A REVIEW ON THE OPERATIONAL IMPLEMENTATION OF POINT-OF-CARE LABORATORY TECHNOLOGIES FOR MONITORING ANTIRETROVIRAL TREATMENT OF PEOPLE LIVING WITH HIV IN LOW AND MIDDLE-INCOME COUNTRIES

Charlie Willie Masiku
Malawi
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KIT (Royal Tropical Institute)
Vrije Universiteit Amsterdam (VU)

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A thesis submitted in partial fulfilment of the requirement for the degree of

Master in International Health

by

Charlie Willie Masiku

Malawi

Declaration:

Where other people's work has been used (either from a printed source, internet or any other source) this has been carefully acknowledged and referenced in accordance with departmental requirements.

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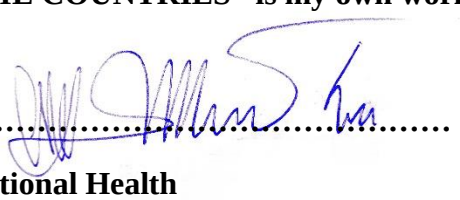

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Table of Contents

List of Tables

List of Figures

Abbreviations

AIDS	Acquired immune-deficiency syndrome
ANC	Antenatal Clinic
ART	Antiretroviral treatment
ASSURED	Affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and delivered to end-user
CD4	Cluster of Differentiation 4
CHAI	Clinton Health Access Initiative
CSOs	civil society organisations
DNA	Deoxyribonucleic Acid
EID	Early infant diagnosis
Hb	Haemoglobin
HIV	Human immunodeficiency virus
KIT	Royal Tropical Institute
Lab	Laboratory
LMICs	Low and middle-income countries
MTB	Mycobacterium tuberculosis
MTB/RIF	Mycobacterium and rifampicin sensitivity test
PEU	Perceived ease of use
PHC	Primary healthcare
PLHIV	People living with HIV
PMTCT	Prevention of Mother to Child Transmission
POC	Point-of-care
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PU	perceived usefulness
QA	Quality assurance
QC	Quality control
RIF	Rifampicin
RNA	Ribonucleic Acid
SDGs	Sustainable Development Goals
TAM	Technology Acceptance Model
TAT	Turn-around-time
TB	Tuberculosis
UHC	Universal Health Coverage
UNAIDS	Joint United Nations Programme on HIV and AIDS
VL	Viral load
WHO	World Health Organisation

Glossary

Abbott m2000rt	Central Lab technology for HIV viral load enumeration
AIDS	The manifestation of destructed immunity by HIV resulting in severe illnesses
Alere Q-NAT	POC Technology for HIV viral load enumeration
ARV	Drugs for the treatment of HIV
ASSURED Criteria	A list of requirements a POC technology should meet to be certified as appropriate for LMICs
BD FACSCalibur	Central Lab Technology for CD4 enumeration
BD FACSCount	Central Lab Technology for CD4 enumeration
BD FACSPresto	POC Technology for CD4 enumeration
CD4	White blood cells that indicate the level of immunity
CHAI	The global organisation supporting HIV POC technology development and utilisation
Cobas TaqMan	Central Lab technology for HIV viral load enumeration
Efavirenz	A drug for treating HIV in combination with other drugs
EID	HIV diagnosis for newborn babies
Genexpert	POC Technology for enumeration of HIV viral load, TB diagnosis etc.
HIV viral load	the measure of the amount of HIV (virus) present in the blood
Lamivudine	A drug for treating HIV in combination with other drugs
PIMA	POC technology for CD4 enumeration
Sysmex	Central lab technology for Hb assessment
Tenofovir	A drug for treating HIV in combination with other drugs
UNAIDS 90-90-90 goal	Ambitious UNAIDS goal to eradicate AIDS by the year 2013
UNITAID	The global organisation supporting HIV POC technology development and utilisation
VICITECT	POC rapid test for CD4 estimation

Abstract

Majority of people living with HIV (PLHIV) worldwide live in low and middle-income countries (LMICs). To keep a healthy living, the continuum of HIV care requires lifelong treatment and continuous monitoring to keep the treatment effective. CD4 count and HIV viral load laboratory tests are used for monitoring the treatment. However, technology for carrying out tests such as these are not widely available in LIMCs except in a few central laboratories. PHC facilities collects specimen from the PLHIV and send to the central laboratories. In an attempt to reach all PLHIV with the services, global actors in HIV such as CHAI and UNITAID have invested in the development of point-of-care technologies which can be used in PHC facilities by non-laboratory health workers yet giving out high quality results. This study was conducted to assess and evaluate point-of-care technologies that may be more suitable for use in the LMICs. Literature on studies carried out from 2013 to 2019 on the use of point-of-care technology to enumerate CD4 and HIV viral load in the LMICs was reviewed. The results indicate that Genexpert and PIMA are the most suitable technologies for use in the large part of LMICs. Genexpert is simpler to be operated by junior laboratory workers. It is also used for diagnosing TB. PIMA is portable and, unlike other machines, tends to yield test results in just about 20minutes. It can easily be used by almost any health worker. Therefore, the two laboratory technologies are highly recommended for use in LMICs.

Keywords: CD4 lymphocyte count, HIV, Viral load, Point-of-care systems, Primary healthcare

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Introduction

In 2007, I joined the international non-governmental organisation MSF as a front line clinician managing people living with HIV. After two years of working, I had an opportunity to change my work position from clinical to Deputy Medical Coordinator for MSF in Malawi. This work introduced me to the field of leadership in public health and working together with the central level of the ministry of health on HIV.

In 2015, I started working as an international volunteer for MSF when I worked in Uganda to establish an HIV service provision project for the people living in landing sites around Lake Victoria. These landing sites are made up of semi-permanent living homes for fishermen, their families and other people trading in all sorts of businesses including commercial sex work. HIV was high and the health system was not able to reach out to the people who needed HIV services. I was part of the people who initiated the project in this area in Kasese district in South West Uganda. In establishing services as a medical team leader, I was responsible for leading all aspects of HIV management and the most challenging was how to establish a laboratory system to provide laboratory services to HIV patients. Because the road networks were not good and were passing through the jungle where all sorts of African wild animals dwelled, movements by simple vehicles such as bicycles and motorcycles, and even smaller cars in the rainy season were almost impossible. It is then I developed a passion in provision of Point-of-Care (POC) lab services to serve the people living in hard to reach places.

After working in Uganda for one year, I later was sent to work in Western Kenya, Homabay county also on the role of Medical Team Leader in a pre-existing HIV project. Even though the setting was different from Ugandan landing sites, in this part of Kenya, the HIV prevalence is high and coupled with poverty. The area is close to Lake Victoria so therefore all trading associated with fishing, including commercial sex work is as well present. The HIV project was run for two years but annual reviews did not show much progress from the baseline study. My role was to improve the project medical systems to be able to impact the HIV situation in the population from awareness and prevention, to testing and treatment including the continuum of care. Having an efficient laboratory system was vital to have people tested and to monitor their treatment progress when initiated on antiretroviral drugs (ARVs). With the above experience, I have worked with Laboratory technologists establishing lab networks and point of care lab technologies for the people served by these two HIV projects in the three countries. I believe there is more that should be done to ensure that there is equity in access to quality HIV management including laboratory service to people living in resource-limited settings otherwise the UNAIDS 90-90-90 agenda, and as well the WHO UHC cannot be achieved.

Objective of review

The purpose of this review is to assess operational successes, challenges and outcomes of the implementation of the available CD4 and HIV viral load POC technologies in low and middle-income countries (LMICs) in order to identify efficient POC technologies and implementation practices

1. Background

Worldwide, in 2017, 36.9 million people had HIV (Human Immune-deficiency Virus), the virus that causes AIDS (acquired immune deficiency syndrome). In 2017, 75% (25.7 million) of the total global population of people living with the human immunodeficiency virus (HIV), was in Africa(1).

The magnitude of the disease burden indicates the global need for adequate diagnostic capabilities, as well as continuous monitoring of people living with HIV (PLHIV) in Africa. In addition, there is also a need for availability and adherence to lifelong treatment to sustain a healthy living(2). The treatment monitoring of the infected individuals involves assessing immunity levels by quantifying CD4 cell count in their blood, and also by quantifying the amount of the HIV virus present in their body. The former is done by checking the blood for Viral Load at intervals of 6 to 12 months for life(3). Knowing the levels of CD4 white cell count and the HIV viral load in the blood help the health provider to make critical decisions on the treatment being given as they assist the health worker to know whether the treatment is working well with the patient or not(4).

Yet, despite the highest number of people living with HIV in low and middle-income countries (LMICs), there is limited health infrastructure and resources for monitoring of HIV disease. HIV viral load and CD4 enumeration in LMICs is done by sending blood and tissue samples to a few centralised laboratories(5)(6). Furthermore, inadequate availability of appropriate health infrastructure and human resource for health as well as the rural-urban divide present challenges which prohibit appropriate management of the disease(7)(2)(8). The situation is worse in rural settings due to the long distance between health facilities, poor transportation and referral systems of patients and tissue samples, and poor networking of laboratory. As a result, many patients fail to access monitoring services(6)(9).

The current global HIV treatment recommendations require that the newly diagnosed PLHIV must be given treatment regardless of physical or laboratory markers of sickness. In addition, patients are now started on a treatment regimen proposed in the WHO 2016 HIV Treatment Guidelines adopted by almost all LMICs. The basic drug regimen for PLHIV (adolescents and adults) comprises of a combination of three drugs, Efavirenz, Lamivudine and Tenofovir. Monitoring the success and the side effects of the drugs require laboratory tests. Patients are required to be screened for key opportunistic infections such as tuberculosis (TB) through urine and sputum samples and Cryptococcus disease(3,10,11).

WHO defines Primary healthcare (PHC) as the whole society's approach to health and well-being, centred on health needs and individual preferences of families and communities(12). This review refers to PHC facilities as health service provision facilities that provide PHC to the communities and are usually situated within the community. Because PHC facilities provide the majority of health needs of people, WHO recommends that treatment and follow up of PLHIV be decentralised to PHC facilities. WHO further recommends shifting of relevant HIV care tasks from senior staff to nurses and junior staff working at PHC facilities(13)(14–16). To provide HIV laboratory services to PLHIV in remote PHC facilities, portable lab tests that can be carried out at the point of care by using portable machines, known as POC Technologies, have been developed (8). These technologies can be operated by non-laboratory health workers in addition to providing other services in HIV care such as clinical consultation and counselling in health facilities (17).

Significant players in global health such as the UNITAID and the Clinton Health Access Initiative (CHAI) among others have invested resources to the development of HIV POC testing technologies as a way forward to improve health care systems of LMICs(18).

2. Problem statement

Continuum of HIV care requires lifelong treatment and continuous assessment of the health of the PLHIV. Much of the monitoring requires that the patients should have access to lab tests for the clinicians to make appropriate decisions on the continuity of treatment(3). Having such testing capabilities based only in centralised laboratories has some advantages such as ease of control and management but it also comes with many disadvantages to the PLHIV who live in remote areas. The challenges include delays in turn-around-time (TAT) of results, lack of proper storage facilities for samples, poor transportation network and missing of results(9).

The last decade has seen the development of a considerable number of POC technologies such as rapid test kits, test strips and portable machines. However, not all POC technologies can efficiently be used in resource-limited settings. This is because each technology has been made to provide a solution to specific challenges. For example, a POC technology made for an emergency room in a high-income country is less likely withstand challenges experienced in remote settings of LMICs such as lack of consistent power supply experienced and inadequate supply of high-skilled health workers to utilise such technologies(19). It is therefore relevant to have an efficient, appropriately developed way for the selection of POC technologies that are not only portable but can also easily be understood and operated by low-skilled health workers in the LMICs. Such POC technologies are more likely to produce desired outcomes(20).

To make the selection process of POC technologies efficient, evidence-based and standardised, for use in resource-limited settings, the World Health Organisation formulated criteria of requirements POC technologies should meet in order to qualify. This list is termed as "ASSURED Criteria" (affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end-users)(20)(8)(21). However, the adoption of these criteria does not always result in improved management of patient outcomes. This is because the criteria might not address all challenges associated with implementing POC technologies such as the magnitude of training needed for workers to use the technologies, the operational independence and the need for other facilities such as refrigerators, power, centrifuge and its acceptability by the PLHIV where it is used(22)(23). POC technology implementation challenges may lead to inefficient utilisation that can be manifested by prolonged clinic visits by PLHIV and workload pressure to existing clinic staff (24)(9). Many of the challenges arising following POC technology implementation goes beyond the scope of diagnostic accuracy to the problems of integration with existing systems such as complicating the health facility workflow, PLHIV or health provider distrust, patient privacy, patient confidentiality and lack of appropriate information communicated about the POC technology(24)(25).

The adoption of POC technologies in hospitals and primary healthcare (PHC) facilities is to speed up laboratory test results turnaround time (TAT), from days to just an hour to enable quick decision-making on test results in order to aid timely the PLHIV(20)(26). However, it has been observed that during the infield practice, a new set of challenges emerge alongside the implementation and use of POC technologies, resulting in failure to reach the desired improvement. In some scenarios, studies have discovered that there is suboptimal use of some of these technologies(9).

In support to these findings, a study carried out in Uganda on POC usage found that health personnel did not have trust in POC technologies, needed more training on the test other than what they went through, and that some of them were concerned about the limitations in diagnostics potency that such technologies may have in comparison with the centralised laboratory-based technologies which are usually wider in their range of test indices(7). Another qualitative study on POC in India in 2015 found that the use of POC in hospitals and PHC facilities failed to improve patient management because of long TAT and lack of use. The study indicates that contrary to the initial intended point of service, the POC

technologies were used in centralised laboratories. It also found that in some health facilities, the POC tests were not carried out due to the shortage of health workers(27)(18).

HIV treatment requires access to lab services for diagnosis and appropriate monitoring of the treatment. However, good quality lab services are not readily available in LMICs for reasons given above. If appropriately implemented, POC technology of minimal footprint has the capability of being used in such settings with minimal demand for extra human resource. On the other hand, it is continually being observed that not all POC implementation is yielding the desired outcome wherever they are being implemented(28)(29). Current studies and reviews have focused on either comparison of different technologies for superiority in giving realistic sample result or comparison of the same technology for use at different levels of service delivery in the health system(30)(6). However, no systematic review has been conducted on the successes, challenges and outcome of implementing CD4 and HIV viral load POC technologies in resource-limited settings in the LMICs.

2.2 Purpose of the review

The purpose of this review is to assess operational successes, challenges and outcomes of the implementation of the available CD4 and HIV viral load POC technologies in low and middle-income countries (LMICs) in order to identify efficient POC technologies and implementation practices. The paper reviews literature on the studies carried out from 2013 to 2019 on the use of POC technology to test CD4 count and HIV viral load in the LMICs.

2.3 Value of the findings

It is hoped that the findings will contribute to my understanding of the operational aspect regarding the use of POC technologies for CD4 count and HIV viral load in resource-limited settings.

2.4 Justification

The universal adoption of new WHO HIV Management Guidelines in 2016 requires that HIV patients access laboratory tests frequently in order to appropriately monitor their treatment. Patients are required to be tested for CD4 blood cell count whenever they feel unwell, and viral load tested every six to twelve months for life(3)(10). Since most of the PLHIV worldwide are in LMICs where health resources are scarce,(1) POC technologies are the ideal tools to reach these people.

POC laboratory technologies continue to be introduced in the field of HIV care. However, not all POC technologies are successful at solving the intended challenges when introduced in the field. With the ever-growing need to manage HIV patients better, WHO continuously updates HIV management Guidelines. The new requirements in the guidelines continue to challenge the capabilities of some POC technologies. Therefore, it is important to assess and evaluate the POC technologies available every few years in order to use the most appropriate and efficient technology available. Hence, the review of research findings in the LMICs regarding the implementation and outcome of POC laboratory technologies is necessary.

2.5 Major Objective

To assess operational successes, challenges and outcomes of the implementation of the available CD4 and HIV viral load POC technologies in low and middle-income countries (LMICs) in order to identify efficient POC technologies and implementation practices.

2.6 Specific Objectives

1. To assess the CD4 and HIV viral load POC technologies suitable for low and middle-income countries.
2. To identify factors that influence and promote the successes and failures experienced in utilising the POC technologies in HIV management at PHC facilities in LMICs.

3. To explore the outcome of using POC lab technologies on HIV management in LMICs.

3. Methodology

3.1 Review of literature

This paper is a review of quantitative and qualitative research findings on the implementation, usage and outcome of POC laboratory technologies in monitoring ARV treatment of PLHIV conducted in LMICs. Documents that were reviewed comprised relevant peer-review journal articles and grey literature. The analysis of the findings was done following the adapted Technology Acceptance Model.

3.2 Search strategy

A systematic search for literature was carried out using Mesh terms in PubMed database shown in the table below to find all literature associated with the use of POC laboratory technology for testing CD4 and HIV viral load on patients taking ARVs in LMICs.

A further search was conducted on Science direct using keywords; HIV POC, HIV Point-of-care, HIV Viral Load, and the intermediate words of either CD4 or Viral Load followed by keywords such as PHC, Primary Health Care, LMIC, Low and Middle-income Countries, RLS, HIV Monitoring, Resource-Limited Settings.

Another search was conducted on google scholar. Keywords that were used include Point of Care, Point-of-Care, Primary Health Care, PHC, Low and Middle-Income Countries, LMICs, Resource-Limited Settings, Viral Load, VL, CD4, HIV Monitoring, Health Centres.

To identify more POC machines ever used in LMICs, the UNITAID HIV/AIDS Diagnostics Technology Landscape 5th edition was used and names of POC machines for Viral load and CD4 were added to search streams on Google scholar. These names include CyFlow Mini POC, PIMA, BDFACSCount, BDFACSPresto, Guava PCA, CyFlow SL3 Partec, Apogee Auti40, Dynal Dynabead, Daktari CD4 counter and CD4 Select for CD4 enumeration, and GebXpert HIV, Alere Q NAT , SAMBA I/II semi-Q, Liat™ HIV Quant, EOSCAPE HIV for HIV Viral Load enumeration.

Table of systematic search keywords

Primary Phrases		**Secondary Phrases**		**Database Search Stream**
"CD4 Lymphocyte Count"[Mesh] OR "HIV"[Mesh] OR "Viral load"[Mesh]	AND	"point-of-care systems"[Mesh] OR "Care, Primary Health"[Mesh] OR "Health Care, Primary"[Mesh] OR "Primary Healthcare"[Mesh] OR "Healthcare, Primary"[Mesh] OR "Primary Care"[Mesh] OR "Care, Primary"[Mesh] OR "Primary Health Care"[Mesh] OR "Primary Healthcare"[Mesh]	AND	"Developing countries"[Mesh] OR low income[tiab] OR middle income[tiab] OR developing countr*[tiab] OR resource poor[tiab] OR rural[tw] OR Armenia[tw] OR Bangladesh[tw] OR Bhutan[tw] OR Bolivia[tw] OR Cabo Verde[tw] OR Cape Verde[tw] OR Cameroon[tw] OR Republic of Congo[tw] OR Cote d'Ivoire[tw] OR Djibouti[tw] OR Egypt[tw] OR El Salvador[tw] OR Georgia[tw] OR Ghana[tw] OR Guatemala[tw] OR Guyana[tw] OR Honduras[tw] OR India[tw] OR Indonesia[tw] OR Ivory Coast[tw] OR Kenya[tw] OR Kiribati[tw] OR Kosovo[tw] OR Kyrgyz Republic[tw] OR Kyrgyzstan[tw] OR Lao[tw] OR Lesotho[tw] OR Mauritania[tw] OR Micronesia[tw] OR Moldova[tw] OR Morocco[tw] OR Myanmar[tw] OR Nicaragua[tw] OR Nigeria[tw] OR Pakistan[tw] OR Papua New

				Guinea[tw] OR Philippines[tw] OR Samoa[tw] OR Sao Tome and Principe[tw] OR Senegal[tw] OR Solomon Islands[tw] OR Sri Lanka[tw] OR Sudan[tw] OR Swaziland[tw] OR Syria[tw] OR Tajikistan[tw] OR Timor-Leste[tw] OR Ukraine[tw] OR Uzbekistan[tw] OR Vanuatu[tw] OR Vietnam[tw] OR West Bank and Gaza[tw] OR Yemen[tw] OR Zambia[tw] OR Albania[tw] OR Algeria[tw] OR American Samoa[tw] OR Angola[tw] OR Azerbaijan[tw] OR Belarus[tw] OR Belize[tw] OR Bosnia and Herzegovina[tw] OR Botswana[tw] OR Brazil[tw] OR Bulgaria[tw] OR China[tw] OR Colombia[tw] OR Costa Rica[tw] OR Cuba[tw] OR Dominica[tw] OR Dominican Republic[tw] OR Ecuador[tw] OR Fiji[tw] OR Gabon[tw] OR Grenada[tw] OR Iran[tw] OR Iraq[tw] OR Jamaica[tw] OR Jordan[tw] OR Kazakhstan[tw] OR Lebanon[tw] OR Libya[tw] OR Macedonia[tw] OR Malaysia[tw] OR Maldives[tw] OR Marshall Islands[tw] OR Mauritius[tw] OR Mexico[tw] OR Mongolia[tw] OR Montenegro[tw] OR Namibia[tw] OR Palau[tw] OR Panama[tw] OR Paraguay[tw] OR Peru[tw] OR Romania[tw] OR Serbia[tw] OR South Africa[tw] OR Saint Lucia[tw] OR Saint Vincent and the Grenadines[tw] OR Suriname[tw] OR Thailand[tw] OR Tonga[tw] OR Tunisia[tw] OR Turkey[tw] OR Turkmenistan[tw] OR Tuvalu[tw]

3.3 Inclusion and exclusion criteria

SCOPE: Documents that discuss POC laboratory technology testing for either CD4 or HIV viral load or both will be included.

REGION: All countries classified as Low and middle-income countries will be included. Countries not falling within this classification were excluded

POPULATION: POC tests performed by all designated health workers shall be included. All tests run by any other individual other than a health worker shall be excluded.

SETTING: All tests performed outside of a health facility shall be excluded.

INTERVENTION: POC tests performed at health facilities that provide primary health care shall be included. Those that are performed elsewhere other than this level of health facilities will not be included.

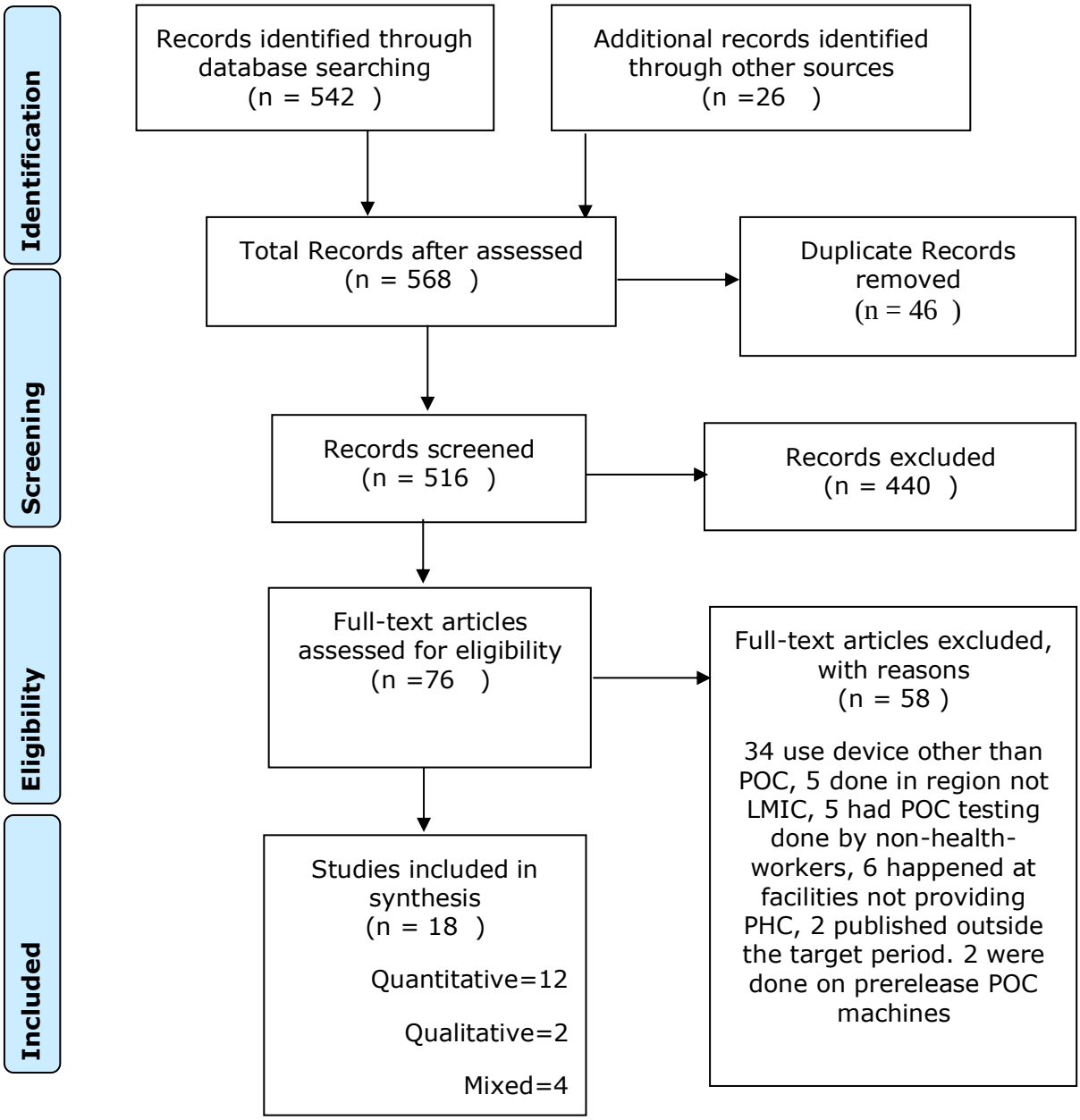
TIME FRAME: studies published between 2013 to 2019 will be included. This is because there was a significant increase in research on POCs in resource-limited settings after the 2013 World Health Organisation HIV treatment guidelines on the need for both HIV load and CD4 count routine testing on all people taking ARVs regardless of being in poor settings(31).

LANGUAGE: Only literature presented in English shall be included. Literature in any other language will not be included due to a lack of knowledge of understanding the other languages by this author.

COST: Due to the limitation of funds, only free access articles shall be able to be included. However, any paid article already paid for and available shall also be included.

STUDY METHODOLOGIES: All relevant qualitative and quantitative research papers shall be considered for inclusion.

Figure 1: PRISMA 2009 Flow Diagram



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3.4 Data extraction and data synthesis

Electronic data tool in form was created in Microsoft Excel 2016. All literature included in this review were read in full. Relevant data were extracted from the original documents, summarised, copied and pasted on the electronic data tool, and the following data items were recorded: name of author, year of publication, title of study, country of study, study type, methodology, population, location, POC technology name, footprint, power source, connectivity, purpose, targeted users, point of use, intervention, perceived ease of use, enablers and barriers, challenges, usefulness, attitudes, output, quality controls, research gaps, and key conclusions. To present findings for the review, narrative, qualitative and descriptive data-analysis methods were used.

3.5 Analytical framework

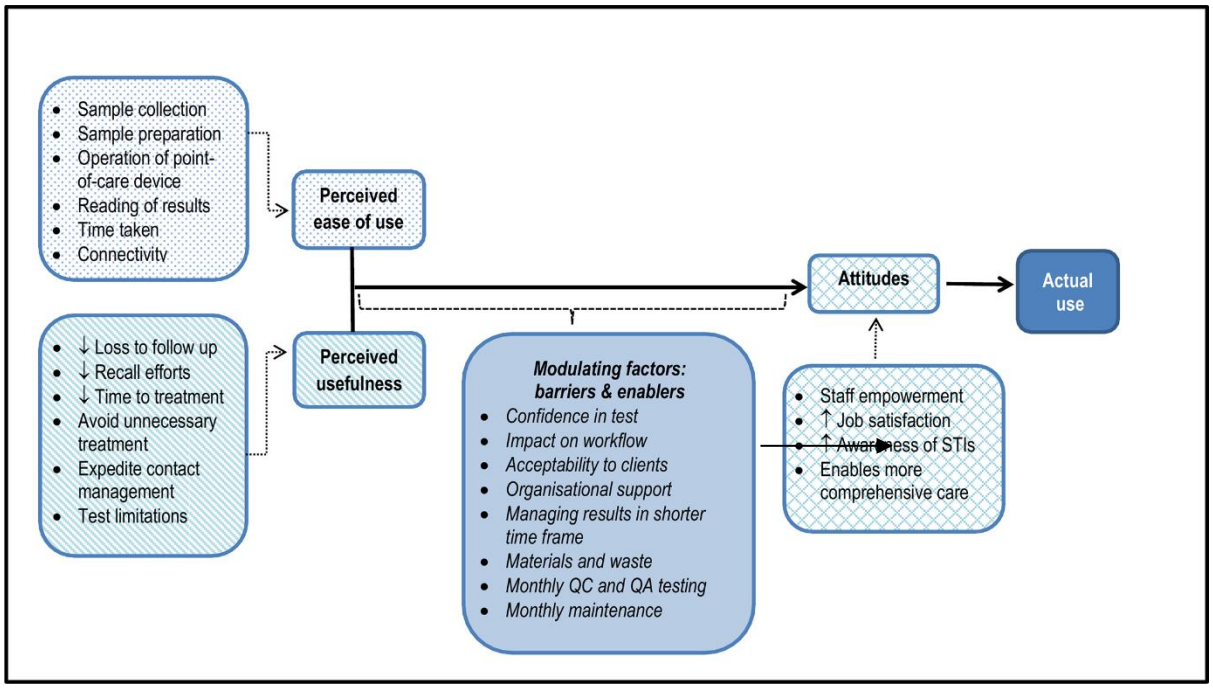


Figure 2: An adapted Technology Acceptance Model (TAM)(32)

TAM model was first introduced in 1986 by Fred Davis(33). The model is specifically used for modelling people's acceptance of using technology. It has frequently been used in technology studies and has been adapted multiple times(34). An adaptation which is relevant for this review was by Natoli L et al. and explored the acceptability of point of care testing for sexually transmitted infections(35). The adaptation was suitable for the current study for three reasons.

First, it was used to analyse innovative point of care for sexually transmitted infections, which are diseases transmitted in the same way as HIV. Second, the study by Natoli L et al. was done by the use of POC technology by junior health workers at PHC facilities. This is similar to the study settings included in this review. POC technologies were used in all PHC facilities of LMICs where junior health workers operated the POC technologies. Third, the level of poverty of the Aboriginal population on which the study was conducted in Australia is closely similar to that of people in LMICs(36).

The conceptual framework model theorises that two specific concepts determine the acceptance of the technology. Perceived usefulness (PU) and perceived ease of use (PEU)(33)(34).

3.5.1 Perceived usefulness (PU)
PU has been described as the subjective likelihood of a potential user anticipating that the use of a specific technology has the potential of improving one's action(34). PU determined by outcomes which include patients lost to follow up, patient recall efforts, the longevity of time to treatment initiation, avoidance of unnecessary treatments, the expedition of contact management and the test limitations(35).

3.5.2 Perceived ease of use (PEU)
PEU is influenced by the way sample has to be collected, Sample preparation, operation of the POC device, reading of the results, the time that is taken performing the test and connectivity of the device with important communications(35)(34).

3.5.3 Modulating factors (Barriers and enablers)
Modulating factors are either barriers or enablers to the use of the technology. These have the potential to influence the user attitude towards the use of a technology(35)(33)(34). These are, the confidence the health provider and patients have in the test, the impact on the workflow, acceptability to the clients, overall organisational support to the use of the technology, managing results in shorter timeframe, materials for use and waste generated, Quality Checks (QC) and Quality Assurance testing (QA) and maintenance(35).

3.5.4 Attitudes
The user attitudes towards the use of POC technology is relevant for POC technology utilisation. Attitude can either be positive or negative towards the use. This can be improved by the feeling of self-empowerment, job satisfaction, awareness of the disease burden and the capacity of the POC technology to enabling more comprehensive care(35).

3.6 Adaptation of conceptual framework
Because this framework was adapted to fit the study of sexually transmitted infection, some indicators are not suitable for the study of HIV. For this reason, such indicators have been omitted from the framework. The following table, (table 1 defines the indicators and illustrates the indicators that have been omitted.

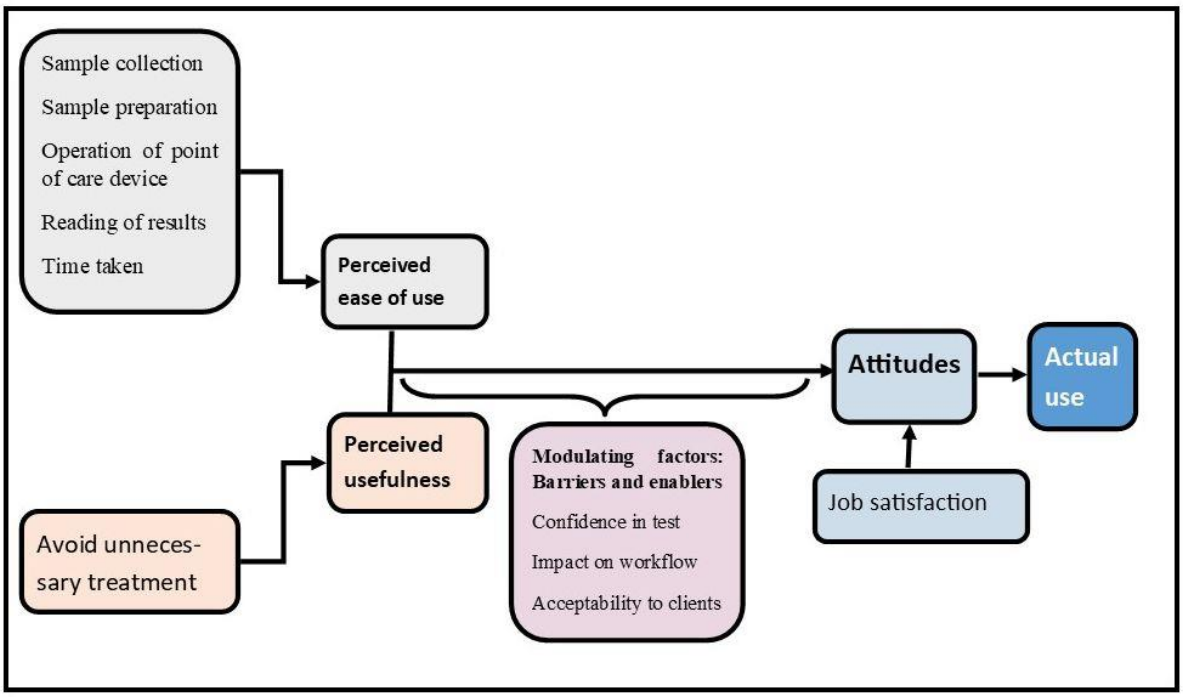
Table 1: Indicators used in the conceptual framework

Parameter	Indicator	Definition	Status for this study
Perceived ease of use (PEU)	Sample Collection	Procedure for collecting of blood sample from PLHIV for testing	Used
	Sample preparation	Procedures which are done on the blood sample collected for it to be ready for testing by the POC machine	Used
	Operation of point of care device	How simple or complicated the health worker feels when operation the POC technology device	Used
	Reading of results	Eligibility and simplicity of interpretation of the result produced by the POC technology	Used

	Time taken	The period from starting the test on the POC technology to the time a final result is produced	Used
	Connectivity	The ability of the POC device to connect with other devices and network needed to work together in simplifying work	Not used
Perceived usefulness (PU)	Lost to follow up	Patients who fail to show up for their test results	Not used
	Recall efforts	The activity of tracing patients who failed to show up for their test results by following them up to their homes.	Not used
	Time to treatment	The period from the time a sample is taken to the time a result is given to the patient for clinical action	Not used
	Avoid unnecessary treatment	Avoidance of using treatment that is not confirmed necessary while waiting for test results	Used
	Expedite contact tracing	Follow up of sexual contacts of a patient whose test is positive to have them treated for the diagnosed disease	Not used
	Test limitations	The inability of a test result to be as comprehensive as the one that is provided by centralised lab technology	Not used
Modulating factors (Barriers and enablers)	Confidence in test	The trust that health workers and patients have in test result being as good as one from the laboratory	Used
	Impact on workflow	How the running of a POC technology affects all aspects of work within the PHC facility	Used
	Acceptability to clients	How PLHIV perceive the use of POC technology on them comparing with centralised laboratory testing	Used
	Organisational support	How the management of the health system supports the day to day running of the POC technology	Not used
	Managing results in short timeframe	How the short time of having the result influences the practice of managing PLHIV	Not used

	Materials and waste	The need for managing storage and disposal of materials associated with the use of POC technology	Not used
	Monthly QC and QA testing	Good laboratory practise of ensuring the POC technology continue to produce results that valid and correct	Not used
	Monthly maintenance	Servicing of the POC technology to keep it in good condition and identify faults if any has developed	Not used
Attitudes	Staff empowerment	The feeling of the health worker as being empowered by the presence of a POC technology at their workplace	Not used
	High Job Satisfaction	The motivation health workers feel when they start operating POC technology at their PHC facility	Used
	High Awareness of disease	Health worker's realisation of the magnitude of the problem of the disease in the population	Not used
	Enables more comprehensive care	The ability for health workers use test waiting time for all other needed health activities on the PLHIV	Not used

Figure 3: Adapted Conceptual framework



4. Findings

18 full-text scientific study articles were identified after the systematic search. Of the 18, 12 reports were from quantitative, 4 four from qualitative-quantitative researches and the rest from a qualitative approach. All the 18 articles were full-text study articles.

Two of the studies were conducted in Asia (India and Papua New Guinea); two in South America (Brazil); three in West Africa (one in Nigeria and two in Senegal); one in North Africa (Ethiopia); three in East Africa (Uganda and two in Kenya); seven in Southern Africa (four in South Africa, and the rest in Botswana, Zimbabwe and in Mozambique).

14 studies focused on CD4 count and four on HIV viral load estimation. Of the studies on CD4 enumeration, seven used PIMA POC Machine, four the BD FACSPresto POC Machine, one Partec Cyflow mini-POC Machine, and one used VICITECT lateral flow semi-quantitative test kit. It was observed that PIMA was the POC technology mostly used for CD4 enumeration studies. The second most commonly used was the BD FACSPresto. For visual understanding, refer to table 2.

The Genexpert POC technology was used in three of the studies on HIV viral load. The Alere Q-NAT POC Machine was used in only one study. Other researchers mostly used the Genexpert POC Technology for HIV viral load tests studies.

For the comparison of characteristics of all the POC technologies used in the studies in this review, refer to table 2 below.

Table 2: POC Technologies used in the studies reviewed

POC technology name	Weight in kilograms	Test result	Time per test in minutes	Throughput per day	Number of studies
Alere PIMA	2.54	CD4	20	20	7
BD FACSPresto	5	CD4 and CD4%	22	50	4
Partec mini POC	6.2	CD4	17	250	1
Vicitect	0.39	CD4	40	120	1
Genexpert	11.3	Viral Load	95	397	3
Alere Q NAT	7.8	Viral Load	60	8	1

Note: In one study, assessing the drawing of blood for POC technology, the Name of the device was not revealed.

Table 3: Characteristics of studies

Author/ Year/ Bojective	Study type	Sample size	Study location	Methodology	Summary of findings
Kulkarni, Smita et al. 2017 The performance evaluation for systematic validation of Genexpert in field	Cross-sectional, Quantitative	HIV-1 positive adult individuals. 314	Pune, India	Genexpert was used to screen patient blood samples in field facilities. Tests were confirmed by Abbott m2000rt Real-Time HIV-1 assay	The GeneXpert compared well with the Abbott with higher sensitivity and specificity (97%, 97-100%), and concordance (91.32%).
Scorgie, Fiona et al. 2019 Exploring the views of healthcare workers on acceptability and feasibility of the VISITECT test	Qualitative in-depth interviews	Health workers 8 1 Medical Officer, 3 registered Nurses, 1 Lab technician, 2 Counsellor	Johannesburg, South Africa	using in-depth, semi-structured interviews	VISITECT was believed to be good because of short TAT but demanded a lot of attention from health provider to operate. Semi-quantitative results were not favoured.

		1 Phlebotomist			
Ndlovu, Zibusiso et al. 2018 To evaluate the operational feasibility of integrated HIV VL, EID and MTB/RIF testing on GeneXpert.	Prospective field feasibility evaluation study by mixed methods	VL: PLHIV on ART over 3 months, aged 18 years and above. n=1,302 EID: HIV-exposed infants, aged 6 weeks to 18 months. n=277 TB: Any patient suspected of TB. n=1,581	Rural Zimbabwe	Whole blood and plasma tested for viral load. DBS samples tested for EID Sputum tested for TB. All on Genexpert POC technology	Minimal training was required A total of 1,302 HIV VL, 277 EID and 1,581 MTB/RIF samples were tested on a four-module Less than 4% error rates Shorter TAT for test results
Negedu-Momoh, Olubunmi, Ruth et al. 2017 To investigate the validity of POC BD FACSPresto™ CD4 analysers for CD4 cell count, in comparison to a reference standard flow cytometry method and the feasibility of use among non-laboratorians.	Cross-sectional Mixed methods	HIV Patients in OPD ART Clinic and ANC clinic 18 years and above and those who were currently attending PMTCT clinic were considered eligible for the study. n=300	Kano, Nigeria	Finger-prick blood samples incubated for 18 minuted and tested on BD FACSPresto, results came out in 4 minutes. Displayed on-screen and printed. Results were used for research purpose only.	The analysis revealed a close agreement between FACSPresto and FACSCount Nurses and technicians produced comparable results. Technicians and nurses expressed that the technology was easy to operate and results were acceptable to use.

Zeh, Clement et al. 2017 To examine the accuracy of Alere's Pima™ POC device on both capillary and venous blood when performed by lay-counsellors and laboratory technicians	Cross-sectional, Quantitative	Patients were enrolled in the study; n=427	Jaramogi Oginga Odinga Teaching and Referral Hospital Kenya	Paired blood from each participant one by finger stick and one using venepuncture were tested by PIMA POC technology. Paired samples were sent to the central laboratory for confirmation of results	PIMA results were similar to those from the central lab. PIMA POC tended to under-classify the CD4 values with an increasingly negative bias at higher CD4 values. Lay counsellors produced compatible results to lab technicians
Malagun, Malin et al. 2014 To carry out pre-implementation field evaluations of low-cost CD4 technologies, Daynal lab-based and PIMA POC technology	Cross-sectional, Multi-site Mixed methods	HIV positive adults, 18years and above n=237	Port Moresby, Asaro District Health Centre and Kainantu Rural Hospital, Papua New Guinea	Paired samples, one tested in the field by Presto and one sent to the central lab to test by FACSCalibur and Danyl lab-based machines. Lab techs were assessed on performance and questioned their feeling of using PIMA and Dynal	PIMA, Danyl and FACSCalibur produced compatible results. The technicians found PIMA easier to use than Danyl. Unlike the rest, Danyl did not have the possibility to perform QC and QA
Daneau, Ge´raldine et al. 2016	Cross-sectional	HIV Adults in HIV clinic in South Africa and Belgium 299 patients and 2	South Africa and Belgium	149 patients had a single finger prick 150 patients had multiple finger pricks	The majority preferred finger prick. The majority allowed finger prick repetitions up to three times. Venous

To assess preferred method patients think either vein puncture or finer capillary stick puncture	Qualitative in-depth interviews	nurses from South Africa and 200 patients and 3 nurses from Belgium. Nurses were those who were drawing blood for POC CD4 testing.		for collection of blood. All had venous blood collected.	sample collection was said to be painful and soreness and tended to bleed more. 30% of patient changed their opinion after a few days
Gebremicael, Gebremedhin et al. 2017 To assess the performance of BD FACSPresto™ analyser in the health facility setting compared to the gold standard BD FACSCalibur and Sysmex XT-1800i™.	Cross-sectional Quantitative	Adults 18 to 65 years old HIV Positive attending HIV services. n=325	Addis Ababa and surrounding health centres, Ethiopia	Fingerstick blood collected and tested by POC BD FACSPresto for CD4 and Haemoglobin(Hb). And venous blood from the same participants for comparison of results using conventional central lab machines. Venous blood for CD4 on BD FCSCalibur Venous blood for Hb on Sysmex XT-1800i™	Acceptable agreement between the BD FACSPresto and BD FACS- Calibur™ for CD4 counting and CD4%; compatible results for Hb test on Presto and Sysmex.
Myer, Landon et al. 2013 Comparison of PIMA POC versus laboratory CD4 cell enumeration on HIV-positive pregnant women in Cape Town, South Africa.	longitudinal, Quantitative.	HIV positive pregnant women n=521	The study took place in a single large antenatal clinic in Cape Town, South Africa, with a heavy burden of antenatal HIV infection, 26%	PIMA was routinely implemented in the ANC clinic. Nurse and Counsellor were involved in testing, alternating.	Generally good agreement. However, PIMA POC underestimated CD4 count relative to flow cytometry. There was a trend towards increasing differences between

			prevalence by 2012.	Capillary finger stick whole blood was used to run on the PIMA. Results were recorded and used on patients.	laboratory and POC testing with increasing gestational age
Pinto, Ione Conceição et al. 2015 Evaluating the accuracy of the PIMA under field conditions in comparison FACSCalibur and to evaluate the operational suitability and acceptability by health professionals and HIV-patients in using the PIMA in health clinics in the Amazon Region in Brazil.	Cross-sectional Mixed methods	HIV patient adults n=408	Amazon region, Brazil	Paired finger prick and venous blood samples collected, tested on PIMA at point of care and on FACSCalibure in lab respectively. Two months later, the health workers who did the testing in the during the study were interviewed.	Poor agreements on the two machines and the PIMA under-estimated CD4 cell counts more pronounced at CD4 counts 500 cell/µl. The PIMA's performance with finger-prick blood was less reliable on venous blood. Health workers and patients accepted a capillary sample drawing very well.
Galiwango, Ronald et al. 2014 To assess the accuracy of PIMA Point-of-Care (POC) CD4 testing in rural Rakai, Uganda.	Retrospective quantitative	HIV positive persons attending field clinics n=903	Rakai district in south-western Uganda	Paired blood tested on PIMA in-clinic labs and on BD FACSCalibur in the centralised lab. Venous samples used collected by nurses.	a high correlation between PIMA and FACSCalibur CD4 counts PIMA sensitivity and PPV significantly went up to at higher CD4 levels. Overall, PIMA POC CD4 counts showed negative

					bias compared to FACSCalibur
Moyo, Sikhulile et al. 2016 To evaluate the performance of Cepheid Xpert HIV-1 viral load test in rural communities in Botswana in order to provide additional data to policymakers regarding the use of this assay in decentralized HIV treatment programs	Cross-sectional, Nested study, Quantitative	HIV positive patients n=302	20 rural communities in Botswana	Venous blood was collected in households and brought to mobile PHC facility where the POC Genepert HIV-1 viral load testing was performed for viral load. Paired blood samples sent to a central reference lab for testing with the Abbott m2000sp/m2000rt	high correlation between the genexpert HIV-1 VL and Abbott results (r2 β 0.92; P < 0.001). The two technologies agreed on their detectability of HIV-1 RNA The POC genexpert HIV-1 VL assay tended to overestimate HIV-1 VL, although the difference was clinically insignificant 0.5 log10 copies/ml.
Bwana, Priska et al. 2015 To evaluate the technical performance of a new point-of-care CD4+ T cell technology, the BD FACSPresto, in field	Cross-sectional, Quantitative	All HIV-positive patients over 18 years of age attending the selected health care facilities; n=264	Busia County of Western Province, Kenya: Alupe Sub-District Hospital and Nambale Health Centre.	100 patient venous blood samples randomly selected for testing on the PIMA in 2 PHC facilities' laboratory to compare the performance of the BD FACSPresto POC CD4 technology. From PHC, samples were sent to the lab in EDTA tubes for testing	Similar results obtained on FACSCalibur, FACSCount, PIMA and the BD FACSPresto. CD4 testing by nurses using the BD FACSPresto at rural health care facilities indicated high technical similarity to test results given by laboratory technicians using the

				using the BD FACSCalibur	BD FACSPresto in a high functioning laboratory
Wade, Djibril et al. 2015 To assess the lab and field performance of the Partec CyFlow mini POC in the National Reference Laboratory in Dakar and in a peripheral laboratory, and compared results with those obtained from FACSCalibur.	Prospective Quantitative	Adults n=297 children, n=24	Hospital in Dakar, and one health centre in Ziguinchor. Senegal	Venous blood samples, collected into K3-EDTA tubes analysed in parallel on CyFlow mini POC, FACSCount CD4 and FACSCalibur to assess CyFlow mini POC precision and accuracy phase one in a controlled lab and phase two the mini POC was under room temperature	CyFlow mini POC had a high agreement with FACSCalibur and FACSCount CD4. The CyFlow mini POC provides both reliable absolute CD4 counts and CD4 percentages including under the field conditions
Rathunde, L et al 2014 Field Evaluation of the Alere Pima™ for CD4+ T lymphocytes counts in HIV-positive outpatients in Southern Brazil. Aimed to identify settings in which the POCT CD4 count would be most valuable in Brazil	Prospective Quantitative	HIV patients n=107	specialised ambulatory facilities in an academic tertiary care hospital in Curitiba, Southern Brazil.	Venous blood samples collected in EDTA tubes. CD4 lymphocyte count was done by flow cytometry and the Alere PIMA simultaneously	PIMA excellent agreement to the standard method. All health professionals (100.0%, 7/7) found the PIMA easy to use and interpret results. Patients said Same day results helped them save time, money for they lived very far from the facility, They also were happy with finger prick than vein

					puncture for blood collection citing pain
Coetzee, Lindi-Marie et al. 2016 To assess the performance of BD FACSPresto CD4 analyser, under ideal laboratory conditions using venous blood sampling, as well as how the manufacturer intended the equipment to be used, in a typical health care clinic with capillary blood sampling	Cross-sectional, Quantitative	HIV patients n=349	South Africa	Phase 1 BD FACSPresto and Beckman coulter parallel testing for CD5 in the lab. vein blood Phase 2 Nurses tested capillary samples in field clinics using the BD FACSPreso	The Presto produced good precision to predicate methods, irrespective of either venous or capillary blood sampling. But had 7% overestimation. Clinic capillary blood produced 5% underestimations of CD4 levels but no significant difference with venous samples
Jani, Ilesh V et al. 2016 Evaluation of the Whole-Blood Alere Q NAT Point-of-Care RNA Assay for HIV-1 Viral Load Monitoring in a Primary Health Care Setting in Mozambique.	Blinded cross-sectional study, quantitative.	HIV patients 18years old and above n=443	Documented HIV infection, and receipt of ART at Primary Health Care Setting in Mozambique	A capillary blood sample collected for immediate testing using a prototype of the Alere Q NAT POC device 2 Venous blood samples were to the HIV reference laboratory, where centrifugation to produce plasma was done and tested on Roche Cobas Ampliprep	Compatible results when using Plasma. When using whole capillary blood samples, the Alere Q NAT overestimated viral load. High estimation was big with those that had viral load levels below 10,000copies/ml.

Faye, Babacar et al. 2016 To compare CD4+ T cell count measurements between the PIMA Alere to the BD FACSCount.	Cross-sectional quantitative (Comparison)	HIV Patients n=200	West of the Dakar, in Senegal	Performed on venous blood collected in K3EDTA tubes. CD4+ T-cell count was performed using the BD FASCount as reference method and the PIMA Point of Care technology	for low CD4 counts, the results from the PIMA Alere provided accurate CD4+ T cell counts with a good agreement compared to the FACSCount mean difference of 22.3 cells/mm3 [95%CI:9.1–35.5] between the BD FACSCountTM and PIMA Alere CD4 measurements though not significantly away from zero. when CD4+ T-cell count was below 350/mm3 (P = 0.76).

4.1 Perceived Usefulness:

One indicator is used to measure perceived usefulness. It is, avoid unnecessary treatment(35).

4.1.1 Avoid unnecessary treatments

Nine studies discussed test results capable of resulting in the unnecessary prescription of treatment.

Health workers running VISITECT POC technology indicated the importance of having CD4 test as it is relevant for detecting the level of Immunity. They said that knowing the level of immunity helps in determining whether a patient needs a change in treatment or a new prescription for opportunistic infection prophylaxis(37).

Four studies compared PIMA POC technology to the centralised laboratory CD4 machines. The comparison has shown that PIMA POC technology underestimated the CD4 count of patients by 22 cells per microliter (38)(39)(40)(41). Underestimation of CD4 to figures below 200 cells per microliter indicated that the patients were wrongly eligible for fungal meningitis treatment prophylaxis. Two studies comparing BD FACSpresto POC technology to the centralised laboratory technologies for CD4 enumeration found that at lower CD4 count, BD FACSPresto POC technology underestimated the CD4 count levels. Bwana P et al. (2015) underestimated CD4 count of 20% of samples and Gebremiceal G et al. (2017) underestimated 10% of low CD4 samples tested(42)(43).

At the 1000 copies/ml viral load cut off point for diagnosing HIV treatment failure, Kulkami S et al. (2017) found that the positive predictive value for Genexpert POC technology was 99%. This PPV was 100% at 400 copies/ml(44). At 1000 copies/ml, Jani I V et al. (2016) found that Alere Q-NAT POC technology had a sensitivity of 96.83% (95% CI, 92.07 to 99.13%) to identify treatment failure compared with centralised laboratory testing. The specificity was at 47.80% (95% CI, 42.19 to 53.44%) and had a positive predictive value and negative predictive value of 42.36% and 97.44% respectively(45).

Test limitations

4.1.2 Test limitation

PIMA CD4 POC technology was not able to give result for CD4 lymphocyte percentage enumeration that is required in the assessment of immune levels in children below 5 years of age which all the centralised laboratory technologies for CD4 testing are able to produce. The VICITECT POC technology gave semi-qualitatively CD4 results with a level cut off point of above or below 350 cells per microliter. Lab-based technologies give out quantitative results. Health workers regarded the semi-quantitative result as inferior to the results produced by centralised lab technologies(37)(46).

4.2 Perceived Ease of Use:

Perceived ease of use is measured by five indicators which are sample collection, sample preparation, operation of point of care device, reading of results, and time taken(35).

4.2.1 Sample collection

Sample collection was discussed in four studies(47)(37)(38)(48). Three of the studies assessed the opinion of health workers on sample collection using qualitative approaches, and one study made a quantitative comparison of using both venous blood and capillary blood on POC technology.

According to Daneau G et al. (2016), the nurses who performed vein puncture and finger pricks to collect blood for testing CD4 enumeration reported that they found finger prick to be faster and easier compared to vein puncture. They preferred finger prick up to 3 possible repetitions in case of an error occurring with each prick. However, they expressed concern

that in case of exposure of the blood to infection, the technique had a higher risk of exposure and contamination than vein puncture. They attributed this to the fact that the blood is not enclosed in a tube as is the case in vein puncture. Besides, multiple pricks predispose a patient to the risk of continuous bleeding(47).

Pinto C et al. (2015), in Brazil, interviewed 7 PHC facility staff who run CD4 tests on PIMA POC technology. Six (85.7%) of them were satisfied with using PIMA POC technology to process capillary whole blood sample from a finger prick. They reported that capillary blood collection technique is simpler and quicker and that they believed capillary blood collection was less painful to the patents(37). However, in an attempt to sort out errors resulting from the use of PIMA POC technology, the health workers resorted to squeezing the fingers in order to collect enough blood samples. Squeezing fingers is against standard procedure for PIMA POC technology (38).

Interviews with non-laboratory health workers running the VISITECT POC technology revealed that they were concerned with the fact that the kit required a precise amount of blood. Any small increase or decrease led to a failed test(37). On the other hand, regardless of whether capillary or venous blood was used on a BD FACSPresto POC technology, no significant difference was noted regarding the clinical relevance of the results as to necessitate alterations inpatient management(48)

4.2.2 Sample preperation

Sample preparation was discussed in three studies(37)(38)(46). One study had qualitative analysis, one had mixed methods and one had a quantitative analysis of findings.

Malagun M et al. (2014), in Papua New Guinea, found out that laboratory technicians preferred sample preparation of PIMA POC technology. It took a shorter time and had only 4 steps than those for the Danyl centralised laboratory-based technology. They reported that the preparation on Danyl required longer time and up to 24 steps of sample manipulation. The laboratory technicians also disliked the Danyl's associated use of a microscope in the testing process. They said that the microscope had to be used for so long a time that their eyes felt strained and tired while in the process of running a test(46). While many POC studies appreciated automation of sample preparation in the use of PIMA and BD FACSPresto POC technologies, non-laboratory health workers, operating sample preparation on VISITECT POC technology were challenged with the 5-step and precise time periods that had to be strictly be followed with the VICITECT POC technology. They believed that it would not work well if they had to multitask as was often the case at the point of care(37)(38). Pinto C et al. (2015), found out that six of the seven nurses that operated BD FACSPresto for CD4 count found sample preparation from the finger prick to the technology easy to perform(37).

4.2.3 Operation of point of care device

Assessment on how health workers managed the operations of POC technology was discussed in nine of the studies. Eight showed that POC technologies were easy to operate and one showed that POC technology was too much a task to operate while doing other work.

In the three separate studies conducted by Scorgie F et al. (2019), Gebremiceal G et al. (2017) and Pinto C et al. (2015) it was found that health staff perceived PIMA, BD FACSPresto and VISITECT POC technologies to be easy to operate (37)(42)(38). All the eight health workers who used VICITECT POC technology reported that the steps carried out in the process of testing the specimen required dedication but not multitasking as is the case with PIMA POC technology. One research participant found it stressful to multitask while the test is running(37).

Gebremiceal G et al. (2017) in Ethiopia found out that all seven laboratory technicians who were running the tests in the study produced good outcomes by conducting tests using the BD FACSPresto POC technology after three days of training on the use of the machine. One of the respondents of a research questionnaire observed that three days of training were necessary to learn how to operate the BD FACSPresto POC technology. However, six of the seven laboratory technicians believed that one day could be enough. The machine was easy to operate because of its automation capabilities in processing the tests(42).

In their study, Bwana P et al. (2015), found that the results obtained by nurses running BD FACSPresto in PHC facilities situated in remote areas were similar to the results obtained by the laboratory technicians operating the machine in a centralised laboratory(43).

Ndlovu Z et al. (2018), revealed that all laboratory technicians, trained for 2 days, attained high proficiency in using Genexpert POC technology for multi-disease testing including HIV viral load and tuberculosis. Tuberculosis microscopists who had prior knowledge in tuberculosis and resistance testing did not face problems in running the machine when the task of running Genexpert POC technology was assigned to them(49).

Negedu-Momoh OR et al. (2017) found that nurses using BD FACSPresto POC technology produced similar results with the ones produced by experienced laboratory scientists who operated the POC technology in the setting of a central laboratory(50). Similarly, Zeh C et al. (2017) found that lay counsellors produced comparable results to laboratory technicians when they operate PIMA POC technology measuring CD4 count(40).

Yakubu A et al. (2017), in Nigeria, found out that tests run by nurses on BD FACSPresto had a sensitivity of 95.2% and specificity of 96.9% for the CD4 cut off point of 500 cells per microliter. The findings were not significantly different from the results by laboratory technicians at the same CD4 cut off point of 500 cells which were a sensitivity of 94.9% and specificity of 97.2%(51).

4.2.4 Reading of results

Two studies reported on how health workers rated the reading of results from POC technology. In a study carried out by Pinto C et al. (2015), it was observed that 100% (7/7) of health worker respondents believed that reading and interpreting test results on PIMA POC technology were not complicated(38). On the other hand, health workers running the CD4 tests on VICITECT expressed that reading of results was easy and that they preferred reading the result with naked eyes to using a machine that was provided for the purpose unless one had lost sight(37).

4.2.5 Time taken

Two studies discussed the time taken to have results using POC technology by analysing the opinion of PLHIV and the health workers operating the POC technology. According to Pinto C et al. (2015), 53.2%, (213/400) of patients interviewed on comparing the use of a centralised laboratory for CD4 counting with the use of PIMA POC technology showed they were not satisfied with the turn-around-time of results in the central laboratory system. 97.5% (387/397) of patients expressed satisfaction with the short time the PIMA POC technology took to produce result unlike the conventional system (38). In addition, 100% of Health Worker respondents reported that the short time that PIMA took to produce results made the machine very relevant for their work. The 40 minutes period of time saved patients time and money(38).

Scorgie F et al. (2019) found out that health workers were happy with the time taken to run the test as it reduced turn-around time of results. Health workers indicated that giving a result

within a short time to PLHIV tends to reduce anxiety in those who wrongly suspected themselves of having low CD4(37)

4.3 Modulating Factors (Barriers and Enablers)

Three indicators are used to measure modulating factors regarding the use of POC technologies. These are confidence in test, impact on workflow and acceptability to clients(35)

4.3.1 Confidence in test)

Two studies assessed confidence in test results. Scorgie F et al. (2019) found out that health workers had general low confidence in POC technologies when compared to centralised lab technologies. They also had low confidence in semi qualitative result of CD4 count citing that it is not reliable in identifying patients who could be at borderline of CD4 cut off points used in categorising the severity of immunosuppression(37).

Pinto C et al. (2015) found that 6/7 of the health workers had confidence in the PIMA POC technology results just as they did with the laboratory centralised FACSCalibur results. They trusted the results and did not have a problem in communicating them to patients and, therefore managed the patients accordingly. Only one health worker mistrusted the POC result and preferred results from the central laboratory instead. Whereas, 78.6% of the patients (313/398) indicated confidence in the results of the PIMA, 47.4% (186/392) of patients said they trusted the results from the central laboratory. This indicates that some individuals tend to trust the results of PIMA regardless of whether it was from a central laboratory or from the POC(38).

Regarding health workers perception on PIMA POC technology, while 71.4% (5/7) believed that the PIMA POC results were trustworthy for patient management, 42.9% (3/7) did not have confidence in the test results(38).

4.3.2 Impact on work flow

The short TAT by PIMA POC technology was impressive to both the PLHIV and the health workers in improving HIV management. 6/7 of health-worker respondents indicated that they would use the PIMA POC technology in their daily clinical work(38). Likewise, the short turn-around time of VISITECT POC technology impressed counsellors and clinicians on having patient flow move faster than centralised laboratory system results(37).

4.3.3 Acceptability to clients

One study assessed POC acceptability to PLHIV. Pinto C et al. (2015), found that 67.1% (265/395) of the respondents said they preferred to checking CD4 count using the PIMA POC technology to using the BD FACSCalibur in a centralised laboratory(38).

4.4 Attitudes:

Attitudes are assessed by one indicator, job satisfaction(35).

4.4.1 Job satisfaction

Job satisfaction was discussed in one study. Ndlovu Z et al. (2018) found that peripheral facility laboratory personnel were comfortable operating the Genexpert POC technology in Zimbabwe. They did not worry about high workload as many functions in running the machine are automated. The staff expressed job satisfaction with having to manage POC technology in their PHC facility and operate it themselves(49).

5. Discussion

The objective of this review was to assess operational successes, challenges and outcomes of the implementation of the available CD4 and HIV viral load POC technologies in low and middle-income countries (LMICs) in order to identify efficient POC technologies and implementation practices.

5.1 Suitable technologies:

One of the study's specific objective was to identify which technologies are most suitable for LMICs. As Ndlovu Z et al. (2018) states, Genexpert requires many resources such as stable electricity supply, centrifuge, refrigerators and air conditioning for it to operate(49). Although Genexpert requires all these, it remains the POC technology of choice in due to its multiplex of use that includes the diagnosis of tuberculosis and TB drug resistance (52)(53)(44). TB is a disease that is endemic in regions where HIV is prevalent. It causes many deaths among PLHIV if not detected and treated appropriately (54). Genexpert is used as well for the HIV diagnosis of newborn babies born mothers carrying the disease in a process known as early infant diagnosis (EID)(55). Owing to this, manufactures of HIV POC technologies should invest more in technologies that can be used for testing multiple disease parameters as this can be favoured by policymakers in LMICs than having multiple technologies in a small PHC facility each testing only one parameter of a single disease. Given the level of seniority and skills of health workers at PHC facilities, it can be complex to manage so many POC technologies at each PHC facility in LMICs.

Second to Genexpert as POC of choice for HIV viral load testing is the Alere Q NAT POC technology. Unlike the Genexpert, which has the potential to test different diseases, Alere Q-NAT POC technology only tests HIV viral load and HIV diagnostic test of EID(45). Researchers found that this POC technology overestimated the whole blood viral load enumeration from finger pricks(45). To have better results, this overestimation indicates that health workers need to use venous blood collected from patients and separation of plasma from blood cells to be done before running the viral load test on the Alere Q-NAT POC technology (45). Health workers preferred as well as patients preferred finger-prick blood specimen collection to venous blood(37)(38)(47). Failure to perform tests on more than one disease and having a technique of specimen collection not well favoured by health workers at PHC facilities in LMICs can be attributed it Alere Q-NAT not being the most widely used.

Among the CD4 POC technologies assessed in this review, the PIMA POC technology has been studied the most in LMICs and has given good results in almost all of the studies done(56)(57)(58)(59)(60)(39)(41). The finding is similar to other reviews before (6)(31). Among other reasons, this can be attributed to the fact that health workers find it simple to operate (38)(37)(42). It is a portable, handheld device, unlike other CD4 POC technologies: They are comparatively heavy and require to be on desktop (61). PIMA POC technology weighs 2.5kg and has a self-powered battery to run where there is no electricity. Health workers find it user-friendly as it only requires a capillary blood sample (61)(62). Health systems in LMIC should, therefore, invest more in PIMA as is proven to be good rather than investing in POC technologies that have not been widely studied and could have a risk of failure of being integrated into the health systems of LMICs

The second widely used CD4 POC technology is the BD FACSPresto(42)(43)(51)(63). This is in line with a recent study by Moran Z et al. (2019), who acknowledged a wide use of the BD FACSPresto in hospitals in urban settings in LMICs(64). The POC technology has a multiplex of use that includes measuring CD4 count, CD4 percentage, and haemoglobin level in a single test. However, at 7kg, it weighs more than double the weight of the PIMA, making it less portable. The CD4 count was overestimated when capillary finger-prick blood was used on BD

FACSPresto compared to venous blood(65)(64). The possibility of running haemoglobin on BD FACSPresto is relevant for the management of HIV in pregnant mothers and children in LMICs.

In their study, Scorgie F et al. (2019) used a supposedly easy CD4 POC technology in the form of a rapid test device. VISITECT POC technology looked simple and could not need electric power to run the test. However, health workers found it not user-friendly as it was so much task involving and difficult for the health worker to multitask. Some health workers were sceptical about trusting the test result citing that semi-qualitative results are seen as inferior to quantitative results. They were concerned of lack of recognition of patients who are categorised as having high CD4 count while in fact, their CD4 count could be at the borderline in which case they would require special clinical attention(37). This raises an important point to consider for implementers and policymakers regarding investment in POC technology.

5.2 Successes and challenges in implementing HIV POC technologies at primary healthcare facilities in LMICs:

5.2.1 Success

The big success of POC technology rest in its simplicity to be operated by health workers other than laboratory scientists. The LMICs have a challenge in having well skilled and adequate human resources(66). This review found that there are POC technologies proven to be operated by health workers who are not laboratory scientists. Some could easily be operated by junior health workers after a few days of orientation training(38)(49)(40). Other previous studies have also reported similar results on the use of POC technology by health workers other than laboratory scientists (6)(17). Such technologies are easily implemented in PHC facilities in rural areas closer to communities where the majority of PLHIV in LMIC live. Implementing such technologies, therefore, should bridge-up the inequity of the rural and urban divide in LMICs.

Another important success of POC technology found by this review is the acceptability of the technology by PLHIV(38). There have been very few studies that assessed the acceptability of POC technologies by PLHIV(6). This is probably because many communities in LMIC regard health service as a privilege provided by the government rather than a right. This may render health beneficiaries powerless as lesser stakeholders to the health systems. However, acceptability of a POC technology is relevant for the health service demand as part of health promotion(67). It is important that PLHIV as beneficiary stakeholders in HIV care, accept the use of POC technology so that they can demand such technologies in remote PHC facilities. To improve POC acceptability by the PLHIV, implementers of POC technologies are required to invest in adequate health education to the public regarding the importance of using the POC technologies in PHC facilities.

5.2.2 Challenges

The first challenge this review found about the use of POC technology is that health workers in LMICs have generally low confidence in POC technology test results when compared to centralised laboratory technologies(38)(37). This lack of confidence could be originating from a personal opinion regarding simplicity to run POC machines when compared to centralised laboratory technologies(37). However, this can result in inadequate utilisation of the POC technology when implemented at the PHC facility. Such health workers can also be a cause for poor understanding of the POC technology and lack of confidence in POC technology expressed by some the PLHIV. This necessitates the need for POC technology orientation

training to include scientific theory emphasising the robustness of new POC technologies over old laboratory centralised technologies.

The second challenge was the misclassification of laboratory results which was seen in most POC technologies when compared to laboratory centralised technologies. If not well managed, this can be bad to both the health system and the patients(38)(42)(43)(40)(39)(41)(44)(45). Patients whose HIV condition is well under good control can be misdiagnosed as being severely immunosuppressed. Also, some patients can be wrongly classified as having treatment failure. As a result, they may be wrongly eligible for special laboratory tests and prophylactic treatment. Such unnecessary treatments may cause side effects on patients and cost money to the health systems of LMICs. It is important therefore that health systems in LMICs (ministries of health and partner NGOs) demand high-quality POC technology innovations from the manufacturers and the global responders to HIV such as WHO, UNITAID and CHAI.

Poor results can also be given out by good POC technology when mismanaged by a poorly trained health worker. It was discovered that even after 3 days of training for the orientation of PIMA POC technology, some health workers did not master pricking of fingers for specimen collection despite communicating that they found PIMA very easy to operate. These health workers squeezed the fingers of PLHIV whom they pricked wrongly, to have enough specimen of blood to run the test. This was against the guidelines for performing CD4 test on PIMA which indicated the necessity of a repeat of pricking in such instance(38). This indicates how training is important and to be followed up with supportive supervision even when health workers give verbal communication about how easy they find POC technology to be.

Some POC technologies, while having the potential of producing results in a short time, complicates the PHC facility workflow. This was seen with VISITEC POC technology where health workers felt the running of CD4 test demanded a lot of dedication. The magnitude of dedication needed make the health workers fail to do other needed work. Health workers at PHC facilities in LMICs usually perform several tasks at once to cover for the missing staff since LMICs have a challenge in human resource. Simple automated POC technologies can assist health workers to perform several tasks at once. Common multitasking at PHC facilities in LMICs includes clinical consultations and POC testing being done simultaneously by a single health worker (37).

5.3 The outcome of using HIV POC technologies:

This review found that health workers who start operating POC technology in remote PHC facilities become highly motivated. This motivation was as a result of job satisfaction the health workers develop when they start to operate the POC technology by themselves at their PHC facility(49). Job satisfaction was also expressed by health workers in a previous study that involved Genexpert POC technology in the screening of sexually transmitted infections (35). Such motivation of health workers in rural areas is highly relevant for the health systems in LMICs. Health systems in LMICs fail to motivate health workers to work in remote PHC facilities(68). Majority of the health workers prefer working in urban settings leaving the rural with great shortages of human resource(68). This review urges the health system managers in LMICs to utilise the motivation brought by the POC technologies into bringing health workers to remote PHC facilities to improve the quality of health services.

Another finding has been that the implementation of POC technologies in PHC facilities in LMICs promotes decentralisation and task shifting of HIV services. The decentralisation and task shifting goes to the PHC facilities and lover level health workers respectively. This is because the POC technology brought to a PHC facility establishes some level of autonomy in PHC facilities regarding the diagnosis, treatment and monitoring of PLHIV. Decentralisation and task shifting of HIV services are important in LMICs to close the gap of inequity of accessing HIV treatment by PLHIV who live in rural areas(69)(70)(71). This review, therefore,

urges the health system managers in LMICs to promote the implementation of POC technologies to remote PHC facilities to achieve universal HIV treatment access.

The implementation of POC technologies to the remote PHC facilities has also been found by this review that it alleviates poverty. This is brought about by the improved turnaround time of test results(37)(38). Rural areas in LMICs are inhabited by people in poverty. Health facilities are widely allocated from one to another. Many people live more than 10 kilometres away from any PHC facility (72). Yet, in many of these countries, PLHIV has to routinely visit the PHC facility frequent times. These visits are doubled when they have to come another day just for a review of their laboratory test result. In some areas, they come in three separate visits one for consultation, one for specimen collection and one for the laboratory test result(73). All these visits cost time and money and robes the PLHIV ample time to engage in their social and economic activities. Reducing the frequent PHC facility visits, therefore, has the potential to save time and economic costs that overburden the PLHIV. It has been highlighted in this review that PLHIV saved time and money when they had their test result given out on the same day(38). This review, therefore, urges the health system stakeholders including civil society organisations (CSOs) in LMICs to expand the implementation of HIV POC technologies to all PHC facilities as a way to lift off the economic burden incurred by PLHIV.

In this review, few papers have included qualitative methodologies. The majority of studies found have been quantitative, designed mainly for evaluating the accuracy of POC technologies in comparison with gold standard methods among other relevant parameters. Qualitative research in this health field is therefore not commonly done(37). This finding has been similar to previous studies and reviews on POC technologies involving HIV(37)(74)(6)(75). While the solely quantitative studies are inevitable at the introduction of each POC technology, moving ahead requires seeking qualitative evidence to complement the knowledge to learn in more detail on how these technologies address the challenges they are made to solve(7). This required the understanding of the perceptions of the health workers, the PLHIV and other relevant stakeholders in as far as quality health

6. Strengths and Limitations

The following are the strengths and weaknesses encountered while conducting this review.

6.1 Strengths:

Strengths in this review include the independence of the author to all the POC technology manufacturers, strong search criteria followed.

Recent research as close as 2019 were included in the literature. This made the data to be rich with information. On top of that, a good amount of recent reports regarding point of care were also accessed and used.

The papers in this review include Quantitative, qualitative and mixed methods. This strengthened the data.

The papers used in this review were the work of research in a wide region of the LMICs including Africa Asia and South America.

6.2 Limitations:

Some parts of the original conceptual framework did not for exactly as they were designed to analyse sexually transmitted infection stud. The Conceptual framework was therefore further adapted leaving out irrelevant indicators.

Study papers included were only those published in English. The limitation could not be overcome as there was no possibility to have documents in other languages be translated.

Funds were not available to purchase paid documents and therefore they were left out. However, this limitation was partially minimised through networking with other students and researchers' personal libraries.

Due to the diversity of studies included, the review was designed to leave out a meta-analysis and do narrative synthesis of findings.

Each study was done fo only one or two of the POC technologies. And no study provided data for the whole of the analytical framework

7. Conclusions and Recommendations

This chapter provides the conclusions and recommendations of the study based on the findings in chapter 4.

7.1 Conclusions

Reaching the ambitious UNAIDS goal of 90-90-90 to end AIDS pandemic relies on access to appropriate ARV treatment and HIV prevention services by all people. While quality treatment is accessible in high-income settings treatment. However, no matter how good POC technology maybe, it can only be used efficiently to produce the desired outcome when it made suitable for use in resource-limited settings and also that it gets implemented in the field in the most appropriate way. This is why this review aimed at assessing operational successes, challenges and outcome encountered upon operational implementation of available Point of Care (POC) laboratory technologies and their outcomes regarding monitoring PLHIV on antiretroviral treatment in Low and Middle Income, it is not the same for the resource-limited setting especially those in LMICs. The development of POC technologies shed new light to better monitoring of PLHIV who are on ARV Countries (LMICs) in order to identify efficient POC technologies and implementation practices that can be adopted elsewhere in the LMICs.

POC technologies should, therefore, be uncomplicated to the user (user-friendly) to the level of health workers and infrastructure that is available in RLS, produce results that are not inferior to centralised laboratory technologies and be able to respond to the HIV health needs of all people infected by HIV without side-lining vulnerable populations especially children. Caution should be taken when adopting technologies regarding the need to manage waste in the most appropriate way to prevent environmental degradation.

7.2 Recommendations

The following are recommendations following the results of this review.

Recommendations to the Global partnership in HIV and the donor community

- Negotiate for lower price high-quality POC technology with the manufacturers so that LMIC can purchase POC technologies they deem appropriate for their setting based on evidence from studies conducted.
- Flex rules over how funds for HIV POC technologies are used regarding the procurement of POC technologies by LMIC to enable countries to gain ownership of the POC technologies they decide to procure for their health system.
- Donor countries should abide by their commitment to international aid contributions rather than empty promises.

Recommendations to country-level political leadership

- Countries should introduce the system of working together in health across borders (OneHealth) in HIV care. This can help bordering countries to strengthen regional partnership so as to have the possibility of using similar technologies where possible in order to increase negotiation power upon procuring reagents together in bulk. This way the cost of running POC technologies can go down and countries can put more HIV POC technologies in the PHC facilities.
- LMICs should form partnerships in the procurement of POC technologies under one market to have high for the same motive of increasing the power to negotiate prices and contracts. (Economies of scale)
- Government of LMIC should abide by the global agreement in the allocation of annual budgetary contribution to health so that the health ministry can perform efficiently in

the procurement and allocation of POC technology as a driving force for decentralisation of HIV treatment and care. (Abuja declaration)

Recommendations to the Legislature

- Formulate laws that should be protective to the PLHIV to protect them from catastrophic expenditure on health care. Free HIV care offered so far away from where PLHIV stay is not as free as perceived.

Ministries of health

- The ministry of health should scale up HIV POC in remote areas to motivate health workers who are otherwise not demotivated when they are sent to work in rural because of among other things, lack of such equipment for health care provision. They should strengthen the leadership of PHC facilities with managerial and technical skills in order to take care of the POC technologies implemented in their facilities.

Civil Society Organisations (CSOs)

- Civil societies should work with PLHIV to strengthen their demand for better HIV POC technologies in all areas. They should as well demand knowledge about POC technologies so that they can negotiate better to policymakers and other relevant stakeholders.

Implementation partners of MOH

- Training for health workers regarding POC technology should be educative enough to include basics in the science of the technology in order to create understanding and interest in POC by health workers. Health workers are key to the giving of health education to the communities, hence their importance to communicate valid information about POC technology.

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Appendices

Appendix 1: Characteristics of studies included in the review (comprehensive notes)

Author/ Year/ Objective	Study type/ study sample size/ Study location	Methodology	Relevant findings and conclusions
Kulkarni, Smita et al. 2017 The performance evaluation for systematic validation of Genexpert in field	Cross-sectional, Quantitative HIV-1 positive adult individuals. 314 Pune, India	Genexpert was used to screen patient blood samples in field facilities. Same patients were bled to have their test results confirmed by Abbott m2000rt Real-Time HIV-1 assay Venous whole blood specimen in 10 ml EDTA collected. Blood transported to the central lab where it was centrifuged within 6 hours, plasma was stored at -70 degrees C. until tested by the Abbott m2000rt Real-Time HIV-1 assay within 2 days	The GeneXpert compared well with the Abbott with higher sensitivity and specificity (97%, 97-100%), and concordance (91.32%). The correlation between two assays was statistically significant and linear regression showed a moderate fit (R2 = 0.784) with differences within limits of agreement. The misclassification rates for three viral load cut-offs of clinical importance were not statistically different (p = 0.736). All seronegative samples were also negative and viral loads of stored samples made a good fit (R2 = 0.896 to 0.982). Conclusion: Good comparison suggesting its use as a point of care assay for viral load estimation in resource-limited settings. Its ease of performance and rapidity will help in the quick diagnosis of ART treatment failures, integrated HIV-TB management and

			consequently facilitate the UNAIDS 90-90-90 target.
Scorgie, Fiona et al. 2019 Exploring the views of healthcare workers on acceptability and feasibility of the VISITECT test	Qualitative in-depth interviews Health workers 8 1 Medical Officer, 3 registered Nurses, 1 Lab technician, 2 Counsellor 1 Phlebotomist Johannesburg, South Africa	The opinion of a small group of healthcare workers was elicited using in-depth, semi-structured interviews. These health- care workers had a prior engagement with the VISITECT® CD4 test during its Field Testing study. This was either in the hospital laboratory or in the antenatal clinic. Individual Interviews were done privately.	Participants interviewed for the study felt that CD4 count testing remains an important diagnostic and monitoring test. Important for measuring the need for OI prophylaxis need. The patients have a good understanding of CD4 than viral load Easy to read result just like other rapid tests Small margin for error regarding sample measurement. Test demands full dedication. No chance to multitask. Needs a dedicated person; Counsellor most appropriate. 5 testing steps are too many However, staff were happy to have the test and perform CD4 test at their facility Good to be using finger prick, easy however risky to accidental exposure to HIV Good short TAT improved patient flow and shortened clinical decision to changes in treatment and alleviate patient anxiety Participants felt POC is inferior to the lab-based test result

			Participants had no confidence in semi-quant result borderline patients can be at risk without clinicians knowing
Ndlovu, Zibusiso et al. 2018 To evaluate the operational feasibility of integrated HIV VL, EID and MTB/RIF testing on GeneXpert.	Prospective field feasibility evaluation study by mixed methods VL: HIV-positive patients on ART for a minimum 3 months, aged 18 years and above. n=1,302 EID: HIV-exposed infants, aged 6 weeks to 18 months. n=277 TB: Sputum samples were collected from any patient, suspected of TB and all study participants in rural Zimbabwe at three sites. n=1,581	Health facility nurses drew venous blood into 4ml K2EDTA tubes for Genexpert HIV- 1 VL. Taken to the facility laboratory within six hours of the collection, DBS spot on filter card was made for centralized viral load (VL) testing. The remaining blood in K2EDTA was centrifuged, 1 mL of the plasma was tested for VL by Genexpert. For the Xpert MTB/RIF testing, sputum incubated for 15 minutes at room temperature was done then tested within the facility laboratory.	The fully automated GeneXpert testing device required minimal training and biosafety considerations. A total of 1,302 HIV VL, 277 EID and 1,581 MTB/RIF samples were tested on a four-module GeneXpert platform in each study site. GeneXpert error rates remained lower than 4% in all sites. Decentralized VL testing had shorter TAT 1 day [IQR: 0–1] compared to centralized testing 26 days [IQR: 23–32]. Among patients with VL >1000 copies/ml (73/640; 11.4%), the median time to enhanced adherence counselling was 8 days and the majority of those with documented outcomes had re-suppressed VL (20/32; 62.5%). Conclusion Implementation of GeneXpert platform for integrated multi-disease testing at district and sub-district settings is feasible and should increase access to VL, and EID testing in priority populations.

	Rural Zimbabwe	DBS samples for HIV VL and for HIV early infant diagnosis (EID) were also tested HIV VL and EID samples were all sent for confirmatory testing at centralized laboratories.	Regular on-site supervision is crucial, and test results must be promptly acted-on by clinicians for patient management.
Negedu-Momoh, Olubunmi, Ruth et al. 2017 To investigate the validity of POC BD FACSPresto™ CD4 analysers for CD4+ cell count, in comparison to a reference standard flow cytometry method and the feasibility of use among non-laboratorians.	Cross-sectional Mixed methods HIV Patients in OPD ART Clinic and ANC clinic 18 years and above and those who were currently attending PMTCT clinic were considered eligible for the study. n=300 Kano, Nigeria	Finger-prick blood sample (capillary) was collected and put in BD FACSPresto labelled cartridge. Placed on BD FACSPresto work station for 18-minute incubation and then put in the machine to read the result. Reading took about 4 minutes. The absolute CD4 count, %CD4 results were displayed on the screen and printed automatically. The print out was stored and not used for patients' clinical management but for research purpose only. BD FACSPresto was run by two lab scientists and a trained nurse. Matching samples were drawn by the Nurse using vacutainer EDTA tubes and sent to the hospital laboratory for comparison with the reference flow cytometer, the BD FACSCount.	The analysis revealed a close agreement between FACSPresto and FACSCount with no significant difference between the two methods (p = .0.95). Using a threshold of 500 cells/μL, the sensitivity and specificity of FACSPresto were 95.1% and 97.1% respectively when compared to BD FACSCount. There was no statistically significant difference in misclassification regarding BD FACSPresto and BD FACSCount results (p = 0.23). Furthermore, sensitivity and specificity were similar when BD FACSPresto machine was operated by either a nurse or laboratory scientist, there was no significant mismatch in testing variability observed Conclusions BD FACSPresto finger-stick capillary blood results is a reliable method in comparison to the venous sample cytometry method. No significant difference variability observed between laboratory personnel and non-laboratory operating the POC technology. The BD FACSPresto is simple, more robust and easy to use by non-laboratory health care

		The acceptability by health care workers was assessed by interviewing the two laboratory scientists and the trained PMTCT nurse conducted the CD4 testing.	workers hence will be a valuable instrument in increasing access and coverage of CD4 testing in developing countries.
Zeh, Clement et al. 2017 To examine the accuracy of Alere's Pima™ POC device on both capillary and venous blood when performed by lay-counsellors and laboratory technicians	Cross-sectional, Quantitative Patients were enrolled in the study; n=427 Jaramogi Oginga Odinga Teaching and Referral Hospital Kenya	Finger prick samples of one or two drops of blood were collected using Sarstedt safety lancets, while 3ml of venous blood was collected in an evacuated tube containing K2EDTA. In Phase 1, remnant venous blood samples were obtained from the laboratory. In Phase II, paired capillary and venous blood obtained from HIV patients attending routine clinical care was obtained. In both phases, convenient sampling of remnant blood from routine testing was used. Samples for Phase 1 were initially tested on BD FACSCalibur™ and then the remainder were re-tested on Pima™ POC. Phase II involved evaluation of the Pima™ device on capillary whole blood samples and also assessing the performance of lay-counsellors comparing them to trained laboratory technicians in a laboratory setting using paired capillary and venous blood samples collected by a	Phase I: PIMA POC sensitivity and specificity were 93.0% and 84.1% at 500 cells/µl, respectively. Phase II: Good agreement was observed for venous PIMA POC results from both lay counsellors (concordance correlation coefficient (CCC) = 0.873, bias −86.4 cells/µl) and laboratory technicians (CCC = 0.920, bias −65.7 cells/µl). The capillary POC had a good correlation: lay-counsellors (CCC = 0.902, bias −71.2 cells/µl), laboratory technicians (CCC = 0.918, bias −63.0 cells/µl). Misclassification of CD4 results at the 500 cells/µl threshold for venous blood was 13.6% and 10.2% for lay-counsellors and laboratory technicians and 12.2% for capillary blood in both groups. PIMA POC tended to under-classify the CD4 values with an increasingly negative bias at higher CD4 values. Conclusions:

		phlebotomist and transported to the KEMRI Lab where the analysis was conducted	Pima results were similar to FACSCalibur for both venous and capillary specimens when run by lay-counsellors. PIMA POC CD4 testing has the potential to improve linkage to HIV care without burdening laboratory technicians in the resource-limited settings.
Malagun, Malin et al. 2014 To carry out pre-implementation field evaluations of low-cost CD4 technologies, Daynal lab-based and PIMA POC technology	Cross-sectional, Multi-site Mixed methods HIV positive adults, 18years and above n=237 Port Moresby, Asaro District Health Centre and Kainantu Rural Hospital, Papua New Guinea	Equal numbers of HIV on ART and those about to start ART had blood collected simultaneously (CD4 count range of study participants: 25–1157 cells/ml) 5 PIMA machines were deployed at different study sites. 5 ml of venous blood collected from each patient into K3-EDTA vacutainer tubes and were tested for CD4 count within six hours of collection On PIMA CD4 testing, 25 microliters fresh whole venous blood loaded onto PIMA cartridges using EDTA capillary tubes and run on PIMA machine within 5 minutes in duplicates for assessing precision and by both lab techs and clinicians to assess interpersonal accuracy. Same samples sent to the lab to be tested on BD FACECalibre (50mls) and on Dynal (125mls) to assess the accuracy	Dynal had a mean bias of 250.35 cells/ml(r250.973, p,0.0001, n5101) and PIMA 222.43 cells/ml(r250.964, p,0.0001, n5139) when compared to BD FACS. Similar results were seen for PIMA operated by clinicians in one urban (n5117) and two rural clinics (n598). PIMA precision was 10.34% CV (low bead mean 214.24 cells/ml) and 8.29% (high bead mean 920.73 cells/ml) and similar %CV results were observed for the external quality assurance (EQA) and for the replicate patient samples. Dynal was not possible to perform using EQA and no internal controls are supplied by the manufacturer, however, duplicate testing of samples resulted in r250.961, p,0.0001, mean bias521.44 cells/ml. Using the cut-off of 350 cells/ml compared to BD FACSCalibur, PIMA POC had a sensitivity of 88.85% and specificity of 98.71% and the Dynal had 88.61% and 100%. 0.44% (2/452) of patient samples were misclassified as ‘‘no treat’’ and 7.30% (33/452) ‘‘treat’’ using PIMA

		All statistical analysis was carried out using Prism software Lab techs were assessed performance and questioned their feeling of using PIMA and Dynal	For Dynal 8.91% (9/101) as ‘‘treat’’ and 0% as ‘‘no treat’’. Conclusion PIMA was found accurate, precise and user-friendly in both laboratory and clinic settings. Dynal performed well in initial centralised laboratory evaluation, however, lacks quality control measures, and was technically more difficult to use, making it less suitable for use at lower-tiered laboratories in LMICs.
Daneau, Ge´raldine et al. 2016 To assess preferred method patients think either vein puncture or finer capillary stick puncture	Cross-sectional Qualitative in-depth interviews HIV Adults in HIV clinic in SA and Belgium 299 patients and 2 nurses from South Africa and 200 patients and 3 nurses from Belgium. Nurses were those who were drawing blood for POC CD4 testing.	Of the 299 patients who answered the questionnaire in Tshwane, 149 had a single finger stick (by the blade) for multiple POC tests (group 1), 150 had multiple finger sticks (needle and blade-based lancets; group 2). Patients in the second group had up to 6 finger sticks performed, as reported previously	The majority of patients preferred the finger prick to the venepuncture. The perceived pain using the blade was superior to a small needle but similar to a large needle. Patients preferred up to three finger sticks over one venepuncture. 30% of the patients changed their mind on what they prefer over two days. The main reason why they chose a finger stick was continued bleeding after venepuncture. The prevalent reason for objection to finger stick was pain/soreness. Conclusion Patient perceptions support the implementation of donating capillary blood with blade-based finger stick during POC CD4 testing.

Gebremicael, Gebremedhin et al. 2017 To assess the performance of BD FACSPresto™ analyser in the health facility setting compared to the gold standard BD FACSCalibur and Sysmex XT-1800i™.	Cross-sectional Quantitative Adults 18 to 65 years old HIV Positive attending HIV services. n=325 Addis Ababa and surrounding health centres, Ethiopia	Fingerstick blood samples collected for CD4 enumeration at 4 health centres and venous blood for comparison of results using conventional central lab machines. All blood transported to the lab at room temperature processed within 8 hours after sample collection Capillary blood for CD4 and Hb on BD FACSPresto Venous blood for CD4 on BD FCSCalibur Venous blood for Hb on Sysmex XT-1800i™ All tests were done by lab technicians.	BD FACSPresto had an absolute mean bias of -13.3 cells/ul (-2.99%) and 28.3 cells/µl (6.4%) using venous and capillary blood, respectively when compared to the FACSCalibur. Absolute CD4 count on the Presto had a regression coefficient (R2) of 0.87 and 0.92 when using capillary blood and venous blood samples, respectively, when compared to FACSCalibur. The percentage similarity of the BD FACSPresto while using capillary and venous blood was 105.2% and 99.3%, respectively. The sensitivity of the FACSPresto using the threshold of 500 cells/µl for ART eligibility by capillary and venous blood was 87.9 and 94.3%, and specificity was 91.4 and 83.8%, respectively. BD FACSPresto gave an absolute mean bias of -0.2 dl/µl (0.0%) (95% LOA: -1.7, 1.3) and -0.59 dl/µl (0.1%) (95% LOA: -1.49, 0.31) for Hb for the use of capillary and venous blood compared with Sysmex XT-1800i respectively. Conclusion Acceptable agreement between the BD FACSPresto and BD FACS- Calibur™ for CD4 counting and CD4%;
Myer, Landon et al. 2013	longitudinal, Quantitative. HIV positive pregnant women n=521	PIMA was routinely implemented in the ANC clinic. Nurse and Counsellor were involved in testing, alternating.	Pima POC underestimated CD4 count relative to flow cytometry: mean difference (laboratory test minus Pima POC) was 22.7 cells/ mL (95% CI, 16.1 to 29.2), and the limits of agreement were 129.2 to 174.6 cells/mL. There was a trend towards increasing differences between laboratory and POC testing with

Comparison of PIMA POC versus laboratory CD4 cell enumeration on HIV-positive pregnant women in Cape Town, South Africa.	The study took place in a single large antenatal clinic in Cape Town, South Africa, with a heavy burden of antenatal HIV infection, 26% prevalence by 2012.	Capillary finger stick whole blood was used to run on the PIMA. Results were recorded and used on patients.	increasing gestational age; ie, in women more than 36 weeks' gestation, mean difference was at 45.0 cells/mL(p?0.04). Discussion: Good agreement between Pima POC CD4 and laboratory-based flow cytometry on HIV-positive pregnant women. The finding for decreasing agreement with increasing gestational age requires further investigation
Pinto, Ione Conceição et al. 2015 To evaluate the accuracy of the PIMA point-of-care CD4 analyzer (PIMA) under field conditions in comparison to the current CD4 count system (FACSCalibur), and to evaluate the operational suitability and acceptability by health professionals and HIV-patients in using the PIMA in health clinics in the	Cross-sectional Mixed methods HIV patient adults n=408 Amazon region, Brazil	Four different PIMA used in multiple sites. Finger prick capillary sample of blood was obtained. The results were provided to the patients 20–30 minutes later. Each patient also provided 5 mL of venous blood collected in BD Vacutainer tubes kept at room temperature and shipped by boat or plane to the reference laboratory where they processed using PIMA POC CD4 analysers and FACSCalibur within 48 hours after venepuncture. Two months after the start of the study, the health professionals running the testing were interviewed to assess performance in using the PIMA	With finger prick whole blood (n = 337), PIMA showed a CCC (Rc) of 0.81, mean difference of -111.9 cell/μL, 93.1%/98.5% sensitivity, and 89.2%/56.7% specificity at <200 and <500 cell/μL thresholds, respectively. Venous whole blood (n = 340) indicated an Rc of 0.89, mean difference of -83.4 cell/μL, 98.3%/97.5% sensitivity, and 93.9%/66.0% specificity at <200 and <500 cell/μL thresholds, respectively. Health workers and patients accepted a capillary sample drawing very well. Conclusions Poor agreements on the two machines and the PIMA underestimated CD4 cell counts, which was more pronounced at CD4 counts 500 cell/μl. The PIMA's performance with fingerprick blood was less reliable than its performance with venous blood.

Amazon Region in Brazil.		POC CD4 analyser and also to identify factors that facilitated or hindered the performance of the test through questionnaires to staff and to patients	
Galiwango, Ronald et al. 2014 To assess the accuracy of PIMA Point-of-Care (POC) CD4 testing in rural Rakai, Uganda.	Retrospective quantitative HIV positive persons attending field clinics n=903 Rakai district in south-western Uganda	PIMA CD4 analysers machines were located next to the clinics, venous blood samples in a sterile 4 mL EDTA tube and inverted 8–10 times collected by the nursing team. All the testing was done by laboratory technicians trained in PIMA usage. A result print out made via external PIMA printer was used for clinical review. The remaining blood was stored in cool boxes and dispatched to the laboratory for testing using BD FACSCalibur. Descriptive statistics were used to summarize patient characteristics	high correlation between PIMA and FACSCalibur CD4 counts (r = 0.943, p,0.001). Relative to FACSCalibur, the PIMA had negative mean bias of 234.6 cells/uL (95% LOA: 2219.8 to 150.6) The dispersion at CD4,350 cells/uL was 5.1 cells/uL (95% LOA: 2126.6 to 136.8). For a threshold of CD4,350 cells/uL, PIMA venous blood had a sensitivity of 88.6% (95%CI 84.8–92.4%), specificity of 87.5% (95%CI 84.9–90.1%), NPV of 94.9% (95%CI 93.1–96.7%), and PPV of 74.4% (95%CI 69.6–79.2%). PIMA sensitivity and PPV significantly went up to 96.1% and 88.3% respectively at a higher threshold of 500 cells/uL. Conclusions: Overall, PIMA POC CD4 counts showed a negative bias compared to FACSCalibur. PIMA POC sensitivity improved much at a higher CD4 threshold of 500 than at 350 cells/uL
Moyo, Sikhulile et al.	a cross-sectional sub-study within the Botswana Combination Prevention	POC testing of HIV-1 RNA. Venous blood was collected in EDTA tubes in households and brought to the mobile community The POC Xpert HIV-1 viral load	high correlation between the Xpert HIV-1 VL and Abbott results (r2 β 0.92; P < 0.001). Overall mean difference in the HIV-1 RNA values obtained by Xpert HIV-1 VL and Abbott was 0.34

2016 To evaluate the performance of Cepheid Xpert HIV-1 viral load test in rural communities in Botswana in order to provide additional data to policymakers regarding the use of this assay in decentralized HIV treatment programs.	Project, Quantitative HIV positive patients n=302 20 rural communities in Botswana	testing was performed in these mobile community-based clinics. Laboratory-based testing of HIV-1 RNA load done with the Abbott m2000sp/m2000rt assay as a comparator at the Reference Laboratory in Gaborone, Botswana.	log10 copies/ml (95% confidence interval [CI], 0.26 to 0.40 log10 copies/ml) (P < 0.001). At 1,000 copies/ml as a threshold, agreement was 90.6% (95% CI, 87.9 to 93.1%), with a sensitivity of 98.6% (95% CI, 97.2 to 100%). The two methods agreed on their detectability of HIV-1 RNA (>40 copies/ml) at 97.1% (95% CI, 95.5 to 98.7%), with a sensitivity of 99.6% (95% CI, 97.2 to 100%). Xpert HIV-1 VL showed high agreement and accuracy with a laboratory-based method of HIV-1 RNA testing. The POC Xpert HIV-1 VL assay tended to overestimate HIV-1 VL, although the difference was clinically insignificant 0.5 log10 copies/ml.
Bwana, Priska et al. 2015 To evaluate the technical performance of a new point-of-care CD4+ T cell technology, the BD FACSPresto, in field	Cross-sectional, Quantitative All HIV-positive patients over 18 years of age attending the selected health care facilities; n=264 Busia County of Western Province, Kenya: Alupe Sub-District Hospital	The BD FACSPresto POC CD4+ T cell technology was placed in two rural health care facilities and was operated by facility health care staff. Compared paired finger-prick and venous samples using the BD FACSPresto and several existing reference technologies, respectively. After 18-minute incubation, the cartridge was inserted into the device for reading. A result print-out was produced automatically. Approximately 100 patient samples were randomly selected for testing on the Alere Pima in	BD FACSPresto had a mean bias of 67.29 cells/ul and r2 of 0.9203 when compared to the BD FACSCalibur. At thresholds of 350 and 500 cells/ul, the sensitivity was 81.5%and 77.2%and the specificities were 98.9%and 100%, respectively. Similar results observed when the BD FACSPresto was compared to the BD FACSCount and Alere Pima. The coefficient of variation (CV) was less than 7% for both the BD FACSCalibur and BD FACSPresto. CD4 testing by nurses using the BD FACSPresto at rural health care facilities indicated high technical similarity to test results given by

	and Nambale Health Center.	the laboratory to compare the performance of the BD FACSPresto POC CD4 technology. The EDTA venous blood sample from each patient was delivered to the Kenya Medical Research Institute (KEMRI) laboratory for testing using the BD FACSCalibur.	laboratory technicians using the BD FACSPresto in a high functioning laboratory. Conclusions The BD FACSPresto performed favourably well in lab setting when compared to the conventional reference standard technologies; but, the lower sensitivities indicated that up to 20%of patients tested in the field in need of treatment would be missed.
Wade, Djibril et al. 2015 To assess the lab and field performance of the Partec CyFlow mini POC in the National Reference Laboratory in Dakar and in a peripheral laboratory, and compared results with those obtained from FACSCalibur.	Prospective Quantitative Adults n=297 children, n=24 Hospital in Dakar, and one health centre in Ziguinchor. Senegal	Venous blood samples, collected into K3-EDTA tubes, were taken consecutively from HIV-patients attending the clinic for routine CD4 counting. Samples analysed in parallel on CyFlow mini POC, FACSCount CD4 and FACSCalibur to assess CyFlow mini POC precision and accuracy. 2 phases done. First in the reference laboratory, The CyFlow mini POC performances in a controlled laboratory environment where the BD FACSCalibur and BD FACSCount CD4 were used as reference instruments.	in reference lab, CyFlow mini POC, compared to FACSCalibur, showed an absolute mean bias of -12.6 cells/mm3 and a corresponding relative mean bias of -2.3% for absolute CD4 counts. For CD4 percentages, the absolute mean bias was -0.1%. Compared to FACSCount CD4, the absolute and relative mean biases were -31.2 cells/mm3 and -4.7%, respectively, for CD4 counts, whereas the absolute mean bias for CD4 percentages was 1.3%. The CyFlow mini POC classified HIV-patients eligible for ART with a sensitivity of 95% at the different ART-initiation thresholds (200, 350 and 500 CD4 cells/mm3). In the field lab, the room temperature ranged from 30 to 35°C during the working hours. At those temperatures, the CyFlow mini POC, compared to FACSCount CD4, had an absolute and relative mean bias of 7.6 cells/mm3 and 2.8%, respectively, for absolute CD4 counts, and an absolute mean bias of 0.4% for CD4

		In phase II, the CyFlow mini POC was installed in room with no air conditioning, and results were compared with those from FACSCount CD4, which was used as the instrument of reference	percentages. The CyFlow mini POC showed sensitivity equal to or greater than 94%. Conclusion CyFlow mini POC had a high agreement with FACSCalibur and FACSCount CD4. The CyFlow mini POC provides both reliable absolute CD4 counts and CD4 percentages including under the field conditions and is suitable for monitoring HIV-infected patients in resource-limited settings.
Rathunde, L et al 2014 Field Evaluation of the Alere Pima™ for CD4+ T lymphocytes counts in HIV-positive outpatients in Southern Brazil. Aimed to identify settings in which the POCT CD4 count would be most valuable in Brazil	Prospective Quantitative HIV patients n=107 specialised ambulatory facilities in an academic tertiary care hospital in Curitiba, Southern Brazil.	Venous blood samples collected in EDTA tubes. The samples were stored for no more than 48hrs in EDTA tubes, and CD4 lymphocyte count was done by flow cytometry and the Alere PIMA simultaneously. After obtaining the flow cytometry results, the samples were processed and analysed by the Alere PimaTM within 3 hours. Each sample was loaded in PIMA cartridge and placed in the PIMA Analyser; after 20 minutes, the results were printed out and noted for statistical analyses.	PIMA performed well, excellent agreement to the standard method. Test results concordant for patients with CD4 values above and below 200 cells/mm3. The performance characteristics it gave were: sensitivity 94% (IC 95% 89.5–98.5%), specificity 93% (IC 95% 88.2–97.8%), positive predictive value 86% (IC 95% 79.4–92.6%), and negative predictive value 97% (IC 95% 94–100%). Patients said Same day results helped them save time, money and energy for they lived very far from the facility They also were happy with finger prick than vein puncture for blood collection citing pain The high sensitivity and specificity of the PIMA suggest its utility as an alternative method for rapid measurement of CD4count in patients with limited access to reference laboratories, enabling

			prompt therapeutic intervention for patients at risk of progression to AIDS.
Coetzee, Lindi-Marie et al. 2016 To assess the performance of BD FACSPresto CD4 analyser, under ideal laboratory conditions using venous blood sampling, as well as how the manufacturer intended the equipment to be used, in a typical health care clinic with capillary blood sampling.	Cross-sectional, Quantitative HIV patients n=349 South Africa	Phase 1 (Laboratory testing on venous samples) to assess the baseline accuracy and precision of the instrument, compared to the predicate method the Beckman Coulter. A total of 214 EDTA random CD4 samples from adult patients were analysed using the PLG/CD4 predicate method. Phase II (Clinic testing on capillary samples) where nursing staff (n = 2) filled FACSPresto™ cartridges with capillary blood from a finger-stick. Samples were tested on-site at the Witkoppen Health Care Facility, individual results printed within 2–3 minutes	Phase-I, 179/217 samples indicated reportable results with Presto™ using venous whole blood-filled cartridges. Compared to the predicate, a mean bias of 40.4±45.8 (LOA of -49.2 to 130.2) and %similarity (%CV) of 106.1%±7.75 (7.3%) were noted for CD4 absolute counts. In Phase-2, 118/135 capillary Presto samples resulted in a mean bias of 50.2±92.8 (LOA of -131.7 to 232) with %similarity (%CV) 105%±10.8 (10.3%), and 2.87±2.7 (LOA of -8.2 to 2.5) with similarity of 94.7±6.5% (6.83%) noted for absolute CD4 and CD4% respectively. The Presto produced good precision to predicate methods, irrespective of either venous or capillary blood sampling. But had 7% overestimation. Clinic capillary blood produced 5% underestimations of CD4 levels but no significant difference with venous samples
Jani, Ilesh V et al. 2016 Evaluation of the Whole-Blood Alere	Blinded cross-sectional study, quantitative. HIV patients 18years old and above n=443	A capillary sample was collected from participants, 25 µl of whole blood. Two additional 5-ml venous blood samples in K2 EDTA-evacuated tubes were collected from each patient.	The whole-blood Alere QNAT POC assay produced results with a bias of 0.8593 log copy/ml when matched to the laboratory-based plasma assay. But at above 10,000 copies/ ml, the bias was 0.07 log copy/ml. With the WHO-recommended threshold of ART failure of 1,000 copies/ml, the sensitivity and

Q NAT Point-of-Care RNA Assay for HIV-1 Viral Load Monitoring in a Primary Health Care Setting in Mozambique.	Documented HIV infection, and receipt of ART at Primary Health Care Setting in Mozambique	A capillary sample for immediate testing using a prototype of the Alere Q NAT POC device which detects HIV-1/2 RNA. This POC technology consists of a cartridge that collects 25 µl of blood and a machine into which the cartridge is immediately inserted to run the test in 60 min. Venous blood samples were transported within 3 hours to the HIV reference laboratory, where centrifugation to produce plasma was done within 6 h of collection. The plasma was then frozen at negative 80°C before getting tested using the Roche Cobas Ampliprep/Cobas TaqMan v2 (CAP/CTM) automated instrument. This viral load testing was performed within a week of sample collection.	specificity of whole-blood Alere QNAT POC were 96.83% and 47.80%, respectively. A cut off of 10,000 copies/ml of whole blood with the Alere QNAT POC appeared to be a better predictor of ART failure threshold (1,000 copies/ml of plasma), with a sensitivity of 84.0% and specificity of90.3%. The precision of whole-blood Alere QNAT POC was compatible with that observed with the laboratory technology (5.4% versus 7.5%) between detectable paired samples.
Faye, Babacar et al. 2016 To compare CD4+ T cell count measurements	Cross-sectional quantitative (Comparison) HIV Patients n=200	Performed on venous blood collected in K3EDTA tubes. A total of 200 subjects including; 50 patients with CD4+ T-cells below 200/mm3, 50 between 200 and 350/mm3,	mean difference of 22.3 cells/mm3 [95%CI:9.1–35.5] between the BD FACSCountTM and PIMA Alere CD4 measurements though not significantly away from zero. when CD4+ T-cell count was below 350/mm3 (P = 0.76). The Passing-Bablok regression in categorized CD4 counts had also shown a concordance correlation coefficient of 0.89 for CD4+ T cell

between the PIMA Alere to the BD FACSCount.	West of the Dakar, in Senegal	50 between 351 and 500/mm3, and 50 above 500/mm3. CD4+ T-cell count was performed using the BD FASCount as reference method and the PIMA Point of Care technology	counts below 350/mm3 whilst it was 0.5 when CD4 was above 350/mm3. Conclusion Overall, our data have shown that for low CD4 counts, the results from the PIMA Alere provided accurate CD4+ T cell counts with a good agreement compared to the FACSCount