Ambitious HIV treatment goals, viral suppression, and laboratory readiness in Maputo, Mozambique

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A thesis

submitted in partial fulfillment of the

requirements for the degree of

Master of Public Health

University of Washington

2018

Committee:

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Program Authorized to Offer Degree:

Global Health

University of Washington

Abstract

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Introduction: Following international recommendations and guidelines, in 2016, Mozambique started implementing the 'test and treat' approach to meet the ambitious HIV treatment targets by 2020, and 'end AIDS' by 2030. Mozambique took a staggered and conservative implementation approach that suggested local reservations about meeting the international targets and is consistent with the slow improvements in epidemiologic and data quality indicators, despite more than a decade of international investment in the response to HIV/AIDS. This thesis describes challenges to achieving the third HIV treatment target at a public health facility receiving technical and logistical assistance from an international nongovernmental organization (NGO) in Maputo, Mozambique.

Methods: I reviewed medical data on all patients whose sample for viral load had been collected between September 1-November 30, 2016, conducted participant observation and ethnographic interviewing between September 2016-February 2017. I conducted thematic analysis using Atlas.ti, version 7.5 (Scientific Software

Development GmbH), and descriptive and inferential analysis (reporting 95% confidence intervals where appropriate) using Stata 13 (StataCorp, 2013) and graphing in R3.5 (Core Team, 2018). The study was approved by the Ministry of Health and the National Bioethics Committee for Health (CNBS) of Mozambique and the University of Washington Institutional Review Board (IRB).

Results and discussion: Between September-November 2016, 362 samples were sent for viral load testing at the reference laboratory. However, they had availability and data quality issues: 43.6% received results by February 2017, 16.9% were available in the NGO electronic-based patient tracking system (e-PTS); 2.8% and 2.2% had missing and duplicate patient ID's, 2.2% had duplicate names, patient IDs (15.7%) and names (5.0%) in the public health system's paper-based laboratory registry did not match with the e-PTS. These challenges occurred in a three-fold context that shaped facility unreadiness to manage viral load. Recoding protocols were implemented before receiving registries from the national level (structural), disconnections between paper-based and electronic registries remained at the facility (process), and new staff at the facility laboratory had not developed the capacity to manage viral load registry and communications (individual). These findings resonate with the low readiness for the ambitious treatment goals and chronic routine HIV data quality issues nationally. They help question the reasonableness of trying to meet internationally-defined targets, that has defined the ending AIDS agenda, without making appropriate investments in public health information system infrastructures that can provide information for timely clinical decision-making and monitoring of progress towards the very targets the international agenda defined.

ACKNOWLEDGEMENTS

I am morally and ethically indebted to my research participants, mostly health workers in the public and international NGO payroll, all working at the health facility where I conduct this research in Maputo. Their generosity in sharing with me their knowledge, wisdom, experience and care for what they do influenced what I am writing about here. To protect their privacy, I decided to conceal their names and the name of the health facility where they work. I hope they will understand and forgive me for this. I am deeply grateful for the mentorship, care and support that James Pfeiffer (my committee chair) and Rachel Chapman gave me, and I hope I and this thesis does not live too short of your expectations.

Steve Gloyd, Sarah Gimbel, Kenneth Sherr, Marnie Chinn, and Cathy Michel from HAI provide me support without which I would not have started and completed this degree. Orvalho Augusto became an intellectual friend and a brother whose analytical insights and broad interests inspired me beyond this thesis.

I would have not completed this degree without the generous financial support of the Wenner-Gren Foundation for anthropological research, which funded most of my coursework, all of my research and write up. I would like to end by thanking those who are first in my life: my wife, partner, friend, and inspiration ('Isa'), thank you for always being there for me, and for our children Simphiwe, Chiquinho, Isis and Péricles.

CONTENTS

1. INTRODUCTION

Background and Problem Statement

Following international recommendations and guidelines (UNAIDS 2014; World Health Organization 2015), in 2016, Mozambique started implementing the 'test and treat' approach (MISAU, Programa Nacional de Controlo de ITS-HIV/SIDA 2016, 2018) to meet the ambitious HIV treatment targets that if met by 2020 were internationally believed to lead to ending AIDS by 2030 (UNAIDS 2014). The targets are also known as 90-90-90: testing 90% of people living with HIV, maintaining in antiretroviral treatment 90% of those diagnosed, and achieving viral suppression in 90% of those in treatment (UNAIDS 2014). They are inspired by the influential mathematical model built by Reuben Garnish and colleagues, assuming a generalized epidemic driven by heterosexual transmission (Granich et al. 2009). Yet, UNAIDS targets set a more ambitious deadline (2030) for the leveling of the epidemic than the one originally proposed by Garnish and colleagues (2050) (Granich et al. 2009; Granich et al. 2012).

Mozambique chose a staggered and conservative implementation approach that suggests reservations about meeting the ambitious targets in the proposed deadline. This approach is consistent with the slow improvements in epidemiologic indicators (INS, INE, and ICF 2018) and data quality ((MISAU, Programa Nacional de Controlo de ITS-HIV/SIDA 2016 2015; McKay 2012) in the country, despite more than a decade

of international involvement in the national response to HIV and AIDS (McKay 2018).

Despite UNAIDS' celebratory tone that the "reduction in AIDS-related deaths continue at a pace that puts the 2020 milestone within reach" (Minchella et al. 2017, 4), nearly a year to the deadline, Mozambique and most countries in Eastern and Southern Africa (15 out of 19), are still far from meeting those targets (UNAIDS 2018, 30–66). To illustrate, only 59% of people of all ages living with HIV know their status, and 54% of those are on treatment in Mozambique (UNAIDS 2018, 51). Consistent with the latest Mozambique's National STI and HIV program report (MISAU, Programa Nacional de Controlo de ITS-HIV/SIDA 2018), the UNAIDS report does not present data on viral suppression for the country, nor for most (11 out of 19) countries in Mozambique's continental region (UNAIDS 2018, 30-66). Without data on viral suppression (the third treatment target) progress towards meeting the 90-90-90 cannot be assessed (Barnabas et al., n.d.; El-Sadr et al., n.d.; R. Granich et al. 2012; Marcus et al., n.d.; Montaner et al. 2006; Peter et al. 2017; Schwartz et al., n.d.; "HIV Viral Load Trends in Six Eastern Caribbean Countries Utilizing a Regional Laboratory Referral Service: Implications for Treatment as Prevention - ProQuest" n.d.).

In addition, the quality of HIV data produced by the national health information system ((MISAU, Programa Nacional de Controlo de ITS-HIV/SIDA 2016 2015; MISAU, Programa Nacional de Controlo de ITS-HIV/SIDA 2018), and by PEPFAR-funded international NGOs responsible for providing technical and logistical assistance to the national HIV program is so low (Inguane et al. 2016) that the Mozambican Ministry of Health uses them with open reservations (MISAU, Programa Nacional de Controlo de ITS-HIV/SIDA 2016 2015). These reservations resonate with ethnographic descriptions that suggest that those data do not help in timely clinical decision-making at the health facility, nor in monitoring the impact of international investments in the response to HIV and AIDS in Mozambique (McKay 2012).

Within this context, Mozambique' implemented the 'test and treat' approach in stages, the first of which is a pilot with three phases (starting in August 16, February 2017 and December 2017). Each stage covers health facilities in few districts, and their progress is monitored through regular readiness assessments, expected to produce results that inform decision-making about national scale up of the approach (MISAU 2016). The pilot included health facilities in only 29 out of the 160 districts of the country (INE 2017), and assessment results show some progress in health facility readiness, albeit unevenly distributed and all below the Ministry of Health expectations of complete readiness (MISAU 2018). The readiness assessments conducted by the National STI and HIV program provide important

findings, yet, their quantitative design prevents understanding of contextual factors that influence the readiness challenges the assessment documents. Understanding contextual factors is also important in decision-making for improvements and planning for implementation scale-up.

Based on ethnographic research conducted at one of the health facilities included in the first implementation phase of the pilot, in Maputo, Southern Mozambique, I describe the context and challenges to the health facility readiness in managing viral load documentation, a measure of health facility readiness related to the third treatment target (viral suppression).

2. METHODS

Study design, sampling, and data collection

I used an ethnographic research design, that combined qualitative and quantitative data collection and analysis methods. I collected data between September 1, 2016 and January 31, 2017, at a health facility in Maputo, Southern Mozambique, that was included in the first phase of the pilot implementation of the test and treat approach.

I used qualitative data collection methods, including participant observation, in-depth individual interviews and conversations (ethnographic interviews) with health facility workers and referral laboratory personnel, and reviewed paper-based laboratory log books, registries, and viral load results slips, and viral load records from the electronic patient tracking system (e-PTS).

I did not determine the study sample in advance. Instead, I collected data on all patients whose sample for viral load had been collected between September 1 and November 30, 2016.

Data management and analysis

I created an excel-based dataset, containing names, patient IDs (locally known by the Portuguese acronym 'NID', for as *Nuúmero de Identificação do Doente* - NID), date of sample collection and referral for viral load testing at the national

laboratory, and dates when results were returned to the health facility, if they were. I also recorded data quality issues in the dataset, including if NID and patient names were complete, correctly written or duplicated within each registry and across registries. I recorded observations through fieldnotes, in a notebook, and typed and extended them using MS Word, on a password-protected computer at the end of each day of work at the health facility. I password protected both the quantitative and the qualitative datasets.

I conducted qualitative (thematic analysis) using Atlas.ti, version 7.5 (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany), based on weekly summary reports that I prepared to record emerging themes and methodological and analytical insights. I conducted descriptive and inferential analysis (reporting 95% confidence intervals where appropriate) of quantitative data using Stata version 13 (StataCorp. 2013. Stata: Release 13. Statistical Software. College Station, TX: StataCorp LP, Texas, United States of America.) and graphic using R3.5 Core Team (2018). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria).

Ethical considerations

The study received approval from the Ministry of Health and the National Bioethics Committee for Health of Mozambique (*Comité Nacional de Bioética para a Saúde* – CNBS) and from the University of Washington Institutional Review Board (IRB). I

password-protected the data files and stored them in a password-protected personal computer. The results are presented without any information that can positively identify individuals or the health facility where I conducted fieldwork.

This study has a broader ethical context, though. I became aware of delays in obtaining viral load results during an interview with a patient on antiretroviral therapy at the facility in question. Instead of investigating what was happening with that particular patient results, however, I thought it would be more ethical if I extended by efforts into all patients that had provided a blood sample for viral load testing at the same time the patient did (September 2016).

3. LABORATORY READINESS FOR VIRAL LOAD

Health Facility Management Context

The health facility is a public health center, located in Maputo, Southern Mozambique, managed by Mozambique's Ministry of Health, and receives technical and logistical assistance from a PEPFAR-funded nongovernmental organization (NGO), also known as an implementing partner (PEPFAR 2016, 2017). As part of the implementing partner's responsibilities of helping improve HIV indicators, the partner seconds technical assistants (clinical, laboratory, pharmacy, and monitoring and evaluation), and staff for the various health facility sectors that are part of the HIV and tuberculosis services. This team is under the responsibility of a regional supervisor, who is in charge of a few other health facilities in the same district. The implementing partner also provides financial assistance to the district directorate of health in which the health facility is located, through a sub agreement with that management entity.

The implementing partner works within a PEPFAR framework and funding approach, through which PEPFAR provides funding directly to international NGOs, instead of directly funding the Mozambican government or the Ministry of Health (Pfeiffer et al. 2017). Under this framework, the implementing partner reports directly to PEPFAR, instead of being accountable to the Ministry of Health. As part of this accountability system, the implementing partner has a health information system that captures data from the public paper-based health

information system managed by the Ministry of Health, to produce indicators on patients in HIV care and treatment. The e-PTS is tone of the most visible parts of the NGO health information system, in which viral load data is also stored[1].

This funding and accountability framework shape the immense power the implementing partner has, including bringing in new hires, as it did with a laboratory assistant who, since mid 2016 became responsible for, among other issues, managing viral load-related data at the health facility laboratory and communicating with the national laboratory that conducted viral load testing.

Challenges to Laboratory Readiness

Despite the NGO support, viral load management protocols were implemented at the health facility before the facility received appropriate registries. Therefore, laboratory personnel improvised with what they had and what they were used to. They documented viral load in the laboratory registry book, in which they usually enter requests for other clinical examinations. However, that book does not have space to enter viral load results, and this led laboratory staff to enter results on another laboratory registry that they improvised for this specific purpose. They also entered data into a notebook that they improvised as a viral load registry.

[1] A less visible part is an electronic system that tracks antiretroviral drug management and distribution

Responsibility for recording of patient samples for viral load, transportation for testing at the referral laboratory, and recording of test results returned from the referral laboratory was assigned to a new and unexperienced laboratory assistant (*motoqueiro*). The assistant had been hired by the implementing partner as part of efforts to meet the ambitious HIV treatment targets.

Given the spread of viral load sample collection and new laboratory assistant's lack of experience, I created an excel sheet in which I entered details of patients who had given a blood sample between September 1 and November 30, 2016 for a viral load testing. The health facility did not have viral load testing capabilities. Therefore, the samples were sent to a national laboratory run by the National Institute of Health in Maputo City (reference laboratory) for testing. The details I recorded where the full name and the patient ID (*número de identificação do doente* – NID), as written in the laboratory registry book, the date when the sample had been sent to the national laboratory and whether the reference laboratory had sent back the results to the health facility. Because patient identification information was spread around the multiple registries, and there were several data quality issues, it took me about two months to completely enter patient viral load test request data in the excel sheet.

When I completed the list, I sent it to the national laboratory and asked them to check whether they had received the requests for testing and if they had sent the results to the health facility and when. I had to do this, because the health laboratory personnel did not have a list of the samples that were sent to the reference laboratory and when they had been sent, and the staff did not feel comfortable calling the national laboratory.

By talking with the laboratory and data entry staff, I learned that several slips containing viral load results that the reference laboratory had sent to the health facility were scattered around the facility. Some slips where in zip lock bags or envelopes at the laboratory, and their results had not been entered in the appropriate registry. Other slips were in the data entry room, and yet others were at the main clinical consultation room. So, with the laboratory assistant's and other health facility staff support, I looked for the slips at the three places where they would be located. I recorded in the excel sheet whether results had been sent back by the laboratory or not. Only after I was sure we had made all efforts to find all slips and entered the results did I call the reference laboratory requesting them to check whether they could send the results to the facility.

When I finally called the national laboratory, inquiring about the missing results, the referral laboratory personnel told me that there had been a delay in sending results to all health facilities that they serve, due to a technical problem they had

had in August 2016. the problem had been resolved and they were sending the results to the health facilities.

In summary, the readiness of the health facility laboratory in managing viral load was part of a context of challenges at three level, summarized in table 1 At the level of the implementation of the 'test and treat approach' (structural), with the health facility management of the public paper-based health information system and the NGO managed e-PTS (process), and with laboratory human resource competencies and experience to deal with viral load (individual).

Table 1: Health facility viral load readiness challenges

Contextual Level	Challenge
Health system and program (structural)	Registries sent late to health facility Improvisation and registry multiplication
Health facility management (processual)	Health information system duplication Disconnected health information systems Lack data flow standard operating procedures Lack communication protocols with referral laboratory
Human resources capacity (individual)	Lack training and work experience Little organization skills Slow communication with colleagues and referral lab.

Viral Load Availability and Data Quality

Over three months (September-November 2016), 362 samples had been sent for viral load testing at the reference laboratory (table 1). A little less than half (43.6%) of the results had been received by February 2017 (figure 1). Details about tests requested, results received, and associated data quality issues are presented in table 2.

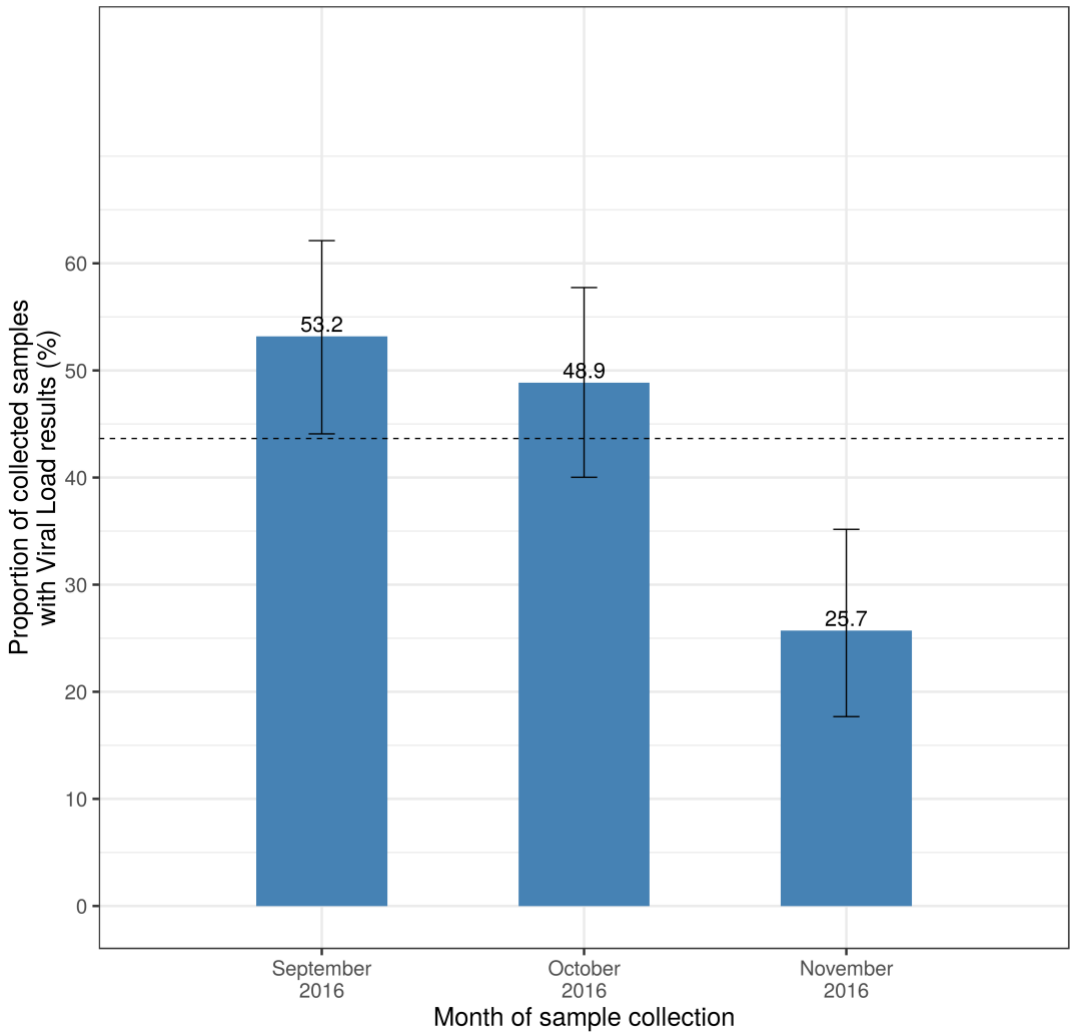

Figure 1: Proportion of viral load results received from the reference laboratory, by February 1, 2017, at a health facility in Maputo, Mozambique

More results of tests requested in September (53.2%) and in October (48.9%) had been received; but only a quarter (25.7%) of those requested in November. Few results were recorded in the paper-based registries, but were missing in the e-PTS, while almost two in every 10 results received were recorded only in the e-PTS, but missing in the paper-based registries, most of which that had been requested in September (38.9%).

Patient information for the samples that had been sent for testing had several data quality issues. NID only included the year in which the patient had been entered in the HIV registry book and the had the patient sequential number. It also indicated, where appropriate. If the patient had been transferred from another health facility. The NID did not include digits that would indicate the province, district or the health facility in which the patient had been registered in HIV care and treatment. Few (10) NID were missing, other NID were duplicated - different patients shared the same NID (8), and nearly two in every 10 NID (15.7%) in the paper-based registries in the laboratory did not match the NID that was recorded in the e-PTS. The e-PTS is housed at the data entry section, which operates at the general reception, about two meters across the corridor.

The proportion of NID in the paper-based laboratory registry that did not match what was in the e-PTS was almost evenly distributed across the months in which the tests were requested (September through November 2016). A small proportion of

patient names were duplicate (2.2%) and a little more (5.0%) in the paper-based laboratory registries did not match the names written in the e-PTS.

Table 2: Viral load requests and results, and data quality issues at a health facility in Maputo, Mozambique, September 2016 – February 2017

	Total		September		October		November	
	N	%	N	%	N	%	N	%
Total Samples on the lab register	362	100.0	126	100.0	131	100.0	105	100.0
Data issues								
Miss NID	10	2.8	6	4.8	3	2.3	1	1.0
Duplicated NID	8	2.2	3	2.4	2	1.5	3	2.9
NID not matching on ePTS	57	15.7	22	17.5	21	16.0	14	13.3
Duplicated names	8	2.2	3	2.4	2	1.5	3	2.9
Name not matching on ePTS	18	5.0	14	11.1	4	3.1	0	0.0
Availability of viral load results (by 1 Feb 2017)								
Available results	158	43.6	67	53.2	64	48.9	27	25.7
Recorded only lab register	5	1.4	5	4.0	0	0.0	0	0.0
Recorded only on ePTS	61	16.9	49	38.9	12	9.2	0	0.0

4. DISCUSSION

Key findings

The health facility laboratory capability to return results for viral load to patients (43.6%) was far below the national and provincial levels (63%, 59%, respectively), based on assessments of the first phase (February 2017) of the 'test and treat' approach in Mozambique (MISAU 2018). Delays in receiving and recording viral load results can compromise timely clinical decision-making and patients' health outcomes (Arpadi et al., n.d.).

Poor data quality challenges are not particular to the health facility. They resonate with data quality challenges nationally, as recognized by Mozambique's National HIV program (MISAU 2015). Incorrect entry of Patient ID at best allows identification of patients from a particular health facility. But, could confuse transferred patients at facility and could be confused in national laboratory. However, this incorrect entry of NID follows national guidelines on the management of medical archives for patients in HIV care and treatment (MISAU, Programa Nacional de Controlo de ITS-HIV/SID 2013), which poses a structural challenge in addition to delays in delays in sending specific viral load laboratory registries to the health facility during the launch of the 'test and treat' approach. Duplicate names or patient ID could be the same patient or different patients sharing the same ID, leading to identification confusions.

These challenges were related to disorganized registries, disconnections between the paper-based national health information system (HIS) laboratory registries and the electronic-based registries managed by the implementing partner responsible for providing logistical and technical assistance to the health facility, district, and province in which the facility is located. These challenges can lead to the irony that, even if viral suppression is achieved, the results might not be reported, because they might not be reliable, which has been documented in the ethnographic (McKay 2012) and public health literature (Inguane et al. 2016) and is acknowledged in various reports from the National HIV program.

Strengths and Limitations

This study has three potential limitations, that suggest that it might underestimate laboratory readiness for viral load, and its findings should not be generalized.

Firstly, the study looked at only one of the measures of laboratory readiness - proportion of results received by the health facility - and left out the proportion of trained staff and availability of stocks for the collection of samples. Yet, the focus on one measure was dictated by the reasons for conducting the analysis (responding to a specific and urgent issue).

Secondly, the study was conducted a few months after the implementation of the pilot of the 'test and treat' approach. Laboratory readiness can improve over time,

as shown by the readiness evaluations conducted at the national and provincial level (from 39% at baseline in July 2016, to 59% after the first phase in February 207, to 73% at the end of the second phase in October 2017) (MISAU 2018). But, there is still room for improvement, and the context for the laboratory data quality issues described in this article, and the historically-established national HIV program data quality issues suggest that it might take longer to improve laboratory readiness.

Finally, although statistical inference is provided (confidence intervals in figure 1), the results should be regarded with extreme caution. The findings that derived from this analysis might be generalizable to patients on antiretroviral therapy at the health facility where the study took place. Greater strength of this analysis, however, lies is in the case-study approach and description of readiness provided in this article helps understand quantitative data on readiness, including data quality issues that are consistent with provincial and national picture. This suggests that this case study can be useful methodological example to understand other cases and could be experimented with as a compliment to the quantitative approach currently used to assess the readiness of both laboratories and health facilities to the 'test and treat' approach in Mozambique.

Conclusions

This study shows that a health facility in which the 'test and treat' approach was implemented since the first phase, in August 2016, in Maputo, Mozambique, was not ready to reliably report viral load suppression due to challenges associated with the lack of human resource capacity, health facility management, and planning for the implementation above the health facility level (individual, process, and structural level challenges). Mozambique is not unique in this (Alemnji, Onyebujoh, and Nkengasong 2017).

If these findings are replicated in other health facilities, as the readiness assessment results from the Ministry of health suggest, broader questions can be asked. These include problematizing the reasonableness of trying to meet internationally-defined HIV treatment targets, without making appropriate investments in the public health information system infrastructure in ways that can, at a minimum, provide information for timely clinical decision-making at health facilities, despite several studies demonstrating the cost-effectiveness of routine viral load (El-Sadr et al., n.d.; R. Granich et al. 2012; Montaner et al. 2006; Peter et al., n.d.; Saito et al., n.d.). More generally, the study can help to call for the need to invest in public health systems that can allow for the monitoring of progress towards nationally and internationally-defined targets and goals. That most countries in Eastern and Southern Africa are not reporting viral suppression (UNAIDS 2018) suggestions that the issues reported in this study are far beyond a single Mozambican health facility (Akullian et al. 2017).

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