as it was noted that some patients even after being found eligible for a VL test needed some convincing in order to go through with the process of collecting a sample for VL testing. Special attention on patient related factors should be made on the pediatric population due to the low VL testing coverage established at baseline. Although not within the scope of this study, change in policy from VL testing every two years after the first initial VL test to annually, including the new guidelines for VL testing amid COVID-19 might have implications on the service of VL testing. Understanding the implications of this change and the role of the transition process from one policy to the other, including barriers to the service in the COVID-19 era would go a long way in ensuring gains made so far in VL testing are maintained.

References

1. USAID- PEPFAR. Malawi Country Operational Plan COP 2019 [Internet]. 2019 Apr [cited 2020 Mar 16]. Available from: http://www.croiconference.org/sessions/effect-tb-screening-and-retention-interventions-early-art-mortality-botswana

2. Hubbard J, Kakwesa G, Nyirenda M, Mwambene J, Bardon A, Balakasi K, et al. Towards the third 90: improving viral load testing with a simple quality improvement program in health facilities in Malawi. Int Health [Internet]. 2019;11(3):215–20. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6676971/pdf/ihy083.pdf

3. Médecins Sans Frontières. Making viral load routine: Successes and challenges in the implementation of routine HIV viral load monitoring [Internet]. UNITAID report. 2016. Available from: aidsfree.usaid.gov/sites/default/files/making_vlprogstrat.pdf

4. Bredfeldt CE, Awad EB, Joseph K, Snyder MH. Training providers: Beyond the basics of electronic health records. BMC Health Serv Res [Internet]. 2013 Dec 2 [cited 2020 Nov 10];13(1):503. Available from: https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-13-503

5. Youngleson MS, Nkurunziza P, Jennings K, Arendse J, Mate KS, Barker P. Improving a Mother to Child HIV Transmission Programme through Health System Redesign: Quality Improvement, Protocol Adjustment and Resource Addition. Marais B, editor. PLoS One [Internet]. 2010 Nov 9 [cited 2020 Sep 30];5(11):e13891. Available from: https://dx.plos.org/10.1371/journal.pone.0013891

6. Crisóstomo Portela M, Pronovost PJ, Woodcock T, Carter P, Dixon-Woods M, Margareth D, et al. How to study improvement interventions: a brief overview of possible study types. [cited 2020 Sep 11]; Available from: http://www.health.org.uk

7. Kekana MM, Susannah Cole-Hamilton R, Mongwe M, Railton J, ChB M, HIV Med P H Peters DR, et al. Quality improvement of the viral load programme in Mopani District, Limpopo Province.

8. Izudi J, Mugenyi J, Mugabekazi M, Muwanika B, Tumukunde Spector V, Katawera A, et al. Retention of HIV-Positive adolescents in care: A quality improvement intervention in mid-western Uganda. Biomed Res Int. 2018;2018.

9. Hubbard J, Kakwesa G, Nyirenda M, Mwambene J, Bardon A, Balakasi K, et al. Towards the third 90: Improving viral load testing with a simple quality improvement program in health facilities in Malawi. Int Health [Internet]. 2019 May 1 [cited 2020 Sep 15];11(3):215–20.

Available from: /pmc/articles/PMC6676971/?report=abstract

10. Kassaid G, Doughertyid G, Madevu-Matson C, Egesimba G, Sartie K, Akinjeji A, et al. Improving inpatient provider-initiated HIV testing and counseling in Sierra Leone. [cited 2020 Sep 15]; Available from: https://doi.org/10.1371/journal.pone.0236358

11. Sunpath H, Hatlen TJ, Naidu KK, Msimango P, Adams RN, Moosa MS, et al. Targeting the third "90":introducing the viral load champion. Public Heal action [Internet]. 2018;I(4):225–31. Available from: http://dx.doi.org/10.5588/pha.18.0063

12. Stokes T, Shaw EJ, Camosso-Stefinovic J, Imamura M, Kanguru L, Hussein J. Barriers and enablers to guideline implementation strategies to improve obstetric care practice in low-and middle-income countries: a systematic review of qualitative evidence.

13. Twum-Danso NAY, Akanlu GB, Osafo E, Sodzi-Tettey S, Boadu RO, Atinbire S, et al. A nationwide quality improvement project to accelerate Ghana's progress toward millennium development goal four: Design and implementation progress. Int J Qual Heal Care [Internet]. 2012 Dec 1 [cited 2020 Sep 16];24(6):601–11. Available from: https://academic.oup.com/intqhc/article/24/6/601/1824631

14. Dixon-Woods M, McNicol S, Martin G. Ten challenges in improving quality in healthcare: Lessons from the Health Foundation's programme evaluations and relevant literature [Internet]. Vol. 21, BMJ Quality and Safety. BMJ Publishing Group Ltd; 2012 [cited 2020 Sep 16]. p. 876–84. Available from: http://dx.doi.

APPENDICES

Appendix I: Plagiarism Declaration

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I **Angella Joy Kamwendo** (Student number: **1896506**) am a student

registered for the degree of **MSc Epidemiology-Implementation Science** in the academic year **2019**.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature:  Date: **9th March 2021**

1

Appendix II: Variable definitions

Variable Definitions	
Variable	**Definition**
Factors affecting viral load testing coverage at the health facility	Factors on the health facility and health care provider side (supply) affecting VL testing coverage
Change idea(s) to be implemented	Proposed solutions by the health care providers and QI team, that can be implemented in a short time and could possibly bring about positive change; i.e. increased VL testing coverage.
Age	Age of the individual due for a VL test in years
Gender	Sex of the individual due for a VL test
Date of diagnosis	Date an individual due for a VL test was found with HIV
Date of ART initiation	Date an individual due for a VL test started ART
Last VL test date	Date an individual last had a VL test
Did individual receive a test: 'Yes or No'	This variable was used to determine whether an individual received a test based on eligibility. If the individual was new on ART and 6 months had elapsed or if a year had passed since the VL test, the individual was due for a VL test
Date of VL test/appointment	ART clinic date for which data was being collected
Most recent viral load test result	The current VL test results
Viral load status	Defined as either being virally suppressed or unsuppressed

Appendix III: Brainstorming guide

Brainstorming Session Guide

H/F name: _____ Date of Session: _____

No. of participants: _____

Start time: _____ End time: _____

1. Can you please describe the flow of patients once they come to the ART clinic for ART treatment?
2. How different is the process if the individual is due for a viral load test?
3. What are some of the cause/factors that you think may have an impact on whether an individual who is due for a viral load test, receives the test or not? (Prove for each factor by applying 5 Whys until the root cause is identified)
4. What are some of the changes or interventions you would propose in order to increase the number of individuals who get a viral load test when they are due?

Brainstorming Session Guide (Chichewa Version)

Dzina la Chipatala: _____Tsiku : _____

Nambala ya anthu otenga nawo mabali: _____

Nthawi yoyambila zokambilana: _____

Nthawi yotsilizila zokambilana: _____

1. Mungathe kundilongosolela momwe wodzalandira mankwala otalikitsa moyo amathandizidwira akafika kuchipatala kuno? Chimachitika ndi chani akafika kufikila pomwe walandira mankhwala?
2. Zimasiyana bwanji munthuyi akakhala kuti akuyenera kutengedwa magazi kuti akayezedwe viral load?
3. Inu mukuona ngati chimatitsa ndichiyani kuti ena asatengwedwe magazi kuti akayezedwe viral load nthawi yawo ikakwana? (Funsani “chifukwa” kasanu kuti mupeze chifukwa chenicheni)
4. Inu mukuona kuti tingasinthe zinthu ziti pachipatala pano zomwe ife patokha tingathe kuzikhazikitsa ndicholinga choti aliyense amene akuyera kuyezedwa viral load, atengedwe magazi nthawi yake ikafika?

Appendix IV: Permission to conduct study

Telephone: Blantyre 0 1875332 / 01 877 401
Fax: 01 875 430 / 01 872 551/01878 539

Communication should be addressed to:
The Director of Health and Social Services
0882002533; gkawalazira @yahoo.co.uk

In reply please quote No. .....

DISTRICT HEALTH OFFICE
P/BAG 66
BLANTYRE
MALAWI

Ref No: BT DHO/MED/9

17th December, 2019

The Chairman
National Health Sciences Research Committee (NHSRC)
Ministry of Health
P.O. Box 300377
Lilongwe 3

Dear Sir/Madam

PERMISSION TO CONDUCT A STUDY IN BLANTYRE MALAWI

Approval has been granted to the bearer of the letter: - **Ms Angella Joy Kamwendo** from University of Witwatersrand to conduct a study at Chilomoni health centre in Blantyre Malawi titled **"Improving Viral Load Monitoring Coverage Using a Quality Improvement Approach in Blantyre, Malawi"**

Any assistance rendered would be appreciated.

Blantyre District Council
Director of Health & Social Services
17 DEC 2019
Private Bag 66
Blantyre

Dr. Gift Kawalazira
DIRECTOR OF HEALTH AND SOCIAL SERVICES

Appendix V: Malawi NHSRC ethics clearance

Telephone: + 265 789 400
Facsimile: + 265 789 431

All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. .....
MINISTRY OF HEALTH AND POPULATION
P.O. BOX 30377
LILONGWE 3
MALAWI

Ref. No. Med /4/36c

21st February, 2020

Angella J. Kamwendo
University of Witwatersrand

Dear Sir/Madam,

Re: Protocol #20/01/2455: Improving Viral Load Monitoring Using a Quality Improvement Approach in Blantyre, Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** the above named study.

- **APPROVAL NUMBER : 2455**
- The above details should be used on all correspondences, consent forms and documents as appropriate.
- **APPROVAL DATE : 21/02/2020**
- **EXPIRATION DATE : 20/02/2021**
  This approval expires on **20/02/2021**. After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC Secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the NHSRC within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using forms obtainable from the NHSRC Secretariat is required before implementing any changes in the protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on phone number *+265 999397913* or by email on mohdoccentre@gmail.com.
- **OTHER**: Please be reminded to send in copies of your final research results for our records (Health Research Database).

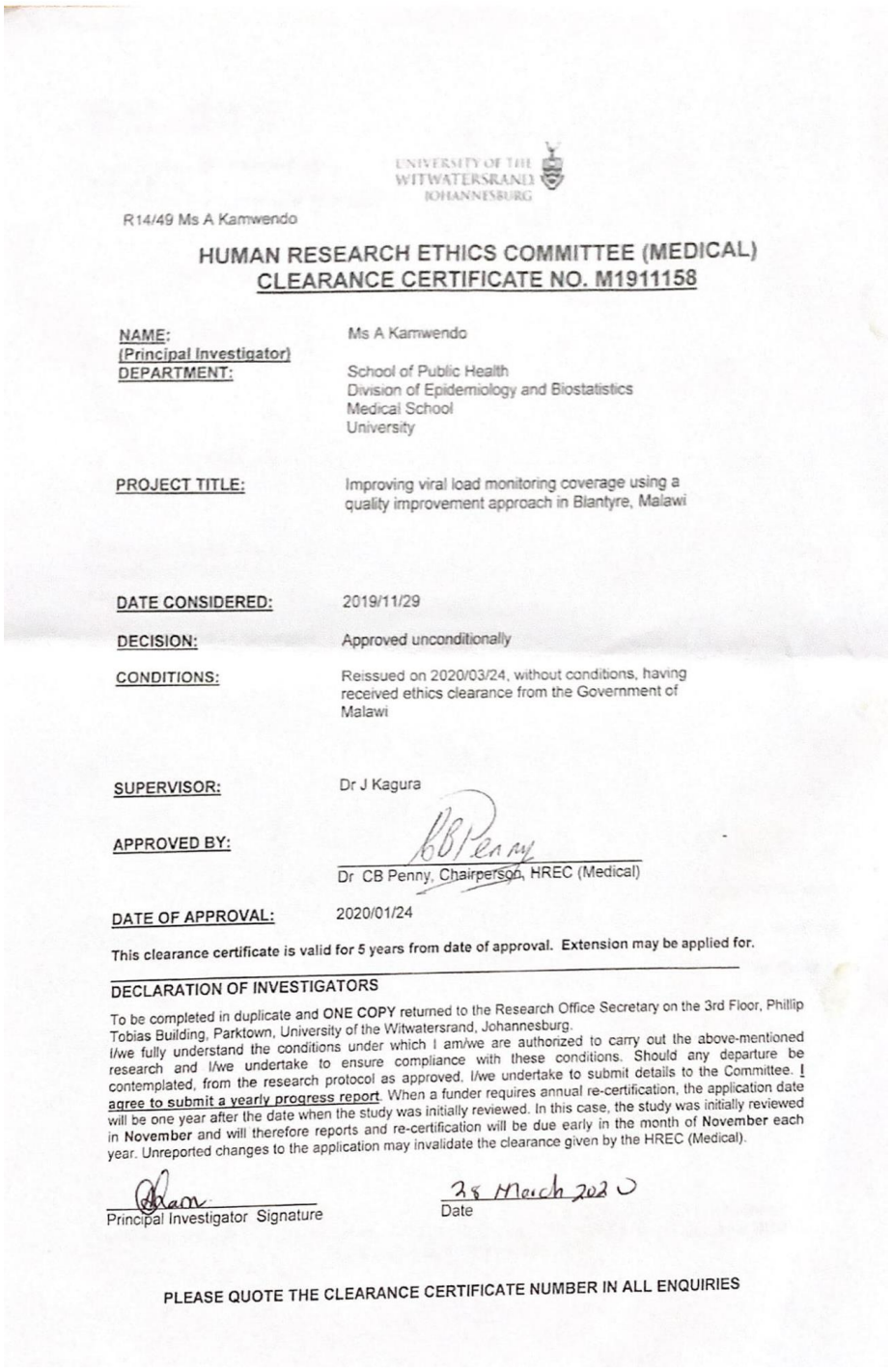
Kind regards from the NHSRC Secretariat.

SECRETARY FOR HEALTH
2020 -02- 21
P.O. BOX 30377, CAPITAL CITY, LILONGWE 3

.....
For: **CHAIRPERSON, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE**
Promoting Ethical Conduct of Research [1]

Executive Committee: *Dr. Martias Joshua (Chairperson), Dr. Evelyn Chitsa Banda (Vice-Chairperson)*
Registered with the USA Office for Human Research Protections (OHRP) as an International IRBIRB Number IRB00003905 FWA00005976

Appendix VI: Wits ethics clearance



UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Ms A Kamwendo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M1911158

NAME: (Principal Investigator)	Ms A Kamwendo
DEPARTMENT:	School of Public Health Division of Epidemiology and Biostatistics Medical School University
PROJECT TITLE:	Improving viral load monitoring coverage using a quality improvement approach in Blantyre, Malawi
DATE CONSIDERED:	2019/11/29
DECISION:	Approved unconditionally
CONDITIONS:	Reissued on 2020/03/24, without conditions, having received ethics clearance from the Government of Malawi
SUPERVISOR:	Dr J Kagura
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/01/24

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report.** When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore reports and re-certification will be due early in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

28 March 2020
Date

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

Appendix VII: Turnitin report

Appendix VIII: Information sheets and consent forms

HEALTH CARE PROVIDERS INFORMATION SHEET AND CONSENT

A. INFORMATION SHEET

Information Sheet for health care providers

Study Title: Improving viral load monitoring coverage using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science)

Dear Sir/Madam,

Introduction

My name is Angella Joy Kamwendo, a student pursuing a master's in Epidemiology majoring in Implementation Science at the University of the Witwatersrand. I am conducting a Quality Improvement study aimed at improving viral load testing coverage here at your health facility. Specifically, my study aims to understand the process of viral load testing at your health facility, what factors affect viral load testing coverage and development of an intervention to help improve viral load testing coverage.

Invitation to participate

I am inviting you to take part in this research because you have a good understanding of viral load testing processes at this facility and any issues that affect this process. I ask that you read this form and ask any questions that you may have before agreeing to participate in the study. The findings of this study will be written as a report and submitted to the School of Public Health Library and may also be shared in conferences, or published in a journal. The results will provide useful information on the application of quality improvement methods in the viral load testing process and generalizability of the results to other health facilities.

Description of the Study

If you agree to take part in the study, I will ask you and a group of other health care workers to answer some questions, which will take about 2 hours of your time. The questions will be asked in form of group brainstorming session where I shall ask questions about the viral testing process, factors that affect viral testing coverage and any interventions or changes

within your capacity that can be implemented in order to improving viral load testing coverage. Factors affecting viral load testing coverage will be documented on a fishbone diagram template and interventions will be documented on a priority matrix. Both templates will be displayed to the whole group as I complete them. A copy of this form and a consent form will be given to you after you agree to participate in this study.

Risks and Benefits of Being in the Study

There are minimal risks. The benefits of participation are that your responses will contribute to the promotion of quality improvement methods in the viral load monitoring continuum so as to get better patient outcomes.

Confidentiality

All documented responses will not have identifiers or links to individuals in the session. You will not be identified in any published work or report. Nevertheless, views of all participants will be summarized and reported. Any information obtained and analysed during this study will be stored for a period not exceeding two years if the research report is published and five years if no publications emanate.

On the same note, the information that is shared in this session will be kept confidential by myself, and by all investigators involved in the study. However, we do not guarantee confidentiality from other participants within the group. Nonetheless, we shall request you and other partcipants in the group to respect each other's confidentiality should you choose to be part of the study.

Payments

There will be no payment for participation in this study.

Right to Refuse or Withdraw

Your participation in this session is voluntary. You may refuse to take part in the study at any time without affecting your relationship with the investigators of this study or with the Blantyre District Health Office.

Right to Ask Questions and Report Concerns

You have the right to ask questions about this research and to have those questions answered by me before, during or after the research. If you have any questions afterwards about this research, feel free to contact me on the details listed below. If you have any queries, concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265 1 726 422/418 Email: mohdoccentre@gmail.com

Principal Investigator: ***Angella Joy Kamwendo***, e-mail address 1896506@students.wits.ac.za, or tel no. +265995670820)

Supervisor: ***Dr. Juliana Kagura***: e -mail addresss Juliana.Kagura@wits.ac.za

Further, this study has also been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is ***Dr Clement Penny***, who may be contacted on telephone number +27 11 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are +27 11 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

February 2020

B. CONSENT FORM

Consent form for health care providers

Study Title: Improving viral load monitoring coverage using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo**,** MSc Epidemiology (Implementation Science)

Informed Consent

I have been adequately informed of (or I have read and understood) the purpose, procedures, potential risks, and benefits of this study.

• I have the opportunity to ask questions about it. Any questions that I have will be answered to my satisfaction.

• I know that I can refuse to participate in the study without any loss of benefit to which I would have otherwise been entitled.

• I understand that if I agree to participate, I can withdraw my consent at any time without any problem.

• I understand that I have to respect other participant's confidentiality

• I freely agree to participate in the study, after signing below I will receive a copy of this consent form.

For Participant

Name of Participant ……

Signature of Participant……. Date: ……. /……. /……..

INFORMATION SHEET AND CONSENT FOR PARENT(S)/GUARDIAN(S)

Information Sheet for Parent(s)/Guardian(s)

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Hello,

Introduction

My name is Angella Joy Kamwendo, a student pursuing a Master's Degree in Epidemiology, majoring in Implementation Science, at the University of the Witwatersrand, Johannesburg. I am conducting a Quality Improvement study aimed at improving viral load testing coverage here at this health facility. Specifically, my study aims to understand the process of viral load testing at this health facility, what factors affect viral load testing coverage and development of an intervention to help improve viral load testing coverage.

I am going to give you information pertaining to the study and because the study includes children, it is required that permission is taken from parent(s)/guardian(s).

Invitation to participate

I am inviting your child to take part in this research, because your child is eligible for this service of viral load testing at this facility. I ask that you read this form or I will read it to you and you are free to ask any questions that you may have before deciding whether to allow your child to participate in the study.

The findings of this study will be written as a report and submitted to the University and may also be shared in conferences, or published in a journal. The results will provide useful information on the application of quality improvement methods in the viral load testing process and generalizability of the results to other health facilities.

Description of the Study

If you agree to take part in the study, I will review your child's medical records and those of other individuals. This will be done in order to help develop interventions that will assist your child to have access to this service at this health facility. A copy of this form and a consent form will be given to you if you agree to participate in this study.

Risks and Benefits of Being in the Study

There are minimal risks. The benefits of participation are that the review of your child's records may contribute to the development of an intervention at this health facility that will help improve the viral load testing service.

Confidentiality

To ensure confidentiality, all data extracted will not link your child to his/her medical records, as unique identifiers will be developed and used. Your child will not be identified in any published work or report. Any information obtained and analyzed during this study will be stored for a period not exceeding two years if the research report is published and five years if no publications emanate.

Payments

There is neither payment nor cost associated with participating in the study

Right to Refuse or Withdraw

Your child's participation in this session is voluntary. Children of seven years and older will be formally invited to participate and they need not do so if they do not wish to, whatever their parent/guardian decides. You or your child may refuse to participate or withdraw from the study at any time without affecting your access to health care at this or any other facility

Right to Ask Questions and Report Concerns

You have the right to ask questions about this research and to have those questions answered by me before, during or after the research. If you have any questions afterwards about this research, feel free to contact me on the details listed below. If you have any queries, concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265 1 726 422/418 Email: mohdoccentre@gmail.com

Principal Investigator: ***Angella Joy Kamwendo***, e-mail address 1896506@students.wits.ac.za, or tel no. +265995670820)
Supervisor: ***Dr. Juliana Kagura***, e -mail address Juliana.Kagura@wits.ac.za

Further, this study has also been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is ***Dr Clement Penny***, who may be contacted on telephone number +27 11 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are +27 11 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

February 2020

CONSENT FORM

Consent form for record review - Parents/Guardians

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi

Principal Investigator: Angella Joy Kamwendo**,** MSc Epidemiology (Implementation Science) Student

• I have been adequately informed of (or I have read and understood) the purpose, procedures, potential risks, and benefits of this study.
• I have the opportunity to ask questions about it. Any questions that I have will be answered to my satisfaction.
• I know that I can refuse to allow my child to participate in the study without any loss of benefit to which he or she would have otherwise been entitled.
• I understand that if I agree to allow my child to participate in the study, I can withdraw my consent at any time without any problem.
• I freely agree to allow my child to participate in the study by signing below I will receive a copy of this consent form.

For Participant

Full name of child: …….

Name of Parent/Guardian……

Signature or Parent/Guardian: ……

Name of Witness if participant is illiterate ……

Signature of Witness if Participant is illiterate……..

Date: ……. /……. /……..

INFORMATION SHEET AND CONSENT FOR PARENT(S)/GUARDIAN(S) -CHICHEWA

Information Sheet for Parent(s)/Guardian(s)

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Tsiku labwino,

Malonje

Dzina langa ndi Angella Joy Kamwendo ndipo ndikuchita maphunziro aukachenjede okhudzana ndikuthandizila kuti zotsatila zakafukufuku wa zaumoyo zovomelezeka komanso zaumboni okwanila, zikugwiritsidwa ntchito. Maphuzirowa ndikuchitila ku Univesite ya Witswatersrand ku Johannesburg.

Ngati mbali imodzi yasukulu yanga, ine ndikupanga kafukufuku wa momwe tingapititsile patsogolo kayezedwe ka vairo lodi (kuchuluka kwa tizilombo mmagazi) pa chipatala pano. Kwenikweni, chifukwa chopangila kafukufukuyi ndi chakuti ndikufuna kumvetsetsa ndondomeko ya momwe anthu amayenda kufikila pomwe atengedwa magazi kuti akayezedwe vairo lodi, zifukwa zimene zimapangitsa anthu ena kuyezedwa vairo lodi pamene ena kusayezedwa komanso kuthandizila achipatala kuti apeze njira yowonetsetsa kuti aliyense amene akuyenera kutengedwa magazi kuti akayezedwe vairo lodi, atengedwe magazi komanso munthawi yake.

Ndicheza nanu monga kholo/oyang'anila mwana zokhudzana ndi kafukufukuyi chifukwa kafukufukuyi akukhudzanso ana. Chotero, ndikuyenera kupempha chilolezo kuti mwanu wanu atenge nawo mbali.

Pempho kuti mutenge nawo mbali

Panthawi ino, ndikakupemphani ngati muli osangalatsidwa kuti mwana wanu atenge nawo mbali mu kafukufukuyi. Mwana wanu wasankhidwa chifukwa ndi mmodzi mwa anthu amene ali ndikuthekela koti atha kutengedwa magazi kuti akayezedwe vairo lodi. Musanapange chiganizo chili chonse, ndikakupemphani kuti muwerenge zokhudzana ndi kafukufukuyi kapena ine ndikuwerengeleni. Muli ndi ufulu ofunsa mafunso ena aliwonse okhudzana ndi kafukufukuyi ndipo ine ndidzakuyankhani mpaka inu mutakhutitsidwa.

Zotsatilia za kafukufukuyi zizalembedwa ngati lipoti yomwe idzaperekedwa ku sukulu ya ukachenjede ya Witwatersrand, komanso pakazapezeka mwayi, lipotili litha kudzaperekedwanso ku misonkhano ya zaumoyo kapena kuyidwa mu bukhu la zotsatila za kafukufuku. Zotsatila za kafukufukuyi zizathandizila a zaumoyo kudziwa mmene angagwiritsile ntchito kafukufuku opititsa patsogolo nkhani za vairo lodi komanso zipatala zina zitha kuzagwiritsa ntchito zotsatirazi kuti zipititse patsogolo kuyeza vairo lodi muzipatala mwawo.

Ndondomeko ya kafukufuku

Mukavomereza kutenga nawo mbali mu kafufukuyi, ine ndizaona nawo mbili ya zaumoyo ya mwana wanu kuchipatala kuno komanso mbiri ya anthu ena. Mbiriyi izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa vairo lodi kuti wina aliyense athe kupindula nawo. Komanso, mukavomereza kuti mwana wanu atenge nawo mbali mu kafufukuyi ine ndizakupatsani fomuyi komanso fomu ina imene inu muzatsimikizile kuti mwavomereza kuti mwanu wanu atenge nawo mbali mukafukufuku.

Za ubwino ndi kuopsya kotenga nawo mbali mu kafukufukuyi

Kutenga nawo mbali mu kafukufukuyi kuli ndi zokayikitsa zochepa kwa mwanu wanu. Ubwino wa mwana wanu kutenga nawo mbali mu kafukufukuyi ndi okuti, mbiri ya zaumoyo wake izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa vairo lodi powonetsetsa kuti anthu atengedwa magazi kuti akayezedwe vairo lodi komanso munthawi yake pa chipatala pano.

Za kusunga chinsinsi

Ndikufuna kukutsimikizilani kuti kafukufukuyi adzasungila chinsinsi mwana wanu ndipo mbiri yake ya zaumoyo ya kuchipatala kuno yomwe tidzagwiritse ntchito siidzakhala ndi dzina lake. Mmalo mwake, tidzagwiritsa ntchito manambala ongopeka ndicholinga choti munthu wina aliyense asadziwe kuti mbiri ya zaumoyo ndi ya mwana wanu. Komanso, ndikatenga mbiriyi, dzina la mwana wanu silizatchulidwa mu lipoti inaliyonse.

Mbririyi idzasungidwa kwa zaka ziwiri ngati tizalembe lipoti loyikidwa mu bukhu lazotsatila zakafukufuku. Zikadzapanda kutero, mbiriyi tidzayisunga kwa zaka zisanu.

Za malipiro

Mwana wanu sadzalipila kapena kulipidwa kuti atenge nawo mbali mu kafukufukuyi. Kafukufukuyi ndi waulere.

Za ufulu osiya kapena kusatenga nawo mbali mu kafukufuku

Kutenga nawo mbali mu kafukufukuyi sikokakamiza. Muli ndi ufulu okaniza mwana wanu kutenga nawo mbali kapenanso kusiya kutenga nawo mbali nthawi ina iliyonse. Izi sizizamuyika mwana wanu pachiospyezo china chili chonse pakalandilidwe kanu ka chithandizo kuchipatala kuno kapenanso kuchipatala china chili chonse.

Za kufunsa mafunso ndi kupereka madandaulo

Muli ndi ufulu ondifunsa mafunso okhudzana ndi kafukufukuyi komanso kuyankhidwa mafunso nthawi ina iliyonse; ndisanayambe kafukufuku, mkati mwakafukufuku komanso kafukufukuyi akadzatha. Mukadzakhala ndi mafunso, ndinu omasuka kundiyimbila pa nambala ya lamya iyi 0995670820 kapena kundilembela pa imelo adilesi iyi 1896506@students.wits.ac.za. Mutha kudzawalembelanso imelo aphunzitsi omwe amandiyang'anila, ***Dr. Juliana Kagura,*** pa imelo adilesi iyi Juliana.Kagura@wits.ac.za.

Mukadzakhala ndi dandaulo lina lililonse lokhudzana ndi kuphwanyilidwa ufulu nthawi yakafukufukuyi, muli ndi ufulu kuyimba lamya ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku ku Malawi kuno pa 01 726 422/418. Muli ndi ufulunso owalembela pa adilesi iyi: ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, kapenanso pa imelo iyi: mohdoccentre@gmail.com

Kuonjezera apo, muthanso kuyimba lamya kwa wamkulu ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku, ***Dr Clement Penny,*** ku South Africa komwe kuli sukulu yanga pa nambala iyi: +27 11 717 2301 komanso pa ma nambala awa 27 11 717 2700/1234. Muthanso kuwalembela pa ma imelo adilesi awa: Clement.Penny@wits.ac.za, Zanele.Ndlovu@wits.ac.za, komanso Rhulani.Mukansi@wits.ac.za

Zikomo kwambiri chifukwa chotenga nthawi kuti muwerenge zakafukufukuyi.

February 2020

CONSENT FORM

Consent form for record review - Parents/Guardians

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

• Ndadziwitsidwa mwatsatanetsatane (kapena kuwerengeledwa) za zolinga za kafukufuku ameneyu, za ndondomeko yake, ubwino komanso kuyipa kwake kwa kafukufukuyi.

• Ndili ndi udindo komanso ufulu ofunsa mafunso okhudzana ndi kafukufuku ameneyu. Mafunso omwe ndingafunse adzayankhidwa mpaka ine kukhutitsidwa.

•Ndili ndi ufulu okaniza mwana wanga kutenga nawo mbali mu kafukufukuyi nthawi inaliyonse opanda vuto linalilionse kapena chiopsyezo choti saalandira chithandizo kuchipatala.

•Ndikudziwa kuti mwana wanga atha kusiya kutenga nawo mbali mukafufukuyi nthawi inali iliyonse popanda vuto kapena chiopsyezo

•Ndikuvomereza mwakufuna kwanga kuti mwana wanga atha kutenga nawo mbali mu kafukufukuyi potsindika dzina langa ndi la mwana wanga pamusipa ndipo ndidzalandila fomu yangati yomweyi pomwe ndatsindika dzina langa ndi la mwana wanga

Za otenga mbali mu kafukufuku

Dzina la mwana: ……

Dzina la kholo/oyang'anila mwana……

Kholo/oyang'anila mwana asaine apa:: ……:

Dzina la mboni ngati kholo/oyang'anila mwana sadziwa kulemba ……

Mboni asaine apa ngati kholo/oyang'anila mwana sadziwa kulemba ……..

Tsiku: ……. /……. /……..

INFORMATION SHEET AND CONSENT SHEET FOR RECORD REVIEW INDIVIDUALS AGED BETWEEN 7 YEARS AND 11 YEARS

Information Sheet for record review individuals aged between 7 years and 11 years

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Hello,

Introduction

My name is Angella Joy Kamwendo and I am student at the University of the Witwatersrand in Johannesburg. I am trying to find out how testing blood for viruses can be made better at this hospital since testing for viruses is good and helps people to not get sick. I will first understand how people get their blood tested for viruses at this hospital, understand why some people get their blood tested for viruses and some do not and come up with a solution so that more people are tested and at the right time.

I am going to tell you about the study and invite you to take part in the study. I have talked to your parent(s)/guardian(s) about the study and they know I am talking to you about this.

Invitation to participate

I am inviting you to take part in this study because your blood can be tested for viruses at this hospital. I ask that you read this form or I will read it to you and you are free to ask any questions that you may have before making a decision to take part in the study. You are also free to talk about this form with your parent(s)/guardian(s) or anyone you trust before making any decision about your participation in this study. If you agree to take part in the study, your parent(s)/guardian(s) also need to agree. You are free to not take part in the study even if your parent(s)/guardian(s) have agreed.

After the study, a report will be written and given to the University I go to and it may also be shared in meetings, or printed in a journal. The results will help give important information on how to make testing blood for viruses better. The results can also help other hospitals to make testing blood for viruses better so that people do not get sick.

Description of the Study

If you agree to take part in the study, I will look at your medical records and those of other people. This will be done in order to help come up with solutions that will help you and others to have your blood tested for viruses. A copy of this form and an assent form will be given to you if you agree to participate in this study.

Risks and Benefits of Being in the Study

There are slight risks to taking part in the study. The benefits of you taking part in the study are the that the review of your records will help in coming up with solutions that will help improve the testing of viruses in blood at this hospital.

Confidentiality

To ensure privacy, all data taken will not link you to your medical records as numbers I will make up will be used and not your names. Your name will not be mentioned in any published work or report. Any information taken during this study will be kept for not more than two years if the research report is printed and five years if not printed.

Payments

You do not have to pay and you will not be paid to be part of the study

Right to Refuse or Withdraw

Your participation in this study is voluntary. You may refuse to take part in the study at any time without getting in trouble with your parent(s)/guardian(s), this hospital or any other hospital.

Right to Ask Questions and Report Concerns

You have the right to ask questions about this research and to have those questions answered by me before, during or after the research. If you have any questions afterwards about this research, feel free to contact me on your own on the details listed below or with the help of an adult you trust. You can also contact the ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265 1 726 422/418 Email: mohdoccentre@gmail.com
Principal Investigator: ***Angella Joy Kamwendo***, e-mail address 1896506@students.wits.ac.za, or tel no. +265995670820)
Supervisor: ***Dr. Juliana Kagura***, e -mail address Juliana.Kagura@wits.ac.za

Further, you can also contact the University I go to through ***Dr Clement Penny***, who may be contacted on telephone number +27 11 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The University can also be contacted using the following phone number +27 11 717 2700/1234 and the following e-mail addresses Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading/paying attention this Study Information Sheet.

February 2020

ASSENT FORM

Assent form for record review individuals aged between 7 years and 11 years

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo**,** MSc Epidemiology (Implementation Science) Student

• I have been read to (or have read) about this study and I understand what it is about
• I can ask questions about the study if I have any. Any questions that I have will be answered until I understand.
• I know that I can refuse to participate in the study without getting in trouble with my parent(s)/guardian(s), the health facility or any other health facility
• I understand that if I agree to take part in the study, I can decide not to take part in the study at any time without any problem or getting in trouble.
• I freely agree to take part in the study by signing below and I will receive a copy of this assent form.

For Participant

Name of Child ……
Signature of Child…….
Name of Witness (not parent) if child is illiterate ……
Signature of Witness (not parent) if child is illiterate……..
Date: ……. /……. /……..

INFORMATION SHEET AND CONSENT SHEET FOR RECORD REVIEW INDIVIDUALS AGED BETWEEN 7 YEARS AND 11 YEARS - CHICHEWA

Information Sheet for record review individuals aged between 7 years and 11 years

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Tsiku labwino,

Malonje

Dzina langa ndi Angella Joy Kamwendo ndipo ndikuchita maphunziro ku Univesite ya Witswatersrand ku Johannesburg.

Ngati mbali imodzi yasukulu yanga, ine ndikupanga kafukufuku wa momwe tingapititsile patsogolo kayezedwe ka kuchuluka kwa tizilombo mmagazi pa chipatala pano popeza kuyezetsa kuchuluka kwa tizilombo ndikwabwino ndipo kumathandizila kuti munthu asadwaledwale. Kwenikweni, chifukwa chopangila kafukufukuyi ndi chakuti ndikufuna kumvetsetsa ndondomeko ya momwe anthu amayenda kufikila pomwe atengedwa magazi kuti akayezedwe kuchuluka kwa tizilombo, zifukwa zimene zimapangitsa anthu ena kuyezedwa kachulukidwe ka tizilombo pamene ena kusayezedwa komanso kuthandizila achipatala kuti apeze njira yowonetsetsa kuti aliyense amene akuyenera kutengedwa magazi kuti akayezedwe kuchuluka kwa tizilombo, atengedwe magazi komanso munthawi yake.

Ndikulongosololela za kafukufukuyi ndikukupempha ngati ungakonde kuti utenge nawo mbali. Ndayankhulana kale ndi kholo/okuyang'anila zokhudzana ndi kafukufukuyi ndipo akudziwa kuti ndikukamba nawe zokhudzana ndi kafukufukuyi.

Pempho kuti utenge nawo mbali

Panthawi ino, ndikakupempha ngati uli osangalatsidwa kuti utenge nawo mbali mu kafukufukuyi. Iweyo wasankhidwa chifukwa inu ndi mmodzi mwa anthu amene ali ndikuthekela koti atha kutengedwa magazi kuti akayezedwe kachulukidwe katizilombo. Usanapange chiganizo chili chonse, ndikakupempha kuti uwerenge zokhudzana ndi kafukufukuyi kapena ine ndikuwerengele. Uli ndi ufulu ofunsa mafunso ena aliwonse okhudzana ndi kafukufukuyi ndipo ine ndidzakuyankha mpaka iwe

utakhutitsidwa. Uli ndi ufulunso okambilana ndi kholo/okuyang'anila kapena munthu wamkulu wina aliyense omwe iwe umamukhulupilila za fomuyi komanso zakafukufukuyi. Ngati ungakonde kutenga nawo mbali mukafukufukuyi, kholo/okuyang'anila akuyenelanso kuti avomereze. Uli ndi ufulu okana kutenga nawo mbali, ngakhale kholo/okuyang'anila lako litavomera.

Zotsatilia za kafukufukuyi zizalembedwa ngati lipoti yomwe idzaperekedwa ku sukulu yomwe ndimaphunzira, komanso pakazapezeka mwayi, lipotili litha kudzaperekedwanso ku misonkhano ya

zaumoyo kapena kuyidwa mu bukhu la zotsatila za kafukufuku. Zotsatila za kafukufukuyi zizathandizila kupitsa patsolo kayezedwe kakuchuluka kwa tizilombo mmagazi komanso kuthandiza zipatala zina kupititsa patsogolo kayezedwe ka kuchuluka kwa tizilombo muzipatala mwawo.

Ndondomeko ya kafukufuku

Ukavomereza kutenga nawo mbali mu kafufukuyi, ine ndizaona nawo mbili yako ya zaumoyo kuchipatala kuno komanso mbiri ya anthu ena. Mbiriyi izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa kuchuluka kwa tizilombo mmagazi ako komanso aanthu ena.

Komanso, ukavomereza kutenga nawo mbali mu kafufukuyi ine ndizakupatsa fomuyi komanso fomu ina imene inu uzatsimikizile kuti wavomereza kutenga nawo mbali mukafukufuku.

Za ubwino ndi kuopsya kotenga nawo mbali mu kafukufukuyi

Kutenga nawo mbali mu kafukufukuyi kuli ndi zokayikitsa zochepa. Ubwino wa iweyo kutenga nawo mbali mu kafukufukuyi ndi okuti, mbiri yako izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa kuchuluka kwa tizilombo mmagazi powonetsetsa kuti anthu atengedwa magazi kuti akayezedwe komanso munthawi yake pa chipatala pano.

Za kusunga chinsinsi

Ndikufuna kukutsimikizila kuti kafukufukuyi azakusunga chinsinsi ndipo mbiri yako ya zaumoyo ya kuchipatala kuno yomwe tidzagwiritse ntchito siidzakhala ndi dzina lako. Mmalo mwake, tidzagwiritsa ntchito manambala ongopeka ndicholinga choti munthu wina aliyense asadziwe kuti mbiri ya zaumoyo ndi yako. Komanso, ndikatenga mbiriyi, dzina lako silizatchulidwa mu lipoti inaliyonse.

Mbririyi idzasungidwa kwa zaka ziwiri ngati tizalembe lipoti loyikidwa mu bukhu lazotsatila zakafukufuku. Zikadzapanda kutero, mbiriyi tidzayisunga kwa zaka zisanu.

Za malipiro

Kafukufukuyi ndi waulere. Sudzalipila kapena kulipidwa kuti utenge nawo mbali mu kafukufukuyi

Za ufulu osiya kapena kusatenga nawo mbali mu kafukufuku

Kutenga nawo mbali mu kafukufukuyi sikokakamiza. Uli ndi ufulu okana kutenga nawo mbali kapenanso kusiya kutenga nawo mbali nthawi ina iliyonse. Izi sizizakuyika pamavuto ena ali onse pakalandilidwe kako ka chithandizo kuchipatala kuno kapenanso kuchipatala china chili chonse, kapenanso kukuyika pamavuto ndi kholo/okuyang'anila.

Za kufunsa mafunso ndi kupereka madandaulo

Uli ndi ufulu ondifunsa mafunso okhudzana ndi kafukufukuyi komanso kuyankhidwa mafunso nthawi ina iliyonse; ndisanayambe kafukufuku, mkati mwakafukufuku komanso kafukufukuyi akadzatha. Ukadzakhala ndi mafunso, ndiwe omasuka kundiyimbila kapena mothandizidwa ndi munthu wamkulu pa nambala ya lamya iyi 0995670820 kapena kundilembela pa imelo adilesi iyi 1896506@students.wits.ac.za. Utha kudzawalembelanso imelo aphunzitsi omwe amandiyang'anila, ***Dr. Juliana Kagura*** pa imelo adilesi iyi Juliana.Kagura@wits.ac.za.

Ukadzakhala ndi dandaulo lina lililonse lokhudzana ndi kuphwanyilidwa ufulu nthawi yakafukufukuyi, uli ndi ufulu kuyimba lamya ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku ku Malawi kuno pa 01 726 422/418. Uli ndi ufulunso owalembela pa adilesi iyi: ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, kapenanso pa imelo iyi: mohdoccentre@gmail.com

Kuonjezera apo, uthanso kuyimba lamya kwa wamkulu ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku, ***Dr Clement Penny,*** ku South Africa komwe kuli sukulu yanga pa nambala iyi: +27 11 717 2301 komanso pa ma nambala awa 27 11 717 2700/1234. Uthanso kuwalembela pa ma imelo adilesi awa: Clement.Penny@wits.ac.za, Zanele.Ndlovu@wits.ac.za, komanso Rhulani.Mukansi@wits.ac.za

Zikomo kwambiri chifukwa chotenga nthawi kuti muwerenge/kumvetsela zakafukufukuyi.

February 2020

ASSENT FORM

Assent form for record review individuals aged between 7 years and 11 years

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

• Ndadziwitsidwa momveka bwino (kapena kuwerengeledwa) za kafukufuku ameneyu, za kachitidwe kake, ubwino komanso kuyipa kwake kwa kafukufukuyi.

• Ndili ndi udindo komanso ufulu ofunsa mafunso okhudzana ndi kafukufuku ameneyu. Mafunso omwe ndingafunse adzayankhidwa mpaka ine kukhutitsidwa.

•Ndili ndi ufulu okana kutenga nawo mbali mu kafukufukuyi nthawi inaliyonse opanda vuto linalilionse ndi makolo kapena ondiyang'anila, kapenanso chiopsyezo choti sindilandira chithandizo kuchipatala.

•Nditha kusiya kutenga nawo mbali mukafufukuyi nthawi inali iliyonse popanda vuto kapena chiopsyezo

•Ndikuvomereza kutenga nawo mbali mu kafukufukuyi mwakufuna kwanga potsindika dzina langa pamusipa ndipo ndidzalandila fomu yangati yomweyi pomwe ndatsindika dzina langa

Za otenga Mbali mu kafukufuku

Dzina la mwana ……

Mwana asaine apa: …….

Dzina la mboni ngati mwana sadziwa kulemba ……

Mboni asaine apa ngati mwana sadziwa kulemba ……..

Tsiku: ……. /……. /……..

INFORMATION SHEET AND CONSENT SHEET FOR RECORD REVIEW INDIVIDUALS AGED BETWEEN 12 YEARS AND 17 YEARS

Information Sheet for record review individuals aged between 12 years and 17 years

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science)

Hello,

Introduction

My name is Angella Joy Kamwendo and I am student at the University of the Witwatersrand in Johannesburg. I am conducting a study aimed at improving the process of testing blood for viruses since it is important and helps prevent people from getting sick. Specifically, my study aims to understand the process of testing blood for viruses at this health facility, why some people get their blood tested for viruses and some do not and development of a solution so that more people are tested and at the right time.

I am going to give you information about the study and invite you to take part in the study. I have talked to your parent(s)/guardian(s) about the study and they know I am talking to you about this.

Invitation to participate

I am inviting you to take part in this study because your blood can be tested for viruses at this facility. I ask that you read this form or I will read it to you and you are free to ask any questions that you may have before making a decision to participate in the study. You are also free to discuss this form with your parent(s)/guardian(s) or anyone you trust before making any decision about your participation in this study. If you agree to take part in the study, your parent(s)/guardian(s) also need to agree. You are free to not take part in the study even if your parent(s)/guardian(s) have agreed.

The findings of this study will be written as a report and submitted to the University I go to and it may also be shared in conferences, or published in a journal. The results will provide useful information on how to make the viral load testing process better and the ability to apply the results to other health facilities.

Description of the Study

If you agree to take part in the study, I will review your medical records and those of other individuals. This will be done in order to help develop solutions that will help you to have access to this service at this health facility. A copy of this form and an assent form will be given to you if you agree to participate in this study.

Risks and Benefits of Being in the Study

There are minimal risks. The benefits of your participation are the that the review of your records will help in coming up with solutions that will help improve the testing of viruses in blood at this health facility.

Confidentiality

To ensure privacy, all data collected will not link you to your medical records as numbers I will make up will be used and not your names. You will not be identified in any published work or report. Any information collected during this study will be stored for a period not exceeding two years if the research report is published and five years if no publication is made.

Payments

You do not have to pay and you will not be paid to be part of the study

Right to Refuse or Withdraw

Your participation in this session is voluntary. You may refuse to take part in the study at any time without affecting your relationship with your parent(s)/guardian(s) or access to health care at this health facility or any other health facility.

Right to Ask Questions and Report Concerns

You have the right to ask questions about this research and to have those questions answered by me before, during or after the research. If you have any questions afterwards about this research, feel free to contact me on the details listed below. If you have any queries, concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265 1 726 422/418 Email: mohdoccentre@gmail.com

Principal Investigator: ***Angella Joy Kamwendo***, e-mail address 1896506@students.wits.ac.za, or tel no. +265995670820)

Supervisor: ***Dr. Juliana Kagura***, e -mail address Juliana.Kagura@wits.ac.za

Further, you can also contact the University I go to through ***Dr Clement Penny***, who may be contacted on telephone number +27 11 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The University can also be contacted using the following phone number +27 11 717 2700/1234 and the following e-mail addresses Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

February 2020

ASSENT FORM

Assent form for record review individuals aged between 12 years and 17 years

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo**,** MSc Epidemiology (Implementation Science) Student

• I have read the information (or have been read to) about this study and have understood the purpose, procedures, potential risks, and benefits of this study.
• I have the right to ask questions about the study if I have any. Any questions that I have will be answered to my satisfaction.
• I know that I can refuse to participate in the study without affecting the relationship with my parent(s)/guardian(s) and my access to health care at the health facility or any other health facility
• I understand that if I agree to participate, I can decide not to participate in the study at any time without any problem.
• I freely agree to participate in the study by signing below and I will receive a copy of this assent form.

For Participant

Name of Child ……
Signature of Child……
Name of Witness (not parent) if child is illiterate ……
Signature of Witness (not parent) if child is illiterate……..
Date: ……. /……. /……..

INFORMATION SHEET AND CONSENT SHEET FOR RECORD REVIEW INDIVIDUALS AGED BETWEEN 12 YEARS AND 17 YEARS -CHICHEWA

Information Sheet for record review individuals aged between 12 years and 17 years

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Tsiku labwino,

Malonje

Dzina langa ndi Angella Joy Kamwendo ndipo ndikuchita maphunziro aukachenjede ku Univesite ya Witswatersrand ku Johannesburg.

Ngati mbali imodzi yasukulu yanga, ine ndikupanga kafukufuku wa momwe tingapititsile patsogolo kayezedwe ka kuchuluka kwa tizilombo mmagazi pa chipatala pano popeza kuyezetsa kuchuluka kwa tizilombo ndikwabwino ndipo kumathandizila kuti munthu amene ali ndi achilombo ka HIV asadwaledwale. Kwenikweni, chifukwa chopangila kafukufukuyi ndi chakuti ndikufuna kumvetsetsa ndondomeko ya momwe anthu amayenda kufikila pomwe atengedwa magazi kuti akayezedwe kuchuluka kwa tizilombo, zifukwa zimene zimapangitsa anthu ena kuyezedwa kachulukidwe ka tizilombo pamene ena kusayezedwa komanso kuthandizila achipatala kuti apeze njira yowonetsetsa kuti aliyense amene akuyenera kutengedwa magazi kuti akayezedwe kuchuluka kwa tizilombo, atengedwe magazi komanso munthawi yake.

Ndikulongosololela za kafukufukuyi ndikukupempha ngati ungakonde kuti utenge nawo mbali. Ndayankhulana kale ndi kholo/okuyang'anila zokhudzana ndi kafukufukuyi ndipo akudziwa kuti ndikukamba nawe zokhudzana ndi kafukufukuyi**.**

Pempho kuti utenge nawo mbali

Panthawi ino, ndikakupempha ngati uli osangalatsidwa kuti utenge nawo mbali mu kafukufukuyi. Iweyo wasankhidwa chifukwa iweyo ndi mmodzi mwa anthu amene ali ndikuthekela koti atha kutengedwa magazi kuti akayezedwe kachulukidwe katizilombo. Usanapange chiganizo chili chonse, ndikakupempha kuti uwerenge zokhudzana ndi kafukufukuyi kapena ine ndikuwerengele. Uli ndi ufulu ofunsa mafunso ena aliwonse okhudzana ndi kafukufukuyi ndipo ine ndidzakuyankha mpaka iwe utakhutitsidwa. Uli ndi ufulunso okambilana ndi kholo/okuyang'anila kapena munthu wamkulu wina aliyense omwe iwe umamukhulupilila za fomuyi komanso zakafukufukuyi. Ngati ungakonde kutenga nawo mbali mukafukufukuyi, kholo/okuyang'anila akuyenelanso kuti avomereze. Uli ndi ufulu okana kutenga nawo mbali, ngakhale kholo/okuyang'anila lako litavomera.

Zotsatilia za kafukufukuyi zizalembedwa ngati lipoti yomwe idzaperekedwa ku sukulu yomwe ndimaphunzira, komanso pakazapezeka mwayi, lipotili litha kudzaperekedwanso ku misonkhano ya zaumoyo kapena kuyidwa mu bukhu la zotsatila za kafukufuku. Zotsatila za kafukufukuyi zizathandizila kupitsa patsolo kayezedwe kakuchuluka kwa tizilombo mmagazi komanso kuthandiza zipatala zina kupititsa patsogolo kayezedwe ka kuchuluka kwa tizilombo muzipatala mwawo.

Ndondomeko ya kafukufuku

Ukavomereza kutenga nawo mbali mu kafufukuyi, ine ndizaona nawo mbili yako ya zaumoyo kuchipatala kuno komanso mbiri ya anthu ena. Mbiriyi izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa kuchuluka kwa tizilombo mmagazi ako komanso aanthu ena.

Komanso, ukavomereza kutenga nawo mbali mu kafufukuyi ine ndizakupatsa fomuyi komanso fomu ina imene inu uzatsimikizile kuti wavomereza kutenga nawo mbali mukafukufuku**.**

Za ubwino ndi kuopsya kotenga nawo mbali mu kafukufukuyi

Kutenga nawo mbali mu kafukufukuyi kuli ndi zokayikitsa zochepa. Ubwino wa iweyo kutenga nawo mbali mu kafukufukuyi ndi okuti, mbiri yako izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa kuchuluka kwa tizilombo mmagazi powonetsetsa kuti anthu atengedwa magazi kuti akayezedwe komanso munthawi yake pa chipatala pano.

Za kusunga chinsinsi

Ndikufuna kukutsimikizila kuti kafukufukuyi azakusunga chinsinsi ndipo mbiri yako ya zaumoyo ya kuchipatala kuno yomwe tidzagwiritse ntchito siidzakhala ndi dzina lako. Mmalo mwake, tidzagwiritsa ntchito manambala ongopeka ndicholinga choti munthu wina aliyense asadziwe kuti mbiri ya zaumoyo ndi yako. Komanso, ndikatenga mbiriyi, dzina lako silizatchulidwa mu lipoti inaliyonse.

Mbririyi idzasungidwa kwa zaka ziwiri ngati tizalembe lipoti loyikidwa mu bukhu lazotsatila zakafukufuku. Zikadzapanda kutero, mbiriyi tidzayisunga kwa zaka zisanu.

Za malipiro

Kafukufukuyi ndi waulere. Sudzalipila kapena kulipidwa kuti utenge nawo mbali mu kafukufukuyi

Za ufulu osiya kapena kusatenga nawo mbali mu kafukufuku

Kutenga nawo mbali mu kafukufukuyi sikokakamiza. Uli ndi ufulu okana kutenga nawo mbali kapenanso kusiya kutenga nawo mbali nthawi ina iliyonse. Izi sizizakuyika pamavuto ena ali onse pakalandilidwe kako ka chithandizo kuchipatala kuno kapenanso kuchipatala china chili chonse, kapenanso kukuyika pamavuto ndi kholo/okuyang’anila.

Za kufunsa mafunso ndi kupereka madandaulo

Uli ndi ufulu ondifunsa mafunso okhudzana ndi kafukufukuyi komanso kuyankhidwa mafunso nthawi ina iliyonse; ndisanayambe kafukufuku, mkati mwakafukufuku komanso kafukufukuyi akadzatha. Ukadzakhala ndi mafunso, ndiwe omasuka kundiyimbila kapena mothandizidwa ndi munthu wamkulu

pa nambala ya lamya iyi 0995670820 kapena kundilembela pa imelo adilesi iyi 1896506@students.wits.ac.za. Utha kudzawalembelanso imelo aphunzitsi omwe amandiyang'anila, *Dr. Juliana Kagura* pa imelo adilesi iyi Juliana.Kagura@wits.ac.za.

Ukadzakhala ndi dandaulo lina lililonse lokhudzana ndi kuphwanyilidwa ufulu nthawi yakafukufukuyi, uli ndi ufulu kuyimba lamya ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku ku Malawi kuno pa 01 726 422/418. Uli ndi ufulunso owalembela pa adilesi iyi: *National Health Sciences Research Committee*, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, kapenanso pa imelo iyi: mohdoccentre@gmail.com

Kuonjezera apo, uthanso kuyimba lamya kwa wamkulu ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku, *Dr Clement Penny,* ku South Africa komwe kuli sukulu yanga pa nambala iyi: +27 11 717 2301 komanso pa ma nambala awa 27 11 717 2700/1234. Uthanso kuwalembela pa ma imelo adilesi awa: Clement.Penny@wits.ac.za, Zanele.Ndlovu@wits.ac.za, komanso Rhulani.Mukansi@wits.ac.za

Zikomo kwambiri chifukwa chotenga nthawi kuti muwerenge/kumvetsela zakafukufukuyi.

February 2020

ASSENT FORM

Assent form for record review individuals aged between 12 years and 17 years

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

• Ndadziwitsidwa momveka bwino (kapena kuwerengeledwa) za kafukufuku ameneyu, za ndondomeko yake, ubwino komanso kuyipa kwake kwa kafukufukuyi.

• Ndili ndi udindo komanso ufulu ofunsa mafunso okhudzana ndi kafukufuku ameneyu. Mafunso omwe ndingafunse adzayankhidwa mpaka ine kukhutitsidwa.

•Ndili ndi ufulu okana kutenga nawo mbali mu kafukufukuyi nthawi inaliyonse opanda vuto linalilionse ndi makolo kapena ondiyang'anila, kapenanso chiopsyezo choti sindilandira chithandizo kuchipatala.

•Nditha kusiya kutenga nawo mbali mukafufukuyi nthawi inali iliyonse popanda vuto kapena chiopsyezo

•Ndikuvomereza kutenga nawo mbali mu kafukufukuyi mwakufuna kwanga potsindika dzina langa pamusipa ndipo ndidzalandila fomu yangati yomweyi pomwe ndatsindika dzina langa

Za otenga Mbali mu kafukufuku

Dzina la mwana ……

Mwana asaine apa: …….

Dzina la mboni ngati mwana sadziwa kulemba ……

Mboni asaine apa ngati mwana sadziwa kulemba ……..

Tsiku: ……. /……. /……..

INFORMATION SHEET AND CONSENT SHEET FOR RECORD REVIEW INDIVIDUALS AGED 18 YEARS AND ABOVE

Information Sheet for record review individuals aged 18 years and above

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Principal Investigator: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Hello,

Introduction

My name is Angella Joy Kamwendo, a student pursuing a Master's Degree in Epidemiology, majoring in Implementation Science, at the University of the Witwatersrand, Johannesburg. I am conducting a Quality Improvement study aimed at improving viral load testing coverage here at this health facility. Specifically, my study aims to understand the process of viral load testing at this health facility, what factors affect viral load testing coverage and development of an intervention to help improve viral load testing coverage.

Invitation to participate

I am inviting you to take part in this research because you are eligible for this service of viral load testing at this facility. I ask that you read this form, or I will read it to you and you are free to ask any questions that you may have before deciding whether to participate in the study.

The findings of this study will be written as a report and submitted to the University and may also be shared in conferences, or published in a journal. The results will provide useful information on the application of quality improvement methods in the viral load testing process and generalizability of the results to other health facilities.

Description of the Study

If you agree to take part in the study, I will review your medical records and those of other individuals. This will be done in order to help develop interventions that will help you have access to this service at this health facility. A copy of this form and a consent form will be given to you if you agree to participate in this study.

Risks and Benefits of Being in the Study

There are minimal risks. The benefits of participation are that the review of your records will contribute to the development of an intervention at this health facility that may help to improve the viral load testing service.

Confidentiality

To ensure confidentiality, all data extracted will not link you to your medical records as unique identifiers will be developed and used. You will not be identified in any published work or report. Any information obtained and analyzed during this study will be stored for a period not exceeding two years if the research report is published and five years if no publications emanate.

Payments

There is neither payment nor cost associated with participating in the study

Right to Refuse or Withdraw

Your participation in this session is voluntary. You may refuse to take part in, or withdraw from the study at any time without affecting your access to health care at this or any other facility.

Right to Ask Questions and Report Concerns

You have the right to ask questions about this research and to have those questions answered by me before, during or after the research. If you have any questions afterwards about this research, feel free to contact me on the details listed below. If you have any queries, concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265 1 726 422/418 Email: mohdoccentre@gmail.com

Principal Investigator: ***Angella Joy Kamwendo***, e-mail address 1896506@students.wits.ac.za, or tel no. +265995670820)
Supervisor: ***Dr. Juliana Kagura***. E~~,e~~-mail addres~~s~~s Juliana.Kagura@wits.ac.za

Further, this study has also been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.
If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is ***Dr Clement Penny***, who may be contacted on telephone number +27 11 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are +27 11 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

February 2020

CONSENT FORM

Consent form for record review individuals aged 18 years and above

Study Title: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi

Principal Investigator: Angella Joy Kamwendo**,** MSc Epidemiology (Implementation Science) Student

• I have been adequately informed of (or I have read and understood) the purpose, procedures, potential risks, and benefits of this study.

• I have the opportunity to ask questions about it. Any questions that I have will be answered to my satisfaction.

• I know that I can refuse to participate in the study without any loss of benefit to which I would have otherwise been entitled.

• I understand that if I agree to participate, I can withdraw my consent at any time without any problem.

• I freely agree to participate in the study by signing below I will receive a copy of this consent form.

For Participant

Name of Participant ……

Signature of Participant: ……

Name of Witness if Participant is illiterate ……

Signature of witness if Participant is illiterate……..

Date: ……. /……. /……..

INFORMATION SHEET AND CONSENT SHEET FOR RECORD REVIEW INDIVIDUALS AGED 18 YEARS AND ABOVE- CHICHEWA

Information Sheet for record review individuals aged 18 years and above

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

Tsiku labwino,

Malonje

Dzina langa ndi Angella Joy Kamwendo ndipo ndikuchita maphunziro aukachenjede okhudzana ndikuthandizila kuti zotsatila zakafukufuku wa zaumoyo zovomelezeka komanso zaumboni okwanila, zikugwiritsidwa ntchito. Maphuzirowa ndikuchitila ku Univesite ya Witswatersrand ku Johannesburg.

Ngati mbali imodzi yasukulu yanga, ine ndikupanga kafukufuku wa momwe tingapititsile patsogolo kayezedwe ka vairo lodi (kuchuluka kwa tizililombo mmagazi) pa chipatala pano. Kwenikweni, chifukwa chopangila kafukufukuyi ndi chakuti ndikufuna kumvetsetsa ndondomeko ya momwe anthu amayenda kufikila pomwe atengedwa magazi kuti akayezedwe vairo lodi, zifukwa zimene zimapangitsa anthu ena kuyezedwa vairo lodi pamene ena kusayezedwa komanso kuthandizila achipatala kuti apeze njira yowonetsetsa kuti aliyense amene akuyenera kutengedwa magazi kuti akayezedwe vairo lodi, atengedwe magazi komanso munthawi yake.

Pempho kuti mutenge nawo mbali

Panthawi ino, ndikakupemphani ngati muli osangalatsidwa kuti mutenge nawo mbali mu kafukufukuyi. Inu mwasankhidwa chifukwa inu ndi mmodzi mwa anthu amene ali ndikuthekela koti atha kutengedwa magazi kuti akayezedwe vairo lodi. Musanapange chiganizo chili chonse, ndikakupemphani kuti muwerenge zokhudzana ndi kafukufukuyi kapena ine ndikuwerengeleni. Muli ndi ufulu ofunsa mafunso ena aliwonse okhudzana ndi kafukufukuyi ndipo ine ndidzakuyankhani mpaka inu mutakhutitsidwa.

Zotsatilia za kafukufukuyi zizalembedwa ngati lipoti yomwe idzaperekedwa ku sukulu ya ukachenjede ya Witwatersrand, komanso pakazapezeka mwayi, lipotili litha kudzaperekedwanso ku misonkhano ya zaumoyo kapena kuyidwa mu bukhu la zotsatila za kafukufuku. Zotsatila za kafukufukuyi zizathandizila a zaumoyo kudziwa mmene angagwiritsile ntchito kafukufuku opititsa patsogolo nkhani za vairo lodi komanso zipatala zina zitha kuzagwiritsa ntchito zotsatirazi kuti zipititse patsogolo kuyeza vairo lodi muzipatala mwawo.

Ndondomeko ya kafukufuku

Mukavomereza kutenga nawo mbali mu kafufukuyi, ine ndizaona nawo mbili yanu ya zaumoyo kuchipatala kuno komanso mbiri ya anthu ena. Mbiriyi izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa vairo lodi kuti wina aliyense athe kupindula nawo. Komanso, mukavomereza kutenga nawo mbali mu kafufukuyi ine ndizakupatsani fomuyi komanso fomu ina imene inu muzatsimikizile kuti mwavomereza kutenga nawo mbali mukafukufuku.

Za ubwino ndi kuopsya kotenga nawo mbali mu kafukufukuyi

Kutenga nawo mbali mu kafukufukuyi kuli ndi zokayikitsa zochepa. Ubwino wa inu kutenga nawo mbali mu kafukufukuyi ndi okuti, inu ndi mbiri yanu izathandizila ine ndi achipatala kuona mmene tingapititsile patsogolo kuyezedwa kwa vairo lodi powonetsetsa kuti anthu atengedwa magazi kuti akayezedwe vairo lodi komanso munthawi yake pa chipatala pano.

Za kusunga chinsinsi

Ndikufuna kukutsimikizilani kuti kafukufukuyi azakusungilani chinsinsi ndipo mbiri yanu ya zaumoyo ya kuchipatala kuno yomwe tidzagwiritse ntchito siidzakhala ndi dzina lanu. Mmalo mwake, tidzagwiritsa ntchito manambala ongopeka ndicholinga choti munthu wina aliyense asadziwe kuti mbiri ya zaumoyo ndi yanu. Komanso, ndikatenga mbiriyi, dzina lanu silizatchulidwa mu lipoti inaliyonse.

Mbririyi idzasungidwa kwa zaka ziwiri ngati tizalembe lipoti loyikidwa mu bukhu lazotsatila zakafukufuku. Zikadzapanda kutero, mbiriyi tidzayisunga kwa zaka zisanu.

Za malipiro

Simudzalipila kapena kulipidwa kuti mutenge nawo mbali mu kafukufukuyi. Kafukufukuyi ndi waulere.

Za ufulu osiya kapena kusatenga nawo mbali mu kafukufuku

Kutenga nawo mbali mu kafukufukuyi sikokakamiza. Muli ndi ufulu okana kutenga nawo mbali kapenanso kusiya kutenga nawo mbali nthawi ina iliyonse. Izi sizizakuyikani pachiospyezo china chili chonse pakalandilidwe kanu ka chithandizo kuchipatala kuno kapenanso kuchipatala china chili chonse.

Za kufunsa mafunso ndi kupereka madandaulo

Muli ndi ufulu ondifunsa mafunso okhudzana ndi kafukufukuyi komanso kuyankhidwa mafunso nthawi ina iliyonse; ndisanayambe kafukufuku, mkati mwakafukufuku komanso kafukufukuyi akadzatha. Mukadzakhala ndi mafunso, ndinu omasuka kundiyimbila pa nambala ya lamya iyi 0995670820 kapena

kundilembela pa imelo adilesi iyi 1896506@students.wits.ac.za. Mutha kudzawalembelanso imelo aphunzitsi omwe amandiyang'anila, ***Dr. Juliana Kagura*** pa imelo adilesi iyi Juliana.Kagura@wits.ac.za.

Mukadzakhala ndi dandaulo lina lililonse lokhudzana ndi kuphwanyilidwa ufulu nthawi yakafukufukuyi, muli ndi ufulu kuyimba lamya ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku ku Malawi kuno pa 01 726 422/418. Muli ndi ufulunso owalembela pa adilesi iyi: ***National Health Sciences Research Committee***, Ministry of Health, P.O. Box 30377, Lilongwe 3, Malawi, kapenanso pa imelo iyi: mohdoccentre@gmail.com

Kuonjezera apo, muthanso kuyimba lamya kwa wamkulu ku bungwe loona za ufulu komanso ndondomeko wa kafukufuku, ***Dr Clement Penny,*** ku South Africa komwe kuli sukulu yanga pa nambala iyi: +27 11 717 2301 komanso pa ma nambala awa 27 11 717 2700/1234. Muthanso kuwalembela pa ma imelo adilesi awa: Clement.Penny@wits.ac.za, Zanele.Ndlovu@wits.ac.za, komanso Rhulani.Mukansi@wits.ac.za

Zikomo kwambiri chifukwa chotenga nthawi kuti muwerenge zakafukufukuyi.

February 2020

CONSENT FORM

Consent form for record review individuals aged 18 years and above

Mutu wa kafukufuku: Improving viral load monitoring using a quality improvement approach in Blantyre, Malawi.

Dzina la otsogolera kafukufuku: Angella Joy Kamwendo, MSc Epidemiology (Implementation Science) Student

• Ndadziwitsidwa mwatsatanetsatane (kapena kuwerengeledwa) za zolinga za kafukufuku ameneyu, za ndondomeko yake, ubwino komanso kuyipa kwake kwa kafukufukuyi.

• Ndili ndi udindo komanso ufulu ofunsa mafunso okhudzana ndi kafukufuku ameneyu. Mafunso omwe ndingafunse adzayankhidwa mpaka ine kukhutitsidwa.

•Ndili ndi ufulu okana kutenga nawo mbali mu kafukufukuyi nthawi inaliyonse opanda vuto linalilionse kapena chiopsyezo choti sindilandira chithandizo kuchipatala.

•Nditha kusiya kutenga nawo mbali mukafufukuyi nthawi inali iliyonse popanda vuto kapena chiopsyezo

•Ndikuvomereza kutenga nawo mbali mu kafukufukuyi mwakufuna kwanga potsindika dzina langa pamusipa ndipo ndidzalandila fomu yangati yomweyi pomwe ndatsindika dzina langa

Za otenga Mbali mu kafukufuku

Dzina la otenga mbali ……

Otenga mbali asaine apa: ……..

Dzina la mboni ngati otenga mbali sadziwa kulemba ……

Mboni asaine apa ngati otenga mbali sadziwa kulemba ……..

Tsiku: ……. /……. /……..

Appendix VIIII: Journal Guidelines for Authors

PLOS ONE

TITLE, AUTHOR, AFFILIATIONS FORMATTING GUIDELINES

Symbol Legend		
Symbol	**Name**	**Definition**
¶	Pilcrow (paragraph symbol)	1st set of equal contributors
&	Ampersand	2nd set of equal contributors
*	Asterisk	Corresponding author(s)
#a	Pound/number sign	First Current address
#b	Pound/number sign	Second Current address
†	Dagger/Cross	Deceased
^	Caret	Consortium/Group Authorship

This is the article title

Article Title
- Italics, bold type, symbols, and other text formatting will all be reproduced in the published article as submitted.
- Titles should be written in sentence case (capitalize only the first word of the title, the first word of the subtitle, and any proper nouns and genus names).

John Doe[1¶], Antonie Data[1¶], Johannes van Stats[1,#a], Marie Testperson[2*], David Ribosome Jr.[3,4], Gregory H.T. McBio[5,#b], Angela Revieweron[1,2&], Marina Measure[1&], on behalf of The Bunny Genome Sequencing Consortium[^]

Author Byline
- Author names will be published exactly as they appear in the accepted manuscript.
- Indicate affiliations by number only.
- Affiliation footnotes should appear in numerical order at first mention.
- Please use the symbols provided in this document for other designations.
- Numbers and symbols should be in superscript.
- Do not include titles (Dr., PhD, Professor, etc.).

[1] Department, Institution, City, State, Country

[2] Department of Dermatology, Division of Rabbit Health, Section of Veterinary Medicine, St. Hare Hospital, San Francisco, California, United States of America

[3] Department of Libraries and Archives, National Contemporary Bunny Museum, Lagomorph, Connecticut, United States of America

[4] Department of Restoration, National Contemporary Bunny Museum, Lagomorph, Connecticut, United States of America

[5] Department of Archaeology, Bunny University, Lagomorph, Connecticut, United States of America

[#a]Current Address: Department of Carrot Science, Bunny University, Lagomorph, Connecticut, United States of America

[#b]Current Address: Department of Canine Evasion, Bunny University, Lagomorph, Connecticut, United States of America

Affiliations
- Affiliations will be published as they appear in the accepted manuscript.
- Include each component in order of small to large (Department, Division, Section, Institution, City, State, Country).
- Do not include ZIP or Postal Codes, street addresses, or building/office numbers.
- Do not use abbreviations (e.g. Dept.).
- Do not list positions within an institution (e.g. Department Chair, Professor, etc.).
- List each affiliation individually and in full.

* Corresponding author

E-mail: testperson@university.ed (MT)

Corresponding Authorship
- Do not include physical addresses; only email addresses are required.
- List corresponding author's initials in parentheses after the email address.

[¶]These authors contributed equally to this work.

[&]These authors also contributed equally to this work.

Contributorship
- Use the symbols provided here to indicate equal contributions.
- If you would like the equal contributions notes to read differently, please specify in your manuscript (e.g., "AR and MM are Joint Senior Authors").

[^]Membership of the Bunny Genome Sequencing Consortium is provided in the Acknowledgments.

Consortia or other Group Authors
- If there is a consortium or group author on your manuscript, please provide a note that describes where the full membership list is available for the readers.
- The membership list can be listed in the Acknowledgments, in Supporting Information, or on the internet.
- Consortia/Group authors can have affiliations, but it is not required.

Modified February 2020

PLOS ONE

MANUSCRIPT BODY FORMATTING GUIDELINES

Abstract

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Vestibulum adipiscing urna ut lectus gravida, vitae blandit tortor interdum. Donec tincidunt porta sem nec hendrerit. Vestibulum nec pharetra quam, vitae convallis nunc. Mauris in mattis sapien. Fusce sodales vulputate auctor. Nam lacus felis, fermentum sit amet nulla ac, tristique ultrices tellus. Integer rutrum aliquet sapien, eu fermentum magna pellentesque vitae. Integer semper viverra mauris vel pulvinar. Suspendisse sagittis malesuada urna. Praesent mauris diam, fringilla id fringilla ac, posuere non lorem. Vestibulum mauris ante, fringilla quis tortor sit amet, accumsan fermentum quam. Nulla dictum consectetur leo. Ut vulputate ipsum purus, a interdum nibh viverra et. Praesent aliquam sapien vel massa sodales bibendum. Nulla interdum accumsan lectus, sed auctor elit accumsan a. Suspendisse quis rhoncus nibh. The verum est de illic.

Introduction

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Vestibulum adipiscing urna ut lectus gravida, vitae blandit tortor interdum. Donec tincidunt porta sem nec hendrerit. Vestibulum nec pharetra quam, vitae convallis nunc.

Materials and methods

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Vestibulum adipiscing urna ut lectus gravida, vitae (Fig 1) interdum. Donec tincidunt porta sem nec hendrerit. Vestibulum nec pharetra quam, vitae convallis nunc. Mauris in mattis sapien. Fusce sodales vulputate auctor. Nam sit amet nulla lacus a, Figs 1 and 2 ultrices tellus. Integer rutrum aliquet sapien, eu fermentum magna pellentesque vitae.

Fig 1. This is the Fig 1 Title. This is the Fig 1 legend.

Fig 2. This is the Fig 2 Title. This is the Fig 2 legend.

Level 1 Heading

- Use Level 1 heading for all major sections (Abstract, Introduction, Materials and methods, Results, Discussion, etc.).
- Bold type, 18pt font.
- Only use italics and text formatting where needed (e.g. genus and species names, genes, etc.).
- Headings should be written in sentence case (capitalize only the first word of the heading, the first word of the subheading, and any proper nouns and genus names).

NOTE: Do not cite figures, tables, supporting information, or references in the Abstract.

Figure Citations

- Cite figures as "Fig 1", "Fig 2", etc.
- Cite figures and tables in order.
- Do not cite "Fig 2" before "Fig 1".
- Cite multiple figures as "Figs 1 and 2", "Figs 1-3", etc.

Figure Captions

- Each figure caption should appear directly after the paragraph in which they are first cited.
- Do not include tables within captions.
- Use bold type for the figure titles.

File Naming for Figures

- Figure files should be saved as "Fig1.tif", "Fig2.eps", etc.
- Acceptable file formats for figures are ".tif", ".tiff", and ".eps"
- Figures should be uploaded separately as individual files.
- PLOS ONE guidelines for figures can be found here: http://journals.plos.org/plosone/s/figures

Appendix X: Author contribution letter

To : The Examiners

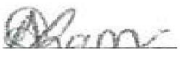
Date : 1st April 2021

Subject: **AUTHOR CONTRIBUTIONS-ANGELLA JOY KAMWENDO**

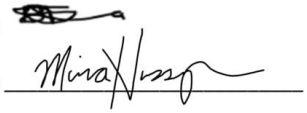
The following were the author contributions made by Angella Joy Kamwendo to the manuscript titled "**Improving viral load testing using a quality improvement approach in Blantyre, Malawi** ":

study conception and design, acquisition of data, analysis and interpretation of data as well as drafting the manuscript.

Dr Juliana Kagura and Prof Mina Hosseinipour were also involved in all the aforementioned tasks including conceptualization of research, including supervision and provision of guidance on revisions. All authors also read and approved the final manuscript that was submitted.

Angella Joy Kamwendo : 

Dr Juliana Kagura : 

Prof Mina Hosseinipour : 

Appendix XI: Submitted Manuscript Draft (PLoS ONE)