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Exploration of the Implementation of an Integrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya.

Kelly Allen

Exploration of the Implementation of an Integrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya.

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Dedication

This capstone project is dedicated to my two children. For the past year, you have travelled with me on this journey through Kenya and India, and lived back home without me waiting patiently for my return. I will never forget your sacrifices and the memories shared as we grew, struggled and persevered together.

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List of Abbreviations:

eLIMS	Electronic Laboratory Information Management System
PALM	Pathology and Laboratory Medicine
TTP	Total Testing Process
HOT-fit	Human, Organization, Technology – fit
TAT	Turn-around-Time
QMS	Quality Management System
EQA	External Quality Assurance
CLB	County Laboratory Coordinator
SCLC	Sub-County Laboratory Coordinator
KCHLSP 2018-2022	Kisumu County Health Laboratory Strategic Plan ’18-‘22
LMIC	Low-and-Middle Income Countries
UHC	Universal Health Care
COVID-19	Sars Covid-2 2019-present Pandemic Era
NCD	Non-Communicable Disease
KEMSA	Kenya Medical Supply Agency
POC	Point-of-Care Services
UTI	Urinary Tract Infection

Abstract

Underinvestment in pathology and laboratory capacity caused by low visibility in research and in prioritization by public health leaders results in limited effective healthcare coverage and an estimated 1.1 million premature deaths annually in Low-and-Middle-Income Countries. Kenya's public health laboratories provide a median 41% of the Essential Diagnostic List to their patients and in Kisumu County, as much as 44.2% of the population has little to no access to essential diagnostics. The government of Kisumu implemented the county Health Laboratory Strategic Plan 2018-2022 to address this public health challenge. Little information exists on the effectiveness of these initiatives and the realized impact on laboratory quality diagnostic services in the era of COVID-19. This study explored the implementation of one of the Strategic Plan's initiatives, an electronic diagnostics data system at a county-level health facility, and the impact that has had on Malaria diagnostics from 2018 to 2022. This study found that the implementation of this electronic data system was not associated with increases in Malaria testing or informed treatment. It found that patients under 5 years old treated for Malaria were 1.07 times more likely to be treated presumptively in 2020 than in 2018. There have been significant decreases in all patients and total tests performed for Malaria since 2018 in spite of a significant Malaria positivity peak in 2020. More research needs to be done on the causes of these decreases and ways in which laboratory test results can better inform provider testing and treatment priorities.

Introduction

According to the recently published "Lancet Commission on Diagnostics: Transforming access to diagnostics", nearly half (47%) of the world population has little to no access to medical diagnostics (Fleming et al., 2021). This results in an estimated 1.1million avoidable premature deaths primarily in Low-and-Middle-Income Countries (LMICs) annually(Fleming et al., 2021). In the Treatment Continuum, or the healthcare service process starting from illness and ending with treatment and recovery, access to Pathology and Laboratory Medicine (PALM) represents the largest gap in service availability (Fleming et al., 2021; Peter et al., 2010). This is termed the "Diagnostic Gap", or the percentage of people with a disease who fail to receive a diagnosis, and ranges in size globally from 35% to 62% of afflicted patients depending on the disease (Fleming et al., 2021; Wilson et al., 2018). Underinvestment in PALM is the result of low visibility in research and advocacy on the global stage and underappreciation by public health leaders of the essential role of diagnostics in targeted health policy and evidence-based treatment. Nevertheless, growing demand for evidence-based treatment and public health policy has created pressure to improve access to diagnostics (Fleming et al., 2021; Gershy-Damet et al., 2010). For instance, the necessity of timely, affordable, accurate, and accessible diagnostics became evident in the world's struggle to address the COVID-19 Pandemic with handicapped surveillance, faulty tests, and slowed government response (Hahn, 2020; Shuren & Stenzel, 2021). Further, efforts to combat rising antibiotic resistance to drugs, achieve the 2030 Sustainable Development Goals, and Universal Healthcare continue to be hampered by a lack of capacity for data-driven targeted public health policy (Newton & Bond, 2019; Wilson et al., 2018; World Health Organization, 2021). Improving access to diagnostics is not enough when poor quality diagnostics and quality control mechanisms in public labs lead to faulty results and cast distrust among patients and clinicians in the value of testing (Wambani &

Okoth, 2022). Lastly, the absence of diagnostics often results in a presumptive diagnosis, overuse of antibiotics, and antibiotic resistance (Kariuki & Dougan, 2014; Leslie et al., 2012; Pai et al., 2019).

Positionality

This project would not be complete without a discussion of the learning process it took to realize the final result. I am a mid-aged Caucasian female born from a cash-crop farming family in the mid-western part of the United States. I have been married for over a decade and have two children, who travelled with me during most of the past year and a half. Part of this learning process involved overcoming the challenges of raising two children in Kenya and India during the COVID-19 Pandemic when schools were closed and budgets were tight. This offered numerous opportunities to learn about the education systems in Kenya and India and connect with local families who shared with me their own struggles during that time. We also came in contact with numerous health facilities of public and private nature. In this I learned that patients seek health care as a "package" of complex life challenges rather than a single discrete diagnosis. As a Caucasian from the United States, I was an affluent outsider and extension of the British Colonial system in Kenya. In India, I was often treated as upper-caste by Hindus. These experiences gave me insights into my privilege, the destructive nature of "class", and the oppressive hold that the Global North continues to enforce upon the Global South. While in India and Kenya, I took every opportunity available to immerse myself into the local culture with the goal of gaining a better understanding of social determinants of health. Over the Summer and Fall of 2022 I lived for 7 months in a rural village in western Kenya. This gave me the most instructive lessons of my life in poverty, insecurity, inaccessible health care, inequity, and perseverance. The topic of this project, an eLIMS, is relevant and timely, and all of the figures in this paper were developed from personal experience, literature, and extensive exploratory interviews with laboratory

professionals. However, without a doubt, it gains its teeth from the understanding of what underinvestment in public health means to the most vulnerable.

Background and Literature Review

The "World Health Report 2002" published by the World Health Organization states that Sub-Saharan Africa broadly lacks the scientific evidence and reliable public surveillance data it needs to formulate evidence-based health policies (World Health Organization., 2002). This, the Lancet concludes, is due to a chronic and widely unacknowledged disregard of medical diagnostics worldwide with few exceptions (notably, the U.S. and U.K.) (Fleming et al., 2021). The results of this neglect have been multifaceted and include many undiagnosed and untreated patients, indiscriminate allocation of resources, and public health leaders that lacked the timely, technical data they needed to guide effective testing and PPE procurement, lock-down procedures, and vaccine distribution in response to COVID-19 (Hahn, 2020; Shuren & Stenzel, 2021). Conservative estimates reveal that 30% of patients with Tuberculosis are not diagnosed, resulting in 1.5 million avoidable deaths annually (World Health Organization, 2019b). In Maternal Health in Mozambique, a recent study found that 38% of maternal deaths had a misdiagnosis and could have been avoided (Menéndez et al., 2020). Another study found that patients receiving HIV treatment without preliminary Anti-retroviral Therapy or routine CD4 and Viral Load testing experienced a one-third higher risk of death (Peter et al., 2010). A delay in diagnosis in chronic conditions such as cancer leads to higher mortality and poorer prognosis (Gichuhi et al., 2017). For example, in England, a study found that delays in cancer diagnosis due to the overwhelming of medical laboratories during the COVID-19 Pandemic are projected to result in 3,000 additional deaths and 60,000 additional Years of Life Lost (YLL) over the next five years (Maringe et al., 2020). The Lancet Commission on Diagnostics found that the theoretical impact of expanding diagnostic access for six key diseases from 47% coverage to 90% coverage globally would result in over 1,076,000 deaths averted annually (Fleming et al., 2021).

Insufficient regulatory systems also allowed for the wide distribution of faulty COVID-19

testing kits in High-Income Countries (HIC) such as the U.S. (Hahn, 2020). In the case of implementing UHC programs in Sub-Saharan Africa that target specific high disease burdens such as HIV, poor quality control in sample collection leads to sample rejection, false negatives, long Turn-around-Times, and reagent wastage (P. Otambo et al., 2020). This further makes scaling up disease treatment programs unnecessarily difficult and costly (Zeh et al., 2010). A lack of quality medical laboratory systems, reliable supplies of commodities, and trained health workers can result in the dysfunctional implementation of government programs like UHC. This is a growing challenge felt around the world that we cannot ignore if we are to meet the 2030 SDGs and improve how we address future pandemics (Fleming et al., 2021). Broadly speaking, four main challenges limit access to and quality of clinical diagnostics in low-income and middle-income countries globally, namely:

1. Insufficient diagnostic workforce size and capacity
2. Limited educational and training opportunities and rate
3. Inadequate facility, equipment and technology infrastructure
4. Insufficient regulatory and accreditation frameworks for quality and standards enforcement.

The result is that access to quality clinical diagnostics is limited to urban areas for strata of the societies that can afford them. Elsewhere, patients experience delays in accurate diagnosis, poor clinical management, and avoidable disability and death (Horton et al., 2018; Sayed et al., 2018; Wilson et al., 2018).

Electronic Laboratory Information Management Systems and Health Systems Development

An Electronic Laboratory Information Management System, the intervention under investigation in this study, is a health information management system that facilitates automatic and electronic test ordering and reporting, diagnostic quality indicator tracking, clinician-lab communications, results validation and verification, inventory and equipment management, sample quality pre-screening, and more. In the absence of such

a system, health laboratories must use paper formats for test ordering, reporting, sample identification, and results verification and tabulation. These are time-and-effort-consuming, prone to transcription error and manipulation (Hawkins, 2012; O' Kane, 2009; Plebani, 2010). Additionally, a poorly integrated, or dysfucntional eLIMS in practice fuctions as a paper-based system would since healthcare providers work around or avoid cumbersome digital systems to deliver efficient care (Matsumura et al., 2014; Yusof et al., 2008). Many laboratories in these cases struggle with incomplete test ordering forms, slow patient registration processes, poor information-sharing between hospital departments, and inefficient application of human resources and time (Asmelash et al., 2020; Kouroubali et al., 2019; Olayemi & Asiama-Broni, 2011). A quality failure in any of these phases of the laboratory process effects patient care when clinicians rely on evidence-based diagnostics to inform care management (Bodenheimer & Sinsky, 2014; O' Kane, 2009). Of all laboratory errors, clinical errors in the test-ordering and test-interpretation phases outside of the laboratory have been found to have lower rates of monitoring and higher rates of error than the in-lab analytical processes (Asmelash et al., 2020; Hawkins, 2012). The following is a diagram that illustrates the role and process flow that paper and electronic information systems follow in a public health facility like the one in this study, and associated challenges:

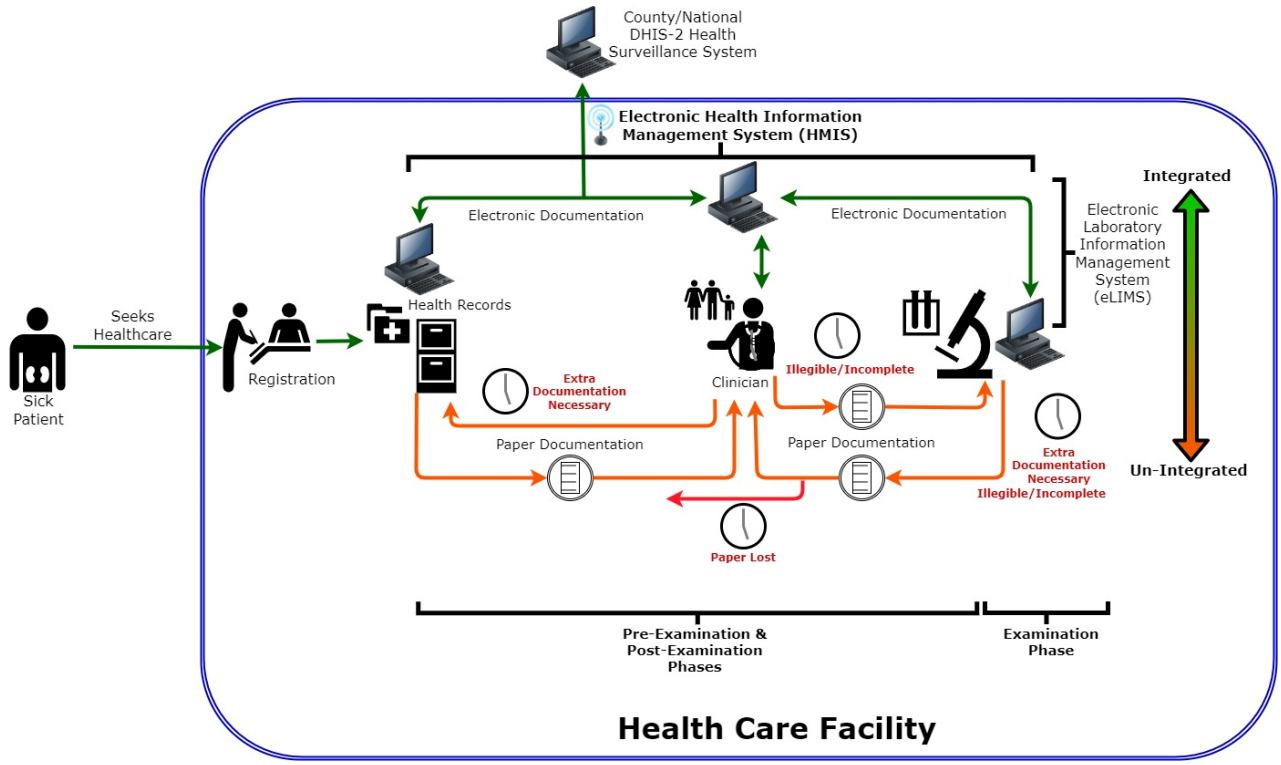

Figure 1: Diagram illustrating the path of information flow in a partially integrated electronic laboratory information management system and hospital information management system. Source: Kelly Allen, 2022.

For these reasons, "Digital Maturity", or upgrading of health information systems, is being viewed as the health system development intervention that will bring improved financial stability, health outcomes, work life for health workers, and public health outcomes (Bodenheimer & Sinsky, 2014; Duncan et al., 2022). However, very few studies have explored and proven the clinical impact of a fully integrated eLIMS and results of electronic health systems such as electronic health records have been mixed (Eden et al., 2018; Nguyen et al., 2022; Zheng et al., 2016). In one study specifically on LIMS, a randomized control trial in Peru showed that implementation of a fully integrated eLIMS for Multi-drug Resistant (MDR) Tuberculosis testing laboratories significantly reduced Tuberculosis Susceptibility testing communication by 6 days and turn-around-time of tuberculosis culture results by 3 days (Blaya et al., 2014; Nguyen et al., 2022). In another study, electronic laboratory test ordering for clinicians, in the context of the British health system, has been shown to markedly reduce pre-analytical errors, and quality of information in clinical histories (medical records) and test requests

for results interpretation (Turner et al., 2013). An eLIMS is not a stand-alone system and in order to function optimally must have interoperability, or "integration", with the facility health information management system so that clinicians can communicate test orders and results with the laboratory electronically. This integration has been identified as a key indicator for "Digital Maturity Models" developed recently for the purposes of strategizing health system development (Duncan et al., 2022). The proposed benefits of a fully integrated eLIMS include: timely and accurate reporting of health surveillance data, efficient use of human and laboratory resources, improved sample quality for accurate results, increased appropriate use of diagnostics by clinicians, increased user satisfaction, and increased patient safety (Georgia et al., 2022; Lukić, 2017; Plebani, 2016; Plebani & Panteghini, 2014; Yusof & Arifin, 2016; Zare et al., 2021). However, moving towards a fully integrated eLIMS is expensive and requires extensive training and capacity building. It is, therefore, a prohibitively difficult task for most resource-limited settings (Zeh et al., 2010). In the event that a health facility can invest in an eLIMS, the process of transition from a paper system and optimization is ongoing and typically requires a minimum of five to ten years (Lukić, 2017). There is a clear impression in the literature and recent diagnostic advocacy proposals that an eLIMS improves the coordination of care and contributes to evidence-based care management. However, more research needs to be done on the implementation science of eLIMS interventions and how these improvements in care management happen (Nguyen et al., 2022).

The Diagnostic Gap in Kenya

Kenya is part of the East African community, has a land mass of 582,646km^2, and estimated population size of 47,564,296 (Kenya Ministry of Health, 2018b). Kenya has experienced continual gains in overall public health indicators in the past two decades. However, these gains have been inequitable and varied in terms of geographic and

socioeconomic strata. The 2019 Kenya National Census showed that the sex-specific average life expectancy in Kenya has increased for both males and females since 2009 (58 years and 61 years respectively) and to 60.6 years and 66.5 years (Kenya National Bureau of Statistics, 2022). This is also an increase from an overall average of 51 years of life expectancy in 2004 (David & Wanjala, 2019). The Parliament of Kenya enacted the Health Act of 2017 to actualize the constitutional right of every Kenyan to the highest attainable standard of health. This Health Act defined this standard in terms of the World Health definition of Universal Health Care and "progressive access to promotive, preventive, curative, palliative, and rehabilitative services" (Republic of Kenya Ministry of Health, 2020). Despite committing to the Abuja Declaration which espoused a minimum national investment in public health and a healthcare sector spending and investment goal of 15% of GDP, the Kenyan Government has stagnated at around 6% investment for the past decade (David & Wanjala, 2019). Socioeconomic status plays a correlative role in patient access to care. In Kenya specifically, a study done using the 2018 Kenya Household Health Expenditure and Utilization Survey found that healthcare access and quality were correlated with patient income, education status, and region of residence (Ilinca et al., 2019). They found that public health facilities in Kenya were primarily used by patients from lower-income brackets, a finding repeated by other studies on health care access in Kenya (Ilinca et al., 2019; W. O. Otambo et al., 2022). Since public health facilities are more acutely affected by government underinvestment in PALM, these challenges present clear equity issues regarding diagnostic access, cycles of poverty, and resource distribution (Braveman, 2006).

To address this equity concern and the mandates of the Health Act of 2017, Universal Health Care (UHC) was gazetted as one of the top priorities of the 2018-2022 Kenyan government "Big Four Plan". Within the goals of the UHC pilots, to be implemented in four counties including Kisumu County in 2018, the administration set

to improve the delivery of laboratory diagnostic supplies from the centralized Kenya Medical Supply Agency (KEMSA) which in 2018 met only 30% of level four and five health laboratories across the country. One result of this push was the development in 2019 of the "Kenya Essential Medical Laboratory Supplies List" for application in the Universal Health Care pilot program (Republic of Kenya Ministry of Health, 2020).

Government leadership, administrative support, the setting of performance standards, and quality standard enforcement are critical for successful laboratory performance initiatives (Barasa et al., 2018; McCollum et al., 2018). Where there is a lack of integrated health sector strategies and government priority-setting in support of PALM systems, public laboratories are most strongly affected because they must rely on their government to provide for their needs (Ayieko et al., 2016; Kihuba et al., 2014; McCollum et al., 2018; National Taxpayers Association, 2021). This is especially true for implementing initiatives and infrastructure investments that have high upfront costs without immediate returns such as accreditation, laboratory information management systems, and the necessary climate control to maintain lab equipment quality and function (Bergeron et al., 2010; Peter et al., 2010). However, it is not enough in the fight to improve diagnostics access to expand diagnostics without improving laboratory performance and testing quality standards. For instance, expanding diagnostics without implementing laboratory quality management systems results in increased test reagent waste, long turn-around time on results, sample rejection, higher operational costs, and patient and clinician distrust of diagnostics (Gershy-Damet et al., 2010; Kenya Ministry of Health, 2018a). Further, most errors in diagnostics occur in the preanalytical (46%-67%) and post-analytical (18%-48%) stages rather than in the assay performance itself (Peter et al., 2010). As an example, the Kenya Medical Research Institute (KEMRI)/ Centre for Disease Control HIV-Research Institute Laboratory in Kisumu, Kenya, was the first laboratory in Kenya to achieve ISO 15189 status in March of 2008. One study in

2010 on their accreditation process found a USD 9,500 annual reduction in reagent wastage costs, a reduction in sample rejection from 4.5% to 0.5%, and an 82% reduction in client complaints (due to improved testing quality and turn-around-time) (Zeh et al., 2010).

Kenya faces vast challenges in improving the timeliness and accuracy of the National health data reporting system, DHIS-2. A recent study on hospital testing capacity across Kenya found that only 41% of the hospitals that reported to the DHIS-2 at all (n=174) reported consistently throughout the year (Bahati et al., 2022). The median testing capacity of these labs was only 40% of the Essential Diagnostics List prescribed by the Ministry of Health (Bahati et al., 2022; Republic of Kenya Ministry of Health, 2020). The connection between accreditation and patient health outcomes is not well-documented. However, studies have shown that performance testing can reduce testing errors in resource-rich and resource-limited environments (Peter et al., 2010).

Malaria-Specific Diagnostic Gaps

Malaria and associated complications have long been serious public health issues in Kenya, especially in high transmission areas such as the Nyanza lakes region of western Kenya where this study takes place. Malaria is a vector-born disease carried by mosquitoes and therefore, the positivity rate fluxuates by rainfall and season. In 2015, Malaria positivity in the Lake Endemic Region was higher in rural areas (10%), and highest in children aged 6 months to 14 years (27%) (National Malaria Control Programme, 2019). Encouragingly, the Malaria positivity rate has fallen in the past 15 years, even in endemic regions such as Nyanza, as evidenced by the follow graph published in the 2018 Kenya Malaria Control Programme Review by the Kenya Ministry of Health:

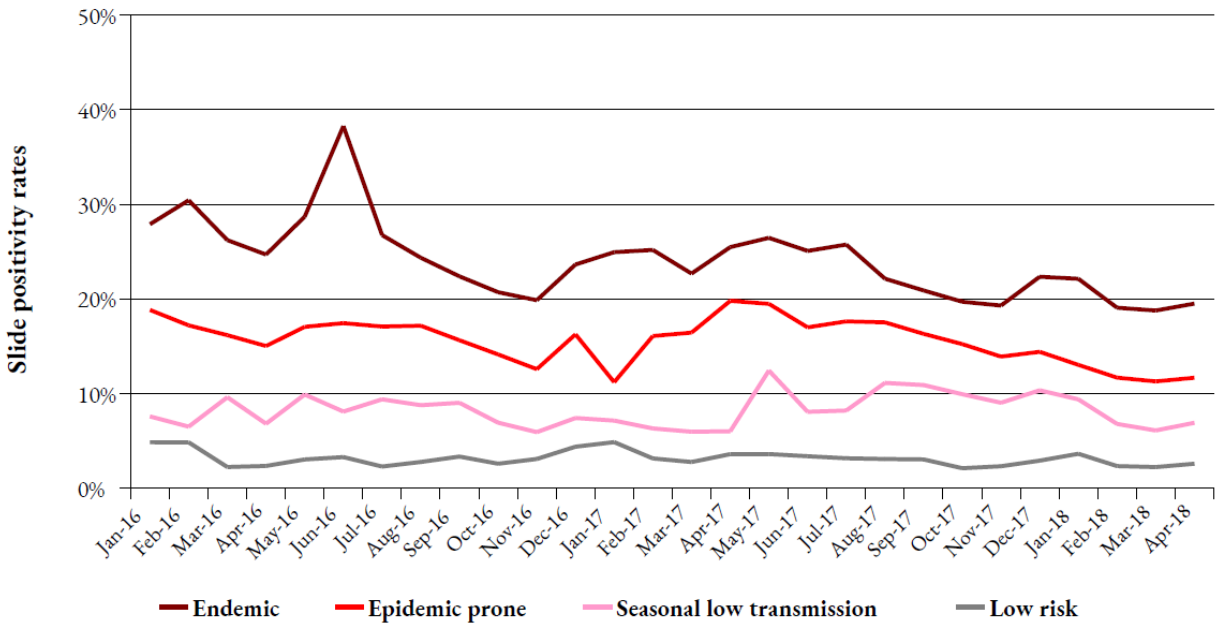

Figure 2: Malaria positivity rates in Kenya over time from 2016 to 2018 by endemicity. Source: National Malaria Control Programme, 2019.

The Malaria disease burden is greatest in low-income rural communities who tend to access public health facilities where care is most affordable. Social determinants of malaria disease burden for these communities include increased vector habitats, rural areas, poor access to timely and effective treatment, and inadequate health surveillance to identify vectors and disease reservoirs (National Malaria Control Programme, 2019). Towards addressing this public health challenge, Kenya, in 2010, released established nationwide guidance on diagnosis, treatment and prevention of Malaria that included universal parasitological testing (Division of Malaria Control, 2010). In Endemic zones, such as Kisumu County, patients tend, after numerous cases of Malaria, to develop an immunity that complicates Malaria diagnosis by clinical signs and symptoms alone. This is because, after acquiring an immunity, Malaria can present in the patient with non-specific symptoms that are similar to other illnesses such as malaise, nausea, and headache (Okyere et al., 2020; Wambani & Okoth, 2022). The symptoms of severe malaria including high fever, delirium, and congestion, are also similar to COVID-19 and may have lead to misdiagnosis or under-diagnosis of Malaria during the early month of the COVID-19 Pandemic (Hussein et al., 2020). Co-infections with Malaria are

common and can be ignored in the case of presumptive Malaria diagnosis, leading to mis-treatment and potential increases in health care costs (Onchiri, et.al., 2015). While clinical diagnosis of Malaria by symptomology especially in Malaria endemic areas has been shown to have poor predictive value for evidence-based case management, it also cannot identify asymptomatic cases which have been found to be community reservoirs for malaria transmission (Ngaba et al., 2022; Peterson et al., 2021; Riley et al., 2018). Therefore, the standard for Malaria parasitology in endemic areas is diagnosed using microscopy examination of thick and thin blood smears stained with Giemsa stain. Typically, parasitemia is quantified and reported using a plus (+) system (Obonyo, 2006). In his study of Severe Malarial Anaemia (SMA), a life-threatening complication of chronic or severe acute Malaria cases, in children under five at a district hospital in Siaya County, Western Kenya, Obonyo states that: "Case management of SMA is complicated because of diagnostic difficulties in the absence of a supportive diagnostic laboratory"(Obonyo, 2006). While considerable progress has been made since the turn of the century in vector control and laboratory capacity for Malarial laboratory diagnostic access (10.6 million Malaria deaths averted from 2000-2020 with 95% of those from the African region), Malaria continues to pose serious public health challenges (World Health Organization, 2022). Namely, COVID-19 has caused disruptions in Malaria prevention, diagnosis, and treatment leading to 47,000 additional deaths globally from 2020 to 2022 (World Health Organization, 2022). Kenya's national prevalence is 11% among children 10-14 years old, three-quarters of the national population are at risk of infection, and there is growing prevalence of anti-parasitic resistant parasites (County Government of Kisumu, 2018). This is also partly because simply expanding diagnostics is not always cost-effective or realistic in resource-limited settings (Lubogo et al., 2021; Zurovac et al., 2006). For example, the "Clinician-Lab Interface", a relationship between clinicians and the medical laboratories they use to

order assays and provide evidence-based case management, plays a critical role in Kenya in the ordering and utilization of Malarial diagnostics (van Duijn et al., 2021). In the case of over-diagnosis of Malaria in Kenya, the common method of Malarial Microscopy, requires experienced laboratory personnel and can be prohibitively expensive and time-intensive in resource-limited settings (Ling et al., 2019; Zurovac et al., 2006). In Nyanza, public health facilities provide the majority of malaria tests but supply the minority of anti-malarial prescriptions (Dixit et al., 2016; Musuva et al., 2017). Filling that gaps are many regulated and unregulated private drug retailers can sell anti-malarial medications without providing or confirming a Malaria diagnosis (W. O. Otambo et al., 2022; Riley et al., 2018). Additionally, due to lack of trust or confidence, long Turn-around-Times (TAT), or academic training, many clinicians will not order malarial microscopy even when available and instead give a presumptive diagnosis for Malaria. In the case of a poor Clinician-Lab Interface, Studies in Sub-Saharan Africa have found clinicians to ignore a negative result and prescribe Anti-Malarial treatment anyway (English et al., 2009; Leslie et al., 2012; Manguin et al., 2017; Ngaba et al., 2022). In addition to resulting in over-consumption of anti-malarial medications, a study in Kenya found that clinicians also failed to diagnose positive Malarial cases at a rate of one in six (Musuva et al., 2017; World Health Organization, 2019a). Lastly, the tendency of patients to self-diagnose and subsequently self-medicate, which has a lower treatment success rate than institutional case management, is growing in areas of Africa such as Kenya where there is limited access to quality healthcare (Dixit et al., 2016; Zurovac et al., 2006). Available, quality Malarial diagnostics and case management is critical for addressing this challenge. Further, optimizing the Clinician-Lab Interface is a part of a medical laboratory's Quality Management System (QMS) with high-functioning management, communications pathways between hospital departments, and a fully integrated eLIMS (Clinical and Laboratory Standards Institute,

2019; Yusof & Arifin, 2016).

The Kisumu County Situation

The global challenge of the Diagnostic Gap applies to Kenya, in particular Kisumu County, as one of four counties to pilot Kenya's 2018 UHC initiative and where as much as 44.2% of the county has little to no access to diagnostics (County Government of Kisumu Department of Health, 2017; Ilinca et al., 2019; P. Otambo et al., 2020).

History and Organizational Structure of the Kisumu County Laboratory System:

The Kisumu County Health Laboratory Strategic Plan was the first of its kind in the history of lab services in Kisumu County and states that:

"The Medical Laboratory Strategic Plan (2018-2022) has been developed in recognition of the need to have a framework for the development and delivery of integrated medical laboratory services in the County" (GCOK, 2017).

This Strategic Plan reflects the assertion by the "Lancet Commission on Diagnostics" that a government strategic plan to address the Diagnostic Gap is a cornerstone and starting place for creating quality public medical laboratory systems(Fleming et al., 2021). Further, the plan uses data from a comprehensive SWAT review in 2016 to detail the status of all medical labs in Kisumu County from lab equipment capacity to staffing deficits and training. Towards the mission of ensuring quality diagnostic services in public health laboratories across Kisumu County, the Strategic Plan's Strategic Object #8 allocated a plan to establish a fully integrated eLIMS system at the seven Level IV and V hospitals in the county with a budget of roughly 6million Ksh. A fully integrated eLIMS at these facilities was intended to help improve the incomplete and backlogged health data reporting system and to support laboratory and hospital Quality Management

Systems (QMS) for the county (County Government of Kisumu Department of Health, 2017; Clinical and Laboratory Standards Institute, 2019).

Health laboratories played a critical role in the policies enshrining the Universal Health Care plan and the roll-out of the Universal Health Care pilot in Kisumu in 2018 (P. Otambo et al., 2020). Recent studies on the effectiveness of the UHC pilot in Kisumu County show that the process could not ensure adequate healthcare resources such as laboratory and hospital commodities, training and preparedness of healthcare workers, and sensitization of the public (P. Otambo et al., 2020) Therefore, long wait times for diagnostics predicated most free healthcare services, making access to healthcare an anomaly of "free-yet-unavailable" (David & Wanjala, 2019; P. Otambo et al., 2020).

Additionally, Kisumu County experiences numerous challenges in staffing shortfalls. The Tax Payers Association (NTA) of Kenya showed in their report on public and private health facilities in Kisumu County shows that the most common reason that a health center and laboratory do not operate on the weekend is due to a lack of staff (National Taxpayers Association, 2019). A lack of staffing limits the ability of hospital laboratories to stay open on weekends or for 24hrs, to provide timely diagnostic service, or to provide laboratory staff with necessary vacation and sick-leave benefits. There is also a reciprocal lack of advancement and job opportunities for laboratory professionals in LMICs, especially if they are not affiliated with a major "Vertical Disease Program" such as the Presidential Emergency Fund for AIDs Relief (PEPFAR) (Prince & Otieno, 2014; Wilson et al., 2018).

International Standards for Measuring Quality Diagnostics Services:

In summary, the Clinical Laboratory Standards Institute and the WHO-AFRO stepwise laboratory accreditation process state that quality diagnostics services are measured by performance in following four core criteria and twelve quality system essentials (QSE)

(Clinical and Laboratory Standards Institute, 2019; Gershy-Damet et al., 2010):

Core Citeria

1. Turn-Around-Times
2. Volume of Testing
3. Internal Quality Controls
4. External Quality Controls

12 Quality System Essentials

1. Organization and Leadership
2. Customer Focus
3. Facilities and Safety Management
4. Personnel Management
5. Supplier and Inventory Management
6. Equipment Management
7. Process Management
8. Documents and Records Management
9. Information Management
10. Nonconforming Event Management
11. Assessments
12. Continual Improvement

Theory of Change and Models

The available evidence shows that the challenge of providing quality diagnostics in Kisumu County is as much an investment issue as it is an administrative process and healthcare priority-setting issue (Barasa et al., 2018; McCollum et al., 2018; Nyikuri et al., 2017; Waithaka et al., 2018). For this reason, this study used the laboratory information system evaluation framework designed by Yusof & Arifin that combines the "Total-Testing Process" as described by Hawkins, originally by Lundberg as the "Brain-

to-Brain-Loop", and a Human, Organization, Technology-fit (HOT-fit) model from Yusof & Arifin (Hawkins, 2012; Lundberg, 1999; Yusof & Arifin, 2016). The Total-Testing Process (TTP) acknowledges that there are nine essential components of the diagnostic process that flow in a forward direction. By identifying up-stream errors in the TTP, such as pre-analytical errors like clinician test ordering, one is able to optimize down-stream analytical processes (Hawkins, 2012). The following diagram from Yusof & Arafi, shows the flow of each step in the Total Testing Process:

By further combining HOT-fit and TTP model, Yusof & Arifi show that human and organizational factors such as user satisfaction, information quality, technological

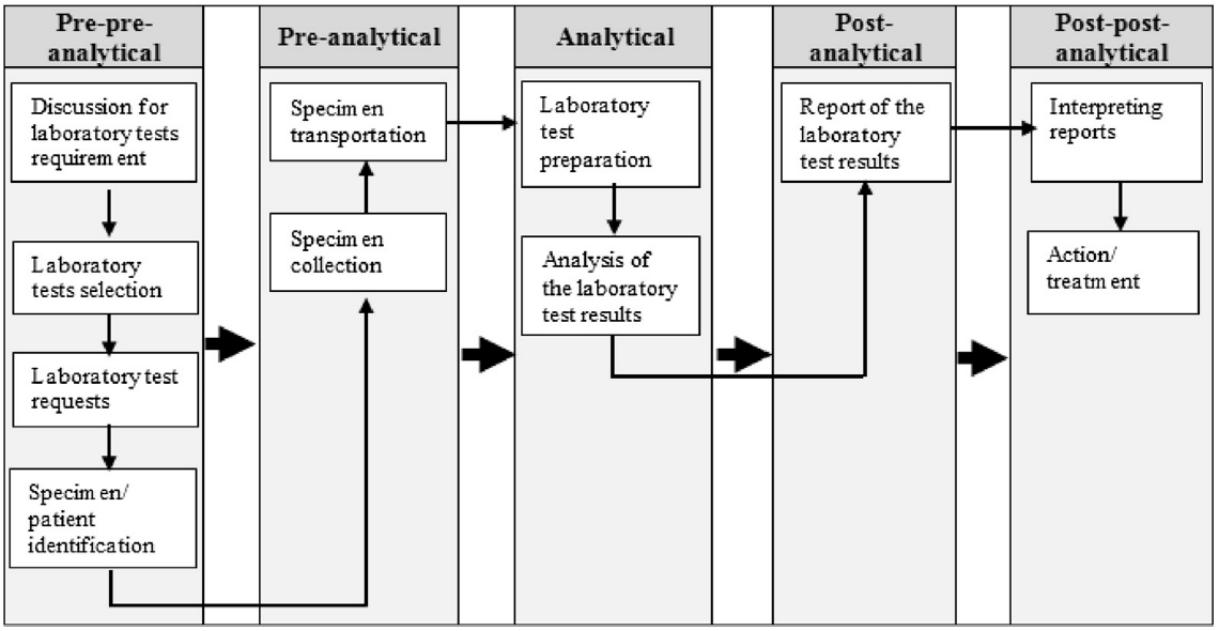

Figure 3: Total testing process model for capturing the flow of steps involved in laboratory diagnostic performance. Source: Yusof & Arafin, 2016.

interface, flexibility of the eLIMS, the Clinical-lab interface, management and user attitude all play an interconnected and critical role in the optimal function of an eLIMS for quality diagnostics and health care delivery (Yusof et al., 2008; Yusof & Arifin, 2016). The following is an image of the HOT-fit Model put forth by Yusof & Arifi in order to evaluate Health information systems:

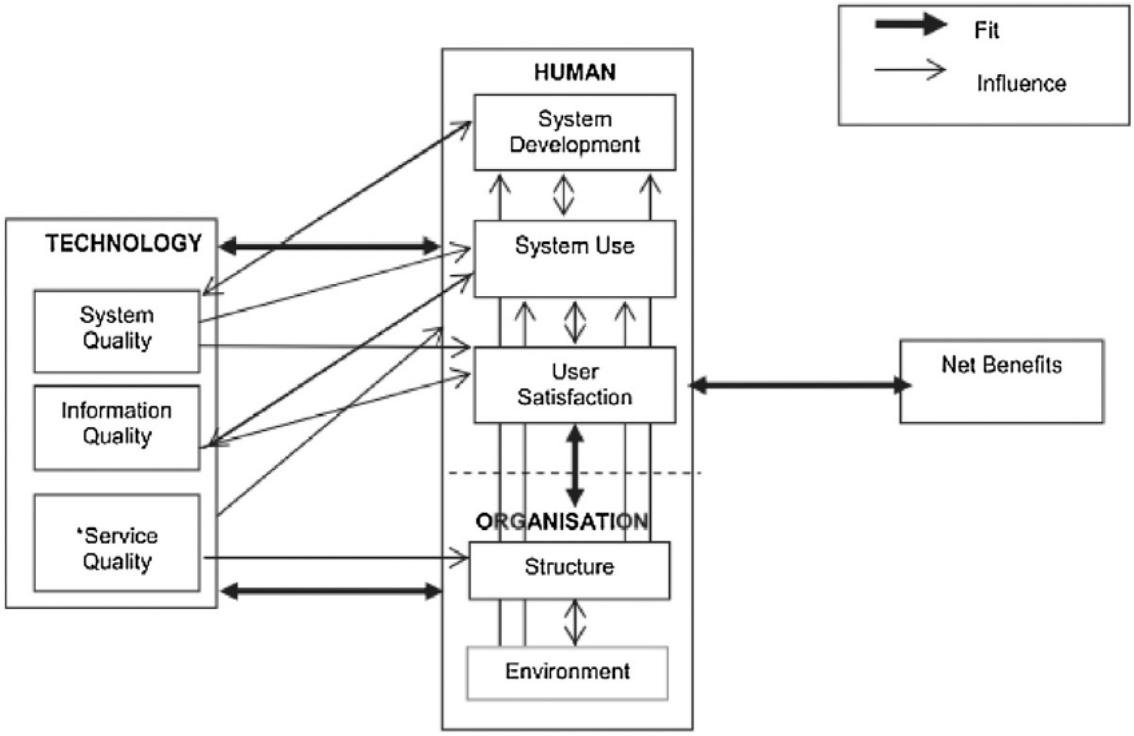

Figure 4: HOT-fit model for health information management systems. Source: Yusof, 2015.

Additionally, this model can be used to evaluate system quality by measuring system use indicators such as frequency of use, voluntary or mandatory use, and accurate output information such as accurate diagnosis (Yusof et al., 2008; Yusof, 2015). The following process diagram illustrates the connection between these CSLI Quality System Essentials of quality diagnostic services, the TTP model and the HOT-fit Model and why they matter to public health policy and quality health care in Kisumu County:

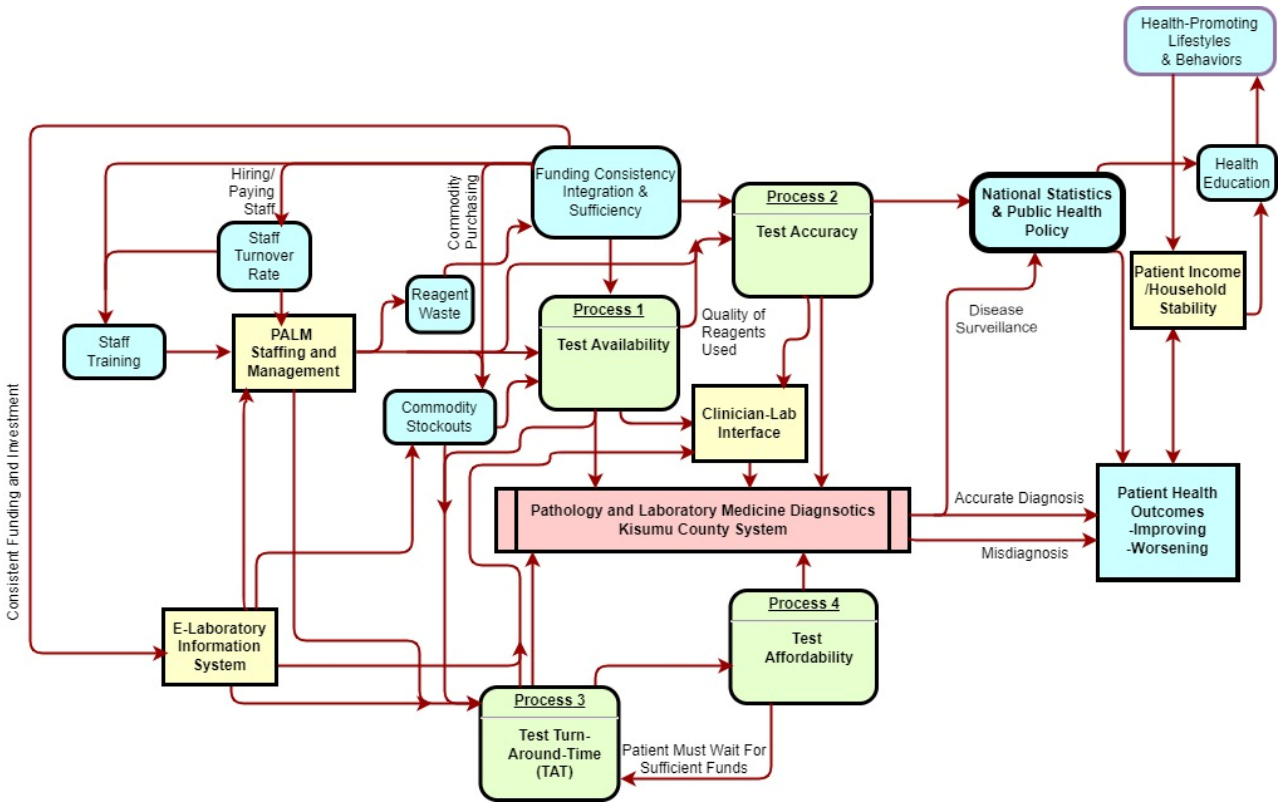

Figure 5: Flow diagram of the relationships between quality diagnostics core criteria, health outcomes, and quality systems essentials. Source: Kelly Allen, 2021.

The following results chain illustrates the theory of change underpinning the hypothesis and objectives of this study. The figure demonstrates how investments in quality diagnostics such as the implementation of a fully integrated eLIMS result in improvement in laboratory quality indicators that this study tracked and ultimately in better health outcomes and public health policy:

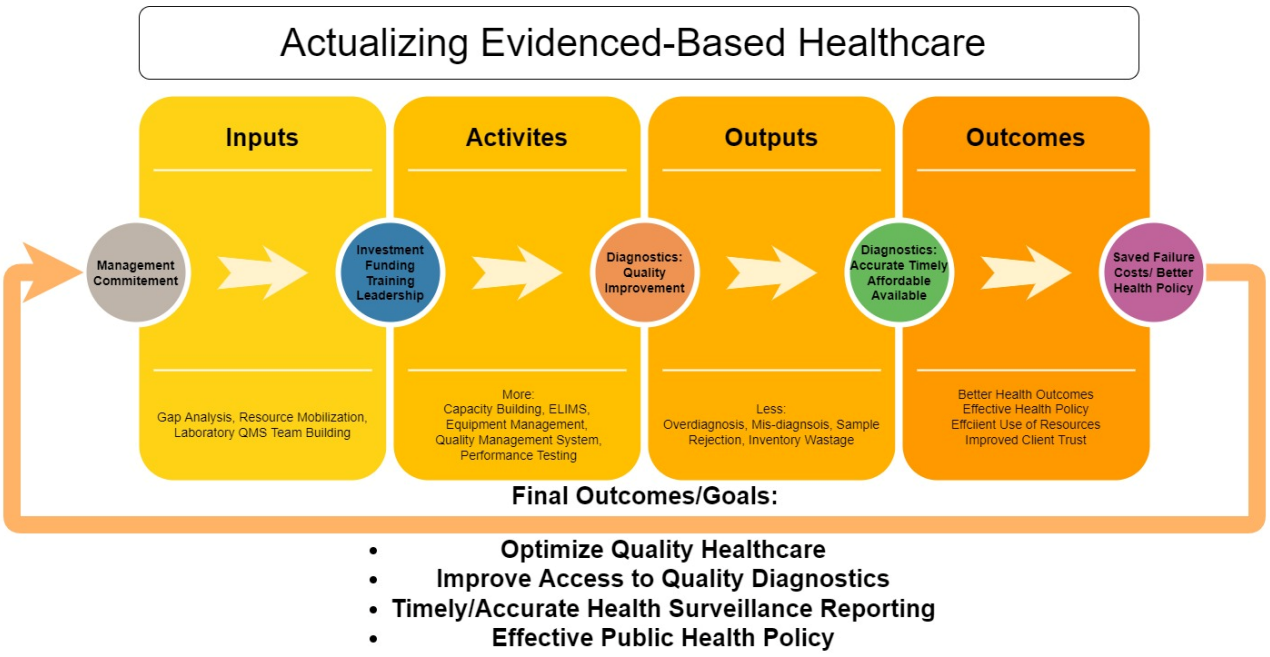

Figure 6: Results chain diagram illustrating the health laboratory quality change process for actualizing evidence-based healthcare. Source: Kelly Allen, 2022.

Justification for this Study:

Addressing the Diagnostic Gap and successfully implementing UHC programs in Kisumu begins with understanding the contextual mechanisms driving it and then advocating through research for better government policy and investments. Finding solutions to expanding diagnostic access requires ingenuity and a willingness to take a systems approach to address all the causes of poor access (World Health Organization, 2009). These include testing practices that are impractical for low-resource settings, a lack of visibility for PALM in the global health agenda and government policies, poor enforceability of national health strategic plans, insufficient workforce capacity, poor healthcare system infrastructure, and socioeconomic factors the decreasing affordability of testing and care-seeking behaviors in patients. It is notable that the eLIMS at the county-level hospital under study (hereafter referred to as: "the Hospital") has been taken up by the Hospital and county government as a budgetary priority given the lack of priority often seen by laboratory networks. Further, increasing cases of anti-malarial and anti-biotic resistance (especially in *E. coli*) make the need for informed case

management a public health imperative. For these reasons, and due to the paucity of research on the relationship of an eLIMS to quality diagnostics services, this case study was unique and beneficial to an understanding of how to meet the growing demand for evidence-based clinical management in resource-limited sub-Saharan Africa. To the best knowledge of the author, there has not been any scientific publication specifically addressing the Diagnostic Gap in Kisumu County and its association with the implementation of eLIMS systems or similar eLIMS systems in Kenya. In documenting these challenges, the researcher hoped to raise awareness of the Diagnostic Gap in Kisumu County and beyond and ways to address it.

Application of Results:

This study expects to aid in an in-depth status assessment of Strategic Objective 8.2 of the Kisumu County Health Laboratory Strategic Plan 2018-2022 for a fully integrate eLIMS at the Hospital at a time when a full analysis of this plan should be underway. In the growing efforts to combat the irrational use of anti-biotics, this study adds to the understanding of the clinician-lab interface and role of the quality diagnostics in evidence-based care. For capacity-building programs such as the CDC, Amref, and Global Implementation Systems, it contributes to a nuanced understanding of the challenges and successes of Kisumu County's efforts to narrow the Diagnostic Gap in the era of COVID-19. Lastly, it informs the current push in Kenya toward Universal Healthcare and how the pilot program has played out in Kisumu County public health laboratories.

Research Questions:

This study asked: How has the implementation of the Electronic Laboratory Information Management System (ELIMS) at the Hospital under study affected the hospital laboratory's ability to provide quality services from 2018 to 2022? It was part of a larger mixed-methods sequential explanatory study that used qualitative data collected from observations and interviews to give context and interpretive value to an analysis of 5-

year longitudinal data on quality clinical diagnostic indicators at the hospital under study (Creswell, 2014). The quantitative analysis assessed the trends over time of several key diagnostic quality service indicators and the correlative relationship between the indicators and the implementation of an integrated ELIMS system at the Hospital's medical laboratory from 2018 through October 2022. The study looked at the following key indicators: rates of presumptive diagnoses for Malaria, Malaria positivity rates, and utilization of diagnostics per patient visit. It compared these indicators from January 2018 till October 2022 using deidentified data from laboratory reports and the National DHIS-2 health statistics reporting systems from the Hospital including the following: "MOH706 Laboratory Summary Report", "AWP Monthly Service Delivery", "Hospital Administrative Statistics", "Inpatient Activities", "Malaria Commodity Dashboard", "MOH 105 Service Delivery", "MOH 705 A Outpatient Summary", "MOH 717 Service Workload", "MOH 743 Malaria Commodities", "Population Estimates for Facility and Ward", "UHC-303-Tracer Diagnostics" and "UHC-302-Tracer Non-Pharmaceuticals".

Hypothesis:

We hypothesized that the eLIMS implementation effectiveness followed the training, troubleshooting, and upgrading trajectory of the hospital laboratory as well as correlated with higher use of Malarial diagnostics by clinicians and lower rates of presumptive Malaria diagnosis.

Objectives:

General Objectives:

To determine at the Hospital the correlative relationship between implementation of an eLIMS and laboratory diagnostic key indicators, the quality of the clinician-laboratory interface, and the nature of ongoing process challenges in the diagnostic path of workflow in the Hospital and across the public laboratory network in Kisumu County that limit laboratory personnel's capacity to provide quality of diagnostic services,

especially in relation to Malaria diagnostics.

Specific Objectives:

1. To determine trends in the rate of presumptive diagnosis for Malaria at the Hospital over time and correlation with the implementation of eLIMS.
2. The determine the Malaria positivity rate and changes over time for the hospital patients between 2018 and 2022.
3. To determine the rate of Malaria tests ordered per patient and changes over time for the hospital patients between 2018 and 2022.
4. To determine the correlative relationship between the rate of Malaria tests per patient and the rates of Presumptive Malaria Treatment over time.

Methodology and Study Design:

Study Design:

This was a longitudinal quantitative study of monthly aggregate hospital data reports from 2018 to 2022. It was part of a larger mixed-methods explanatory sequential study of the implementation of an eLIMS at the Hospital under study. De-identified quantitative data was accessed from the Kenya National DHIS-2 for the Hospital and its laboratory starting from 2018 just before the eLIMS was implemented till the end of 2022. This data included whole-population data from all age groups, including children, for variables. These variables were analyzed using a series of models to test for single or joint correlative relationships to determine the correlative nature between the key laboratory performance indicators while adjusting for relevant events and constants that are identified through the qualitative analysis such as the initial install of the eLIMS system and the COVID-19 Pandemic. Then, the analysis measured the correlation between the implementation of the eLIMS system on each laboratory performance indicator. The selection of the time period for qualitative data was convenience sampling in order to meet the program requirements for a master's degree capstone project and to

provide analysis of a 5-year timeline corresponding to the Kisumu County Health Laboratory Strategic Plan 2018-2022.

Study Setting:

Kisumu County has 111 medical laboratories (private and public) across six sub-counties, and an estimated population of 1,145,747 (County Government of Kisumu, 2018; County Government of Kisumu Department of Health, 2017). Since the devolution of governance authority from the central government to the county levels in 2010, county governments are responsible for managing all their administrative processes, reporting, funding, supply systems, and requests for procurement to the Kenya Medical Supply Agency (KEMSA) (County Government of Kisumu Department of Health, 2017; County Government of Kisumu, 2018; Irimu et al., 2018). This authority is further devolved to the sub-county level where sub-county administrative processes report to the county government, and so on. The National government provides country-wide training, performance, and administrative guidelines, accreditation services, and KEMSA for organizing public procurement of medicines, equipment, and commodities. In Kisumu County, health facilities have been stratified into five levels based on service menus and capacity where level one facilities provide only very basic primary care, and level IV through V are hospitals with increasing capacity for diagnostics, surgery, and treatment. Level V facilities are subdivided into two more levels commonly referred to as “Level VA” and “Level VB” where “A” hospitals are more advanced teaching and research facilities. In most sub-counties, Level I and II facilities (Community Health Volunteers, and Dispensaries, respectively) do not have medical laboratory services but may offer some Point-of-Care (POC) testing services such as Community Health Volunteers who provide Malaria Rapid-Tests in the communities (Republic of Kenya Ministry of Health, 2015).

A patient often seeks care at a facility such as the Hospital after first seeking care

elsewhere. For this reason, it is considered a “referral hospital” (County Government of Kisumu Department of Health, 2017). In order to fully appreciate the role of a county-level health laboratory within the Kisumu County-wide health laboratory network, the following figure is a visual model of that organizational structure and the path of referral for a patient seeking care in the Kisumu East Subcounty of the Kisumu County Health System:

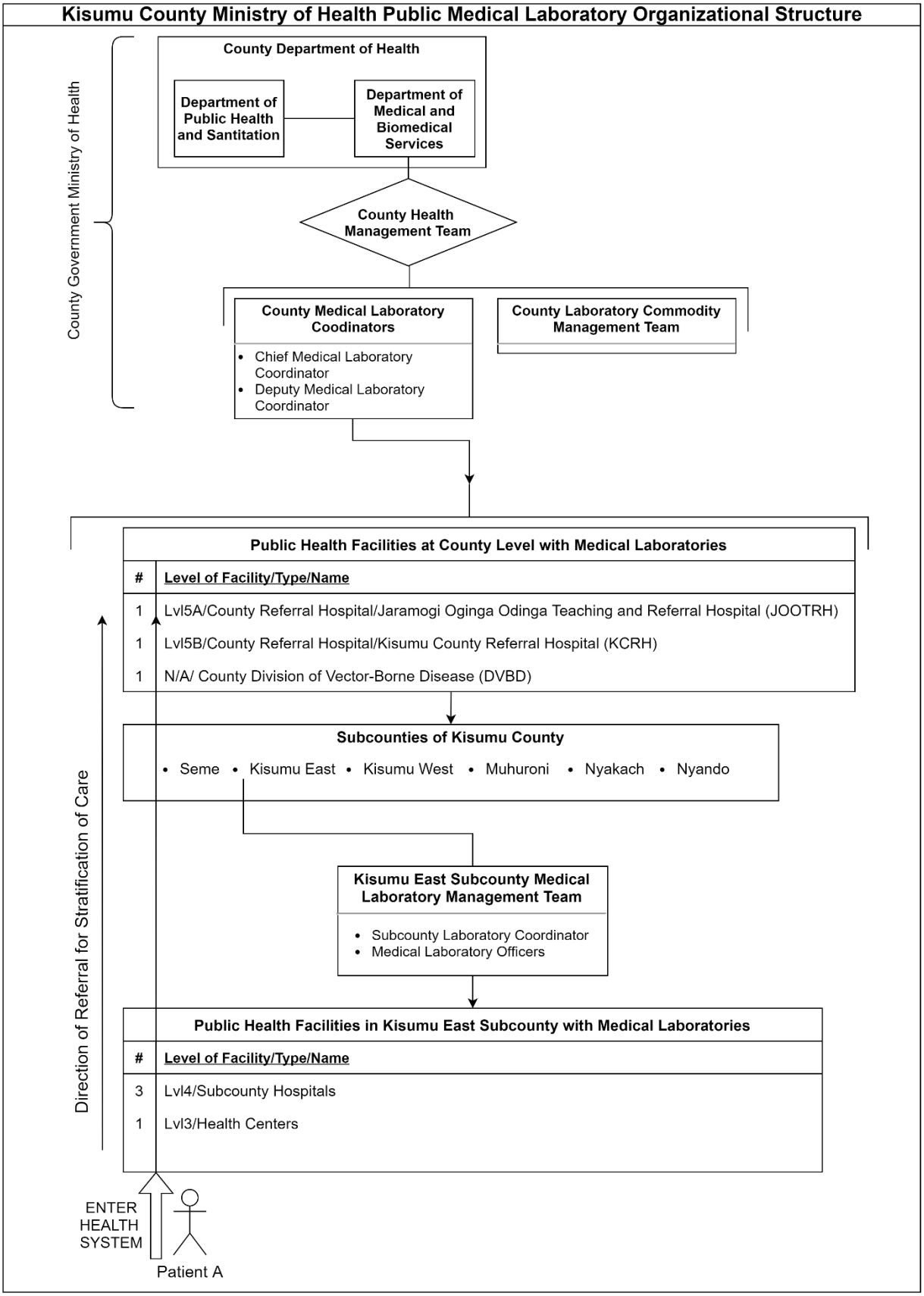

Figure 7: Diagram illustrating the typical referral pathway of a patient in Kisumu County starting from the periphery of the health system, Source: Kelly Allen, 2021.

The Hospital is a Level V referral facility in Kisumu County with 158 patient beds and

15 specialty departments. In 2021, its catchment population contained an estimated 33,564 people (17,118 female; 16,446 male) with an average monthly outpatient attendance of 5,881 patients (3,174 female; 2,707 male). The Hospital began uploading electronic health data to the National DHIS-2 in late 2017 at the end of the 2016/17 Public Sector Physician and Nurse Strikes and riots in Kisumu during the 2017 post-election violence (Irimu et al., 2018).

Health laboratories, as part of a quality management system, will have a form of documentation for their pre-analytical, analytical, and post-analytical processes which can be in paper form, electronic form or a combination of the two. The paper form of documentation is prone to transcription errors, data omissions, delays and loss of paperwork as described in the background portion of this paper. For this reason, the Hospital received a grant to implement an eLIMS in 2018. While the installation of an eLIMS in theory should optimize laboratory documentation and management systems, most eLIMS in this and similar settings fall on a scale between fully operationalized or "integrated" eLIMS and the paper-based unintegrated system. Thus, they are often using both paper and electronic systems, at varying degrees, at the same time. This is due to the training, advocacy, technical expertise, and clinician test ordering behaviors. The eLIMS system was active until the grant ended in 2020, at which point the laboratory returned to a paper-based system. In January of 2022, the county government and hospital administration successfully contracted to have the eLIMS system revived. The following diagram illustrates the path of information and documentation in a health facility similar to the Hospital that has both a paper and electronic form of data management system and related documentation challenges. One thing to note is that all data must be entered into the electronic HIMS in order for it upload to the national DHIS-2 system. For this reason, any paper documentation may experience delays in being fully uploaded and visible in the national data system.

As a Level V referral facility, the health laboratory in the Hospital is mandated to perform the following essential diagnostics (County Government of Kisumu Department of Health, 2017):

Parasitology

Stool Microscopy

Blood Slide Malaria Microscopy

Haematology

Haemoglobin level estimation

Sickling Test

Total WBC Count

Peripheral Blood Film

Differential Count

Platelet Count

Reticulocyte Count

MCHC

Bleed Time

Prothrombin Time

ESR

PTT

HB electrophoresis

Lupus Erythromatosus

Blood Transfusion Services

ABO grouping

Bacteriology/Microbiology

Gram staining

Wet preparation

H. pylori

Stool, urine, blood, CSF, aspirate cultures

Pus swabs

Drug sensitivity testing

Semen analysis

Skin snip for OV

AFB Microscopy

Genexpert

Mycology

Salmonella Antigen

Brucella

Clinical Chemistry

Blood Glucose

Urinalysis (Chemistry +Microscopy)

Liver Function

Renal Function

Rh Typing	**Serology**
Histology/Cytology	Pregnancy testing
Pap Smears	Syphilis
Aspirates	HIC rapid testing
Biopsies	Rheumatoid factor test
Electrophoresis	Widal Screening
Immunology/Virology	ASOT
CD4/CD8	HBV screening
Viral Load	HCV screening
EID	

Study Population:

In 2022, Kisumu County has an estimated population of 1,358,837 constituents (up from 1,193,103 in 2017) with a life expectancy at birth of 61years for females and 58years for males, as compared to the national average of 66 years and 61years, respectively (Kenya National Bureau of Statistics, 2022). The county has a Malaria caseload of 46,444/100,000 and a Malaria positivity rate of 45%, as compared to a national average of 20,252/100,000 and 41%, respectively.

Kisumu County employs an estimated 177 health laboratory personnel in the public laboratory network, 345 short of the required staffing need. Of these, the KCHLSP states that 64% are employed by Government of Kenya, 32.3% by Donor Partners, and 3.4% by communities (County Government of Kisumu Department of Health, 2017).

Sampling Procedure:

For quantitative data collection, we selected laboratory key indicators that are indicated by the Clinical and Laboratory Standards Institute as indicative of quality

diagnostic service (Clinical and Laboratory Standards Institute, 2019). For Malaria diagnostics, we compared presumptive Malaria diagnosis to confirmed or "Positive" Malaria test results and number of Malaria tests and overall diagnostics ordered per patient over time. The data was extracted from aggregate data sets from the DHIS-2 and stratified into two age categories: Below 5 years and over 5 years of age. Additionally, we chose the time frame starting from January 2018 that corresponds with when the Hospital began uploading their aggregate hospital data into the DHIS-2. This is also before the initial purchase, install, integration, and training for the Electronic Laboratory Information Management System (eLIMS) at the Hospital in 2018. We chose to analyze the data for the full 5 years from January 2018 to present in order to analyze rate ratio changes and properly analyze for data gaps and major events such as the Universal Healthcare Pilot in 2018 and the Covid-19 Pandemic till the present.

Data Management

Data Collection:

The quantitative portion of this study analyzed hospital-wide data for the Hospital from the DHIS-2 Kenya national health statistics reporting system. Some of these data sets and variables of interest include children under the age of 18 years. These data sets were de-identified before uploading into the DHIS-2 and supplied as aggregate facility-level data. This data was uploaded first to Excel for data cleaning and cross-checking. Then it was analyzed using Excel and Stata software. This portion of the study did not interact with children or patients directly.

Variables, Measures, Definitions and Analysis

Data for this study was first downloaded from the DHIS-2 to the PI's computer and loaded into Excel software. The data was cleaned and cross-checked across reporting forms for completeness and accuracy. Once complete, the data was shared with two research assistants where it was stored on their computers for processing. Data was

analyzed using Stata Software for distribution, trends over time including logarithmic regression for correlative relationships between variables to explore the impact of the eLIMS implementation on variables (Gertler et al., 2016). This analysis stratified the data by age group (<5 years; >5 Years) as it is typically reported to the national system and compared the testing time of year to the typical rainy seasons and Malaria positivity rates in Nyanza (van Duijn et al., 2021). “Population Estimate by Facility” by month reported from the DHIS-2 from form “Population Estimates by Facility and Ward” and “Inpatient” and “Outpatient Attendance” by month reported from the DHIS-2 from form "MOH 105 Service Delivery", "MOH 705 Outpatient Summary", "MOH 717 Service Workload" were used as control variables for analysis. The theoretical model for this analysis, that an increased in the use of laboratory Malarial diagnostics would accompany a decrease in the rate of presumptive Malarial diagnosis over time, was be tested using correlative measures.

Objective #1:

This study accessed de-identified aggregate data from the DHIS-2 on “Presumptive” and “Confirmed” Malaria diagnosis for all age groups attending the Hospital between January 2018 and December 2022. This study defined “presumptive diagnosis” of Malaria as a clinical treatment without the use of confirmed or “Malaria Positive” laboratory results. This was calculated using the following formula:

$$rate\ of\ presumptive\ diagnosis = 1 - (\frac{\#\ of\ \text{Positive}\ Malaria\ test\ results}{\#\ Patients\ treated\ for\ Malaria})$$

We calculated this per monthly data sets. This was expressed as a percentage. We calculated correlation between variables using Pearson’s Correlation Coefficient. We calculated significant difference using a Confidence T-test. We calculated change in likelihood of receiving a presumptive diagnosis by calculating a Poisson’s Incident Rate Ratio analysis comparing rates in 2018 with rates in 2021 and 2022.

Objective #2:

We defined the Malaria positivity rate as the ratio, expressed as a percentage, of Malaria total tests that had a "Positive" results using the following equation:

$$Malaria\ Positivity\ Rate = (\#\ of\ "Positive\ Malaria\ test\ results) /(\#\ total\ Malaria\ tests\ performed)"$$

We calculated this rate per month and expressed it as a percentage. We calculated significant difference using a Confidence T-test.

Objective #3

We defined "Total Malaria Tests Performed" as the total number of tests reported in the MOH706 Lab Summary Report each month. Changes in total number of tests reported over time were calculated using a Confidence T-test. Correlations between total Malaria tests performed, total patients treated for Malaria, and total outpatient attendance were calculated per month and using a Pearson's Correlation Coefficient.

Objective #4

The Malaria testing rate was defined as the average number of Malaria tests received by one person who has been treated for Malaria. We calculated this per month using the following formula:

$$Malaria\ Testing\ Rate = \frac{\#of\ Malaria\ Tests\ reported}{\#\ of\ Patients\ Treated\ for\ Malaria}$$

We calculated significant difference using a Confidence T-test and change in likelihood over time using a Poisson's Incident Rate Ratio analysis. We calculated significant difference using a Confidence T-test.

Objective #5

We calculated the correlation between Malaria Testing rate and the Malaria Presumptive Diagnosis rate using the definitions above and a Pearson's Correlation Coefficient.

This data came from the following data forms:

"MOH 105 Service Delivery", "MOH 705 A Outpatient Summary", "MOH 717 Service Workload", and “MOH706 Laboratory Summary Report”, “Population Estimates for Facility and Ward”.

Data Storage and Management:

Before collecting data, all participants, consent forms, data collection forms and aggregate data from laboratory reports and DHIS-2 data sets were de-identified of patient, laboratory reporting officer and participant personal identifiers. The only location identifier that was retained was that of the Hospital for related data. However, this name was not reported in the final paper for privacy reasons. Within 5 days of data collection, data was uploaded to the Principal Investigator’s Computer and one research assistant’s computers where it was cleaned, processed and analyzed. All computers were password-protected and not shared with any other parties. After data analysis was complete, all study-related files were expunged from research assistant/consultant computers. Data collection forms are to be stored together at the School for International Training campus in Milimani, Kisumu for five years for audit purposes. The custodian of these files is Dr. Vincent Were, study advisor. After this time period, they will be destroyed. To protect the digital data, all computers used anti-theft and anti-virus software packages and were password-protected.

Selection and Training of Study Team:

All study team personnel, including the Principal Investigator, research assistants, and advisor had current ethics training certificates as well as training in qualitative and quantitative data collection and analysis techniques. They were also trained in use of Excel, Nvivo and Stata.

Ethical Considerations and Confidentiality:

This study received internal review board approval from the School for International

Training and ethical approval from Maseno University Ethics Review Committee. The full study protocol and authorization can be found in the accompanying appendix. Since there are only two public health facilities in Kisumu that have a working eLIMS and since the timeline of the install of the eLIMS at the Hospital is unique, we could not reasonably expect the name of the Hospital for the quantitative data analysis to be truly anonymous. For this reason, this study did not publish the specific performance or audit ratings of the hospital. Rather it will report on the correlative relationship between the eLIMS install investment and the key indicators as a function of the impact of the investment. Before publishing any results, discussion of results or conclusion, the final results were to be disseminated to the Hospital, County Director of Public Health and other relevant stakeholders. Those dissemination reports were reviewed beforehand by the study advisor for appropriateness, quality and confidentiality.

Results and Discussion:

Data Quality and Processing

As described above, there tends to be delays in the reporting of data sets between the Hospital departments, Hospital data system, County-wide data system and finally the National health data system (DHIS-2) from which the data for this study came. For this reason, for most of the data sets used, November of 2022 was incomplete. Therefore, this study only looked at data from January of 2018 to October of 2022. The Hospital under study treated a total of 498,026 patients of all ages from January 2018 to October 2022. Initial processing of this data revealed a number of data quality challenges. The nature of these data quality challenges included a lack of clarity in data labels, missing data both completely at random, at random within certain data sets or data series, and data missing across several months (not at random). After cross-checking the data sets, we found that the MOH 706 Laboratory Summary Report did not include Inpatient laboratory tests in their monthly reports of test totals. Thus, the analysis is only applicable to outpatient cases. A resulting 472,511 outpatient records were used. Of these cases, 45,010 (9.5%) were reported as

"Under 5 Years" and 427,501 (90.5%) were reported as "Over 5 Years". During cross-checking and verifying the MOH 705 Outpatient Summary Report we also encountered two data rows labeled: "Outpatient New Attendances" and "Outpatient Re-attendances". In order to verify and how the "Outpatient Re-attendances" were factored into the total outpatient attendance report and cross-check the quality of the data, we compared the total for "Outpatient New Attendances" with and without "Outpatient Re-attendances" from the MOH705 Outpatient Summary with the "OPD Attendance" total (instructed as the "Total Outpatient Attendance including new and re-attendances" in the official guidance), by month, reported in the MOH 105 Monthly Service Delivery Report (Government of Kenya Ministry of Health, 2008). With this, we found that "OPD Attendance" equaled the sum of "Outpatient New Attendances" and "Outpatient Re-Attendances" by "<5 Years" and ">5 Years". We used the combined "Outpatient New Attendances" and "Outpatient Re-Attendance" totals per month for our analysis. We assumed, based on the official guidance on diagnosing and reporting of Malaria cases in Kenya, that "Confirmed Malaria" case numbers in the MOH 705 Outpatient Summary were equal to the number of "Malaria Positive" cases reported in the MOH 706 Laboratory Summary Report and sought to evaluate this assumption (Government of Kenya Ministry of Health, 2008). We ran a Pearson's Correlation Coefficient for the "Confirmed Malaria" variable from the MOH 705 and the "Malaria Positive" variable from the MOH 706 from January 2018 to October 2022 which was: 3,842 "<5years cases" and 10,499 ">5 years cases". We found this to be a very strong relationship.

Under Five		
	Positive malaria test<5	Confirmed malaria test<5
Positive malaria test <5	1	
Confirmed malaria test<5	0.9998	1
Above five years		
	Positive malaria test>5	Confirmed malaria test>5
Positive malaria test >5	1	
Confirmed malaria test>5	0.9999	1

Table 2: Pearson's Correlation Coefficient for Variables "Malaria Positivity" and "Confirmed Malaria"

With these in place, for missing data at random, points were identified and imputed by replacing the missing data with the average value calculated from three months before and after the missing point. It is important to note that this method of imputing missing data caused an inherent loss of variability in the data set, which may be critical to accurately assessing a significant impact (Mislevy et al., 1991). For missing data not at random, we hypothesized that health system challenges had influenced the reporting of the data. This is reflected in the literature regarding COVID-19 and the UHC Pilot in Kisumu County(National Taxpayers Association, 2021; People's Health Movement of Kenya, 2020). Based on this assumption, we extended the calculation of the mean for replacing the data points to six months before and after the missing data points. It is important to note here that we found a significant and non-random data gap from December 2020 through June 2021. However, that did not seem to impact the results of the data.

In order to visualize the data across time, assess trends and minimize variability in the data sets for Presumptive Malaria Treatment rates, we presented the results graphs by indicating the dry and rainy seasons typical to the Nyanza Region using the following month categories:

Dry Season	Long-Rains	Dry Season	Short-Rains
January-March	April-June	July-September	October-December

In addition to this, in the results graphs, we noted the period of non-random missing data from December 2020 to July 2021 found in the data sets and three main events significant to this study:

1. **Event A**: May 2018 Donor-funded initial installation of the ELIMS
2. **Event B**: March, 2020 Donor withdraws funds due to COVID-19 related funding shifts, ELIMS server fails, and Lab uses paper-based system
3. **Event C**: January, 2022 Kisumu County Government adopts ELIMS as a part of their budget and ELIMS server is renewed

The following is a detailed sample graph that shows these attributes for clarity:

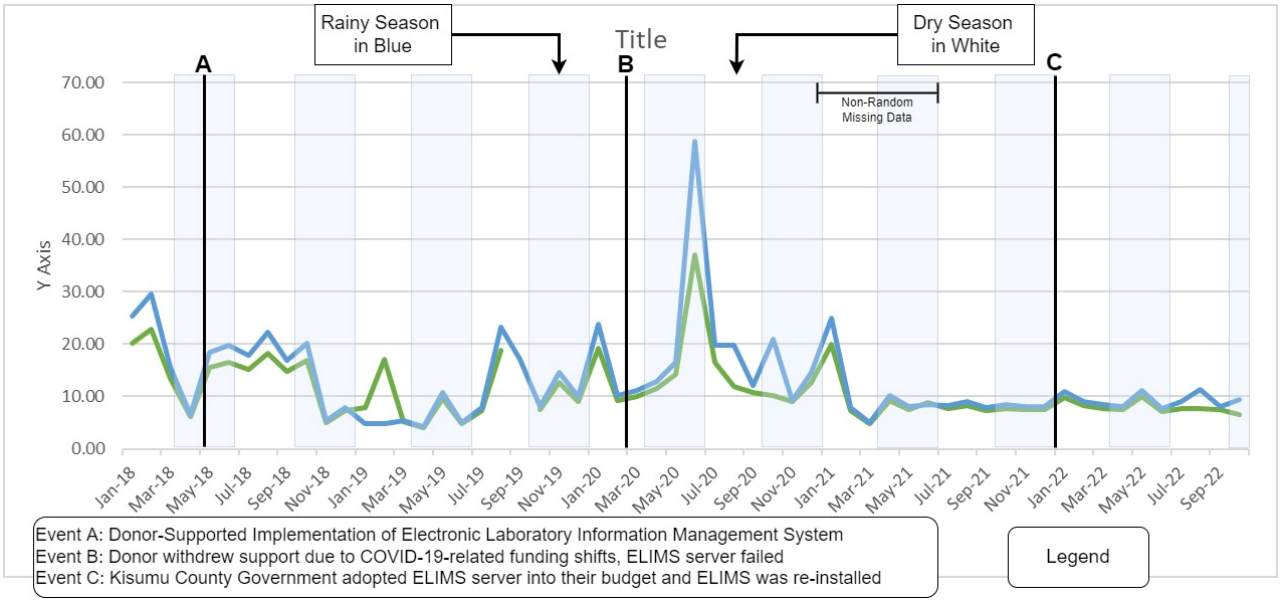

Figure 8: Sample graph showing key labels and descriptions for visualization.

Malaria Positivity Rate

We found that the Malaria Positivity rates varied by season and year between 15% and 59%. The average positivity rate for patients under 5 years for all years was 13.8%, and the average positivity rate for patients over 5 years for all years was 11.3%. This is significantly lower (with a 95% confidence interval) than the reported average Malaria positivity rate (45%) in Nyanza Province (Kenya National Bureau of Statistics, 2022). Additionally, Malaria is seasonal and tends to peak during the two rainy seasons in one calendar year in Western Kenya. Thus, Malaria positivity rates tend to have a natural undulating pattern that was not present in the data set for the later 2021 and 2022 portions.

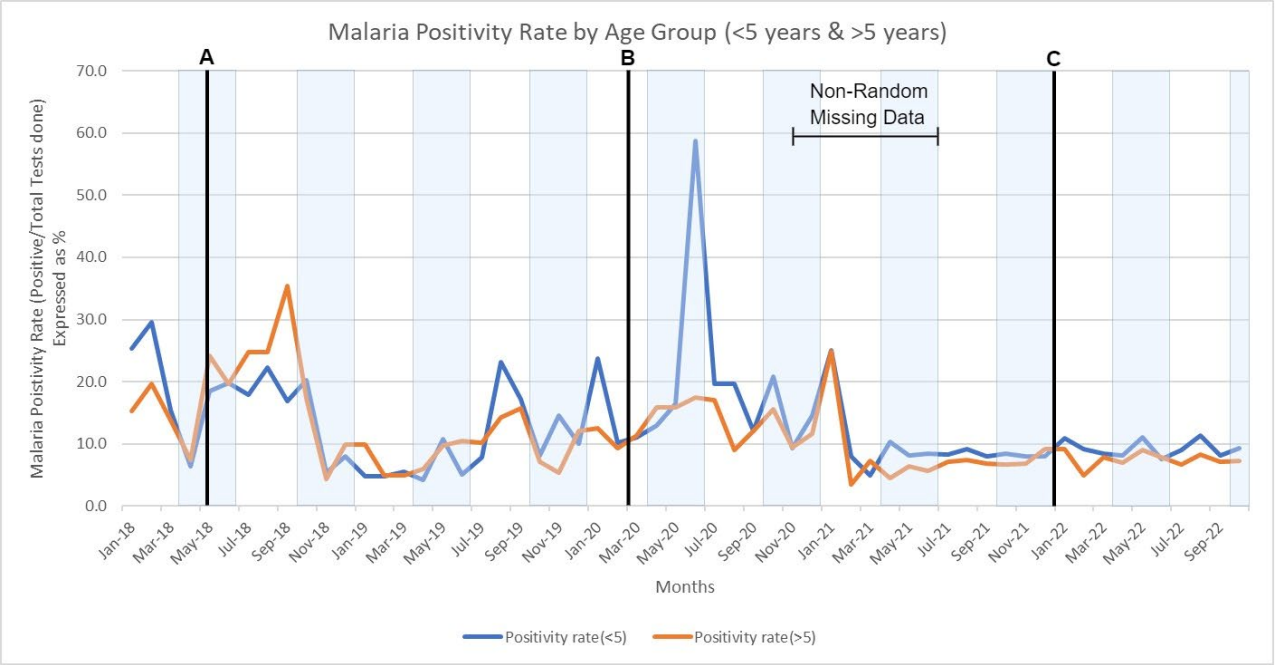

Figure 9: Malaria positivity rate for each age group attending the outpatient department of the Hospital from 2018 to 2022.

Rates of Total Malaria Testing, Patients Treated for Malaria and Outpatient Attendance

We found that the total number of Malaria tests performed, disaggregated by age, was significantly higher (95% confidence) in 2018 than in 2022 for the under 5 group ($t < 0.000$) and for the over 5 group ($t < 0.000$). The average number of Malaria tests performed per month for patients under 5 years in 2018 was 974 (95% CI: 1102, 846) and in 2022 was 365 (95% CI: 449, 281). The average number of Malaria tests performed per month for patients over 5 years in 2018 was 1957 (95% CI: 2157, 1757) and in 2022 was 1383 (95% CI: 1600-1160). The following tables and graph illustrate these results:

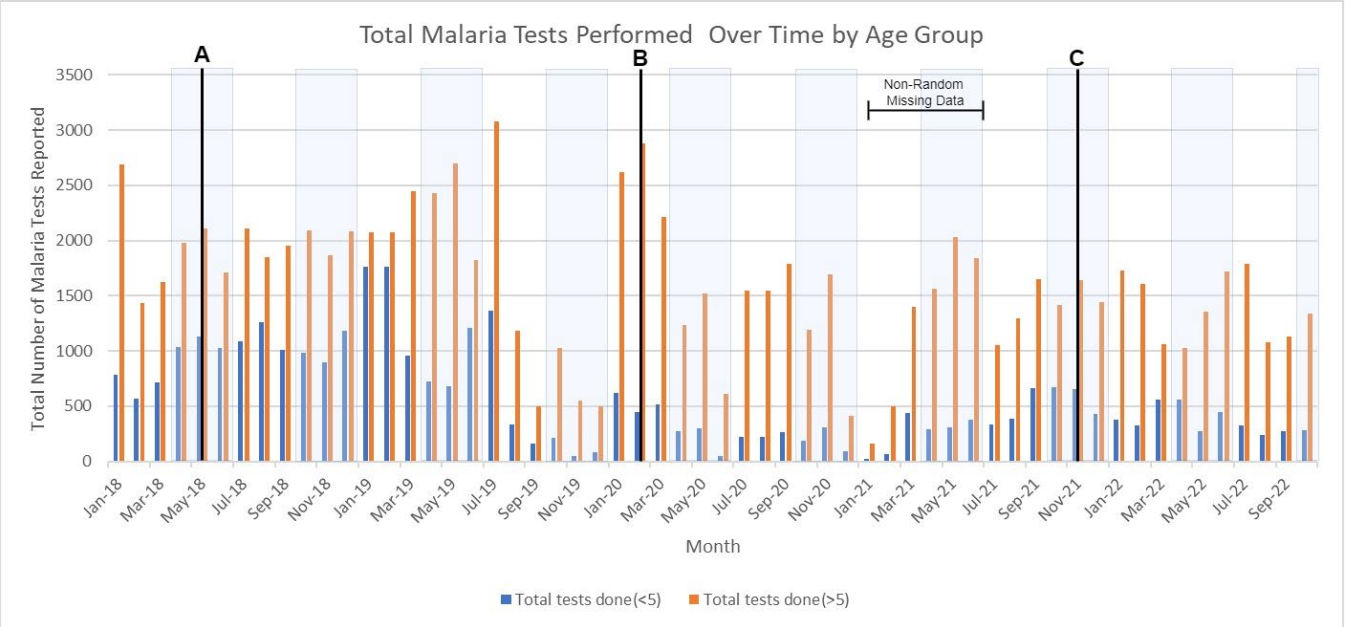

Figure 10: Graph illustrating the total number of Malaria tests performed per month for over 5 and under 5 age groups from January 2018 to October 2022.

```
. ttesti 12 974 201 10 365 118

Two-sample t test with equal variances
```

	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
x	12	974	58.0237	201	846.2907	1101.709
y	10	365	37.31488	118	280.5879	449.4121
combined	22	697.1818	74.91285	351.3724	541.392	852.9716
diff		609	72.26685		458.254	759.746

```
    diff = mean(x) - mean(y)                                      t =   8.4271
Ho: diff = 0                     degrees of freedom =       20

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 1.0000         Pr(|T| > |t|) = 0.0000          Pr(T > t) = 0.0000
```

Table 3: T Test results comparing the total Malaria tests performed for patient under 5 years per month in 2018 (Variable X) and per month in 2022 (Variable Y).

Two-sample t test with equal variances

	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
x	12	1957	90.64399	314	1757.494	2156.506
y	10	1383	96.13324	304	1165.532	1600.468
combined	22	1696.091	89.65352	420.5123	1509.646	1882.536
diff		574	132.5371		297.5325	850.4675

diff = mean(x) - mean(y) t = 4.3309
Ho: diff = 0 degrees of freedom = 20

Ha: diff < 0 Ha: diff != 0 Ha: diff > 0
Pr(T < t) = 0.9998 Pr(|T| > |t|) = 0.0003 Pr(T > t) = 0.0002

Table 4: T Test calculating the significant difference in total malaria tests performed per month for patients over 5 years in 2018 (Variable X) and 2022 (Variable Y).

Next, we looked at the total number of patients treated for Malaria per month by age group and found that there were significantly more under 5 patients treated for Malaria in 2018 than in 2022 ($t < 0.000$) and significantly more over 5 patients treated for Malaria in 2018 than in 2022 ($t < 0.000$). The following graphs and tables illustrate this finding:

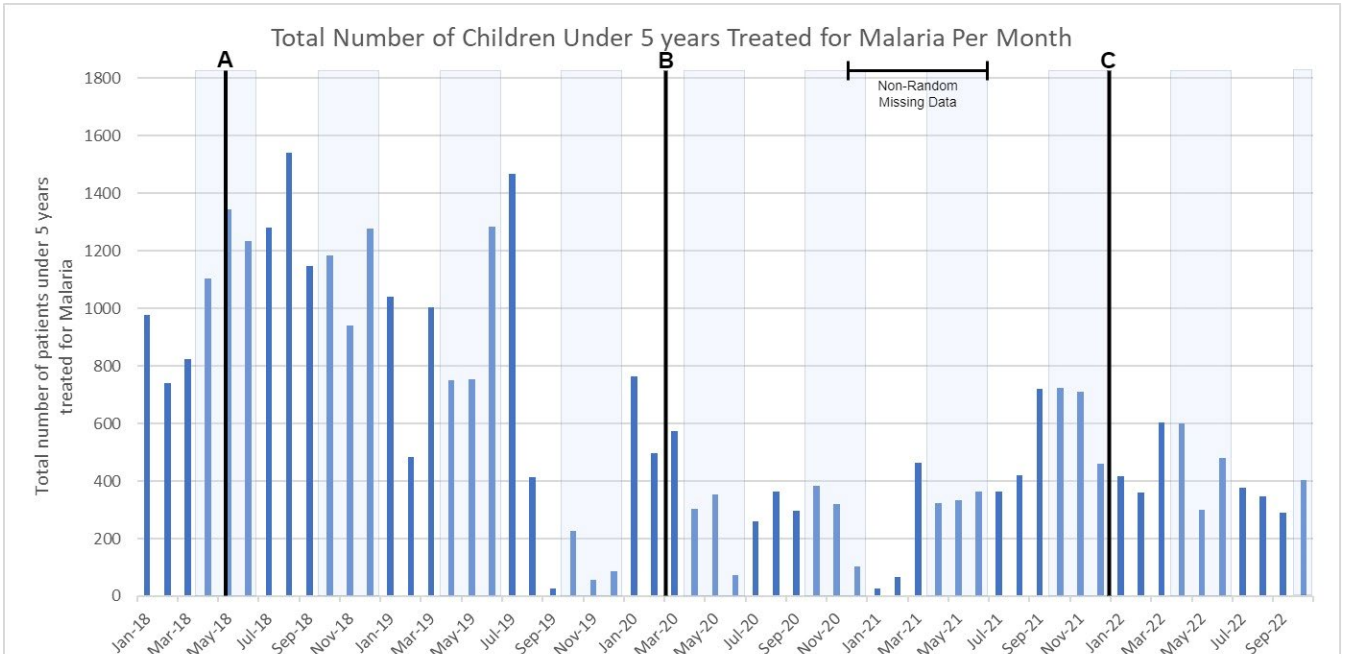

Figure 11: Graph illustrating the total number of patients under 5 years treated for Malaria per month from January 2018 to October 2022.

Two-sample t test with equal variances

	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
x	12	1133	66.10661	229	987.5003	1278.5
y	10	418	35.41751	112	337.88	498.12
combined	22	808	86.76793	406.9777	627.5562	988.4438
diff		715	79.51529		549.134	880.866

diff = mean(x) - mean(y) t = 8.9920

Ho: diff = 0 degrees of freedom = 20

Ha: diff < 0 Ha: diff != 0 Ha: diff > 0

Pr(T < t) = 1.0000 Pr(|T| > |t|) = 0.0000 Pr(T > t) = 0.0000

Table 5: T Test comparing the total number of under-5 patients treated for Malaria per month in 2018 (Variable X) and in 2022 (Variable Y).

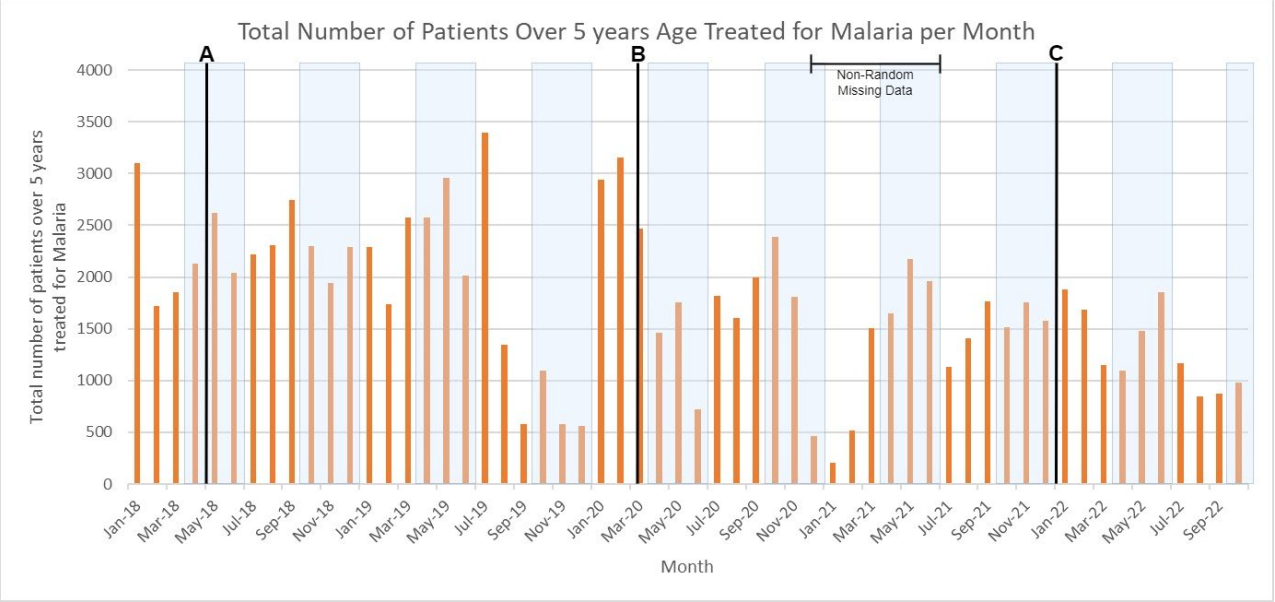

Figure 12: Graph illustrating the total number of patients over the age 5 years treated for Malaria per month from January 2018 to October 2022.

Two-sample t test with equal variances

	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
x	12	2273	113.1607	392	2023.935	2522.065
y	10	1301	124.5937	394	1019.149	1582.851
combined	22	1831.182	133.5561	626.4334	1553.437	2108.927
diff		972	168.2303		621.0778	1322.922

diff = mean(x) - mean(y) t = 5.7778
Ho: diff = 0 degrees of freedom = 20

Ha: diff < 0 Ha: diff != 0 Ha: diff > 0
Pr(T < t) = 1.0000 Pr(|T| > |t|) = 0.0000 Pr(T > t) = 0.0000

Table 6: T Test comparing total number of patients over the age of 5 being treated for Malaria per month in 2018 (Variable X) and 2022 (Variable Y).

We ran a correlation analysis on the total number of Malaria tests performed per month and the total number of patients treated per month for each age group from 2018 to 2022. This revealed a strong correlative relationship for both age groups and reflects the central role clinicians play in Malaria test ordering and patient treatment choice. This is as demonstrated in the following table:

Under five years

	Total tests<5	Treated for malaria<5
Total tests<5	1	
Treated for malaria<5	0.8636	1

Above five years

	Total tests>5	Treated for malaria>5
Total tests>5	1	
Treated for malaria>5	0.9451	1

Table 7: Pearson's Correlation Coefficient analyzing the strength of correlation between the total number of patients tested for Malaria and the total number of patients treated for Malaria for both age groups over time.

We evaluated the theory that fewer patients treated for Malaria might be associated with fewer patients arriving at the hospital (as defined as "Outpatient Attendance" per month). Thus, we looked at the correlative relationship between these variables over time for each age group and found that there was a high degree of correlative relationship between those variables, especially for the under 5 age group. This suggests that one of the reasons for why there is a decrease in total

patients treated and tested for Malaria is because those patients are presenting at the outpatient department in fewer numbers or that they are seeking care, but not able to register or receive it. This is consistent with two studies that found that patients, in the context of high out of pocket cost of Malaria diagnostics, are less likely to seek care at a health facility and may self-treat for Malaria instead (Dixit et al., 2016; Musuva et al., 2017).

Under five years

	Total treated for malaria<5	Outpatient attendance<5
Total treated for malaria<5	1	
Outpatient attendance<5	0.7804	1

Above five years

	Total treated for malaria>5	Outpatient attendance>5
Total treated for malaria>5	1	
Outpatient attendance>5	0.5789	1

Table 8: Pearson's Correlation Coefficient comparing correlative relationship between total number of outpatient attendance with total treated for Malaria from 2018 to 2022 for each age group.

Rates of Malaria Testing per Patient Treated and Presumptive Malaria Treatment

We looked at the number of Malaria tests performed per patient treated for Malaria. We performed an incident rate ratio test comparing the number of tests per patient performed per patient treated for Malaria in 2018 versus 2020 and 2022. We found that the testing rate for under 5 patients treated for Malaria did not change significantly from 2018 to 2022. However, we did find that patients treated for Malaria over 5 years were 1.28 times more likely to receive a Malaria test in 2022 than in 2018.

Testing Rate<5

Variable	IRR	95% CI	P-value
Year			
2018	1.00	1.00	1.000
2020	0.96	0.86-1.06	0.421
2022	1.01	0.94-1.09	0.810

Testing Rate>5

Variable	IRR	95% CI	P-value
Year			
2018	1.00	1.00	1.000
2020	0.99	0.91-1.08	0.851
2022	1.28	1.11-1.46	**<0.001**

Table 9: Incident Rate Ratio analysis of Malaria Testing rate per patients treated for Malaria by age group from 2018 to 2022.

Even still, we noted that the number of tests per patient was consistently below one from 2018 to 2022. Official guidance is that at least one Malaria test should be performed per patient treated, and theoretically more than one test per person treated should be reported due to suspected cases of Malaria that received a negative result and were not treated (Division of Malaria Control, 2010; National Malaria Control Programme, 2019). This suggested that a significant number of patients who were treated for Malaria did not receive a test at all and was consistent with findings of other studies in Nyanza Province (Manguin et al., 2017; Ngaba et al., 2022; W. O. Otambo et al., 2022; Pham et al., 2018; van Duijn et al., 2021). The minimum rate of one test per patient treated was indicated by a red line on the following graph:

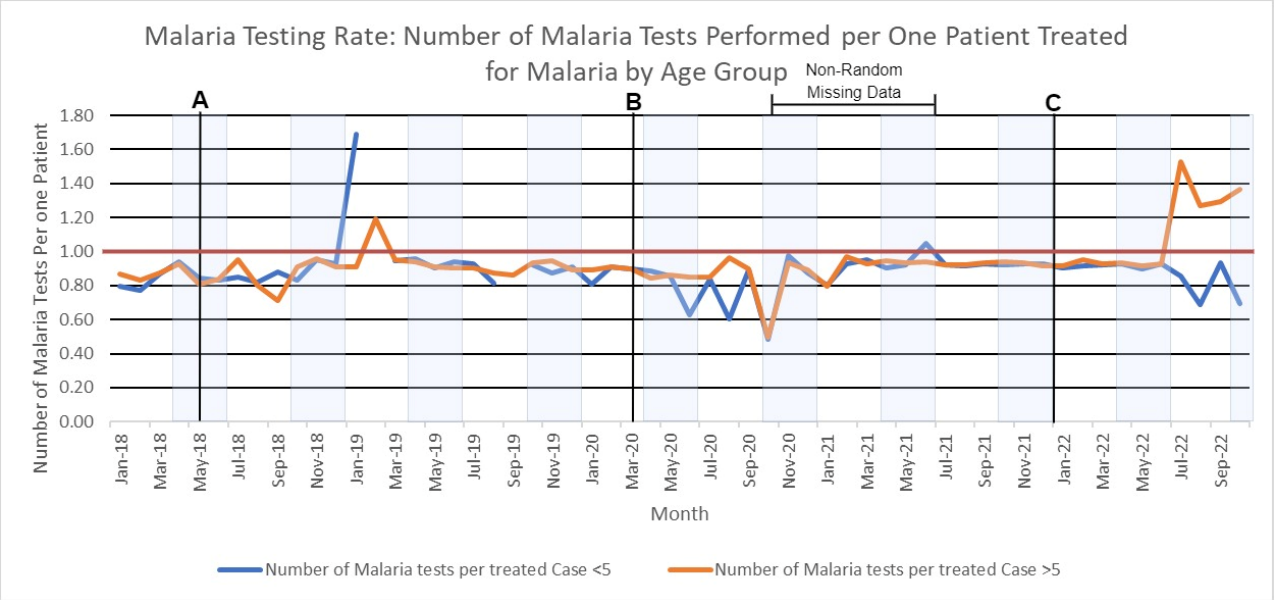

Figure 13: Malaria testing rate over time from 2018 to 2022, measured as tests performed per patients treated for Malaria.

We looked at Presumptive Diagnosis as a percentage share of patients treated for Malaria who did not get a "Positive" Malaria diagnosis by month and stratified by age group. We found that the average presumptive diagnosis rate across all years for the under 5 age group was 89.1% and for the over 5 age group was 89.92%. This was significantly higher than one study on presumptive Malaria diagnosis in Kisumu County (W. O. Otambo et al., 2022). However, it is consistent with other studies conducted in Sub-Saharan Africa (D'Acremont et al., 2014; Manguin et al., 2017; Peterson et al., 2021). We evaluated the theory that an increase in overall testing would be correlated with an increase in the share of those treated to receive a "positive" test. This analysis did not show a significant correlative relationship (Table 14). We believe that this was due to the overall decrease in testing while the rate of presumptive diagnosis remained relatively stable. This also suggests that increasing testing does not necessarily inform clinician treatment choices. Lastly, we compared the likelihood of a patient being treated for Malaria presumptively, or without a "positive" test result in 2018 to one in 2021 or 2022. We found that patient under 5 years were 1.07 times more likely to be treated presumptively in 2022 than in 2018. Patients over 5 years were 1.08 times more likely to be treated presumptively for Malaria in 2022 than in 2018. Thus, the eLIMS, from this analysis, did not appear to have a positive impact on Malaria test utilization,

presumptive Malaria diagnosis and the Clinician-lab Interface. This data is represented in the table below:

Under Five

	Presumptive diagnosis rate<5	Testing Rate<5
Presumptive diagnosis rate<5	1	
Testing rate<5	-0.4131	1

Above five years

	Presumptive diagnosis rate>5	Testing Rate>5
Presumptive diagnosis rate>5	1	
Testing rate>5	-0.2766	1

Table 10: Table 11: Pearson's Correlation Coefficient analyzing the relationship between Malaria testing rate and Presumptive Malaria Diagnosis for both age groups over time.

Treated but no positive test<5

Variable	IRR	95% CI	P-value
Year			
2018	1.00	1	1
2020	1.00	0.94-1.06	0.998
2022	1.07	1.04-1.11	**<0.001**

Treated but no positive test>5

Variable	IRR	95% CI	P-value
Year			
2018	1.00	1.00	1.000
2020	1.05	1.00-1.10	**0.038**
2022	1.08	1.04-1.13	**<0.001**

Table 11: Incident Rate Ratio analysis of the likelihood of a patient who is being treated for Malaria to be treated Presumptively (i.e. without a "positive" test result) by age group over time.

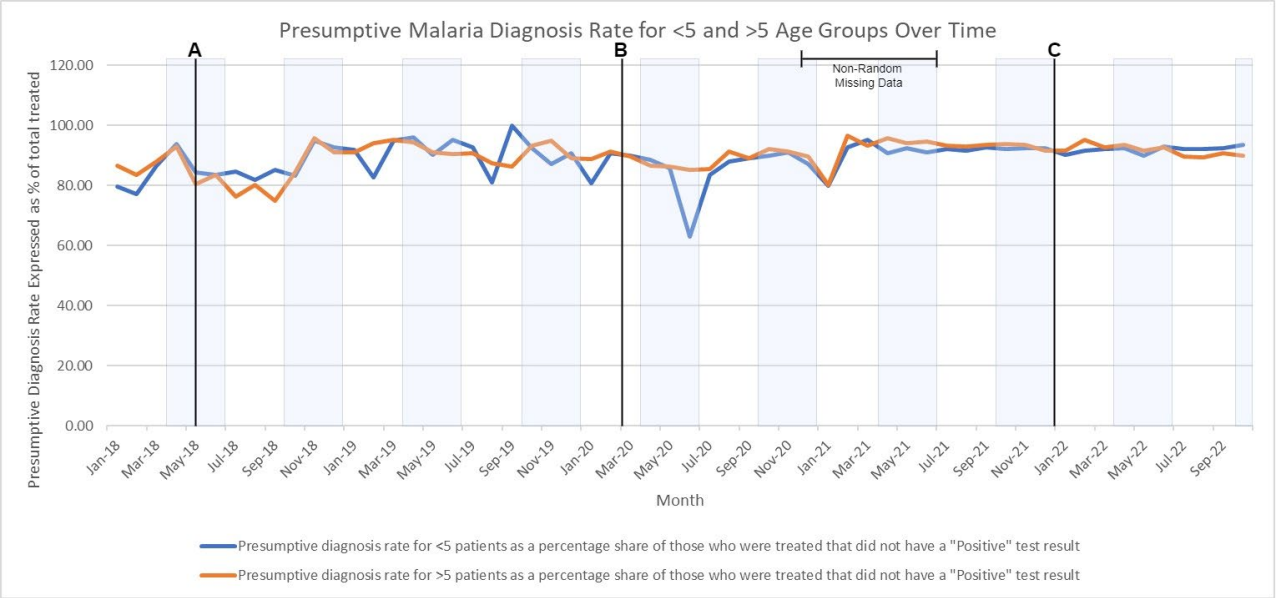

Figure 14: Graph illustrating the Malaria presumptive diagnosis rate over time for under 5 patients and over 5 patients.

Study Limitations

A number of data quality challenges potentially limited the accuracy of this analysis. First, we found missing data both at random and not at random across these hospital reports. The method we used to impute the missing data points, while standard statistical method, caused an inherent loss of variability in the data (Mislevy, et.al, 1991). This may explain why there was a lack of natural undulation in the Malaria positivity rates in late 2021 and 2022 and may also limit the accuracy of our assessment of impact. This study did not directly solicit the perspectives of clinicians despite being a critical link in the Cascade of Care and in determining which diagnostic tests were utilized and interpretation of test results and could not speak to those perspectives. The Malarial Overdiagnosis portion of this study implied a connection between over-diagnosis and over-prescription of antimalarial drugs. However, the public health sector in Kenya, compared to the private health sector, has a minority hold on antimalarial drugs for prescribing and often experiences medication stock-outs (Musuva et al., 2017). Thus, the connection between over-diagnosis and over-prescription was too nuanced for this study's scope. Without accompanying financial data and cost-effective analysis, this study could not speak to the financial implications of an eLIMS.

Conclusion

This study evaluated Malaria testing practices over time at a County-level public health facility in Kisumu County. Its goal was to evaluate the impact that the implementation of an electronic laboratory Information Management system might have had in promoting evidence-based Malaria treatment practices by providers in that facility. It is part of a larger study exploring the impact of this eLIMS on quality diagnostic services at the Hospital. It analyzed aggregate patient data in hospital reports from January 2018 to October 2022 on Malaria treatment, Malaria presumptive diagnosis, Outpatient Attendance and total Malaria tests performed.

In combination with the testing and treatment rates, this analysis shows that a patient at this facility whom the provider suspects has Malaria, will receive Malaria treatment regardless of the Malaria test result. Even though patients over the age of 5 receiving treatment for Malaria were 1.28 times more likely to get a Malaria test in 2022 than in 2018, the test result is not necessarily playing a role in provider treatment decision. Even more, patients for both age groups who did receive treatment for Malaria were more likely to be treated without a "positive" Malaria test in 2022 than in 2018. An overall decrease in testing and treatment in spite of an increase in Malaria positivity rate for the under 5 group in 2020 suggests that overall positivity rates were not informing provider practices and many children who had Malaria in 2020 to 2022 may not have been identified or treated. This may be because the symptoms of severe Malaria are similar to COVID-19 and, during the initial stages of the COVID-19 Pandemic, may have been misdiagnosed as COVID-19 (Hussein et al., 2020). There was a decrease in the number of patients seeking care at the outpatient department over time, which was highly correlated with the total number of patients being treated for Malaria. This, similar to other studies, suggested that patients, during the COVID-19 Pandemic, were either going elsewhere for their care or not seeking care for Malaria (Dixit et al., 2016; Musuva et al., 2017). Thus, in spite of having an eLIMS system installed in 2018, there does not appear to be a positive impact on Malaria testing practices other than an

increase in the likelihood of adult patients being treated receiving a Malaria test. This could be due to the COVID-19 Pandemic and related funding shifts and health care disruptions that continue to interfere with prior gains in health system development and progress on Malaria elimination (World Health Organization, 2022). More research needs to be done on why providers are, more than before, choosing to treat Malaria presumptively and what the County Health Department can do to improve provider testing practices. It must also explore why patients are attending this facility less over time and if this is impacting access to quality Malaria diagnostics and treatment, especially for children under 5 and especially when public health facilities provide the majority of Malaria diagnostics in Kisumu County (W. O. Otambo et al., 2022; Zurovac et al., 2006). Malaria continues to be a serious public health challenges in western Kenya and without renewed investment and attention to Malaria diagnostics, treatment and control, we may continue to lose ground in the long-term battle to control this disease. Additionally, it must address the role that providers play in quality diagnostics and the limited agency that public health laboratories have to promote rational diagnostic use. This is the first study to analyze the impact of an eLIMS on quality diagnostics at a public health facility in western Kenya and the first to assess changes in Malaria testing practices in this context before and after the COVID-19 Pandemic. It informs future priorities in public health action in western Kenya and the next Kisumu County Health Laboratory Strategic Plan.

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Exploration of the Implementation of an Integrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya.

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Abbreviations:

eLIMS	Electronic Laboratory Information Management System
KCRH	Kisumu County Referral Hospital
PALM	Pathology and Laboratory Medicine
TAT	Turn-around-Time
QMS	Quality Management System
EQA	External Quality Assurance
CLB	County Laboratory Coordinator
SCLC	Sub-County Laboratory Coordinator
KCHLSP 2018-2022	Kisumu County Health Laboratory Strategic Plan ’18-‘22
LMIC	Low-and-Middle Income Countries
UHC	Universal Health Care
COVID-19	Sars Covid-2 2019-present Pandemic Era
NCD	Non-Communicable Disease
KEMSA	Kenya Medical Supply Agency
POC	Point-of-Care Services
UTI	Urinary Tract Infection

Abstract

Underinvestment in pathology and laboratory medicine capacity caused by low visibility in research and low prioritization by public health leaders results in limited healthcare service quality and an estimated 1.1 million premature deaths annually in Low-and-Middle-Income Countries. Kenya's public health laboratories provide a median 41% of the Essential Diagnostic List to their patients and In Kisumu County, Western Kenya, as much as 44.2% of the population has little to no access to essential diagnostics. The government of Kisumu implemented the county Health Laboratory Strategic Plan 2018-2022 to address this public health challenge. While an objective of this strategic plan was to implement fully integrated electronic laboratory information management systems **(eLIMS)** at two County-level public health facilities by 2019 and five sub-county level health facilities by 2021, little information exists on the effectiveness of these initiatives and the realized impact on laboratory quality diagnostic services in the era of COVID-19, Universal Health Care, and a burgeoning Non-Communicable Disease burden. Further, few researchers have explored the experiences of public health laboratory professionals as they strive to meet growing demands for their services and improve the quality of evidence-based care in Western Kenya. This study seeks to explore the implementation of a fully integrated eLIMS at a county-level health facility in Kisumu County while investigating the experiences of health laboratory professionals across Kisumu County. Specifically, this study will collect observational data and interviews at Kisumu County Referral Hospital on how health professionals interact with the eLIMS, analyze quantitative data from laboratory reports and the National DHIS-2 on diagnostic quality indicators from 2018 to the present, and conduct 13 key informant interviews with laboratory professionals across Kisumu County. Data collection for this study will take place across two months in the last quarter of 2022. This study will contribute immediately to the final assessment of the Kisumu County Health Laboratory Strategic Plan's eLIMS objective as well as ongoing public laboratory capacity-building initiatives in Kisumu County to address the health needs of Kisumu County.

Introduction

According to the recently published "Lancet Commission on Diagnostics: Transforming access to diagnostics", nearly half (47%) of the world population has little to no access to medical diagnostics[1]. This results in an estimated 1.1million avoidable premature deaths primarily in Low-and-Middle-Income Countries (LMICs) annually[1]. In the Treatment Continuum, or the healthcare service process starting from illness and ending with treatment and recovery, access to Pathology and Laboratory Medicine (PALM) represents the largest gap in service availability [1][2]. This is termed the "Diagnostic Gap", or the percentage of people with a disease who fail to receive a diagnosis, and ranges in size globally from 35% to 62% of afflicted patients depending on the disease [1][3]. Underinvestment in PALM is the result of low visibility in research and advocacy on the global stage and underappreciation by public health leaders of the essential role of diagnostics in targeted health policy and evidence-based treatment. Nevertheless, growing demand for evidence-based treatment and public health policy has created pressure to improve access to diagnostics[1][4]. For instance, the necessity of timely, affordable, accurate, and accessible diagnostics became evident in the world's struggle to address the COVID-19 Pandemic with handicapped surveillance, faulty tests, and slowed government response [5][6]. Further, efforts to achieve the 2030 Sustainable Development Goals and Universal Healthcare continue to be hampered by a lack of capacity for data-driven targeted public health policy [7][8][3]. Improving access is not enough when poor quality diagnostics and quality control mechanisms in public labs lead to faulty results and cast distrust among patients and clinicians in the value of testing. Lastly, the absence of diagnostics often results in a presumptive diagnosis, overuse of antibiotics, and antibiotic resistance [9][10][11].

Background

The "World Health Report 2002" published by the World Health Organization states that Sub-Saharan Africa broadly lacks the scientific evidence and reliable public surveillance data it needs to formulate evidence-based health policies[12]. This, The Lancet concludes, is due to a chronic and widely unacknowledged disregard of medical diagnostics worldwide with few exceptions (notably, the U.S. and U.K.) [1]. The results of this neglect were multifaceted and included many undiagnosed and untreated patients and public health leaders that lacked the timely, technical data they needed to guide effective testing and PPE procurement, lock-down procedures, and vaccine distribution in response to COVID-19 [5][6]. Conservative estimates reveal that 30% of patients with Tuberculosis are not diagnosed, resulting in 1.5 million deaths annually [13]. In Maternal Health in Mozambique, a recent study found that 38% of maternal deaths had a misdiagnosis and could have been avoided [14]. Another study found that patients receiving HIV treatment without preliminary Anti-retroviral Therapy or routine CD4 and Viral Load testing experienced a one-third higher risk of death [2]. A delay in diagnosis in chronic conditions like cancer leads to higher mortality and poorer prognosis. For example, in England, a study found that delays in cancer diagnosis due to the overwhelming of medical laboratories during the COVID-19 Pandemic are projected to result in 3,000 additional deaths and 60,000 additional Years of Life Lost (YLL) over the next five years [15]. The Lancet Commission on Diagnostics found that the theoretical impact of expanding diagnostic access for six key diseases from 47% coverage to 90% coverage globally would result in over 1,076,000 deaths averted annually[1].
Insufficient regulatory systems also allowed for the wide distribution of faulty COVID-19 testing kits in High-Income Countries (HIC) such as the U.S. [6]. In the case of implementing UHC programs in Sub-Saharan Africa that target specific high disease burdens such as HIV, poor quality control in sample collection leads to sample rejection, false negatives, long Turn-around-Times, and reagent wastage [16]. This further makes scaling up disease treatment programs unnecessarily

difficult and costly [17]. A lack of quality medical laboratory systems, reliable supplies of commodities, and trained health workers can result in dysfunctional government programs like UHC. This is a growing challenge felt around the world that we cannot ignore if we are to meet the 2030 SDGs and improve how we address future pandemics[1]. Broadly speaking, four main challenges limit access to and quality of clinical diagnostics in low-income and middle-income countries globally, namely:

1. Insufficient diagnostic workforce size and capacity
2. Limited educational and training opportunities and rate
3. Inadequate facility, equipment and technology infrastructure
4. Insufficient regulatory and accreditation frameworks for quality and standards enforcement.

The result is that access to quality clinical diagnostics is limited to urban areas for strata of the societies that can afford them. Elsewhere, patients experience delays in accurate diagnosis, poor clinical management, and avoidable disability and death[3], [18], [19].

The Diagnostic Gap in Kenya

Kenya is part of the East African community, has a land mass of 582,646km^2, and estimated population size of 47,564,296 [20]. The sex-specific average life expectancy in Kenya increased for both males and females since 2009 (58 years and 61 years respectively) and to 60.6 years and 66.5 years respectively, in the 2019 National Census [21]. This is also an increase from an overall average of 51 years of life expectancy in 2004 [22]. The Parliament of Kenya enacted the Health Act of 2017 to actualize the constitutional right of every Kenyan to the highest attainable standard of health. This Health Act defined this standard in terms of the World Health definition of Universal Health Care and "progressive access to promotive, preventive, curative, palliative, and rehabilitative services" [23]. Despite committing to the Abuja Declaration and a healthcare sector spending and investment goal of 15% of GDP, the Kenyan Government has stagnated at around 6% for the past decade [22]. Socioeconomic status plays a correlative role in patient access to care. In Kenya specifically, a study done using the 2018 Kenya Household Health Expenditure and Utilization Survey found that healthcare access and quality were correlated with patient income, education status, and region of residence [24]. They also found that public health facilities in Kenya were primarily used by patients from lower-income brackets [24]. Since Public health facilities are more strongly affected by government underinvestment in PALM, these challenges present clear equity issues regarding diagnostic access, cycles of poverty, and resource distribution [25].

For this reason, UHC became one of the priorities of the 2018-2022 Kenyan government's "Big Four Plan". Within the goals of the UHC pilots, to be implemented in four counties including Kisumu County, the administration set to improve the delivery of laboratory diagnostic supplies from the centralized Kenya Medical Supply Agency (KEMSA) which in 2018 met only 30% of level four and five health laboratories across the country. One result was the development in 2019 of the "Kenya Essential Medical Laboratory Supplies List" for application in the Universal Health Care pilot program [23]

Government leadership, administrative support, the setting of performance standards, and quality standard enforcement are critical for successful laboratory performance initiatives. Where there is a lack of integrated health sector strategies and government priority-setting in support of PALM systems, public laboratories are most strongly affected because they must rely on their government to provide for their needs [26]. This is especially true for implementing initiatives and infrastructure investments that have high upfront costs without immediate returns such as accreditation, Laboratory management systems, and the necessary climate control to maintain lab equipment quality function [2], [27]. However, it is not enough in the fight to improve diagnostics

access to expand diagnostics without improving laboratory performance and testing quality standards. For instance, expanding diagnostics without implementing laboratory quality management systems results in increased test reagent waste, long turn-around time on results, sample rejection, higher operational costs, and patient and clinician distrust of diagnostics [4], [28]. Further, most errors in diagnostics occur in the preanalytical (46%-67%) and post-analytical (18%-48%) stages rather than in the assay performance itself [2]. As an example, the Kenya Medical Research Institute (KEMRI)/ Centre for Disease Control HIV-Research Institute Laboratory in Kisumu, Kenya, was the first laboratory in Kenya to achieve ISO 15189 status in March of 2008. One study in 2010 on their accreditation process found a USD 9,500 annual reduction in reagent wastage costs, a reduction in sample rejection from 4.5% to 0.5%, and an 82% reduction in client complaints (due to improved testing quality and turn-around-time)[17].

Additionally, Kenya faced vast challenges in improving the timeliness and accuracy of the National health data reporting system, DHIS-2. A recent study on hospital testing capacity across Kenya found that only 41% of the hospitals that reported to the DHIS-2 at all (n=174) reported consistently throughout the year [29]. The median testing capacity of these labs was only 40% of the Essential Diagnostics List prescribed by the Ministry of Health [23], [29]. The connection between accreditation and patient health outcomes is not well-documented. However, studies have shown that performance testing can reduce testing errors in resource-rich and resource-limited environments[2]

Disease-Specific Diagnostic Gaps

Certain disease diagnostic assays have significant reagent, infrastructure, and personnel training requirements that render them inaccessible in resource-limited settings. Although not a direct subject of the study, access to cancer diagnostics is an example of such a case and a growing public health concern in Kenya. Cancer is the third-leading cause of death in Kenya, causing an estimated 28,000 Kenyan deaths each year [30]. Even more, as much as 80% of cancer cases are diagnosed at a late stage, when they are difficult to treat successfully. According to a study by Wambalaba et.al on cancer screening and diagnosis in Kenya: “This is largely due to the low awareness of cancer signs and symptoms, inadequate screening services, inadequate diagnostic facilities, and poorly structured referral facilities” [31]. Many of the specialized cytological and histological diagnostic tests used to diagnose cancer are not available outside of Nairobi with only 12 cancer care facilities nationwide [32]. This became a particular challenge for rural patients in Western Kenya during the COVID-19 Pandemic when the government of Kenya instituted a travel ban barring rural residents from traveling to Nairobi without provisions for cancer screening and treatment [33]

In contrast, Non-Communicable diseases (NCD), particularly Hypertension, Diabetes and Malnutrition diagnostics are available in proven Point-of-Care (POC) testing methods and are of growing concern in Kenya [20], [34]. For instance, a study found that in Western Kenya from 2003 to 2010 the proportion of deaths attributable to NCDs, including cancer, increased from 35% to 45% [35]. Nationwide, NCDs account for 39% of deaths annually, yet the Kenyan Ministry of Health estimates that 59% of diabetic cases and 60% of hypertensive cases are undiagnosed in the country [20], [36].

Global estimates of the burden of urinary tract infections are between an annual 150millio-250million people with women of childbearing age and those with Diabetes Mellitus being the most affected [37]. It is one of the most common community-acquired infections globally. While the risk factors for UTIs are numerous, pregnancy and Diabetes, due to the high fertility rate and growing prevalence of NCDs in Kenya, are of principal concern here [20], [21], [34], [36]. Pregnancy has been found to increase the

risk of UTIs, and the consequences of these infections on pregnancy outcomes can be serious. Studies on bacteriuria (symptomatic and asymptomatic) in pregnant women have found infection to be significantly associated with low birth weight, preterm labor, hypertension/preeclampsia, stillbirths, perinatal infection, and death[38]–[44]. Additionally, there is a strong epidemiological link between Type 2 Diabetes and increased risk of UTIs [45]–[48]. Therefore, as the disease burden of Diabetes increases in Kenya, so also will the incidence of UTIs and associated complications[20], [34], [49]. Even more, the WHO states that global rates of *E. coli* resistance to Ciprofloxacin, a common and first-line treatment for urinary tract infections, are as high as 92.9% of cases [50]. A study in Uganda, for instance, on bacteriuria in pregnancy, found multidrug resistance in 82.4% of gram-negative bacterial cases (most commonly *E. coli*) and in 72.4% of gram-positive bacterial cases (most common *S. aureus*)[39]. Another study in Bangladesh reported that as much as 1/3rd of pregnancy-related *E. coli* bacteriuria was resistant to 3rd generation Cephalosporins[40]. While demonstrating the critical need to diagnose and treat UTIs in pregnant women, limited attention has been given to the efficacy of diagnostic methods in these resource-limited settings. One study found that urine chemistry reagent dip sticks, similar to those used in western Kenya, testing for nitrite and Leukocyte esterase were significantly associated with positive bacteriuria results (as determined by bacterial culture dip slides). Similar to other studies noting that symptoms of dysuria are natural and common during pregnancy, this study also found that reports of symptomatic dysuria had low specificity and predicate value for identifying positive bacteriuria cases[38], [40], [44]. The Kenyan Ministry of Health's Clinician's Handbook on Diagnostic Stewardship dictates that "Urinalysis" is the assay of choice for all categories of UTIs: Cystitis, Pyelonephritis, and Urosepsis [51]. However, it does not acknowledge the widely divergent capacities and techniques for performing "urinalysis" in facilities across Kenya. These all underscore the importance of optimal access to quality laboratory-confirmed diagnostics for ensuring effective and evidence-based treatment of UTIs for all patients worldwide as well as the role that uropathogens are playing in the global crisis of anti-microbial resistance.

Malaria and associated complications have long been serious public health issues in Kenya, especially in high transmission areas such as the Nyanza lakes region of Western Kenya. Malaria is commonly diagnosed clinically using microscopy examination of thick and thin blood smears stained with Giemsa stain. Typically, parasitemia is quantified and reported using a plus (+) system [52]. In his study of Severe Malarial Anaemia (SMA), a life-threatening complication of chronic or severe acute Malaria cases, in children under five at a district hospital in Siaya County, Western Kenya, Obonyo states that: "Case management of SMA is complicated because of diagnostic difficulties in the absence of a supportive diagnostic laboratory"[52]. While considerable progress has been made since the turn of the century in vector control and laboratory capacity for Malarial laboratory diagnostic access (10.6 million Malaria deaths averted from 2000-2020 with 95% of those from the African region), Malaria continues to pose serious public health challenges [50]. Namely, COVID-19 has caused huge disruptions in Malaria prevention, diagnosis, and treatment leading to 47,000 additional deaths globally from 2020 to 2022 [50]. Kenya's national prevalence is 11% among children 10-14 years old, three-quarters of the national population at risk of infection, and growing prevalence of anti-biotic resistant parasites [53]. This is also partly because simply expanding diagnostics is not always cost-effective or realistic in resource-limited settings[54], [55]. For example, the "Clinician-Lab Interface", a relationship between clinicians and the medical laboratories they use to order assays and provide evidence-based case management, plays a critical role in Kenya in the ordering and utilization of Malarial diagnostics[56]. In the case of over-diagnosis of Malaria in Kenya, the common

method of Malarial diagnostics, Malarial Microscopy, can be prohibitively expensive and time-intensive in resource-limited settings[54]. Additionally, due to lack of trust or confidence, long Turn-around-Times (TAT), or academic training, many clinicians will not order malarial microscopy even when available and instead give a presumptive diagnosis for Malaria. In the case of a poor Clinician-Lab Interface, Studies in Sub-Saharan Africa have found clinicians to even ignore a negative result and prescribe Anti-Malarial treatment anyway [11], [57]–[59]. In addition to resulting in over-consumption of anti-malarial medications, a study in Kenya found that clinicians also failed to diagnose positive Malarial cases at a rate of one in six [60], [61]. Lastly, the tendency of patients to self-diagnose and subsequently self-medicate, which has a lower treatment success rate than institutional case management, is growing in areas of Africa such as Kenya where there is limited healthcare access [54], [62]. Available, quality Malarial diagnostics and case management is critical for addressing this ongoing public health challenge. Further, optimizing the Clinician-Lab Interface is a part of a medical laboratory's Quality Management System (QMS) and high-functioning management and communications pathways between hospital departments, including a fully integrated eLIMS [63]. The connection between these facets of quality diagnostic services and why they matter to public health policy and quality health care are illustrated in the following diagram taken from Nkengasong and Birx[64]:

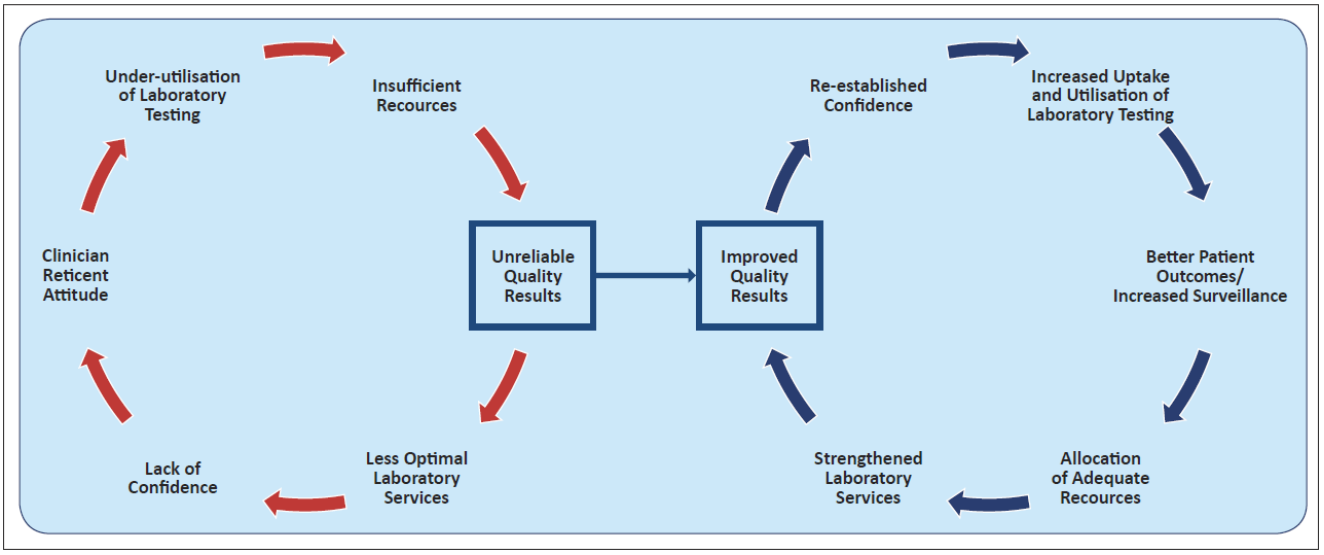

Figure 1 The connection between improved quality diagnostics, strategic allocation of health resources, and improved public health outcomes. Source: Nkenggasong & Birx, 2014 [64]

The Kisumu County Situation

The global challenge of the Diagnostic Gap applies to Kenya, in particular Kisumu County, as one of four counties to pilot Kenya's 2018 UHC initiative and where as much as 44.2% of the county has little to no access to diagnostics [16], [24], [65].

History and Organizational Structure of the Kisumu County Laboratory System:

The Kisumu County Health Laboratory Strategic Plan was the first of its kind in the history of lab services in Kisumu County and states that:

"The Medical Laboratory Strategic Plan (2018-2022) has been developed in recognition of the need to have a framework for the development and delivery of integrated medical laboratory services in the County" (GCOK, 2017).

This Strategic Plan reflects the assertion by the "Lancet Commission on Diagnostics" that a government strategic plan to address the Diagnostic Gap is a cornerstone and starting place for creating quality public medical laboratory systems[1]. Further, the plan uses data from a comprehensive SWAT review in 2016 to detail the status of all medical labs in Kisumu County from lab equipment capacity to staffing deficits and training. Towards the mission of ensuring quality diagnostic services in public health laboratories across Kisumu County, the Strategic Plan's Strategic Object #8 allocated a plan to establish a fully integrated eLIMS system at the seven Level IV and V hospitals in the county with a budget of roughly 6million Ksh. A fully integrated eLIMS at these facilities was intended to help improve the incomplete and backlogged health data reporting system and to support laboratory and hospital Quality Management Systems (QMS) for the county [65][63].

Health laboratories played a critical role in the policies enshrining the Universal Health Care plan and the roll-out of the Universal Health Care pilot in Kisumu in 2018[66]. Recent studies on the effectiveness of the UHC pilot in Kisumu County show that the process could not ensure adequate healthcare resources such as laboratory and hospital commodities, training and preparedness of healthcare workers, and sensitization of the public[66] Therefore, long wait times for diagnostics predicated most free healthcare services, making access to healthcare an anomaly of "free-yet-unavailable" [22], [66].

Additionally, Kisumu County experiences numerous challenges in staffing shortfalls. The Tax Payers Association (NTA) of Kenya showed in their report on public and private health facilities in Kisumu County shows that the most common reason that a health center and laboratory do not operate on the weekend is due to a lack of staff [67]. A lack of staffing limits the ability of hospital laboratories to stay open on weekends or for 24hrs, to provide timely diagnostic service, or to provide laboratory staff with necessary vacation and sick-leave benefits. There is also a reciprocal lack of advancement and job opportunities for laboratory professionals in LMICs, especially if they are not affiliated with a major "Vertical Disease Program" such as the Presidential Emergency Fund for AIDs Relief (PEPFAR) [3][68].

The available evidence shows that the challenge of providing quality diagnostics in Kisumu County is as much an investment issue as it is an administrative process issue[69], [70]. For this reason, the study uses the following process diagram to illustrate the relationships between laboratory staffing, appropriate financing, a fully integrated eLIMS, Clinician-Lab interface, and key diagnostic quality indicators like assay accuracy, Turn-around-Time, availability, and public health outcomes:

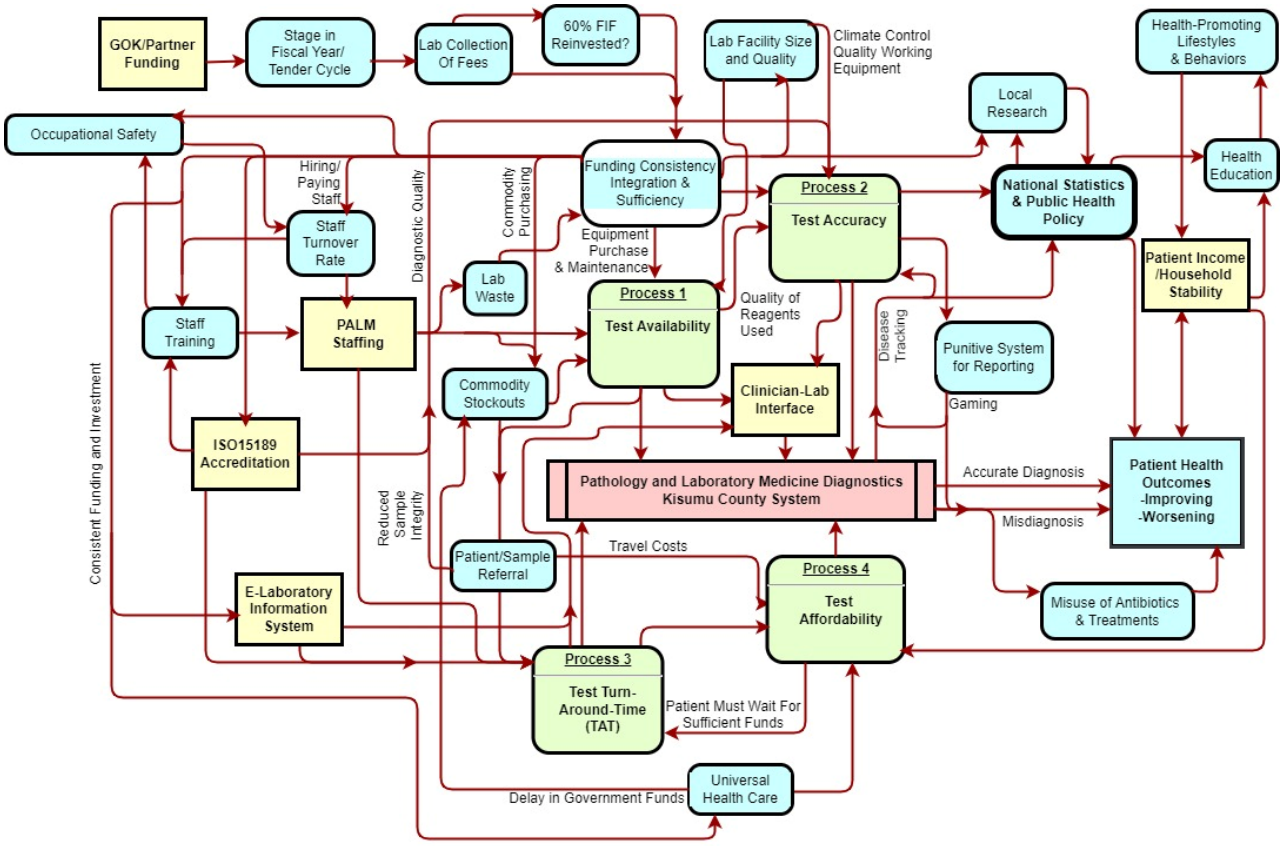

Figure 2: Flow diagram illustrating the theoretical diagnostic activity and component process flows that impact the quality of pathology and laboratory diagnostics in Kisumu County. Source: Author & Principal Investigator, Kelly Allen, 2021.

Justification for this Study:

Addressing the Diagnostic Gap and successfully implementing UHC programs in Kisumu begins with understanding the contextual mechanisms driving it and then advocating through research for better government policy and investments. Finding solutions to expanding diagnostic access requires ingenuity and a willingness to holistically address all the causes of poor access. These include testing practices that are impractical for low-resource settings, a lack of visibility for PALM in the global health agenda and government policies, poor enforceability of national health strategic plans, insufficient workforce capacity, poor healthcare system infrastructure, and socioeconomic factors the decreasing affordability of testing and care-seeking behaviors in patients. It is notable that the eLIMS at Kisumu County Referral Hospital has been taken up by the hospital and county government as a budgetary priority given the lack of priority often seen by laboratory networks. Further, increasing cases of anti-malarial and anti-biotic resistance (especially in *E. coli*) make the need for informed case management a public health imperative. For these reasons, and due to the paucity of research on the relationship of an eLIMS to quality diagnostics services, this case study is unique and beneficial to an understanding of how to meet the growing demand for evidence-based clinical management in resource-limited sub-Saharan Africa. To the best knowledge of the author, there has not been any scientific publication specifically addressing the Diagnostic Gap in Kisumu County and its association with UHC initiatives and COVID-19 response. This paper seeks to ask how PALM professionals in Kisumu County grapple with this persistent underinvestment and the growing demand for their services. It also investigates the mechanisms in the Kisumu County public health system that drive the lack of access. In documenting these challenges, the researcher hopes to raise awareness of the Diagnostic Gap in Kisumu County and ways

to address it.

Study Limitations and Application of Results:

This study does not directly solicit the perspectives of clinicians despite being a critical link in the Cascade of Care and in determining which diagnostic tests are utilized and interpretation of test results. The Malarial Overdiagnosis portion of this study implies a connection between over-diagnosis and over-prescription of antimalarial drugs. However, the public health sector in Kenya, compared to the private health sector, has a minority hold on antimalarial drugs for prescribing and often experiences medication stock-outs[61]. Thus, the connection between over-diagnosis and over-prescription is too nuanced for this study's scope. Without accompanying financial data and cost-effective analysis, this study cannot speak to the financial implications of an eLIMS. Rather, this study expects to aid in an in-depth status assessment of Strategic Objective 8.2 of the Kisumu County Health Laboratory Strategic Plan 2018-2022 for a fully integrate eLIMS at KCRH at a time when a full analysis of this plan should be underway. In the growing efforts to combat the irrational use of anti-biotics, this study will add to the understanding of the clinician-lab interface and role of the quality diagnostics in evidence-based care. For capacity-building programs such as the CDC, Amref, and Global Implementation Systems, it will contribute to a nuanced understanding of the challenges and successes of Kisumu County's efforts to narrow the Diagnostic Gap in the era of COVID-19. Lastly, it will inform the current push in Kenya toward Universal Healthcare and how the pilot program has played out in Kisumu County public health laboratories.

Research Questions:

This study asks: How has the implementation of the Electronic Laboratory Information Management System (ELIMS) at Kisumu County Referral Hospital (KCRH) affected the hospital laboratory's ability to provide quality services. It is a Mixed-Methods sequential explanatory study that used qualitative data collected from observations and interviews to give context and interpretive value to an analysis of 5-year longitudinal data on quality clinical diagnostic indicators at Kisumu County Referral Hospital [71]. An observational portion explores the outstanding challenges with laboratory functions at KCRH in relation to the use of their ELIMS including rates of paper versus electronic test orders. How common are these challenges throughout Kisumu County Public Health Laboratories and how do challenges in facility functionality above and below KCRH in the patient referral pathway influence the KCRH laboratory's functionality. This is a mixed-methods study including retrospective and ongoing quantitative analysis, key-informant interviews, and observational data collection. The qualitative portion of this study involves 13 key informant interviews with senior medical laboratory personnel working in the public health laboratory system in Kisumu County. The observational data collection will collect event-sampling and rate-sampling data on how KCRH personnel interact with the ELIMS system to complete key laboratory functional tasks. This will seek to determine the functional or integrated status of the ELIMS within the hospital information management system. The observational study also conducts day-end debriefing interviews with a KCRH lab manager to reflect on observations collected. The quantitative analysis will assess the trends over time of several key diagnostic quality service indicators and the correlative relationship between the indicators and the implementation of an integrated ELIMS system at KCRH's Medical Laboratory from 2018 through November 2022. This analysis will combine with interviews with County-wide public laboratory personnel and laboratory personnel within KCRH to build models with contextual data for interpretative purposes**.** The study looks at the following key indicators: Diagnostic Turn-around-Time (TAT), rates of presumptive diagnoses for

Malaria, total Urinary tract infection diagnosis versus Leukocyte/ ketone/ protein diagnostics tests performed, utilization of diagnostics per patient visit, diagnostic reagent stock-outs including those for urinalysis, reagent waste, and diagnostic service interruptions with facility patient population estimates as controls. It compares these indicators from May 2017 till November 2022 using deidentified data from laboratory reports and the National DHIS-2 health statistics reporting systems from KCRH including the following: "MOH706 Laboratory Summary Report", "AWP Monthly Service Delivery", "Hospital Administrative Statistics", "Inpatient Activities", "Malaria Commodity Dashboard", "MOH 105 Service Delivery", "MOH 705 A Outpatient Summary", "MOH 717 Service Workload", "MOH 743 Malaria Commodities", "Population Estimates for Facility and Ward", "UHC-303-Tracer Diagnostics" and "UHC-302-Tracer Non-Pharmaceuticals".

Hypothesis:
We hypothesis that there is low overall use of the electronic laboratory ordering system by clinicians with lower rates of electronic test ordering from hospital departments that are less integrated into the hospital HMIS system. We hypothesize that the eLIMS implementation effectiveness will follow the training, troubleshooting, and upgrading trajectory of the KCRH laboratory as well as correlate with shorter Turn-around-Times, higher use of Malarial and urinalysis diagnostics by clinicians, fewer instances of service interruptions in the laboratory. We anticipate that this study will identify numerous gaps in process optimization in the preanalytical and post-analytical phases of diagnostic utilization within KCRH and across the county that will be explained by qualitative data collected across the county and within KCRH.

Objectives:
General Objectives:
To determine at Kisumu County Referral Hospital the correlative relationship between implementation of an eLIMS and laboratory diagnostic key indicators, the quality of the clinician-laboratory interface, and the nature of ongoing process challenges in the diagnostic path of workflow in KCRH and across the public laboratory network in Kisumu County that limit laboratory personnel's capacity to provide quality of diagnostic services, especially in relation to Malaria diagnostics, urinalysis diagnostics, and major public health events including COVID-19 and the UHC pilot. To explore the perspectives of public laboratory professionals on the challenges of providing quality diagnostics and mechanisms that drive lack of diagnostic access.

Specific Objectives:
1. To identify through key informant interviews common challenges faced by public laboratory personnel in Kisumu County in relation to providing quality diagnostic services during the 2018 UHC Pilot in Kisumu County and the COVID-19 Pandemic.
2. To determine the rate and nature of the use of the electronic test ordering system and diagnostics generally by clinicians within KCRH.
3. To analyze the relationship between turn-around-time, reagent waste, and reagent stock-outs across the timeline of the implementation of the eLIMS at KCRH.
4. To determine trends in the rate of presumptive diagnosis for Malaria at KCRH over time and correlation with the implementation of eLIMS at KCRH.
5. To determine the nature of correspondence between diagnostic methods for Urinary Tract Infections at KCRH and correlation between this correspondence and the

implementation of eLIMS at KCRH.

6. To examine the nature of current use of the eLIMS within KCRH and how that might be related to delivery of quality diagnostic services.

Methodology and Study Design:

Study Design:
Qualitative data will be collected using semi-structured key-informant interviews and observation guides with results transcribed as notes on the interview and observation guides while following the guide(s) instructions. The key informant interviews and observation guide have been pre-tested for validity and design quality in a similar public health setting and in collaboration with experienced professionals in qualitative tool design in this field**. Before beginning each data collection step, participants in the observation guide and key informant interviews are de-identified using a random numbering system**. Then, these notes are coded and analyzed using qualitative analysis software for thematic relationships. A portion of the Observation guide will collect data using rate-sampling. This data will be analyzed using quantitative statistical methods to determine if certain diagnostic assays are more likely to be ordered by clinicians via paper or electronic script and the over-all rates of paper versus electronic orders. This sampling occurs in the morning and afternoon, on rotating weekdays and occasional weekend days to capture variations in patient flow and increase the external validity of the results. No data collected as part of the qualitative portion of this study will involve interacting with children or patients of any age. De-identified quantitative data will be accessed from the Kenya National DHIS-2 for Kisumu County referral Hospital and its laboratory starting from 2018 just before the eLIMS was implemented till the end of 2022. This data will include whole-population data from all age groups, including children, for variables. These variables will be analyzed using a series of models to test for single or joint correlative relationships to determine the correlative nature between the key laboratory performance indicators while adjusting for relevant events and constants that are identified through the qualitative analysis such as the initial install of the eLIMS system and the COVID-19 Pandemic. Then, the analysis will measure the correlation between the implementation of the eLIMS system on each laboratory performance indicator. The qualitative data is collected at the end of the quantitative data collection and combined with the quantitative data analysis in a sequential explanatory mixed-methods design. The selection of the time period for qualitative data is also partly convenience sampling in order to meet the program requirements for a master's degree capstone project and partly to provide analysis of a 5-year timeline corresponding to the Kisumu County Health Laboratory Strategic Plan 2018-2022.

Study Setting:
Kisumu County has 111 medical laboratories (private and public) across six sub-counties, and an estimated population of 1,145,747 [53], [65]. Since the devolution of governance authority from the central government to the county levels in 2010, county governments are responsible for managing all their administrative processes, reporting, funding, supply systems, and requests for procurement to the Kenya Medical Supply Agency (KEMSA) [65], [72] [53]. This authority is further devolved to the sub-county level where sub-county administrative processes report to the county government, and so on. The National government provides country-wide training, performance, and administrative guidelines, accreditation services, and KEMSA for organizing public procurement of medicines, equipment, and commodities. In Kisumu County, health facilities have been stratified into five levels based on service menus and capacity where level one facilities provide only very basic primary care, and level IV through V are

hospitals with increasing capacity for diagnostics, surgery, and treatment. Level V facilities are subdivided into two more levels commonly referred to as “Level VA” and “Level VB” where “A” hospitals are more advanced teaching and research facilities. In most sub-counties, Level I and II facilities (Community Health Volunteers, and Dispensaries, respectively) do not have medical laboratory services but may offer some Point-of-Care (POC) testing services such as Community Health Volunteers who provide Malaria Rapid-Tests in the communities[73]. This study is focused on the medical laboratory network at Levels III, IV, and V.

A patient often seeks care at a facility such as Kisumu County Referral Hospital after first seeking care elsewhere. For this reason, it is considered a “referral hospital” [65]. In order to fully appreciate the role of a county-level health laboratory within the Kisumu County-wide health laboratory network, the following figure is a visual model of that organizational structure and the path of referral for a patient seeking care in the Kisumu East Subcounty of the Kisumu County Health System:

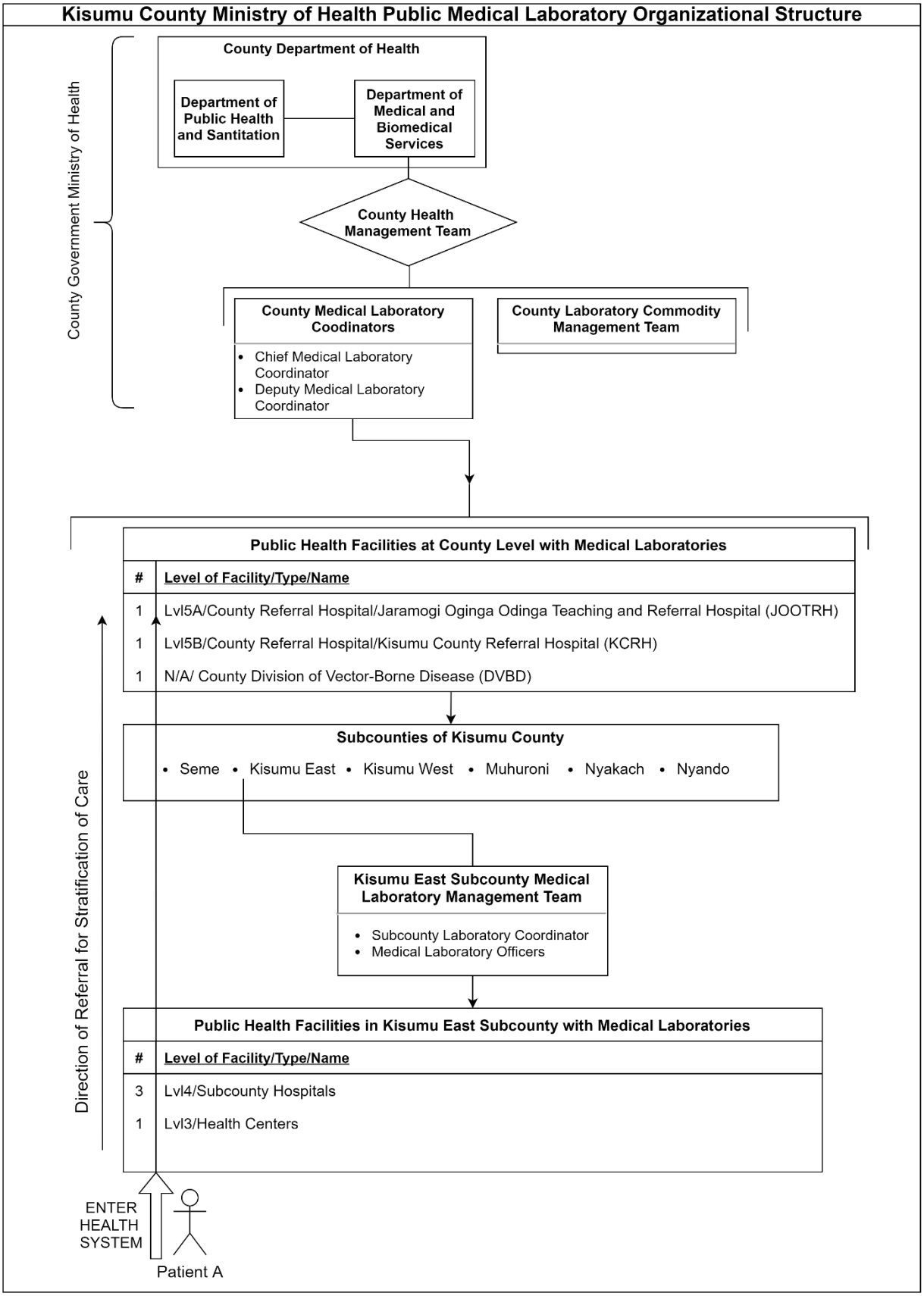

Figure 3: The tiered organizational structure of Kisumu County public health facility laboratories and the referral path for a patient starting from the periphery of the health system. Source: Author, Principal Investigator, Kelly Allen, 2021.

Kisumu County Referral Hospital is a Level V referral facility in Kisumu County with

158 patient beds and 15 specialty departments. In 2021, its catchment population contained an estimated 33,564 people (17,118 female; 16,446 male) with an average monthly outpatient attendance of 5,881 patients (3,174 female; 2,707 male). KCRH began uploading electronic health data to the National DHIS-2 in late 2017. It received a grant to implement an eLIMS in 2018. This system was active until the grant ended in 2020, at which point the laboratory returned to a paper-based system. In January of 2022, the county government and hospital administration successfully contracted to have the eLIMS system revived.

As a Level V referral facility, the health laboratory in KCRH is mandated to perform the following essential diagnostics[65]:

Parasitology
Stool Microscopy
Blood Slide Malaria Microscopy
Haematology
Haemoglobin level estimation
Sickling Test
Total WBC Count
Peripheral Blood Film
Differential Count
Platelet Count
Reticulocyte Count
MCHC
Bleed Time
Prothrombin Time
ESR
PTT
HB electrophoresis
Lupus Erythromatosus
Blood Transfusion Services
ABO grouping
Rh Typing
Histology/Cytology
Pap Smears
Aspirates
Biopsies
Electrophoresis
Immunology/Virology
CD4/CD8
Viral Load
EID

Bacteriology/Microbiology
Gram staining
Wet preparation
H. pylori
Stool, urine, blood, CSF, aspirate cultures
Pus swabs
Drug sensitivity testing
Semen analysis
Skin snip for OV
AFB Microscopy
Genexpert
Mycology
Salmonella Antigen
Brucella
Clinical Chemistry
Blood Glucose
Urinalysis (Chemistry +Microscopy)
Liver Function
Renal Function
Serology
Pregnancy testing
Syphilis
HIC rapid testing
Rheumatoid factor test
Widal Screening
ASOT
HBV screening
HCV screening

Study Population:

In 2022, Kisumu County has an estimated population of 1,358,837 constituents (up from 1,193,103 in 2017) with a life expectancy at birth of 61years for females and 58years for males, as compared to the national average of 66 years and 61years, respectively [21]. The county has a Malaria caseload of 46,444/100,000 and a Malaria positivity rate of 45%, as compared to a national average of 20,252/100,000 and 41%, respectively. It also has a diagnosed UTI caseload of 3,372/100,000 [53].

Kisumu County employs an estimated 177 health laboratory personnel in the public laboratory network, 345 short of the required staffing need. Of these, the KCHLSP states that 64% are employed by Government of Kenya, 32.3% by Donor

Partners, and 3.4% by communities [65]. The key informant interview portion of this study seeks to interview 13 “Senior” health laboratory personnel. This study defines "senior" personnel as having managerial roles in the facility they currently work or having worked in their current facility for at least 3 contiguous years.

This excludes any managerial personnel that has worked in their current role for less than 6 months. This study excludes any officers working in Dispensaries since few dispensaries in Kisumu County have digital health information management systems and often only one laboratory personnel. Thus, scheduling interviews with these laboratory officers would require them to apportion time away from patients or close the laboratory in order to meet with me. We deem this an undue burden on the participant. For that same reason, we do not conduct more than three interviews within one facility, including KCRH. Gender is used as a sociodemographic variable in the Key Informant Interviews to assess whether the share of males to females in health laboratory roles reflects the current national trends including employment and income gaps.

The Observation Guide of this study looks first at the rate, ratio, and types of test orders that come to the health laboratory in paper versus electronic form. This rate sampling takes place for one hour in the morning and one hour in the afternoon on workdays evenly distributed across the work week and occasionally on weekends. This method is designed to capture variations in patient attendance. The event sampling portion of the Observation guide collects observations of how hospital personnel interact with the eLIMS system in order to complete necessary diagnostic tasks and then reflects on these observations with the hospital laboratory officer. In order to limit the intrusiveness of this portion of the study, event sampling will collect a maximum of three event samples per work day.

Sampling Procedure:

For the Key Informant Interviews, this study will begin by listing all levels three, four, and five Ministry of Health-owned health facilities in Kisumu County. It will cluster facilities by sub-county and randomize within the sub-county using Excel “Rand” function to ensure limited bias in facility selection. An initial round of sampling will select two facilities per sub-county and confirm with the Kisumu County Laboratory Coordinator whether those facilities have functioning health laboratories and available staff for interview. A review of the selected facilities will also confirm that the selected facilities conform to the external validity requirements of the study. In other words, if necessary, a second round of sampling by sub-county will be performed to reach sample size and required number of facilities by facility level[74]**.** We will request from the Kisumu County Laboratory Coordinator the contacts of senior public health laboratory personnel that meet the study inclusion criteria at the Ministry of Health County and Sub-County Laboratory level and at all Public health facilities at the Health Center, District Hospital, Sub-County Hospital, and County Referral Hospital levels. Key informant interview eligibility criteria includes those who:

1. Work for the Kisumu County Department of Public Health as a senior public laboratory professional in a Tier II, III or IV facility (Health Center, Suc-County Hospital, District Hospital, or County Referral Hospital) or at a County or Sub-County Ministry of Health Office.
2. This study defines “Senior Professional” as: “Someone whose main role in the laboratory of interest is managerial, or who has worked in this laboratory for more than 3 continuous years.”
3. The participants must be willing to commit the time requirements for participation in this study.

This study requires a minimum of two interviews from personnel at each level of the public health system and a maximum of 4 interviews from the same level. Additionally, we will ensure that at least each of the seven sub-counties in Kisumu County receives at least one interview. This aims to increase the external validity of the interview findings for the Kisumu County-wide public laboratory network, as well as protect participant privacy**.** For interviews within KCRH, these will be selected and approved by the hospital administrative team based on their needs.

As part of the Observation Guide, we will perform both event sampling and rate sampling. The event sampling will focus on a select list of possible ELIMS-related events in the KCRH medical lab. We do not randomize these events by time of day or event priority. However, we do randomize them by day of the week in order to capture variations in laboratory functions such as high patient-flow days and low availability of hospital and laboratory staff to support laboratory functions on weekends. The rate sampling collects data for one hour in the morning and one hour in the afternoon to capture variations in patient flow and clinician office hours throughout the day. This is particularly important in Western Kenya where women tend to access care in the morning and men tend to access care in the afternoon.

For quantitative data collection, we are selecting laboratory key indicators that are indicated by the Clinical and Laboratory Standards Institute as indicative of quality diagnostic service [63]. For Malaria diagnostics, we are comparing Presumptive Malaria Diagnosis to Confirmed Malaria and Number of Malaria tests and overall diagnostics ordered per patient over time. For Urinary Tract Infections, we are comparing the prevalence of UTI diagnosis with the number of Urine Microscopy tests versus Urine Chemistry tests. Additionally, we chose the time frame starting from January 2018 corresponds with when KCRH began uploading their aggregate hospital data into the DHIS-2. This is also before the initial purchase, install, integration, and training for the Electronic Laboratory Information Management System (eLIMS) at Kisumu County Referral Hospital (KCRH) in 2018. We choose to analyze the data for the full 5 years from January 2018 to present in order to properly adjust for data gaps and major events such as the Universal Healthcare Pilot in 2018 and the Covid-19 Pandemic till the present. We will analyze the same data sets from October to November 2022 to correspond with the observational study that will be done within the laboratory.

Data Collection:
The quantitative portion of this study analyzes hospital-wide data for KCRH from the DHIS-2 Kenya national health statistics reporting system. Some of this data sets and variables of interest include children under the age of 18 years. These data sets are de-identified before uploading into the DHIS-2 and supplied as aggregate facility-level data. This data will be uploaded first to Excel for data cleaning and cross-checking. Then it is analyzed using statistical software. This portion of the study does not interact with children or patients directly. All observational and interview data focuses on medical laboratory personnel.

The Qualitative portion of this study will conduct 13 key informant interviews with County Government Ministry of Health Officials and Laboratory Officers in Public Laboratories, including KCRH. These will be selected using the process explained in "Sampling Procedure"**. Interview participants can decline to be recorded at any time during the interview**. During the consent process, all participants will receive a unique identifier (ID) using a randomly assigned number from a random number generator. This

ID will protect the participants' identity and ensure anonymity. All notes will be transcribed on the interview and observation guides. These interviews will cover aspects of public health laboratory and laboratory network function in Kisumu County such as staffing, testing, and facility capacity, laboratory consumable supplies, equipment challenges, funding, and the role of donor "Partners" in connection to quality diagnostic services. These interviews are expected to last no more than two hours each and can be broken up into two meetings if necessary. An observation portion will also collect observations of laboratory function through an observation guide in the KCRH laboratory. This study asks observational respondents to allow the researcher to observe them and functions within the lab. During each of these sessions, the participants will also receive a unique identifier using a randomly assigned number from a random number generator. This ID will protect the participants' identity and ensure anonymity. It also includes debriefing interviews with the KCRH managerial staff to reflect on the observations and their place in context within time, culture, and place. Thus, debriefing interviews ask that KCRH managerial staff give one hour of their time at the end of observational data collection days for a maximum of two days a week and between one and two weekend days in a month. This is estimated to total at 12 observation days and must ensure that each "Event Category Variable" is observed a minimum of two times.

The principal investigator (PI) will conduct the interviews themselves in the laboratory officials' offices or their office of preference. The interviews will be in English, an official language of Kenya and spoken fluently by almost all government officials and public laboratory personnel in Kisumu County. Meetings will be scheduled at the convenience of the official but held within the place of work to keep the setting professional.

Variables, Measures, and Definitions:

Objective #1:

Inclusion criteria for this portion of the study requires that the participant be a "Senior" health laboratory personnel. This study defines "Senior Professional" as: "Someone whose main role in the laboratory of interest is managerial, or who has worked in this laboratory for more than 3 continuous years."

Key Information Interviews collect data on the following variables in order to determine normal distribution, ensure participants meet the study inclusion criteria, and for analysis of qualitative data collected:

- Sex
- Age
- Highest level of education attained (and degree focus)
- Length of time in service as a health laboratory professional
- Length of time in service as a senior lab professional in the current capacity:
- Current average monthly income in this capacity
- Type of employment
- The Health Facility Level they currently serve in (as defined in the "Study Setting" section above)

For Objectives #2-#5:

Data on "Population Estimates" and "Inpatient" and "Outpatient Attendance" by month for Kisumu County Referral Hospital from January 2018 through December 2022 are used as controls for variables selected. This data comes from the DHIS-2 form: "Population Estimates for Facility and Ward".

Objective #2:

The Observation Guide Rate Sampling portion uses the test labeling scheme used on

form MOH706 Laboratory Summary Reporting to list types of tests ordered and sub-categorize them into “paper order” or “electronic order”. “Electronic Order” is defined as: “A test that arrives at the laboratory through the HIMS-eLIMS system”.

Objective #3:

This study accesses de-identified aggregate data on Turn-Around-Time, reagent waste, reagent stock-outs, Total laboratory tests performed versus “Outpatient” and “Inpatient attendance” and service interruptions from KCRH laboratory reports, "MOH 105 Service Delivery", "MOH 705 A Outpatient Summary", "MOH 717 Service Workload", "Population Estimates for Facility and Ward", “MOH706 Laboratory Summary Reporting”, "UHC-303-Tracer Diagnostics" and "UHC-302-Tracer Non-Pharmaceuticals” forms across time from 2018 to December 2022.

Objective #4:

This study accesses de-identified aggregate data from the DHIS-2 on “Presumptive” and “Confirmed” Malaria diagnosis for all age groups attending KCRH between January 2018 and December 2022. This study defines “presumptive Diagnosis” of Malaria as a clinical diagnosis without the use of confirmed laboratory diagnostics. This study defines “over-diagnosis” as ratio of “confirmed diagnosis” to “presumptive diagnosis” less than one. It assumes an inverse relationship between “overdiagnosis” of Malaria and this ratio. This data will come from the following data forms: "AWP Monthly Service Delivery", "Hospital Administrative Statistics", "Inpatient Activities", "Malaria Commodity Dashboard", and "MOH 743 Malaria Commodities".

Objective #5:

This study accesses De-identified aggregate data from the DHIS-2 on total “Urinary Tract Infection” diagnosis versus “Urine Microscopy” defined as “Leukoctye” diagnostic test and Urine Chemistry defined as: “Ketone”/ “Protein” diagnostics tests performed. This data comes from the following forms: "MOH 105 Service Delivery", "MOH 705 A Outpatient Summary", "MOH 717 Service Workload", and MOH706 Laboratory Summary Report

Objective#6:

The Observation Guide Event Sampling portion observes and categorizes laboratory activities that fall into the following categories:

A. On-going training of personnel in use of the eLIMS
B. Initial training of new personnel on use of the eLIMS
C. Troubleshooting issues related to the eLIMS
D. Generating and disseminating laboratory internal reports
E. Generating and disseminating external reports
F. Managing laboratory-related equipment performance
G. Communicate with other hospital clinics and departments
H. Manage diagnostic turn-around-time
I. Performing internal diagnostics results validating procedures
J. Managing laboratory reagent stocks

Then it collects observations about the difficulty of the task, number of individuals involved in completing the task, number of hospital departments involved in completing the task, length of time needed to complete task, the ways in which the eLIMS was used to complete the task, and observed behaviors of participants as they interact with the eLIMS. These observations focus on ways in which the eLIMS eases the challenge of completing diagnostic quality-related laboratory tasks and out-standing difficulties that staff encounter while using the eLIMS.

Data Storage and Management:

Before collecting data, all participants, consent forms, data collection forms and aggregate data from laboratory reports and DHIS-2 data sets will be de-identified of

patient, laboratory reporting officer and participant personal identifiers. The Key Informant Interview and Observation Guide have their own individual consent forms labelled (respectfully): “Participant Informed Consent Form” and “Facility Informed Consent Form”. The only location identifier that will be retained is the Kisumu County Referral Hospital for related data. Each data collection day, at end of day all data **and notes** will be visually inspected and cross-checked by research team for quality. Within 5 days of data collection, data from the Key Informant Interviews and Observation Guide will be uploaded to the Principal Investigator’s Computer and two research assistants’ computers where it will be cleaned, cleaned processed and analyzed. All three computers are password-protected and not shared with any other parties. Data from the Key Informant Interview Guide and the Event Sampling Portion of the Observation Guide will be uploaded into a qualitative statistical program.
After data analysis is complete, all study-related files will be expunged from research assistant/consultant computers. Consent forms and data collection forms will be stored together at the School for International Training campus in Milimani, Kisumu for five years for audit purposes. The custodians of these files shall be Dr. Vincent Were, study advisor. After this time period, they will be destroyed. To protect the digital data, all computers will use anti-theft and anti-virus software packages and are password-protected.

Data Analysis

Objective#1:

Data collected through the Key Informant Interview Guide will be verified for quality and then uploaded to three computer databases. These include the Principal Investigator’s computer, and two research assistant computers. The data will be coded for themes and analyzed using Nvivo version 12® to perform thematic qualitative analysis for distribution, median, mean, and rate by themes and social demographic cases listed in Objective#1 “Variables, Measures, and Definitions” above.

Objective#2:

Data collected for this objective will follow the Rate Sampling portion of the Observation Guide and be transcribed manually onto the Observation Guide at each data collection period. After being de-identified of personally identifiable information and verified visually for quality, this data will be uploaded to three computer databases. These include the PI and two research assistants. The data will be pre-coded by the data collection form using the MOH706 Laboratory Summary Report coding system (on the Observation Guide) and analyzed using Stata software for distribution, mean, rate, and trends over time. “Population Estimate by Facility” by month reported from the DHIS-2 from form “Population Estimates by Facility and Ward” and “Inpatient” and “Outpatient Attendance” by month reported from the DHIS-2 from form "MOH 105 Service Delivery", "MOH 705 Outpatient Summary", "MOH 717 Service Workload" will be used as control variables for analysis.

Objective #3:

Data for this study will first be downloaded from the DHIS-2 to the PI’s computer and loaded into Excel software. The data will be cleaned and cross-checked across reporting forms for completeness and accuracy. Once complete, the data will be shared with two research assistants where it will be stored on their computers for processing. Data will be analyzed using Stata Software for distribution, trends over time, logarithmic regression to determine correlative relationships between variables, and “Difference-in-Differences” approach to explore the impact of the eLIMS implementation on variables [75]. “Population Estimate by Facility” by month reported from the DHIS-2 from form “Population Estimates by Facility and Ward” and “Inpatient” and “Outpatient

Attendance" by month reported from the DHIS-2 from form "MOH 105 Service Delivery", "MOH 705 Outpatient Summary", "MOH 717 Service Workload" will be used as control variables for analysis.

Objective #4:

Data for this study will first be downloaded from the DHIS-2 to the PI's computer and loaded into Excell software. The data will be cleaned and cross-checked across reporting forms for completeness and accuracy. Once complete, the data will be shared with two research assistants where it will be stored on their computers for processing. Data will be analyzed using Stata Software for distribution, trends over time including logarithmic regression for correlative relationships between variables, and "Difference-in-Differences" approach to explore the impact of the eLIMS implementation on variables [75]. This analysis will stratify the data by age group (<5 years; 5-18 years; >18years) and compare the testing time of year to the typical rainy seasons and Malaria positivity rates in Nyanza [56]. "Population Estimate by Facility" by month reported from the DHIS-2 from form "Population Estimates by Facility and Ward" and "Inpatient" and "Outpatient Attendance" by month reported from the DHIS-2 from form "MOH 105 Service Delivery", "MOH 705 Outpatient Summary", "MOH 717 Service Workload" will be used as control variables for analysis.

Objective #5:

The data will be cleaned and cross-checked across reporting forms for completeness and accuracy. Once complete, the data will be shared with two research assistants where it will be stored on their computers for processing. Data will be analyzed using Stata Software for correspondence between urine microscopy and urine chemistry tests including distribution, trends over time including logarithmic regression for correlation. Finally, it will use a "Difference-in-Differences" approach to explore the impact of the eLIMS implementation on variables[44], [75].

Objective #6

Data collected through the Event Sampling and associated Key Informant Interviews from the Observation Guide, after being de-identified of personally identifiable information and verified for quality, will be uploaded to three computer databases. These include the Principal Investigator's computer, and two data research assistants' computers. The data will be coded for themes and analyzed using Nvivo version 12® to perform thematic qualitative analysis for distribution, median, mean, and rate by themes and by "Event Category" variable listed in Objective#6 "Variables, Measures, and Definitions" above. Interview reflections will be coded by themes, stratified by "Event Category Variable", and analyzed using Nivo version 12® software for distribution, median, mean, and rate.

Selection and Training of Study Team:

All study team personnel, including the Principal Investigator, research assistants, and advisor have current ethics training certificates as well as training in qualitative and quantitative data collection and analysis techniques. They are also trained in use of Excel, Nvivo and Stata.

Ethical Considerations:

This study protocol will first seek IRB ethics approval by the Principal Investigator's university, the School for International Training. Then it will seek ethics review and approval through Maseno University Ethics Review Committee.

Potential Harm and Risks and Overview of Mitigation Measures:

The participants in the Key Informant Interviews may experience embarrassment over questions that might reveal practices divergent from official policy. In order to limit the risk of respondent

discomfort or embarrassment, we will reassure them that they can skip any interview questions they do not feel comfortable answering and can end the interview and their participation in the study at any time. **Participants can request that the interview not be recorded at any time.** Further, to protect the professional interests of the respondents I ask in the consent process that the interviews be arranged to maximize their comfort and privacy while still being held in their office of work. This location should be as private and free of distractions as reasonably possible. Participants may risk their professional standing by giving the time commitment to participation. Key informant interview participants can request that the interview meetings be broken up into two shorter meetings to mitigate interference with their work schedule. The consent process will discuss the time commitments for participation in the study and ensure the participants are fully aware of and willing to meet those commitments before consenting or re-consenting to participation. The participants may have their professional standing impaired by being associated with a particular facility or location of poor reputation. To protect this, this study requires a minimum of two interviews from personnel at each level of the public health system and a maximum of 4 interviews from the same level. Additionally, we will ensure that at least each of the seven sub-counties in Kisumu County get at least one interview. This study will not conduct more than three interviews in one facility. This will help to protect the time constraints of the participants and the facility. It will also protect the privacy of the facility by spreading the data collection across a broad geographic and administrative region. The observational portion cannot guarantee the confidentiality of behaviors performed in groups or public areas where the respondent cannot expect to have privacy. However, we will also ensure through debriefing interviews of the observational process that event sampling is appropriately captured. In order to protect the professional integrity of the KCRH hospital, the quantitative portion of this study will analyze the correlation between events and lab key indicators and publish only functions of correlation. It will not publish lab performance measures alone or in comparison to official standards. It will not publish the name of Kisumu County Referral Hospital. The Key Informant interviews and Observation guide do not collect information on facility names, respondent names, or other personally identifiable information. All study documents will be kept in The PI's personal safe or on their person and not discussed outside of study-related collaborations with investigators or advisors. Any digital documents with personal information are kept on the PI's personal computer with a keyed authentication lock. Emails with official documents will be sent through the PI's School for International Training official account for security. Before disseminating reports of the study findings to the participants, we will review them carefully with study advisors to ensure the reports are culturally appropriate.

Informed Consent:

We will collect written consent forms from all participants of key informant interviews and the observation study as part of the observational study. This study contains two different consent processes and forms. First, the consent form titled "Participant Informed Consent" will be used for the Key Informant Interviews. The consent form titled "Facility Informed Consent" will be used for the observation study and guide at KCRH. Initial written consent will be taken from individual respondents for the key informant interviews and initially with the KCRH laboratory for the Observational study. The observational guide study consent will be signed by the KCRH laboratory manager. Re-consents for key informant interviews must be obtained when the interviews must be broken into two meetings. The re-consent must be obtained at the second interview meeting before beginning. Re-consent for the observational process must be done each morning and afternoon of observation days after the initial written consent. These re-consents must be obtained from the KCRH Laboratory manager. All consent forms will use unique identifiers (ID) linked to the associated data collection forms. These IDs will use random numbers generated

at the time of consent from a random number generator on a smart phone. For the observational portion of the study, we will first gain consent from the County Director of Public Health and the County Medical Laboratory Coordinator for the study protocol.

For the key informant interviews, we will send via email or personal copy an invitation to participate and the consent agreement. During the interview, we will obtain written consent. We will ask for written consent after they have reviewed the consent agreement and we are meeting in-person.

We will ensure participant understanding of the objectives and procedures of the study through several initial contact events. This gives them time to review the risks, any discomfort they might experience from answering the questionnaire, or agreeing to the observational study. We will do everything in our power to work within whatever location and time would be most convenient for the participants for the internship and interviews. We will make it clear that a participant, or the case of the attachment the hosting laboratory director, can end an interview or observational study at any time and reschedule or withdraw from the study without implications for their jobs or the study.

Confidentiality:
For the quantitative data collection process and desk review, approval for credentials to access the DHIS-2 aggregate database will be sought. Data within the DHIS-2 will be de-identified of personal information and accessed in the aggregate form to make it anonymous. During presentation of these findings, only aggregate variables of interest to the study will be presented.

For the qualitative data collection process, we will not contact any interview participants outside of their official means of contact. All contact information will be kept confidential on the PI's phone and only used for purposes of follow-up and interview scheduling. The Key Informant interviews and Observation guide do not collect information on facility names, respondent names, or other personally identifiable information. Each respondent will receive a unique identifier that is assigned using a random number generator on a smartphone. In this way, the consent forms, interview guides, and observation guides begin by de-identifying the respondents and not collecting any personal information that might identify them as the respondents. All study documents will be kept in the PI's personal safe or on their person and be kept confidential outside of study-related collaborations with investigators or advisors. Any digital documents with personal information are kept on the PI's personal computer with a keyed authentication lock. Emails with official documents will be sent through the PI's School for International Training official account for security.

Any data collected will be used for a final Capstone paper and may be published. Before I disseminate reports of the study findings to the participants, we will review them carefully with study advisors to ensure the reports are culturally appropriate and devoid of any personally identifiable information. Additionally, we only report themes that are common to all interviews in the background information for the quantitative study. This study will not publish directly the laboratory performance indicators of Kisumu County Referral Hospital. All activities and notes for the observational study will be reviewed by the study advisor twice a week to ensure a backup protection for proper protocol adherence.

The key informant interview questionnaire will not collect data on names, official titles, phone numbers or similar personal information that could be linked back to the respondent. Each interview receives a randomly generated unique identifier that is generated on a smartphone with a

random number generator app at the beginning of the interview process. This code will be used to link consent forms and interview data together and analyze the data while maintaining the privacy of the respondent in relation to the data. While we will refer to the study location as Kisumu County in the final report, there are 18 Sub-County Hospitals and 31 Health Centers in Kisumu County. Since we are collecting 13 interviews that must have at least one interview in each of the seven sub-counties, and we will not report the locations covered by the study interviews, this will limit the ability of anyone reading the final reports to identify the specific locations of the interviews. Additionally, this study only reports themes that are common to all interviews in the background information for the quantitative study. We will request that all data for the quantitative analysis be de-identified before delivery to me. We will receive the data in-person to protect from security breaches via email.

To protect the facility participants during the observational study, we will not collect observations of personal behaviors, performance, qualifications, or other characteristics that personnel in the facility could reasonably expect to remain private. We will not collect personally identifiable or medical information on any patients.

Since there are only two public health facilities in Kisumu that have a working eLIMS and since the timeline of the install of the eLIMS at Kisumu County Referral Hospital is unique, we cannot reasonably expect the name of Kisumu County Referral Hospital for the quantitative data analysis to be truly anonymous. For this reason, this study will not report on the specific performance or audit ratings of the hospital's laboratory. Rather it will report on the correlative relationship between the eLIMS install investment and the key indicators as a function of the impact of the investment.

No elements of identity, titles, education, or qualifications will be published for the qualitative interviews.

Intellectual Property Considerations:
This study grants the Principal Investigator's university, SIT, permission to publish a capstone drawn from this study. All data collected through the DHIS-2 will be treated as property of Kisumu County. The Principal Investigator retains the right to publish the findings of this study.

Time Frame Duration of Project:
The data collection for this study is envisaged to begin in October 2022 or as soon as ethical clearance is obtained. This project will take place over 18 months starting in May of 2022 and ending in the last quarter of 2023. This study estimates that 12 work days will be required for the Observation Guide data collection and 16 work days for the Key Informant Interview data collection. 7 work days will be necessary for quantitative data collection and cleaning, and 15 work days will be necessary for data analysis. The following diagram illustrates the implementation stages of the study:

Study Timeline

May-July '22	Aug '22	Sept '22	Oct-early Nov'22	Nov-Dec '22	Jan '23	Feb-April '23	May-Dec '23
Protocol Development	Submit protocol to Principal Investigator's University IRB for Approval	Recieve SIT IRB approval; submit to Maseno University ERC for in-country external approval	Receive MUERC approval. Submit proposal to Kenya NACOSTI for research license approval. Engage with relevant Kisumu County stakeholders. Submit proposal to Kisumu County Health Department and Kisumu County Referral Hospital Administration for approval and declaration of support.	Data Collection, cleaning, processing, and analysis.	Final analysis and reports. Dissemination of reports to stakeholders. Submit study close-out report to MUERC and SIT IRB.	Write-up of manucript.	Publish of manuscript

PROJECT BUDGET

STUDY PROJECT BUDGET ITEMIZED

Principal Investigator	**Kelly W. Allen**	**Study Title**	**Exploration of the Implementation of an Integrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya**
Email	Kelly.allen@mail.sit.edu	**Study Time Frame**	May 2022-October 2023
Phone Contact	+254-0794581927	**Location**	Kisumu County, Kenya
Advisor	Dr. Vincent Were		
Email	vincentwere@gmail.com		

Expenses

Category	Dates	Details	Es
Personnel, Salaries, and Benefits			**$0**
Participant costs, travel, food, and supplies			**$0**
Major Equipment			**$0**
Operating Expenses, postage, printing		**Printing** **Participant Consent Forms 56 @$0.50** **Key Informant Interview Guides 13 @$0.50** **Observation Guides 12 @$1.50**	 **$28** **$6.5** **$18**

		Proposal Hard Copy Submission 1 @10	**$10**
Travel and Accommodation **Vehicle repairs, insurance**		**Study Work Days Travel to Kisumu 76 @$7** **Key Informant Interview Travel 16 @$15** **Accommodation**	**$523** **$240** **$0** **$0**
Consultancy Fees		**Quantitative Data Processing 4 Obj @ $150** **Qualitative Data Processing 2 Obj @ $200**	**$600** **$400**
Regulatory Fees		**Maseno University Ethics Review Non-Kenyan Master's** **NACOSTI Research Permit Non-Kenyan Master's**	**$100** **$350**
Institutional Administrative Overhead		**15%**	**$341.32**
Contingency		**15% for Inflation**	**$341.32**
Other			
		Subtotal Subtotal (Ksh)	**$2,958.15** **356,739Ksh**

JUSTIFICATION OF THE BUDGET:
The Principal Investigator resides outside of Kisumu and therefore must travel into Kisumu daily during the project timeline to engage with stakeholders, consultants, and to collect data. Days that involve Key Informant Interviews will require traveling out to each sub-county of Kisumu County. Thus, the transportation cost for those days is higher. Data processing will be charged by a consultant at a specific rate based on the type of data collected for each objective.

Role of Investigators:
The Principal Investigator (Kelly W. Allen) will be the lead investigator responsible for all data collection, ethics and confidentiality procedures, data analysis and write-up. Vincent Were will oversee data management and analysis. Violet Gisore will assist with qualitative data collection, processing, and analysis. Felix Okoth will assist with quantitative data collection, processing and analysis.

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Appendix I: Key Informant Interview Letter of Invitation to Participate

Attention:
Kisumu County government laboratory professional

Re: Request for your participation in an academic research project regarding public health laboratories in Kisumu County.

Principal Investigator
Kelly W. Allen
Graduate Student of Global Health
School for International Training, Kisumu, Kenya
Kelly.allen@mail.sit.edu
+254 0794581927

Project Advisor
Dr. Vincent Were
+254 721876573

Summary:
This research proposal seeks to study the complex factors that influence public medical laboratory function in Kisumu County. It performs ethnographic research through interviews with laboratory personnel in Kisumu County to add the context of events in time (such as the COVID-19 Pandemic) and how they impacted lab function. It is also interested in general laboratory functions and challenges.

For this purpose, the researcher humbly requests your willingness to host an interview on these topics. It will use the information from the interview to inform the interpretation of County-level public laboratory performance challenges and the benefits of investment in computer-based laboratory information management systems. This study is a part of my graduate studies in global health.

The title of this study is:
Exploration of the Implementation of an Integrated Electronic Laboratory Information Management System on Quality Diagnostic Service Indicators at a County-Level Public Hospital in Western Kenya

If you are willing to host an interview and participate in this study, please contact the principal investigator at the following:

Kelly W. Allen
WhatsApp: +254 0794581927
Email: Kelly.Allen@mail.sit.edu

Appendix II: Key Informant Interview Consent Form

PARTICIPANT INFORMED CONSENT FORM

Title of Study: Exploration of the Implementation of an Integrated Laboratory Information Management System on Quality Diagnostic Service Indicators at a County-Level Public Hospital in Western Kenya

Investigators: Kelly W. Allen

Invitation to be Part of a Research Study

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate—please review it carefully. Research studies include only people who choose to take part—your participation is completely voluntary. You can decline to participate or have your previous participation withdrawn at any time without stated reasons.

Please ask the project staff any questions you have about the study or about this form before deciding to participate. Please retain this form for your records should you wish to review the information at a later time. You can request a copy of this consent form from the project staff at any time.

Introduction and Purpose of the Study

The purpose of this study is to learn about the challenges faced by public health laboratories to provide quality care in Kisumu County and study the role of computer-based health laboratory information tools in public laboratory work.

This study is part of my studies as a student in Global Health.

Eligibility to Participate

You are eligible to participate in this study if you work for the Kisumu County Department of Public Health as a senior public laboratory professional in a Tier II, III or IV facility (Health Center, Suc-County Hospital, District Hospital, or County Referral Hospital) or at a County or Sub-County Ministry of Health Office. This study defines "Senior Professional" as: "Someone whose main role in the laboratory of interest is managerial, or who has worked in this laboratory for more than 3 continuous years." You must be willing to commit the time requirements for participation in this study.

You should not participate if you do not meet the eligibility requirements, you cannot fulfill the time commitments of participation, you have worked in the laboratory of interest for less than six months, or you feel for any reason that participation in the study could jeopardize your professional standing or health.

To determine if you are eligible, we will only initiate contact with you if you have been identified to be eligible for the study. If we find that we have contacted you in error, we will remove your participation from the study after informing you of the mistake. If, after receiving the consent form, we do not receive consent or do not receive a response from you within one week, will remove you from study. This is intended to protect your right to personal privacy.

Description of Study Procedures

If you agree to participate, you will be asked to:

- Verbally verify your employment in a Kisumu County Health Center, District Hospital, Sub-County Hospital, County Referral Hospital or Ministry of Health laboratory position.
- Read and understand the goals of the study, the requested time allowance for your participation, and the risks you might encounter due to involvement in the study.
- Allow a study researcher to interview you on a topic related to your work in a Kisumu County public health laboratory at a time and location convenient to you.
- This study will ask questions about:
    - Your working environment
    - How samples are moved from laboratory to laboratory
    - The relationship between doctors and laboratory professionals
    - What factors do you find play a role in providing good test results on time.
    - Challenges you face in doing your assigned tasks related to the laboratory:
        - Equipment
        - Supplies
        - Facility
    - Ways in which you overcome these challenges

These interviews will inform a current study on public health laboratories in Kisumu County.

This study will not record the interviews. However, it will take down notes during the interview process. It is the goal of the study to understand your work and work-related challenges as best as possible.

Expected Time or Duration of Participation:

Your participation will last for 1 1/2 – 2 hours to complete the interview process, depending on how much information you wish to share.

This will occur at a time convenient to you at your office. Interviews can be broken up into two meetings for your convenience or rescheduled if necessary. It is important that the interview does not inconvenience you.

Risks or Discomforts

While we do not anticipate that you will experience discomfort during the interview process, you may experience the following:

- Privacy concerns
- Embarrassment when discussing politically sensitive topics
- Concerns over how the study might change your job

This study does not ask about your personal information or the location of where you work. The

interview will gain a randomly designated unique identifier that helps the researchers process the data, but is not linked to your or your facility names or personal information. The study is not connected to the government of Kisumu, a private company, or a "Partner", and any information that might personally identify you will be kept confidential to the research team. The interview should be arranged for a time and office that gives you maximum privacy and convenience. **You will be asked to consent for recording on the interview which you are free to decline without affecting the interview.** You may request that the interview be split up into two shorter meeting periods if you feel that that accommodates your work schedule best.

All findings of the study will be kept private and are intended to help the research student gain a better understanding of how public laboratory professionals in Kisumu County work to provide quality care.

After the information form this study is cross-checked, processed, and reported it will be destroyed. There may be risks or discomforts that we cannot foresee at this time. We will tell you about any significant new information we learn that may relate to your willingness to continue participating in this study.

Benefits to You and to Others

It is hoped that the information gained in this study will also benefit Kisumu County by identifying effective investments in public laboratory systems that help the Ministry of Health meet the Kenya National Health Sector Strategic Plan 2018-2023 Objectives.

You may not directly benefit from participation in this study.

Your Rights as a Research Participant

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. During the interview, you can skip any questions that you do not wish to answer. **You will be asked to consent for recording on the interview which you are free to decline without reason or without affecting the interview. You can request that the interview not be recorded at any time.**

You have a right to have your involvement in the study kept completely confidential through non-disclosure of any information that might reasonably identify you.

You may be concerned that any information given about "Donor" involvement in the lab may impact the "Donor" and your job. This study will not report on specific Donors or financial relationships between the Government of Kisumu and other organizations. Rather, it will ask some questions about the general role of Donor-involvement in public laboratory function.

- If you withdraw from the study early, your interview information will be removed from the study.
- We may end your participation in the study if we learn of an unanticipated risk to you or of a change in your eligibility for the study. You will be informed before we remove your participation.

Confidentiality

Research records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available without your permission. However, it is possible that other people and offices responsible for making sure research is done safely and responsibly will see your information. The School for International Training Institutional Review Board, research study supervisors, and Maseno University Ethics Review Committee may inspect and/or copy study records for quality assurance and data analysis. These records will not contain private information that can be directly linked back to individual participants.

Additionally, this study cannot guarantee the privacy of words or actions given in the presence of others or in public spaces.

To protect the confidentiality of the study records and data, the following measures will be taken:

- This study does not ask about your personal information or the location of where you work. While the interview should be held at your place of work, that information is not taken down during the interview or connected to the information gained.
- Your interview will receive a unique identifier in place of your name and work location so as to keep that information private to you alone. This code is a randomly generated number placed on the consent form and interview data linked to your interview. No voice recordings will be taken during the interview. Written notes from the interview will be kept confidential.

To protect your confidentiality when the results of the study are reported, the following measures will be taken:

The reports will go through a series of reviews with the necessary ethics review committees to ensure the anonymity of the results. In cases where you report either abuse/neglect of a minor or dependent adult, or the imminent threat of harm to yourself or others, we may have to break confidentiality by notifying the appropriate authorities to assure the safety of you and others.

Future Use of Your Information

Information about you collected for this study will not be used in any future studies or shared with other researchers for use.

Questions

You are encouraged to ask questions at any time during this study. For further information ***about the study,*** contact Kelly W. Allen +254 0794581927; Email: Kelly.allen@mail.sit.edu; and Research Supervisor Dr. Vincent Were +254 721876573

Your Consent

Is this a re-consent? Yes/No Written Consent Given: Yes/No Verbal Consent: Yes/No
Interview Code:

Date: Signature:

Appendix III: Observational Study Consent Form

FACILITY INFORMED CONSENT FORM

Title of Study: Exploration of the Implementation of an Integrated Laboratory Information Management System on Quality Diagnostic Service Indicators at a County-Level Public Hospital in Western Kenya

Investigators: Kelly W. Allen

Invitation to be Part of a Research Study

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate—please review it carefully. Research studies include only people who choose to take part—your participation is completely voluntary. You can decline to participate at any time without stated reasons.

Please ask the project staff any questions you have about the study or about this form before deciding to participate. Please retain this form for your records should you wish to review the information at a later time. You can request a copy of this consent form from the project staff at any time.

Introduction and Purpose of the Study

The purpose of this study is to learn about the Electronic Laboratory Information Management System (eLIMS) that is used in the Level 4 and above public health facilities in Kisumu County and its relationship to laboratory quality service delivery.

This study is part of my studies as a graduate student in Global Health.

Eligibility to Participate

This study seeks to perform an observational study that uses an eLIMS to manage its laboratory functions. You are eligible to participate in this study:

- You are a Public Health Laboratory Manager that can consent for observational research done within your lab.
- You work in a public health laboratory in Kisumu Couty that uses an eLIMS.

You should not participate if your laboratory does not meet the eligibility criteria or you feel for any reason that participation in the study could jeopardize the professional standing of your laboratory or the wellbeing of personnel and patients using the laboratory.

To determine if you are eligible, we will only initiate contact with you if you have been identified to be eligible for the study. If we find that we have contacted you in error, we will remove your participation from the study after informing you of the mistake. If, after receiving the consent form, we do not receive consent or do not receive a response from you within one week, will remove you from study. This is intended to protect your right to personal privacy.

Description of Study Procedures

If you agree to participate, you will be asked to:

- Verify that the laboratory under study meets the inclusion criteria.
- Read and understand the goals of the study, the requested time allowance for your participation, and the risks you might encounter due to involvement in the study.
- Allow a study researcher to observe operations in the laboratory of interest two times a week and occasionally on a weekend and interview your lead hospital personnel about laboratory operations in relation to the eLIMS. These interviews will involve exploring observations made by study investigators during specified periods of time in the laboratory.
- This study will ask questions about use of the eLIMS in relation to the following laboratory management task:
    - On-going training of personnel in use of the eLIMS
    - Initial training of new personnel on use of the eLIMS
    - Troubleshooting issues related to the eLIMS
    - Generating and disseminating laboratory internal reports
    - Generating and disseminating external reports
    - Managing laboratory-related equipment performance
    - Communicate with other hospital clinics and departments
    - Manage diagnostic turn-around-time
    - Performing internal diagnostics results validating procedures
    - Managing laboratory reagent stocks
- Observation times will occur on a maximum of two weekdays and at least one weekend day in a month. Observation times will take place between 9am and 4pm.

These observations and interviews are part of a larger study comparing key laboratory quality diagnostics indicators with the implementation and integration of electronic health data systems in Kisumu County.

This study will not record the interviews and observation periods. However, it will take down notes. It is the goal of the study to understand your work and work-related challenges as best as possible.

Expected Time or Duration of Participation:

This study requires 4 hours per day, two days a week from Monday to Friday and between one and two weekend days in a month for data collection. This study requires One hour in each data collection day of your time for interviewing and debriefing of the data collection process. The estimated number of needed Observation days is twelve. However, this may be less or more depending on the quality of the observational opportunities and scheduling availability of the lab. This study will run from during the last two months of 2022.

This study will rotate data collection days across the days of the week over the course of the data collection time period to ensure that weekly fluctuations in laboratory functions are captured. It is important that the data collection process does not inconvenience your laboratory.

Risks or Discomforts

While we do not anticipate that you will experience discomfort during the study process, you may experience the following:

- Privacy concerns
- Embarrassment when discussing politically sensitive topics
- Concerns over how the study might change your job

While interviews will occur at your place of work, this study does not ask about your personal information. The study is not connected to the government of Kisumu, a private company or a "Partner".

All findings of the study will be kept private and will not be shared with anyone outside the project. Before final reports are disseminated, the researcher will review the results with the laboratory director to ensure appropriate protections for the privacy and well-being of the lab. Daily debriefings over observational data collection are intended to give the laboratory director an opportunity to review the study and re-consent to their lab's participation in the study. While the observation does not collect information on the names, or personal details of patients or lab personnel, the study cannot guarantee the confidentiality of behaviors observed in public or shared spaces.

The study is intended to help the research student gain a better understanding of how public laboratory professionals in Kisumu County work to provide quality care. After the information form this study is cross-checked, processed, and reported it will be destroyed. There may be risks or discomforts that we cannot foresee at this time. We will tell you about any significant new information we learn that may relate to your willingness to continue participating in this study.

Benefits to You and to Others

It is hoped that the information gained in this study will also benefit Kisumu County by identifying effective investments in public laboratory systems that help the Ministry of Health meet the Kenya National Health Sector Strategic Plan 2018-2023 Objectives.

Your Rights as a Research Participant

1. Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences.
2. During the debriefing interviews, you can skip any questions that you do not wish to answer.
3. During observations, participants can end observation of the task for any reason.
4. You have a right to have your involvement in the study kept completely confidential through non-disclosure of any information that might reasonably identify you.
5. We may end your participation in the study if we learn of an unanticipated risk to you or of a change in your eligibility for the study. You will be informed before we remove your participation.

Confidentiality

Research records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available without your permission. However, it is possible that other people and offices responsible for making sure research is done safely and responsibly will see your information.

The School for International Training Institutional Review Board, research study advisors, and Maseno University Ethics Review Committee may inspect and/or copy study records for quality assurance and data analysis. These records will not contain private information that can be directly linked back to individual participants. However, the study site, Kisumu County Referral Hospital, will be linked to the documents.

Additionally, this study cannot guarantee the privacy of words or actions observed in the presence of others in the laboratory or in public spaces.

To protect the confidentiality of the study records and data, the following measures will be taken:

- Each data collection event will give participants a unique identifier so as to keep their personal information private to them. This study does not collect information about your or any lab personnel's personal information such as name, phone numbers or place of residence.
- All data collected through official MOH documents will be de-identified of all patient or officer's personal information.

To protect your confidentiality when the results of the study are reported, the following measures will be taken:

- The reports will go through a series of reviews with the necessary ethics review committees to ensure the anonymity of the results.
- Daily debriefings over the observational data collection will give the Laboratory to re-consent to participation and review the privacy procedures of the study.

In cases where you report either abuse/neglect of a minor or dependent adult, or the imminent threat of harm to yourself or others, we may have to break confidentiality by notifying the appropriate authorities to assure the safety of you and others.

Future Use of Your Information

Information about you collected for this study will not be used in future studies or shared with other researchers.

Questions

You are encouraged to ask questions at any time during this study. For further information ***about the study,*** contact Kelly W. Allen +254 0794581927; Email: Kelly.allen@mail.sit.edu; and Research Supervisor Dr. Vincent Were +254 721876573

Your Consent

Re-Consent: Yes/No
Written Consent Given: Yes/ No

Signature: Date:

Appendix IV: Key Informant Interview Questionnaire

Key Informant Interview Guide for Senior Public Health Laboratory Professionals in Kisumu County

Instructions: This interview guide must be accompanied by a matching, signed participant consent form. Verbal consent can be taken by the researcher if the respondent prefers this to written consent. This interview guide requires probing skills and provides probing options as "Examples:" (shortened as "Ex:"). Note that some questions have special topics specific to county and sub-county Ministry of Health MOH health officers (ex: Sub-county Laboratory Coordinator). The investigator should keep in mind the recommendations for improvement provided by the participant for gaps indicated. The interviewer does not need to follow the interview questions in order. However, the interview should not last more than 2 hours. The interview can be broken up into two sessions with the consent of the participant and after gaining a second re-consent before starting the second session.

1. Gender (circle one): Male / Female 2. Age:
3. Highest level of education achieved (and degree focus):
4. Length of time in service as a health laboratory professional:
5. Length of time in service as a senior lab professional in the current capacity:
6. Current average monthly income in this capacity (circle one range):

15,000Ksh and Below
16,000Ksh-25,000Ksh
26,000Ksh-35,000Ksh
36,000Ksh-45,000Ksh
46,000Ksh-55,000Ksh
56,000-65,000Ksh
66,000-85,000Ksh
86,000-100,000Ksh
100,000Ksh+

7. Employment Status (circle all that apply):
   Locum / Temporary / "Partner" / Contract / Full-time / Permanent

8. Level of Health Facility/capacity within the Kisumu County Public Health system where you currently work (circle one):

Level II Dispensary / Level III Health Center / Level IV County& Sub-County / Level V JOOTRH / MOH (Sub-County) / MOH (County)

9. Is this facility a Tuberculosis test-processing facility: Yes/No

10. What is the Administrative Structure above and below your laboratory?
    a. Ex: Organograms of the lab and of the health facility
11. What is the specimen referral pathway for specimens coming to or leaving your facility?
    a. Note: If the respondent is a MOH employee at the County or Sub-County level, this question refers to the sample referral **network** within their jurisdiction.
    b. Ex: Sources or destinations of samples; types of tests that are typically referred out; types of tests that are typically referred in; funding structures

for the referral transport; challenges with maintaining sample integrity during referral; length of time for referred sample results to return

12. What is the Hospital Layout and the lab's placement in that structure?
    a. Ex: Is the size of the lab suitable; does it have easy patient access to a lavatory; is it large enough to accommodate a biosafety cabinet; does it have running water and electricity.
13. Catchment Area
    a. What challenges do patients face when accessing these lab services?
        i. Ex: the cost and typical mode of transport; seasonal changes in road or transport quality; patient population needs/disease prevalence; affordability of diagnostics; patient confidence in diagnostic availability and quality; clinician availability; health-seeking behaviors that affect use of diagnostics.
14. Lab testing capacity:
    a. What are the most requested lab tests?
        i. Of these, which tests are the lab regularly unable to provide?
        ii. For what reasons are the lab unable to provide these tests and what do you believe is the impact on the facility's patients?
            1. Ex: Equipment failures; test reagent stock-outs; shortage of personnel; training of lab personnel; high patient load to lab capacity; increased cost of care; lower quality of care/misdiagnosis; patient health negatively affected; patient loss of confidence in diagnostic usefulness; misuse of anti-biotics.
            2. Note: for County and Sub-County level employees this refers to the citizens within their jurisdiction that typically use the Public Health network to access healthcare.
    b. What tests are under-utilized based on clinician behaviors and for what reasons are they under-utilized?
        i. Ex: Paper-based system versus electronic records use; preference of clinicians; clinician lack of confidence in diagnostic usefulness; lack of clinician training in results interpretation; Long turn-around-time of diagnostic results.
        ii. What avenues are in place to communicate between labs and clinicians to encourage better diagnostic utilization?
    c. What is the nature of the relationship between laboratory equipment functions and quality diagnostic services?
        i. What challenges do you face with equipment in terms of meeting the needs of the laboratory?
        ii. Ex: Equipment that is difficult to maintain; equipment that is difficult to repair; training and personnel requirements of equipment; gaps in necessary equipment for essential services or biosafety requirements;
    d. How do you think a computer-based laboratory information management system would change your laboratory work environment?

e. Commodity stock-outs and over-stocks (Note: For County and Sub-County MOH officers this topic refers to KEMSA and supply issues to their entire catchment area).
    i. What commodities are the hardest to keep in stock?
    ii. How do laboratory commodity stock-outs affect your laboratory function?
    iii. What review and feedback systems do you have for correcting stock-outs and over-stocks?
    iv. How are your administrative systems responsive to your stock-out challenges?
    v. How are unused or expired commodities managed, disposed of, or allocated?
f. What is the process for communicating "Service Interruptions"?

15. Role of "Vertical Disease Funding" and "Partners" on Lab function
    a. How much lab function depends on "Partners"?
        i. Ex: What ratio of lab employees are employed by "Partners"; "Partner" supply of certain (essential) equipment, lab consumables, and lab capacity improvements; Funding and reporting requirements of "Partners" in relation to government reporting requirements; employee pay inequities; training opportunities such as SLMPTA and ISO accreditation
    b. Challenges associated with Partner withdrawal and diverging Partner agendas
        i. Ex: funding gaps due to voluntary or involuntary tender withdrawal; employee work priorities based on employment; tender graft; vertical disease program agendas; status of essential services that are not supported by vertical disease programs.
16. Staffing
    a. How many staff does the laboratory have and their training levels:
        i. Ex: education status; temporary/contract/full-time or life-time MOH employee status; how many staff also employed in the private health sector
    b. Can you describe their retention trends?
        i. Ex: Bonding contract strategies; reasons for low or high retention
    c. How does your laboratory overcome staffing gaps and staff training challenges, if any?
    d. (For County and Sub-County MOH officers **only**): Can you describe the status of your county/subcounty's "Supportive Supervision" program and challenges you face in maintaining it?
        i. Ex: vehicle transport issues; internet connectivity in rural areas; poor road infrastructure; poor electricity infrastructure; size of catchment area; seasonal flooding; lack of administrative support.
17. Can you describe the effect of the following events on your laboratory/work functions:
    a. 2010 Kenya Government Devolution

        i. Ex: Funding changes; leadership and administrative priority changes; the role and status of “Supportive-Supervision” in relation to the facility
    b. ISO 15189 Accreditation and Electronic Laboratory Information Systems
        i. Ex: What is your labs Kenya Certification of Care accreditation status; ISO accreditation status; future plans for gaining accreditation; effect of accreditation on results Turn-Around-Time, equipment maintenance and quality, lab personnel expertise; changes in biosafety standards in lab; changes to quality of lab management and staff retention
18. What solutions and successes have you found in meeting your objectives as a public health laboratory professional?
    a. Ex: Whatsapp groups; innovative use of space; collaboration with local universities and stakeholders to fill gaps

Appendix V: Observational Guide

Semi-structured Observation Guide

Background

The principal research study evaluates the relationship between an Electronic Laboratory Information Management System (eLIMS) at Kisumu County Referral Hospital and key laboratory quality service indicators including: diagnostic Turn-around-Time (TAT), rates of presumptive diagnoses for Malaria, utilization of diagnostics per patient visit, diagnostic reagent stock-outs, reagent waste, and diagnostic service interruptions. Due, however, to data gaps in the DHIS-2 (Kenya national health data system) it is not possible to draw accurate conclusions about laboratory function through DHIS-2 data sets alone. This method is intended to fill in information gaps on how and why certain trends occur in laboratory activities and challenges arise in public health laboratories for managing diagnostics to deliver quality healthcare services. The observations will combine with key informant interviews with laboratory personnel from the laboratory and similar laboratories in terms of facility level and public status. It will also complement quantitative analysis of aggregate data at the facility level to assist in the interpretation of diagnostic trends for key laboratory indicators. I will rotate these observation days to cover all weekdays equally. The event sampling guide will occur as often as events occur. However, the rating scale guide for lab request forms will take place on each observation day every morning between 10-11am and afternoon from 2-3pm in order to account for hourly fluctuations in patient flow. These observations are limited in generalizability to other public medical laboratories in Kenya due to the unique clientele, patient load, and history of the laboratory under study. Additionally, hospital patient flow and disease rates tend to fluctuate from season to season and year to year. This study will only cover the short-rain season for two months in a post-national-election atmosphere.

Purpose

This Observation Guide will collect data on medical laboratory personnel interactions with an Electronic Laboratory Information Management System (eLIMS) in order to perform essential health laboratory services. It seeks to understand the relationship between the eLIMS, laboratory functions, and data reported to the HMIS system.

The Observations

This guide has four types of observations: event sampling, rate sampling, key-informant reflection, and self-reflection.

1. Event Sampling Guide

First, an event sampling observation guide will seek to identify events relating to use of the eLIMS and observe healthcare personnel's interactions and behaviours towards the eLIMS as a tool for managing the laboratory towards delivering quality care. I will use the event sampling guide for a maximum of 3 times per work day to respect the time limitations of laboratory personnel and limit the obtrusiveness of the research process. Before beginning the event sampling observation, I will first select which of the following events of interest I am observing and document that category in the table:

K. On-going training of personnel in use of the eLIMS
L. Initial training of new personnel on use of the eLIMS

M. Troubleshooting issues related to the eLIMS
N. Generating and disseminating laboratory internal reports
O. Generating and disseminating external reports
P. Managing laboratory-related equipment performance
Q. Communicate with other hospital clinics and departments
R. Manage diagnostic turn-around-time
S. Performing internal diagnostics results validating procedures
T. Managing laboratory reagent stocks

The "Difficulty Rating of Task" will be assessed through a response by the principal participant performing the task, and it asks the participant to: "Please rate the difficulty of this task when using the eLIMS compared to not using the eLIMS". It will use the following scale:

1 Very Easy
2 Fairly Easy
3 About the Same
4 Fairly Difficult
5 Very Difficult

Date/ Time	Task Category	# of facility personnel actively involved in completing the task	Length of time taken to complete task (in min)	Relative Difficulty Rating	Uses of eLIMS to perform task and resolve challenges	Behaviours by participant in use of eLIMS

2. Paper/Electronic Request Rating Scale Guide

The following rating scale guide will sample the number of laboratory diagnostic request samples arriving to the laboratory either in paper or electronic form within a one-hour time span in the morning and the afternoon of work days (including the two

weekend days per month). The "Test Code" corresponds to the DHIS-2 MOH706 Laboratory Summary Reporting Form 2020 found in the following table:

1. Urinalysis 1.1 Urine Chemistry 1.2 Glucose 1.3 Ketones 1.4 Proteins 1.5 Urine Microscopy 1.6 Pus cells (>5/hpf) 1.7 Shistosoma haematobium 1.8 Trichomona vaginalis 1.9 Yeast cells 1.10 Bacteria **2. Blood Chemistry** 2.1 Blood sugar 2.2 OGTT 2.3 Renal Function Test 2.4 Creatinine 2.5 Urea 2.6 Sodium 2.7 Potassium 2.8 Chlorides 2.8 Liver Function Test 2.9 Direct bilirubin 2.10 Total bilirubin 2.11 ASAT (SGOT) 2.12 ALAT (SGPT) 2.13 Serum Protein 2.14 Albumin 2.15 Alkaline Phosphatase 2.16 Lipid Profile 2.17 Total cholesterol 2.18 Triglycerides 2.19 LDL **(Hormonal Test)** 2.20 T3 2.21 T4 2.22TSH **(Tumour Markers)** 2.23 PSA 2.24 CA 15-3 2.25CA19-9 2.26CA125	**5. Bacteriology** 5.1 Urine 5.2 Pus swabs 5.3 High Vaginal Swabs 5.4 Throat swab 5.5 Rectal swab 5.6 Blood 5.7 Water 5.8 Food 5.9 Urethral swabs 5.17 Neisseria meningitidis A 5.18 Neisseria meningitidis B 5.19 Neisseria meningitidis C 5.20 Neisseria meningitidis W135 5.21 Neisseria meningitidis X 5.22 Neisseria meningitidis Y 5.23 Neisseria meningitidis (indeterminate) 5.24 Streptococcus pneumoniae 5.25 Haemophilus influenzae (type b) 5.26 Cryptococcal Meningitis 5.27 B. anthrac 5.28 Y. pestis **(Tuberculosis Sputum Samples)** 5.29 Total TB smears 5.30 New presumptive TB cases 5.31 TB Follow up 5.32 Rifampicin Resistant TB 5.33 MDR TB **6. Histology and Cytology (Smears)** 6.1 PAP smear 6.2 Touch preparations 6.3 Tissue impressions **(Fine Needle Aspirates)** 6.4 Thyroid 6.5 Lymph nodes 6.6 Liver 6.7 Breast 6.8 Soft tissue masses **(Fluid Cytology)** 6.9 Ascitic fluid 6.10 CSF 6.11 Pleural fluid 6.12 Urine

2.27 CEA

2.28 AFP

(CSF Chemistry)

2.29 Proteins

2.30 Glucose

3. Parasitology

3.1 Malaria BS (Under five years)

3.2 Malaria BS (5 years and above)

3.3 Malaria Rapid Diagnostic Tests (Under five years)

3.4 Malaria Rapid Diagnostic Tests (5 years and above)

(Stool Examination)

3.5 Taenia spp.

3.6 Hymenolepis nana

3.7 Hookworm

3.8 Roundworm

3.9 S. mansoni

3.10 Trichuris trichura

3.11 Amoeba

4.

4. Haematology

4.1 Full blood count

4.2 HB estimation tests(other techniques)

4.3 Hemoglobin A1c (HbA1c)

4.4 CD4

4.5 Sickling test

4.6 Peripheral blood films

4.7 BMA

4.8 Coagulation profile

4.9 Reticulocyte

4.10 Erythrocyte Sedimentation rate

(Blood Screening at Facility)

4.19 HIV

4.20 Hepatitis B

4.21 Hepatitis C

4.22 Syphillis

(Tissue Histology)

6.13 Prostrate

6.14 Breast tissue

6.15 Ovary

6.16 Uterus (Cervix)

6.17 Uterus (Endometrium)

6.18 Skin

6.19 Head and Neck

6.20 Oral

6.21 Esophagus

6.22 Colorectal

6.23 Hepatobiliary

6.24 Soft tissue and bone

6.25 Lymph nodes tissue

(Bone Marrow Studies)

6.26 Bone marrow aspirate

6.27 Trephine biopsy

7. Serology

7.1 VDRL

7.2 TPHA

7.3 ASOT

7.4 HIV

7.5 Brucella

7.6 Rheumatoid factor

7.7 Helicobacter pylori

7.8 Hepatitis A test

7.9 Hepatitis B test

7.10 Hepatitis C test

7.11 HCG

7.12 CRAG Test

8. Sample referral (all types)

9. Drug Resistance (all types)

Date	A.m./ P.m.	Test Code	Received in Paper Form	Received in Electronic Form

3. Key Informant Reflection Guide

This key informant reflection is intended to verify the accuracy of the observers notes in the Event Sampling Guide and to mitigate for observer bias. It should be performed with my host supervisor, the laboratory director, or the laboratory quality assurance officer for every event. In order to limit the obtrusiveness of the research process, this can be done at one time for a maximum of three events at the end of the work day. It should be completed within **one day** of the event sampling date to limit recall bias. The "Date/Time/Activity Code" is derived from the unique combination of the Date, Time and Activity Category associated with each activity.

Date/ Time	Date/Time/ Activity Code	Please reflect on the task performed and challenges faced:	Please reflect on the observations of participant behaviors in relation to use of the eLIMS. How do you feel the observations are or are not accurately reflecting how the

			laboratory performs that task?

4. Self-Reflection

The following guide is a series of questions intended for independent self-reflection to be done at the end of each work day where observational data was collected. They should reflect on the event sampling and rating scale guide observation experiences. To limit recall bias, they must be completed within **one day** of the event sampling and rating scale observations under question.

Date: Date/Time/Activity Code:	Responses
How did my presence affect the participants experience of the activity?	
What difficulties did I encounter in conducting the observation?	

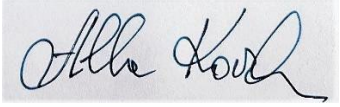
Do I need to inquire further in order to understand a dynamic observed today? (Please explain)	
How were my observations similar/different to the respondents in the Key Informant Guide?	
Would a stranger reading these observations be able to understand the key points relating to eLIMS use, quality diagnostic service delivery, and quality	

patient care?	

Appendix VI: Ethics Approval from the School for International Training Internal Review Board

SIT SCHOOL FOR INTERNATIONAL TRAINING
GRADUATE INSTITUTE

Human Subjects Review IRB ACTION FORM

IRB Application Number: 0000178 **Name of Applicant:** Kelly Allen **Project Title:** Evaluation of the Implementation of an Integrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in Western Kenya **Date Submitted:** 7/13/2022 **Date Revisions Submitted:** 8/29/2022 **Program/Department:** GML.GH **Type of review:** Expedited	**Institution:** World Learning Inc. **IRB organization number:** IORG0004408 **IRB registration number**: IRB00005219 **Expires:** 27 September 2024 **IRB members:** Alla Korzh, Ed.D. Deepa Srikantaiah, Ph.D. Isabelle Onians, Ph.D. Juan Alex Alvarez del Castillo, Ph.D. Peter Weinberger, Ph.D. Melissa Whatley, Ph.D. Victor Tricot, Ph.D. **IRB REVIEW BOARD ACTION:** __X__Approved as submitted ___Revise and resubmit ___Revisions approved ___Disapproved **IRB Chair Signature:**  **Date: September 7, 2022**

Reviewer comments:
Your HSR application has been approved

Second-round comments:

The following two comments from my previous review were unaddressed in this resubmiss

Section 4, L: You still have not answered the question posed here - please describe potential harm that participants might experience. This section currently speaks to participant privacy concerns rather than potential harm. Please ensure that you discuss risks that are mentioned in your interview consent forms.

Section 4, S: Please clarify how qualitative data will be deidentified. Until now, only the quantitative data have been referred to as deidentified. (Note: Is there a typo on your response that is leading me to the incorrect interpretation of what you have written?)

Regarding the first comment, you mention potential harm that participants might experience in your interview consent form. This potential harm also needs to be discussed in Section 4, L, in response to the primary question for that section ("What potential harm might be experienced by participants?"). Regarding the second comment, please double check that you mean qualitative and not quantitative in this section.

Previous comments:

Section 4 A, B: Please clarify the inclusion of data from minors in this study. In Section 3, you checked the box indicating that your research does not involve children, yet in Section 4 A, you indicate that you expect to collect data from 92,330 children. I suspect that children are part of the deidentified data that you will analyze but not your interview or observation data. Please make this explicit in your description in Section 4 B.

Section 4, L: You still have not answered the question posed here - please describe potential harm that participants might experience. This section currently speaks to participant privacy concerns rather than potential harm. Please ensure that you discuss risks that are mentioned in your interview consent forms.

Section 4, N: Please describe how participants will provide oral consent should they decline to give written consent. How will you ask for consent? How will participants indicate their consent?

Section 4, S: Please clarify how qualitative data will be deidentified. Until now, only the quantitative data have been referred to as deidentified. (Note: Is there a typo on your response that is leading me to the incorrect interpretation of what you have written?)

Informed consent (interviews): Please correct the typo on page 3 where you specify for participants what type of identifier they will be assigned.

Informed consent (observations): Please revise the bullet points on page 1 so that they follow from the prior sentence ("You are eligible to participate in this study if your laboratory…"). "Your laboratory" cannot be the subject of the first two bullet points.

Previous comments:

Please clarify whether external IRB approval is needed for this study. Currently, the answer to this question has been indicated as "No," but plans for seeking approval are then detailed. Please clarify the role of the Maseno University Ethics Review Committee mentioned in the consent form.

Section 2, A: Please provide the research questions as well as a description of the observational data you plan to collect.

Section 2, B: Please describe how you will collect your observation data. Please describe how you plan to transcribe interview data if interviews are not recorded.

Section 4, A: Please specify if your study includes data from 13 individuals total, including both quantitative and qualitative data collection.

Section 4, G: Please ensure that your inclusion and exclusion criteria in your HSR form match those in your consent form. Currently, they do not.

Section 4, L: Please describe potential harm that participants might experience. This section currently speaks to participant privacy concerns rather than potential harm. Please ensure that you discuss risks that are mentioned in your interview consent form.

Section 4, M: Please provide the written consent form that interview participants will sign. Please clarify in your observation consent form whether interviews form part of your observations or if interviews are separate. If the latter, please remove references to interviews from this consent form. Please specify who will sign your observation consent form and the data that will be collected in this part of the study.

Section 4, P: Please clarify. You indicate that participants will not receive a summary of results but then explain how you will share your results with participants.

Section 4, S: Please clarify how qualitative data will be deidentified. Until now, only the quantitative data have been referred to as deidentified.

Section 4, S: What measures will you put in place to safeguard participants' privacy during data collection? You only address recruitment and presentation of findings in your response

MASENO UNIVERSITY SCIENTIFIC AND ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
Fax: +254 057 351 221
Private Bag - 40105, Maseno, Kenya
Email: muerc-secretariate@maseno.ac.ke

REF: MSU/DRPI/MUSERC/01152/22 **Date** : 4th November, 2022

TO: Kelly W. Allen
School for International Training
Graduate Program in Global Health
Kipling Road, Brattleboro
Vermont, 05302-0676, USA

Dear Sir,

RE: Exploration of the Implementation of an Intergrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya

This is to inform you that **Maseno University Scientific and Ethics Review Committee (MUSERC)** has reviewed and approved your above research proposal. Your application approval number is MUSERC/01152/22.The approval period is **4th** November , 2022 - 3rd November, 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by Maseno University Scientific and Ethics Review Committee (MUSERC).
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to Maseno University Scientific and Ethics Review Committee (MUSERC).

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerel

MASENO UNIVERSITY ETHICS REVIEW COMMITTEE 04 NOV 2022 P.O. BOX PRIVATE BAG MASENO

Prof . PhilifS 0 . Owuor, PhD, FAAS, FKNAS
Chairman , MUSERC

MASENO UNIVERSITY SCIENTIFIC AND ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
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Private Bag – 40105, Maseno, Kenya
Email: muerc-secretariate@maseno.ac.ke

REF: MSU/DRPI/MUSERC/01152/22 **Date**: 28th November, 2022

TO: Kelly W. Allen
School for International Training
Graduate Program in Global Health
Kipling Road, Brattleboro
Vermont, 05302-0676, USA

Dear Madam,

RE: Exploration of the Implementation of an Intergrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya

This is to inform you that **Maseno University Scientific and Ethics Review Committee (MUSERC)** has reviewed and approved your above **amended** research proposal. Your application approval number is MUSERC/01152/22**.** The approval period is 28th November, 2022– 3rd November, 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by Maseno University Scientific and Ethics Review Committee (MUSERC).
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to Maseno University Scientific and Ethics Review Committee (MUSERC).

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely

Prof. Philip O. Owuor, PhD, FAAS, FKNAS
Chairman, MUSERC

MASENO UNIVERSITY ETHICS REVIEW COMMITTEE 28 NOV 2022 PRIVATE BAG MASENO

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **745010**

Date of Issue: **12/January/2023**

RESEARCH LICENSE

This is to Certify that Ms.. Kelly Whaley Allen of School for International training, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Kisumu on the topic: Exploration of the Implementation of an Integrated Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Hospital in western Kenya for the period ending : 12/January/2024.

License No: **NACOSTI/P/23/22038**

745010

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013 (Rev. 2014)

Legal Notice No. 108: The Science, Technology and Innovation (Research Licensing) Regulations, 2014

The National Commission for Science, Technology and Innovation, hereafter referred to as the Commission, was the established under the Science, Technology and Innovation Act 2013 (Revised 2014) herein after referred to as the Act. The objective of the Commission shall be to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto.

CONDITIONS OF THE RESEARCH LICENSE

1. The License is granted subject to provisions of the Constitution of Kenya, the Science, Technology and Innovation Act, and other relevant laws, policies and regulations. Accordingly, the licensee shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under the Act, or prescribed by provisions of International treaties of which Kenya is a signatory to
2. The research and its related activities as well as outcomes shall be beneficial to the country and shall not in any way;
    i. Endanger national security
    ii. Adversely affect the lives of Kenyans
    iii. Be in contravention of Kenya's international obligations including Biological Weapons Convention (BWC), Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO), Chemical, Biological, Radiological and Nuclear (CBRN).
    iv. Result in exploitation of intellectual property rights of communities in Kenya
    v. Adversely affect the environment
    vi. Adversely affect the rights of communities
    vii. Endanger public safety and national cohesion
    viii. Plagiarize someone else's work
3. The License is valid for the proposed research, location and specified period.
4. The license any rights thereunder are non-transferable
5. The Commission reserves the right to cancel the research at any time during the research period if in the opinion of the Commission the research is not implemented in conformity with the provisions of the Act or any other written law.
6. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research.
7. Excavation, filming, movement, and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
8. The License does not give authority to transfer research materials.
9. The Commission may monitor and evaluate the licensed research project for the purpose of assessing and evaluating compliance with the conditions of the License.
10. The Licensee shall submit one hard copy, and upload a soft copy of their final report (thesis) onto a platform designated by the Commission within one year of completion of the research.
11. The Commission reserves the right to modify the conditions of the License including cancellation without prior notice.
12. Research, findings and information regarding research systems shall be stored or disseminated, utilized or applied in such a manner as may be prescribed by the Commission from time to time.
13. The Licensee shall disclose to the Commission, the relevant Institutional Scientific and Ethical Review Committee, and the relevant national agencies any inventions and discoveries that are of National strategic importance.
14. The Commission shall have powers to acquire from any person the right in, or to, any scientific innovation, invention or patent of strategic importance to the country.
15. Relevant Institutional Scientific and Ethical Review Committee shall monitor and evaluate the research periodically, and make a report of its findings to the Commission for necessary action.

National Commission for Science, Technology and Innovation(NACOSTI),
Off Waiyaki Way, Upper Kabete,
P. O. Box 30623 - 00100 Nairobi, KENYA
Telephone: 020 4007000, 0713788787, 0735404245
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MASENO UNIVERSITY SCIENTIFIC AND ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
Fax: +254 057 351 221
Private Bag – 40105, Maseno, Kenya
Email: muerc-secretariate@maseno.ac.ke

REF: MSU/DRPI/MUSERC/01152/22 **Date**: 4th November, 2022

TO: Kelly W. Allen
School for International Training
Graduate Program in Global Health
Kipling Road, Brattleboro
Vermont, 05302-0676, USA

Dear Sir,

RE: Exploration of the Implementation of an Intergrated Electronic Laboratory Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in western Kenya

This is to inform you that **Maseno University Scientific and Ethics Review Committee (MUSERC)** has reviewed and approved your above research proposal. Your application approval number is MUSERC/01152/22.The approval period is 4th November, 2022 – 3rd November, 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by Maseno University Scientific and Ethics Review Committee (MUSERC).
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to Maseno University Scientific and Ethics Review Committee (MUSERC) within 24 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to Maseno University Scientific and Ethics Review Committee (MUSERC).

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely

MASENO UNIVERSITY ETHICS REVIEW 04 NOV 2022 COMMITTEE P.O. BOX PRIVATE BAG MASENO

Prof. Philip O. Owuor, PhD, FAAS, FKNAS
Chairman, MUSERC

REPUBLIC OF KENYA

COUNTY GOVERNMENT OF KISUMU

Telegrams: "PRO (MED)"
Tel: 254-057-2020105
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E-mail: kisumucdh@gmail.com

Director of Public Health, Preventive/
Promotion and Environmental Health
P.O. Box 721 – 40100,
Kisumu.

DEPARTMENT OF HEALTH & SANITATION

Our Ref: GN 133 VOL. XII/(532) **Date:** 23rd January, 2023

To:

CEO - JOOTRH

All SCMOHs

Medsupt. – KCRH

RE: AUTHORIZATION TO CONDUCT STUDY IN KISUMU COUNTY

The Department has reviewed and approved this study titled '***Exploration of the Implementation of an Integrated Electronic Information Management System on Quality Diagnostics Service Indicators at a County Level Public Hospital in Western Kenya'.***

This is a solutions- oriented mixed-methods study of the electronic laboratory information management system (eLIMS) based at KCRH and the Public Laboratory Network in Kisumu County.

The research proposal seeks to study the complex factors that influence Public Medical Laboratory functions in Kisumu County.

Kindly give them all the necessary support.

Regards,

COUNTY DIRECTOR OF HEALTH KISUMU

Lilyana Dayo
Ag. Director - Public Health, Preventive/Promotion and Environmental Health
Kisumu County

CC Kelly W. Allen, BA