

Readiness of Primary Health Care Diagnostic Laboratory Services to Support UHC Programme in Kenya: A Case Study of Three Counties

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Abstract: Medical diagnostic laboratories have always played a significant role in determining clinical decisions. Given that laboratory diagnosis accounts for up to 70% of all medical decisions, reliable laboratory services is therefore critical to basic clinical care and universal healthcare coverage (UHC) programme. Apparently, a pilot UHC programme in four counties ahead of nationwide roll-out was being tested in Kenya from December 2018 to December 2019. Significantly, a reliable laboratory diagnostic service also support a sustainable functional referral system. However, in majority of low to middle income countries (LMICs) and through-out sub-Saharan Africa including Kenya, common infrastructural, technical and human resource deficiencies are endemic, consequently impacting on the coverage of services, quality, availability, affordability and accessibility of diagnostic tests as well as their ability to provide basic clinical care. For that reason, studies to determine the current status of laboratory diagnostic services, especially at the primary health care (PHC), coverage and their readiness to provide basic clinical care as well as in supporting UHC. The purpose of this pilot descriptive study was to investigate the status and readiness of laboratory diagnostic services in three counties in Kenya to support UHC at a resource-limited PHC setting. By use of structured, pretested questionnaires, general observations and key informant interviews, the study-specific information was obtained from participants. The data was analyzed using SPSS statistical package, interpreted, summarized and presented in tables and bar graphs. Based on the WHO-defined three categories of essential diagnostic list (EDL) for UHC at PHC, all the general basic tests were available in the sampled facilities. However, for the disease-specific and infectious diseases-specific tests there were major gaps in their availability. In addition to common infrastructural, technical, human resource deficiencies, only in 3% of the facilities, the more advanced, molecular-based disease-specific and infectious diseases-specific tests were available. This indicated low readiness to provide reliable basic clinical care and to support of UHC programme implementation at PHC level. Therefore, building of capacities of these services at PHC will have a direct impact not only in the diagnosis, treatment and prevention of diseases but also help in the successful up-scaling nationwide of the UHC programme, hence assisting in attainment of the 'Big Four' agenda of UHC, United Nations (UNs) sustainable development goals (SDG) number three (3) on ensuring health for all and promoting well-being for all ages, and the Kenya's Vision 2030 economic blue print.

Keywords: Medical Diagnostic Laboratories, Quality Control and Assurance Management, Primary Health Care (PHC)

1. Introduction

That medical diagnostic laboratory plays a critical role in determining clinical decisions by providing clinicians with

information that assists not only in diagnosis of diseases, antimicrobial resistance, monitoring of response to therapy screening of diseases for their early diagnosis, timely commencement of prescribed standard of treatment or

prevention but also in epidemiological surveillance for investigating outbreaks or epidemics is not in doubt in both high income as well as low to middle income countries (LMICs) including the sub-Saharan Africa [1, 2]. This is despite the clear variabilities gulf in availability, accessibility of quality and reliable essential laboratory diagnostics between the two economically as well as technologically developed distinct countries. In line with that, laboratory diagnosis accounts for up to 70% of all medical decisions, highlighting how critical the quality and reliability of laboratory diagnostic services is to health disease outcomes [2-4].

Fundamentally, access to essential laboratory diagnostic tests has been identified not only as the primary step in improving the quality of clinical care [2] towards a sustainable universal healthcare coverage (UHC), but also the “heart” of UHC and the “fulcrum” through which it should rotate [5]. UHC entails three critical components of equity, quality services and protection from financial risk. Subsequently, UHC has been defined as “ensuring that all have access to quality health services to the level of their need without conferring on them financial hardships” [6]. For that reason, ensuring quality and reliable health care laboratory diagnostic services is not only central to provision of basic clinical care but also for supporting successful implementation and achievement of UHC at PHC as well as the other levels of health care. Importantly, the WHO has defined an essential diagnostic list (EDL) as “a list of essential diagnostics test that satisfy the priority healthcare needs of the population, selected with due regard to specific disease prevalence, public health relevance, evidence of efficacy, accuracy and comparative cost-effectiveness” [7, 8].

Pertinent to the vital role of health care laboratory diagnosis in ensuring quality clinical care and UHC, diagnostic errors have been identified as the most costly and dangerous medical mistakes [9, 10]. In the same line, poor quality testing, misdiagnosis, geographical distance and affordability barriers, late or prolonged test results turn-around time, delays in relaying or communication of the results and thus late diagnosis, have all been implicated in the subsequent late commencement of treatment sometimes leading complications as well as poor outcomes [11-14]. Tellingly, 8 out of 10 cancers in Kenya are detected late due to misdiagnosis [11, 12]. As a result, this not only increases the risk of developing complications (sometime with severe consequences such as heart diseases, neural damage/gangrenes leading to amputations, kidney damage or blindness) in diseases such as Diabetes Mellitus, Cancers, Pneumonia or Tuberculosis (TB), but notably also, the late presentation with advanced stages of the illness by patients, particularly in cancers when the likelihood of cure is almost negligible [11, 14-16]. In addition, development of chronic illnesses with associated inflammation due to delayed diagnosis and commencement of standard of care treatment increases the risk of developing malignancies and the overall reduced life expectancy [15, 16].

Also, considering that Kenya is one of the 22, WHO-

identified high burden countries and biggest contributors to the global TB cases, the significance of reliable health care laboratory diagnostic services particularly at PHC is highlighted [1, 15]. Additionally, with 41 million annual deaths from NCDs, which account for more than 70% of all global deaths [17], the notable recent upsurge in their burden and the anticipated further increase due to climate change as well as the prolonged life expectancy of HIV-infected people from the successful universal antiretroviral therapy (ART) [18], the urgent need for a functional and sustainable UHC at PHC is implied. Significantly, fundamental variabilities in affordability and accessibility of health care across countries globally is highlighted by the fact that while three NCDs (Cardiovascular disease, Diabetes and Cancers) accounted for only 8% deaths in men and 10% in women in high income countries, the same accounted for 22% and 35% deaths in males and women respectively in LMICs [19].

Therefore, a functional PHC supported by a working referral system are critical drivers and enablers of UHC. Unfortunately, the state of laboratory diagnostic services, in particular at PHC level in majority of LMICs is inadequate, characterized by major gaps in availability of essential laboratory diagnostic tests, not only intra or inter-countries’ variabilities but also between private as well as public health care systems [20-23]. In addition, insufficient laboratory diagnostic services coverage, quality of services, infrastructural, technical, human resource capacities, availability and accessibility of diagnostic tests, sustainability of the services, documentation of coverage and quality of services gaps in not only most of LMICs but also through-out sub-Saharan Africa, thus implying they were insufficiently equipped to provide even the basic clinical care have been reported previously [22, 23].

Consequently, this negatively impacts on their ability to provide reliable laboratory diagnostic services, which is an essential prerequisite for quality clinical care and UHC. Arising from several years of under appreciation and the critical role of diagnostic laboratories in clinical care being overlooked, at the expense of other components of health care services such as essential treatment, the sector has received inadequate or little attention. To highlight this, for instance, though the Kenya’s Health Act 2017, S (1) states that “every person has the right to the highest attainable standard of health, which shall include; progressive access for provision of promotive, preventive, curative, palliative and rehabilitative services”, reality on the ground is different [21].

Therefore, refocusing on equitable investment in both laboratory diagnostic and curative services for UHC at PHC will have a transformative impact on health care. In that respect, the WHO has defined PHC as “a setting where there is no diagnostic laboratory or where only a basic laboratory with identified basic general tests, disease-specific testing and infectious disease-specific tests is available” [7, 8]. Accordingly, WHO has developed a standardized EDL lists suitable for different levels of health care including level 1, 2, and 3 [4, 7, 8]. Of significance, WHO has broadly

categorized laboratory diagnostic tests into two major levels of health care delivery systems; those for PHC (levels 1, 2, and 3 without a laboratory or with a basic facility) and those with clinical laboratories [4, 8]. Notably, the first version of WHO-EDL contained 113 diagnostics of which 58 were for general laboratory testing and 55 for disease-specific tests [7].

For successful UHC programme implementation and up-scaling, integration of the WHO-EDL or suitable alternative as part of the programme's basic medical health insurance cover (NHIF) package is imperative. Notably, according to a [24] World Bank report, (2018), only 20% of Kenyans had access to a form of medical insurance cover. Further, about one million Kenyans are driven into poverty annually by the high cost of medical bills. In realization of this, the government of Kenya (GoK) was piloting an ambitious UHC programme in four (4) counties of Kisumu, Machakos, Nyeri and Isiolo selected on the basis of prevalence of specific health concern such as infectious diseases, non-communicable diseases (NCD), accident injuries or pastoralistic/nomadic way of life. After the piloting, the UHC programme will be up scaled to the remaining 43 counties in the future. However, in a recent UHC pilot programme reality survey, up to 64% of Kenyans travel for up to 3 kilometers to access the nearest public health care facility. The same survey noted that only 43% of Kenyans were happy with public health care services and with only a few months to the up-scaling of the UHC programme, a staggering 69% of them were not aware of the impending UHC programme [25]. In addition, high cost of essential diagnostic tests critical in deciding correct treatment, accessibility barriers, knowledge, awareness gaps and misconceptions on how the UHC programme was supposed to work were also noted [13, 25]. This was in agreement with previous studies. For that reason, preliminary studies to identify gaps, deficiencies in the current PHC settings, piloting programme and whether it is on track to accomplish intended objectives as well as to provide vital lessons before further up scaling are important.

The critical role of quality control and assurance management in ensuring reliable clinical care has been highlighted and documented previously [9, 22, 23]. In particular, recognition of pre-analytical, analytical and post analytical stage diagnostic errors as strictly deficiencies in quality control and assurance management issues which can be effectively addressed by adoption, application of total quality management (TQM) principles, ISO 15189 certification and accreditation [9, 10]. For that reason, interested stakeholders, partners initiated programmes geared to encourage, promote quality, reliability of laboratory diagnostic services for resource-limited settings in sub-Saharan Africa by building their capacities for TQM in medical laboratories and preparedness for international organization for standards (ISO) 15189 certification as well as accreditation. [9, 10, 26].

It is worth noting that the ISO 15189 certification, is specifically a quality standard for medical diagnostic

laboratories, which provided guidelines and procedures for ensuring quality as well as reliability of the tests results [26]. Basically, ISO 15189 certification provided quality standards, procedures and guidelines, which if applied to the latter, ensured not only accurate and reliable testing but also the safety of laboratory staff [9, 10, 26]. On the other hand, international accreditation verified adherence or level of conformity by medical laboratories to established laboratory quality management standards such as the ISO 15189 certification [27, 28]. In essence, accreditation of a clinical laboratory, implied that the diagnostic tests carried out was done by qualified, competent staff, using validated methods, equipment, quality supplies (reagents), and in a controlled environment [27, 29]. Some of the recognized quality accreditation organizations include the South African national accreditation system (SANAS) and the International Laboratory Accreditation Cooperation (ILAE) [27, 28]. Ultimately, the accreditation of a medical laboratory to ISO 15189; involves the independent assessment of the facility to determine competence, neutrality and consistency of services. Moreover, it addresses the qualifications and the availability of on-going or continued competency improvement programmes of personnel involved in medical laboratory examinations or testing. Additionally, the accommodation, equipment, reagents, supplies, pre-analytical, analytical and post-analytical factors, internal or external quality controls and assurance management aspects are also considered during accreditation process [9, 10, 27, 28, 30].

However, attaining ISO 15189 certification is a long and costly journey lasting from 12-18 months that starts with a program of Strengthening Laboratory Management Towards Accreditation (SLMTA), a competency-based programme that uses successions of short courses, work-based learning projects to upshot instantaneous as well as measurable laboratory improvement, while empowering laboratory managers to implement practical quality management systems to ensure better patient care [9, 26, 27]. In recognition of this and to promote accessibility, affordability for the ultimate ISO 15189 certification by laboratories specifically in resource-limited settings of as sub-Saharan Africa, a framework for improving quality of public health laboratories in the African region was developed through a consensus on the WHO-AFRO- Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) policy guidance and checklist documents was reached in July 2011, in a Nairobi-Kenya conference [27, 28]. This was aimed at achieving ISO 15189 certification standards, based on the principles of affordability, scalability, measurability and accessibility. Principally, SLIPTA promoted country ownership of the process and sustainability of the improved quality of the laboratories [27, 28]. Since SLMTA training programme spans from 12 to 18 months; after each workshop, the participants are required to implement improvement projects, which are supported by regular supervisory visits or on-site mentoring. In order to assess strengths, weaknesses and improvement made by the

laboratory, audits are conducted using the WHO's regional office for Africa (WHO-AFRO) SLIPTA checklist, which is based on ISO 15189 certification requirements [26]. In view of that, laboratories participating in SLMTA are audited in the beginning (baseline) and at the end (exit) using the SLIPTA checklist. The difference between baseline and exit scores, and their respective star ratings, is calculated to quantify the effect of the program on laboratory function and quality [9, 27, 28].

Apparently, not even the adoption of a stepwise approach to improve laboratory quality system towards accreditation by facilities in these resource-limited settings reduced the high costs of the implementation of SLMTA programmes or increase accessibility. Of significance, majority of these laboratories continued to lag behind in adoption of quality control and assurance management and uptake of ISO 15189 certification as well as accreditation [22, 23]. Tellingly, in 37 out of 49 sub-Saharan Africa countries surveyed, there was not a single clinical laboratories accredited to internationally recognized quality standards by December, 2016 [22, 23, 31]. Specifically, in Kenya where the implementation has been ongoing albeit slowly had only 16 (8 in private and 8 in public healthcare systems) accredited by KENAS by 2015 [29]. Significantly, only eight (8) of medical diagnostic laboratories had been internationally accredited by 2017 [29]. Previous studies have highlighted lack of capacities of in some of the laboratories to even perform the basic diagnostic tests are not available. For instance, in a study of ten LMICs, only 2% of the facilities were able to perform basic tests of blood glucose, Haemoglobin (Hb) level, malaria test, urinalysis/dipstick for proteins and sugar, HIV, Syphilis and pregnancy [21]. In addition, further evidence indicated limited access to essential laboratory diagnosis testing, especially at primary health care (PHC) level in many LMICs [2, 20, 21]. Therefore, low or sometimes non-existent digitization of records/data and the subsequent low application of evidence-based decision making continue to bedevil this key field in healthcare. In addition, other previous studies on status, have identified common deficiencies between private and public systems [4, 20, 21, 22, 23] implying lack of readiness to provide basic clinical care. For that reason, they concluded that most of the LMICs were inadequately equipped to provide basic clinical care, especially at PHC level, a critical aspect that implied unpreparedness towards UHC and hence required urgent intervention [4].

Considering the centrality of an efficient PHC as the fulcrum for UHC particularly so in the rural and remote areas in Kenya, increasing accessibility, availability and affordability of laboratory diagnostic services for UHC at PHC through reliable diagnostic services, realistic, sustainable country-specific EDLs and fast-tracking adoption of quality control and assurance management therefore becomes paramount.

Although, several studies on the quality status of diagnostic laboratory services, availability, accessibility, international accreditation in LMICs and across Africa,

similar studies in Kenya and for readiness of PHC laboratory services to support UHC programme are few if at all, thus the evidence to support the hypothesis is inadequate. Hence, studies focusing specifically not only the current status of laboratory diagnostic services for a resource-limited PHC setting such as Kenya's to identify gaps, deficiencies, weaknesses are required. The devolvement of health services under the new Kenyan Constitution (2010) [32] and the impending massive roll out of the UHC programme across the country, make this requirement even more urgent.

This will have a direct impact on not only reliability of laboratory diagnostic, curative but also preventive services of diseases. In addition, it will ensure reliable basic clinical care, thus UHC at PHC, strengthening of the current referral system, Enhance healthy treatment outcomes and the overall life expectancy, therefore, ultimately helping in attainment of the governments "Big Four" agenda of UHC, the UNs SDG number three (3) and Kenya's Vision 2030 blue print. Currently, there is no study conducted to investigate or determine readiness of PHC laboratory diagnostic services to support UHC programme implementation in Kenya or the causes of their low or slow adoption of quality control and assurance management, the uptake of ISO 15189 certification as well as accreditation. The purpose of this study was to determine the status of laboratory diagnostic services at PHC level in three Kenya counties, their readiness to support UHC programme implementation in terms of availability of WHO-EDL defined diagnostic tests, extent adoption of quality control and assurance management as well as factors for the slow or low uptake of ISO 15189 certification and accreditation. The authors hypothesized that the readiness of laboratory diagnostic services at PHC level in Kenya to support UHC programme was insufficient and if not addressed could greatly undermine its successful implementation. In addition, that the WHO-EDL list for UHC at PHC was unrealistic and unsustainable and as it is not applicable for resource-limited settings such as sub-Saharan Africa and Kenya in particular. Further, the high cost, inaccessibility and lack of or low awareness levels of the proposed current SLIMPTA/SLPTA training programmes model of attaining ISO 15189 certification and Accreditation in resource-limited settings of sub-Saharan Africa were still key hindrances.

The study was conducted in three counties of Kirinyaga, Embu and Nyeri. Worth mention, Nyeri is one of the four (4) counties piloting the proposed GoK UHC programme selected on the basis of its high burden of NCDs and in particular Diabetes Mellitus. Accordingly, the main objective of this descriptive pilot study was to investigate the preparedness of laboratory diagnostic services at PHC level in three Kenyan counties to support a successful and sustainable UHC programme implementation. To achieve this, the specific objectives of the pilot study were; to determine the current status of health care laboratory diagnostic services at PHC level, the extent of availability of the WHO-EDL defined diagnostic component for UHC at PHC level to estimate readiness of these services to support

quality basic clinical care for UHC, adoption and consistent routine application of basic quality control and assurance management to ensure reliable results/diagnosis by the services and the factors for the slow or low uptake of ISO 15189 certification and accreditation. By piloting in the three counties, this would generate evidence-based proof of concept, insights on the state of preparedness of diagnostic laboratory services for UHC implementation at PHC settings in Kenya to inform the impending UHC programme implementation and future larger studies.

The authors were trying to answer the following research questions;

On the basis of the WHO-EDL for PHC and UHC, what is the infrastructural, technical, human resource capacity status, thus the extent of availability of essential diagnostics in sampled laboratory diagnostic facilities at PHC level, thus their overall readiness to provide basic quality clinical care to support UHC programme implementation in the three Counties?

What are the driving factors for the low or slow adoption of quality control and assurance management, uptake of ISO 15189 certification or accreditation?

The proposal of developing, standardization of country-specific EDLs for UHC suitable for a resource-limited PHC setting as defined by WHO, which can be incorporated as part of the basic health insurance cover package, change of user's/clients perception, disregard for PHC and obsession with higher level health-care services by strengthening the current referral system and the refocusing of PHC as the engine of UHC through increased, concurrent and equitable investment in not only curative but also laboratory diagnostic services at PHC and a tailor-made 2-3 weeks short course modular Total Quality Management (TQM) staff development training programme, which is a condensed version of the current SLMTA/SLIPTA training programmes to sustainably accelerate adoption of quality control and assurance management, thus assure reliable clinical care for UHC at PHC is the innovation or originality in this study.

2. Design and Methods

2.1. Study Design

This was a qualitative descriptive pilot study conducted in three Mount Kenyan region Counties of Kirinyaga, Embu and Nyeri from December, 2017 to November 2019.

2.2. Study Area

The study area included identified PHC settings as defined by WHO as a "*setting where no laboratory at all is available OR where only basic laboratories with capacities for identified general tests, disease-specific testing and Infectious diseases-specific tests are available*" [8, 20] in the aforementioned three Counties, which bordered Kirinyaga University, the affiliation of the authors. The specific tests for WHO-EDL for UHC at PHC settings have been outlined in more details in the introductory section. Close proximity of

the three to the affiliation institution of the authors, one of them (Nyeri) being one of the four (4) piloting the GoKs UHC programme, their rural set-ups, thus close representation of PHC level health care and constraints of time as well as financial resources were the reason they were selected for this pilot study.

2.2.1. Embu County

Embu county lied some 120 kilometers north east of Nairobi, on south-eastern side of Mount Kenya. The county covers an area of 2,818 square kilometers. According to the KNBS [33], Embu county population was estimated to be 608, 599 (304, 208 males and 304, 367 female). Its location at the foothill of Mt. Kenya, gives the county an estimated temperature of an average of between 9°C - 28°C. The county receives substantial rainfall with average annual precipitation of 1206 mm. The wettest season is experienced between March and July while the hottest comes between January and mid-March. Agriculture is the main driver of the economy in this county with over 70% of the residents being small scale farmers. A small percentage of residents are business people and civil servants working in government institutions. Tea, coffee and cotton have been the main cash crops. However, due to their falling prices, many farmers have in the recent years started growing other crops. Mango farming has become a robust economic activity, finding market as far as Nairobi. Among the most prominent health facilities include Embu Provincial General Hospital (Embu town), Runyenjes District Hospital, (Runyenjes town) Siakago District Hospital (Siakago), Consolata Hospital, Kyeni (near Runyenjes), Liberty nursing Home (Embu town), Ishiara sub-District Hospital, Kibugu Health Center and Joy Kim Nursing Home in the outskirts of Embu town that all serve the needs of the residents. The county's population health care priority or needs include ante-natal care, malaria, intestinal parasites, NCDs, arthritis, Tuberculosis, neglected tropical diseases (e.g. Bilharzia) and infectious diseases [34].

2.2.2. Kirinyaga County

Sitting at the foothills of Mount Kenya, some 112 km from Nairobi, Kirinyaga county covers 1479.09 square kilometers and with a total population of 610, 411 (302, 011 males and 308,369 females), according to the latest population KNBS census [33]. Kirinyaga county is set directly below Mt. Kenya, hence one of the wettest counties. With annual temperatures ranging between 12 °C and 26 °C or an average of 20°C and annual precipitation of about 1250mm. Kirinyaga enjoys two rainy seasons - the long rains (March-May) and short rains (October-December). Agriculture is Kirinyaga's main economic activity, with over 70% of residents being small scale farmers. Others careers include business people, teachers, civil servants working in government institutions and those who work for the various tea, coffee and rice factories. The county's leading farming industries include coffee, tea, rice, horticulture, dairy farming, maize and beans. Fish farming is being practiced lately with many farmers now creating space for fish ponds.

The urban centers are well served by government hospitals, health centers and dispensaries the county has 103 medical facilities, several private and mission health facilities in different towns. The most notable include Kerugoya District Hospital (Kerugoya town), Kiyanaga sub-District Hospital (Kiyanaga town) and Kimbimbi sub-District Hospital (Mwea). Some of the mission hospitals include Mwea mission near Wanguru town and managed by the Catholic Church, A. C. K Mt. Kenya hospital located along Kerugoya-Karatina road and Hope Medical Clinic along Sagana-Karatina road.

Some of the county's population health care priority or needs include ante-natal care, Malaria, intestinal parasites, neglected Tropical Diseases (Bilharzia), NCDs, arthritis, Tuberculosis and infectious diseases. The poverty index of the county is rated at 25.2% [35].

2.2.3. Nyeri County

Nyeri county, one of the counties piloting the UHC programme in Kenya, is located in the former Central province of Kenya, about 150 kilometers north of Nairobi. It covers an area of 3,337 square kilometers, with a total population of 759, 164 (374, 288 males and 384, 845 females) according to the latest [33] KNBS population and Housing census of 2019. Nyeri county has some of the lowest temperatures in Kenya, which range between 12°C in the cold months (June and July) and 27°C in the hot months (January-March and September-October) with high precipitation all year round. The rainfall average lies between 500 mm and 1500 mm during the short and long rains periods making it conducive for its diverse agricultural activity. Nestling between Mt. Kenya and the Aberdares ranges, agriculture is the main economic activity in Nyeri. The county is renowned for its high production of tea and coffee, which are grown mainly for export. Many other residents are engaged in retail business across the main towns and in open-air markets selling agricultural produce.

Nyeri is also renowned for horticultural farming, where large scale flower farms in the county include; Mweiga Blooms in Kieni and Wilmar Flowers in Sagana area. Green house farming is also becoming popular among small scale vegetable farmers, where they engage in growing tomatoes, courgettes, green pepper, strawberry and capsicum among others. Other agricultural activities which act as a source of income include dairy farming and fish keeping in Tetu, Aguthi, and Chinga dam areas. Dairy farming is mostly practiced on a small scale basis mainly at homes. There is Trout rearing around the base of Mt. Kenya, and along the Chania and Gura rivers. Nyeri County has a number of light industries which provide employment opportunities and markets for local produce. Notable factories include Maisha flour millers, Brookside dairy, Mt. Kenya bottlers and Highlands mineral water. Organizations such as USAID, DFID, the UN and NACADA are involved in funding and sustenance of humanitarian projects such as environmental conservation, bee keeping, horticulture, health and other socio-economic activities that have impacted the lives of the

county residents. There are several hospitals and health centres in Nyeri. Notable healthcare facilities include the Nyeri Provincial General Hospital, Karatina District Hospital, Mukurwe-Ini sub-District Hospital and Othaya sub-District Hospital. Church-run health facilities include Consolata Hospital, PCEA Tumu Tumu and Mary Immaculate Hospital in Mweiga. Private hospitals include the Outspan Hospital, Mt. Kenya Hospital, Jamii Nursing Home, Nyeri Surgicare Centre, and Waka Ruring'u Maternity. Although, the Nyeri population health care priority include NCDs especially Diabetes Mellitus is noted hence selected to pilot the UHC, ante-natal care, a significant prevalence of malaria, intestinal parasites or worms, Tuberculosis, Arthritis and Infectious diseases, The poverty index of the county is rated at 32.7% [36].

2.3. Study Population

A proportionate sampling of small to medium medical laboratories in the three (3) Counties based on physical size and population density) was done. The study population comprised the permanent employees of the sampled laboratories and were used for data collection.

2.3.1. Data Collection

In order obtain study-specific information on the status of PHC laboratory diagnostic services in terms of infrastructural, technical and human resource capacities, quality management knowledge/awareness levels as well as the extent of availability of the WHO defined EDL component for UHC at PHC [7, 8, 20] of the three counties, structured, pre-tested, self-administered questionnaires, were issued to the participants after obtaining an informed consent form. Likewise, information on the availability, accessibility of quality control and assurance management training programmes, perceptions towards certification, accreditation as well as hindrances to certification and accreditation were collected using the same research instruments. Whereas, using the aforementioned questionnaires, general observation and interviewing of staff in-charge or supervisors as the key informants, information on availability, consistent application of quality control and assurance management standards (clear organizational structure/organogram, SOPs, QMS, quality policy, objectives) or guidelines (professional development, use of LIMS, standards/controls, internal or external quality controls, equipment calibration and maintenance schedule), automation level, number of permanent staff and the average time around time for basic EDL test such as blood slide for malaria parasites as well as opinion on major barrier to certification was obtained.

2.3.2. Sample Size Determination

The sample size was computed using Fisher's (1991) formula [37].

Subsequently, a sample size of 313 (n=313) was obtained, which was proportionately apportioned to the three counties, based on population and physical size as described previously. As a result, Nyeri, the biggest in size and most

populated of the three was apportioned 119, while, Embu, which was second was assigned 97 and Kirinyaga, the smallest in size least populated was allocated 97 of the study samples.

2.3.3. Eligibility

Inclusion Criteria: The samples for this pilot study included both public and private medical diagnostic laboratories in a PHC setting in the three defined counties of Kirinyaga, Nyeri and Embu. In accordance with the WHO, a PHC setting was defined as “one where no basic diagnostic laboratory or where only basic laboratories with capacities to conduct basic WHO-defined EDL specified general tests, disease-specific and Infectious diseases-specific tests” [4, 7, 20]. Subsequently, both public and private Levels I (without basic laboratory), II and III (with basic or a clinical laboratory) PHC diagnostic laboratory facilities were included for the study. In addition, the WHO-EDL definition of essential diagnostic list (EDL) for UHC at PHC as “that satisfy priority health care needs of local population, prevalent disease, public health relevance, efficacy, accuracy and comparative cost-effectiveness of the test” [4, 8], was used as a criteria for suitability and eligibility of the diagnostic laboratory. Consequently, based on specific-disease prevalence of the counties, priority health care needs, other tests such as Rheumatoid factors for arthritis, Stool test for intestinal Parasites, Leishmania staining for neglected topical diseases e.g. Bilharzia, Gram’s Staining for Bacterial Infection, Sepsis, Sputum test of Ziehl-Nelson (ZN) staining for Acid-Fast Bacilli (AFB) or Mycobacterium, Widal test for Typhoid and antenatal care testing (Pregnancy test, Slide test for ABO & Rhesus Blood grouping, Syphilis test, Urinalysis/Dipsticks for urine proteins and sugars & glycated Haemoglobin (Hb) test) were added to the county-specific EDL specifically developed for this study.

Exclusion Criteria: The exclusion criteria for the study included all the level 4, 5 and 6 health facilities, those with sophisticated, automated testing machines, capable of performing advanced tests, with more than 20 permanent employees, those conducting more than 20 tests daily and those outside the defined three counties. Hence, all public or private medical diagnostic laboratories considered Levels IV and above, those located outside the three defined study counties of Kirinyaga, Nyeri and Embu, were excluded from this study.

2.3.4. Sampling

In order to avoid bias, for study validity and generalizability proportionate, probability random sampling of small to medium medical laboratories in a PHC setting, based on the population and where appropriate the physical size of the three counties was applied. The three counties were selected due to their close proximity to the authors’ affiliations and funding limitation. After identification of a list of sample frame, a list of sample units was drawn, which was followed by a systematic random sampling, where counties were grouped as clusters. Then using the laboratories in the counties were further grouped into strata of towns. By simple random sampling, assigned proportions

of samples were selected from the strata using the K^{th} value. Permanent employees of the sampled laboratories were issued with structured, pre-tested, self-administered questionnaires. The staff-in-charge of the sampled laboratories, such as the manager or supervisor, were used for the key informant interviews. General observation of the working space, existence, use of SOPs, guidelines, test controls, standards, calibration schedules and procedures by the interview was also used in data collection.

2.3.5. Data Analysis

The data from the questionnaires, key informant interviews and general observation were coded appropriately and transcribed into SPSS software and analysed using descriptive statistics by IBM SPSS software version 22. After coding of the obtained information appropriately, it was transcribed into SPSS software (IBM version 22.0), analyzed by descriptive statistics, interpreted, summarized and presented in the form of summary tables and graphs. For judging statistical significance, a $p=0.005$ was used. The results were summarized, interpreted and presented in the form of tables and graphs figures as shown in the result section.

2.3.6. Ethical Considerations and Protection of Participants

The pilot descriptive study was conducted in accordance with Helsinki declaration. In view of that an informed consent was obtained from each participant before being issued with the study questionnaire. For instance, respondents were allowed to participate in the study only after being briefed on the purpose, benefits and the risks (if at all) of the study and were satisfied. In order to protect participants information, guarantee confidentiality and anonymity, not only was their identity concealed by only ticking yes or no if they agreed to participate in the survey, but also their information was locked in safety cabinets, which were only accessible to the principal investigator (PI).

3. Results

Table 1. Study Participants’ Demographics.

Count	Column N %
70	56.5%
54	43.5%
45	36.3%
65	52.4%
12	9.7%
2	1.6%
108	87.1%
15	12.1%
1	0.8%
35	28.2%
82	66.1%
7	5.6%

Table 1 summarizes the demographic distribution of the participants. The majority were males, between 30- 40 years of age, Technologists with diploma level of education.

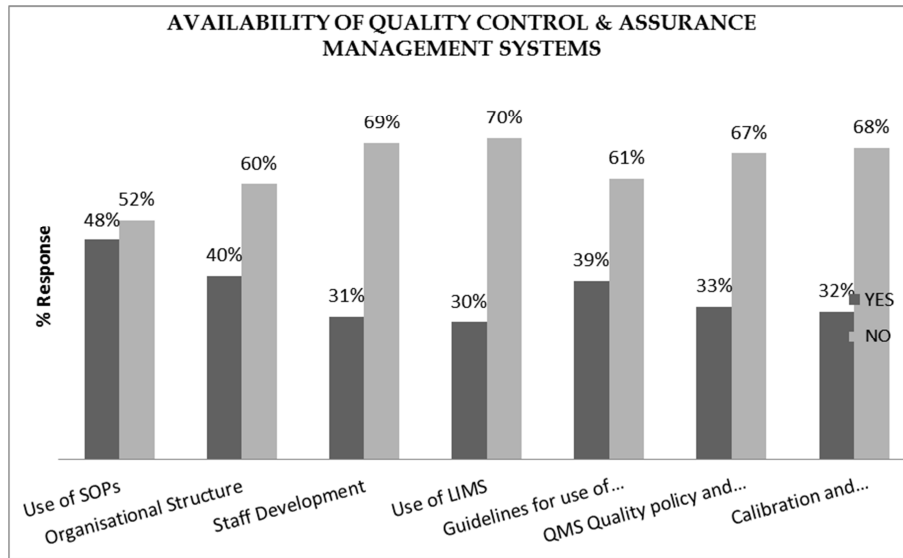


Figure 1. Adoption and Consistent Application of Basic Quality Control, Assurance Management.

Figure 1 shows responses to availability and consistent application of quality control and assurance management systems standards, guideline and procedures. Importantly, availability and consistent application of the aforementioned

in majority of sampled laboratories was less than 50%, with the best response being on SOPs at and worst being use of LIMS at 30%.

Table 2. Significant Factors for Adoption and Consistent Application of Basic Quality Control and Assurance Management Systems.

	Gender	Age	Role/Rank	Education
Use of SOPs	0.182	0.343	0.550	0.020*
Organizational Structure	0.517	0.673	0.415	0.170
Staff Development	0.568	0.794	0.624	0.001*
Use of LIMS	0.290	0.881	1.320	0.010*
Guidelines for use of STDs and CTRLS	0.441	0.881	0.440	0.470
QMS Quality policy and objectives	0.410	0.927	0.253	0.027*
Calibration and Maintenance Schedule	0.511	0.887	0.274	0.680

Table 2 shows that education level was a significant factor in the consistent application of SOPs (p=0.020*), use of LIMS (p=0.010*), availability of Staff development

programmes (p=0.001*), QMS, Quality policy and objectives (p=0.027*), in small to medium laboratories. A * indicates statistical significance (P ≥ 0.005).



Figure 2. Perceptions/Attitudes toward Adoption of Quality Control and Assurance Management Systems in the Laboratory.

Figure 2 shows the perception/ attitudes of the participants towards quality control and assurance management system in the medical diagnostic laboratories. Although, there was a

strong consensus among Degree and Diploma with a total of 97% of Technologists (Degree and Diploma education level) and 100% of Technicians (Certificate level) on importance of

application of quality control and assurance management systems in medical diagnostic testing, 3% of technologists disagreed.

Table 3. Overall/General Factors for the Low or Slow Uptake of Certification and Accreditation.

		Count	Column N %
Non Certification & Accreditation	Cost & Duration	47	38.2%
	Lack of knowledge	53	43.1%
	Accessibility	21	17.1%
	Not important	2	1.6%

Table 3 shows that, in general, the main factors cited for the low or slow uptake of ISO 15189 certification and accreditation were lack of knowledge/Awareness (43.1%) of the processes including the SLMTA training programme in readiness for Certification and Accreditation, closely followed by the Cost and Duration (38.2) of the processes and In accessibility of the programmes (17.1%).

4. Discussion

The objective of this study was to investigate status of PHC laboratory diagnostic services in terms of availability of the WHO defined EDLs for PHC and UHC, their readiness in supporting UHC at PHC. In addition, the study aimed to determine availability and consistent application of quality control and assurance management and the driving factors for the low, slow uptake of certification and accreditation. Further, by determining the extent of availability of EDLs component of UHC as defined and highlighted by the WHO [4, 8] in the facilities, essentially, the readiness of the counties towards supporting the up-scaling and mass roll-out of the ambitious GoK's UHC programme implementation could be estimated. The pilot study involved permanent staff of randomly selected medical diagnostic laboratories in PHC settings of three Kenyan counties. Specifically, these were both public and private health facilities at PHC levels I (Clinics with or without basic laboratory) III (Dispensaries with basic laboratory) and III (Health centres with basic onsite or autonomous laboratories. The number of permanent staff working in these facilities ranged from one (1) to sixteen (16). Accordingly, those with one to two permanent staffs at 28%, were the majority, followed by those with four (17%), three (9%), with only about 5% having between five to sixteen permanent staff. The average turn-around time for basic EDL general test such as blood slide for malaria parasites was 23 minutes and a range of 8 to 45 minutes. This highlighted the common deficiencies of severe shortage of health-care workers, challenges of attracting as well as retaining them especially in rural remote areas in particular after devolvement of health services previously reported [22, 23, 38]. The response rate for the study was more than 49%, with the majority of participants (57%) being males educated up to diploma falling under the 30-40 years age group, followed by those with degree level of education and within 20 – 30 years age bracket as summarized in Table 1.

It is worthwhile to mention that the WHO has identified the essential diagnostic tests that should be available at different levels/tiers of the health care system. For a PHC

setting, the basic general tests include;-Urinalysis/Dipsticks, Complete Blood Count (CBC), White Blood Count (WBC), Blood lactate, Glucose and Microscopy (for Anaemia, Malaria parasites, Tuberculosis and intestinal or blood parasites). Likewise, WHO has listed RDTs (for HIV, Malaria, Syphilis and Viral Hepatitis {A, B & C}), Glycated Haemoglobin, LAMP as the disease-specific tests, whereas AFB, ATT, CBNAAT, Chemiluminescence Immune Assay, Drug Susceptibility tests, EIA, FACS, G6PD, HPV Interferon Gamma Release Assay, LAMP, LPA for M. Tb and Nucleic Acid Amplification are listed as infectious diseases-specific tests that should be available at PHC level [4, 8, 20].

Nevertheless, while most of the WHO-EDL defined general tests for PHC level might be available in majority of LMICs, a "PHC settings" might mean different things to high income and LMICs. Similarly, variabilities among the two in terms of availability and accessibility of the three categories of the WHO-EDL for PHC settings in the high Income as well as LMICs are clear. Hence, application of the WHO-EDL as it is currently constituted across the board is not only unrealistic but also unsustainable for resource-limited PHC settings such as sub-Saharan Africa. For instance, some of the disease-specific or infectious diseases-specific molecular tests such as LAMP, CBNAAT, Nucleic Acid Amplification or immunoassays e.g. Chemiluminescence Immune Assay, Fluorescence- Activated Cell Sorting (FACS) as well as Interferon Gamma Release Assay or LPA for M. Tb, are beyond the reach and capacities of majority, if not all of resource-limited PHC settings such as Kenya but also across sub-Saharan Africa. Therefore, development and standardization of not only more Country-specific, but also resource-limited suitable EDLs as sustainable alternatives to the WHO-defined ones. Of essence, such cost effective EDLs, which will be based on specific disease prevalence and prioritizing the relevant public health needs of a country are highly recommended.

Nevertheless, based on the WHO-EDL for UHC at PHC, although there was almost 100% availability of the general test, however in more than 76% of the facilities, only about 3% of the disease-specific or infectious diseases-specific tests were available, implying not only low readiness of these laboratories and PHC in general to provide basic clinical care in the three counties but also to support the nationwide up-scaling of the UHC programme.

The significance of a standardized, globally acceptable EDL for UHC at PHC notwithstanding, the WHO-EDL as currently constituted may not be realistic and sustainable for resource-limited settings such as Kenya. Hence, may be of

little if at all benefit or impact to successful implementation of the UHC programme. Whereas only 24% of the facilities had capacities for the more advanced testing for drug susceptibility for antimicrobial resistance, Blood Lactate, Hepatitis B, C or Anti-HIV/P24 Rapid tests, importantly none of the facilities had capacities for the molecular-based tests including LAMP testing, ATT, CBNAAT, Nucleic Acid Amplification, immune Assays e.g. Chemiluminescence Immune Assay, G6PD, LPA for M. Tb, Interferon Gamma Release Assay for M. Tb and FACS. The primary role of access to essential diagnostics in improving quality and reliability of clinical care [2], in resource-limited PHC settings, provision of the aforementioned WHO-EDL, as it is not realistic, viable and sustainable.

Consequently, considering the glaring differences between the high-income and LMICs, the unsuitability, unrealistic and unsustainable application of the WHO-EDL as it is across the board identified in this study should be urgently addressed. A more cost-effective, realistic, sustainable and tailor-made country-specific EDLs using simple technologies that does not rely on expensive infrastructural support such as advanced skills to perform or where applicable electricity that suitable for resource-limited PHC settings was required. Developed and defined in accordance with WHO definition of EDLs, PHC, such a country-specific EDL which takes into the account priority local population health care needs, specific diseases prevalence and public health relevance is proposed herein;- A) General Tests:- Stool test for intestinal parasites, Microscopy for malaria/Blood parasites, Blood lactate, Cholesterol, Glucose, Urinalysis/Dipsticks for sugars and proteins, Gram staining for Bacteria, Erythrocyte Sedimentation Rate (ESR), C-Reactive Proteins (CRP) and Fibrinogen for acute or chronic inflammation, CBC/WBC, sputum test (ZN) for AFB, RDTs for HIV, Malaria, HPV and Viral Hepatitis, Widal test for Typhoid fever, Rheumatoid Factor for Arthritis and Ante-natal care testing (Pregnancy test, Glycated Haemoglobin, Slide Test for ABO & Rhesus Blood Grouping, Syphilis, Urinalysis/Dipsticks) B) Disease-specific Tests;- RDTs for HIV, Syphilis, HPV and Viral Hepatitis Tests. C) Infectious Diseases-specific Testing;- the AFB test, Chemiluminescence Immune Assay, Drug Susceptibility Test, E Immune Assay and Interferon gamma release assay etc.

Importantly, with the global cancer burden estimated to have risen to 18.1 million new cases and 9.6 million deaths in 2018 according to WHO International Agency for Research on Cancer (IARC), 2018, and with 1 in 5 men, 1 in 6 women globally developing cancer during their lifetime, 1 in 8 men and 1 in 11 women dying from the disease empowering and building capacities of PHC to detect the disease early cannot be overemphasized. Therefore, to support screening, early primary diagnosis of NCDs at PHC, surveillance and investigation of outbreaks, other diseases-specific tests worth consideration for the country-defined EDL include the following;- basic exfoliative and interventional diagnostic cytology tests of Pap smear test of Cervical Cancer and Fine Needle Aspiration Cytology (FNAC) for palpable swellings

of lymph nodes or glands etc., Blood 2-hydroxyglutarate (2HG) onco-metabolite for oxidative damage-induced cell senescence, FIT-Stool –based Occult Blood for stomach Cancers and basic Cytogenetics for structural and numerical chromosomal changes or aneuploidy. This will not only reduce the cost of UHC implementation but will also strongly impact on health outcomes by reducing delays in diagnosis or turn-around time, misdiagnosis, timely initiation of treatment, reducing the risks of disease complications, developing malignancies and late presentation of patients with advanced stage illnesses. Equally important will be expanding the scope of basic laboratory diagnostics training (general testing EDL of blood sugar, lactate, Haemoglobin, blood slide for malaria parasites, pregnancy test, ABO Blood grouping, RDTs for HIV, Malaria, Syphilis, sputum test for TB, HPV, Hepatitis, Stool test for intestinal parasites, Urinalysis for sugar, protein and antenatal care testing) to include other cadres of health care such as clinical officers, pharmacists, nurses, public health officers and community health workers. Of significance, this will not only strengthen the current referral system, change perception of users at PHC, their preference for higher levels thus reducing their rampant overcrowding but also motivate the workers, attract as well as retain them in remote and rural areas.

Notably, despite the centrality of PHC to UHC, significant gaps and deficiencies in capacity to provide basic quality, reliable health care services (e.g. perform essential tests or adoption of quality control and assurance management) were identified, thus highlighting the low readiness to support successful nationwide up-scaling of the programme in the three study counties as summarized in Figure 1 and Table 2. Specifically, in less than 50% of the sampled medical diagnostic laboratories, there were no clear quality control and assurance management systems, 67% of the sampled facilities lacked quality management systems (QMS) policy and objectives, in 69% of the sampled facilities, there was no staff development programmes with the good response being availability and consistent application of standard operating procedures (SOPs) and the worst being use of LIMS (Table 2). This was in agreement with previous studies on quality of individual laboratories documentation of coverage and quality of laboratory services throughout Africa, external quality assurance, readiness for health care service delivery index coverage testing [22, 23]. Although the size of the diagnostic laboratory could be a factor, notably availability of a clear quality organizational structure with an organogram, a quality assurance department with designated quality assurance officer or manager for responsibilities and accountability was not available in 60% of the facilities as seen in Table 2. Subsequently, there was lack of, thus inconsistent application of not only guidelines for experimental standards, controls (39%), but also machine or equipment calibration or maintenance schedule (32%) as well as low use of LIMS (30%) as shown in Table 2.

Further, substantial deficits not only in knowledge, awareness levels and availability of quality training programmes or institutions, but also their accessibility were

highlighted. For instance, only 6% of the respondents knew of any quality training programmes or institutions, but which were 10 to more than 20 kilometres away from them this is notwithstanding that a good measure of respondents acknowledged the importance of ISO 15189 certification and accreditation. Nonetheless, the cost, lack of knowledge or awareness and accessibility were the main barriers to certification and accreditation cited according to Table 3. Notably, previously the affordability or cost of the processes and geographical accessibility has been identified as key obstacles to access and UHC [22, 23]. Of significance, other barriers cited included; shortage of staff, low motivation, ignorance, insufficient capacity building and lack of equipment or reagents. The challenges of weak laboratory infrastructure, quality and reliability of, availability, accessibility of laboratory services, the low capacities for not only basic quality clinical care but also readiness for UHC in these Counties as identified in this study, are in agreement with previous studies by [21].

4.1. Barriers to ISO 15189 Certification

Conspicuously, the lack of clear organizational structures with clear lines of accountability underlined majority of the identified deficiencies and shortcomings such as; - the lack or low staff/professional development programmes, use of SOPs, LIMS, low adoption of basic quality control and assurance management, lack of guidelines for standards, controls, internal and external quality control, QMS, quality policy and objectives, calibration as well as maintenance schedule. Tellingly, this explained the low or slow uptake of ISO 15189 certification and accreditation, which was in total agreement with previous studies [4, 22, 23]. Therefore, in this respect, by simply designing organizational structure/organogram, that integrates quality control and assurance management with designated quality management personnel as well as its enforcement, is highly recommended.

Notably, the cost, lack of knowledge or awareness were the main factors cited for the low or slow uptake of certification and accreditation as summarized in Table 2. This was in agreement with a study by Schroeder et al. [23] and Elbireer et al. [21], which identified geographical access barriers and affordability of laboratory diagnostic tests as key obstacles to healthcare access and UHC.

However, considering the staggered started and a multi-staged process nature, of SLMTA/SLIPTA training programmes, its long duration of between 12 – 18 months, the time constraints to the up-scaling of the UHC programme across Kenya, new, creative short-term measures as urgent stop-gap and long-term intervention measures to support a sustainable implementation and up-scaling of the UHC programme are required. Despite all the good intentions of the resource-limited-specifically developed SLMTA/SLIPTA programmes to fast-track quality control, and assurance management, ISO certification and accreditation, they have had little if at all impact. The willingness to adopt quality control and assurance management still slow, hence the low uptake of ISO

certification and accreditation in sub-Saharan Africa (Table 1 and Figure 2). Subsequently, short-term intervention measures including redesigning of organizational structure or organograms, enforcing incorporation of designated quality assurance personnel with clear lines of accountability is recommended. Further, tailor-made, user-friendly short courses or professional development training programme in TQM to fast-track adoption of quality control and assurance management, thus reliable clinical care are required. A good starting point is partnering with training institutions to develop condensed versions of the current SLMTA/SLIPTA for staff professional development. Such a training programme comprising of but not limited to the following proposed herein:

Laboratory Safety and Management, Quality Management System Model, Quality Control Program 1.

Quality Control Program 2 and Quality Assurance Program.

Trends in Laboratory Quality Management Systems and Laboratory Information Managements.

For this to happen, a linkage of health-care laboratory diagnostic services and medical laboratory training is necessary to develop and provide training as a matter of priority a shortened or condensed two (2) to three (3) version of the current SLMTA training programme. The use of LIMS should be promoted and supported. For long term measures, staff development programmes for continued quality improvement, should be enforced, development, adoption of QMS, quality policy and objectives in readiness to the ultimate ISO 15189 certification and accreditation should be promoted. In addition, the linkage of health-care laboratory diagnosis services with medical laboratory science training in the long term should work towards reviewing the current academic training curriculum for medical laboratory sciences with the aim of incorporating SLMTA training programme to not only strengthen them but prepare graduates for the ISO 15189 certification and accreditation.

To investigate determining factors for this low and slow of uptake state, independent association of several explanatory factors such as gender, age, role/rank and education level, with dependent variables of availability and application of quality control and assurance management systems, perceptions were tested using regression analysis. Significantly, education level of the participants' variable was statistically significant. Likewise, it was also significantly associated with availability and consistent application of SOPs, staff development training, use of LIMS QMS, quality policy as well as objectives. Worth mentioning, knowledge and awareness levels for quality control and assurance management systems, certification, accreditation was significantly higher in those with degree or diploma levels of education as opposed to certificate holders. Considering the differences in degree and diploma curricula, their respective expected learning outcomes and programme goals could explain the disparities. Specifically, degree programme in medical laboratory sciences aimed to produce human resource to supervise or manage the laboratories, hence more

emphasis on quality control and assurance management component as opposed to the certificate level, whose goal is to produce hands on Technicians or staff to do the actual tests. Importantly, this implies a gap in the medical laboratory science curricula or knowledge acquisition hence highlighting the need for review of the content and programme goals as well as quality control and assurance management content for these two cadres of medical laboratory staff. Such a review might include incorporating the SLMTA training programme in the academic programmes.

4.2. Barriers to Accreditation

Importantly, lack of or low knowledge/awareness level of the process and SLMTA training programme, cost and duration of the programmes as well as accessibility were the most cited barriers to certification as summarized in table. Apparently, this was in agreement and supported the findings of a study by Elbireer *et al.* [21] and Schroeder *et al.* [22] that identified geographical access barriers, and affordability of laboratory tests as key obstacles to access of quality health and UHC. Notably, there was a significant difference between the education, ISO certification ($p=0.01$), and accreditation ($p=0.01$) knowledge and awareness levels, and application of QMS standards and guidelines (0.16). Therefore, to further explore independent association of sub-categories of Degree, Diploma and Certificate with knowledge and awareness levels of quality control, assurance management, certification or accreditation, a multinomial linear regression was used. As expected, A person with a degree was 1.972 times more likely to have heard about ISO 15189 certification and accreditation of medical diagnostic laboratories compared to one with a diploma (1.972). Likewise, a person with a certificate was 0.683 times less likely to have heard about certification and accreditation compared to a diploma (-0.683) holder, a finding which was significant ($p=0.01$). Probably, disparities in the objectives and expected learning outcomes of the medical laboratory training curricula different sub-categories of laboratory workers could account for these differences.

A person with a degree was 1.189 times more likely to be aware and likely apply quality control and assurance management standards and guidelines in medical diagnostic laboratories compared to a diploma holder (1.852). While most of the respondents were aware knew the importance of quality control and assurance management, ISO certification and accreditation, however the willingness to adopt them was low. Accordingly, the rank/role of the respondents, thus a clear line of accountability to the seniors was a determining factor. ($p=0.000$). Seemingly, the education levels of the participants appeared to play a key role in shaping willingness to adopt the quality control, assurance management, ISO certification and accreditation thus perceptions. For instance, there was a significant difference between education level and availability as well as use of (SOPs ($p=0.02$), Staff development awareness ($p=0.001$), use of LIMS ($p = 0.01$) and awareness of the laboratory's' quality

management system (QMS), quality policy and objectives ($p = 0.027$). To understand more how education level variable related with compliance of SOPs availability and their application, Nominal regression was used. Subsequently, while a person with a degree was 1.566 times more likely to use SOPs compared to one with a diploma (1.566), a person with a certificate was 1.956 times more likely to use SOPs compared to one with a diploma (1.956). This finding was significant ($p=0.02$). Again, Degree holder Technologists were supposed to be supervising or managing the diploma and certificate employees, hence the disparities.

Predictably, a person with a degree was 19.252 times less likely to be aware of the laboratory's' professional staff development for continuous improvement compared to a diploma holder (19.52). A Diploma holder due to feeling of inadequacy will want to further develop him or herself. Similarly, due to the same feeling of inadequacy, a person with a certificate was 18.003 more likely to be aware of the laboratory's' professional staff development compared to one with a diploma (18.003), a finding was significant ($p=0.001$).

In general, there was low embracing of LIMS for documentation and digitization of records in 60% of the facilities, which was in agreement with study by Schroeder *et al.* [22] and Elbireer *et al.* [21], which found inadequate documentation of coverage and quality of laboratory services throughout. Considering their more advanced training programme, a person with a degree was 84.414 times more likely to embrace and use LIMS compared to a diploma (84.414) holder. Probably, due to their hands on work of Technicians, a person with a certificate was 30.118 times more likely to adopt the use SOPs compared to a diploma holder (30.118), a finding which was statistically significant ($p=0.01$). In consideration of the key role played by laboratory data and LIMS in linking quality clinical care to UHC the adoption of an appropriate LIMS is highly recommended. This is in addition to evidence based decision making, knowing the geographical distance to the nearest public health care facility, coverage of laboratory diagnostic services, county-specific prevalent disease, the priority local population health care needs, what patients test for, Tests available, their cost and turn-around times is key to not only improving reliability of clinical care, health outcomes but also assessing overall readiness of services at PHC to support UHC.

Likewise, a low percentage of facilities with and consistently using QMS, quality policy and objectives of only 33% was noted, which was supported by findings of other previous studies of Moussa *et al.* (2018), Schroeder *et al.* [22] and Elbireer *et al.* [21]. However, a person with a degree was 17.447 more likely to be aware of the laboratory's' QMS, quality policy and objectives compared to one with a diploma (17.447). Contrastingly, a person with a certificate was 2.660 less likely to be aware of the laboratory's' QMS, quality policy and objectives compared to one with a diploma (-2.660), a finding which was statistically significant ($p=0.027$). In the same line, the main factors cited for low or slow uptake of certification and accreditation by

these facilities were; lack of knowledge or awareness of SLMTA, other TQM training programme or institution offering quality training, cost or affordability of the process and accessibility in that order. This finding concurred with other previous studies including [22, 23]. Accordingly, this highlighted the need for innovative measures such as incorporating an equivalent version of SLMTA/SLPTA training programmes into academic programmes for Medical Laboratory Science training, tailor-made TQM short courses for professional development as well as increased awareness or sensitization campaigns efforts.

In summary, based on the WHO-EDL for PHC level and UHC, the capacities of the sampled PHC level laboratories in the three counties to provide some testing considered essential for UHC were inadequate, hence their readiness to support further up-scaling of the programme nationwide need to be addressed. The main driving factors for the low adoption of quality control and assurance management, certification and accreditation were cost of the process, lack of knowledge or awareness and accessibility to training programmes. So central to UHC are; a well-supported, functional PHC and referral system. Considering that the average Kenyan travels for at least 3 kilometers to access the nearest health care facility [25], there is need of not only increasing the coverage, particularly in rural or remote areas but also equipping the existing ones to enhance accessibility. Since, Health is a devolved function; the role of both the national and county governments as important stakeholders for UHC is essential for the programme. Hence, joint, well-coordinated efforts, productive engagements, consultations as well as collaborative Interventional measures from the two levels of government are critical to success of UHC programme.

Other minor factors included insufficient capacity building, ignorance, low motivation, low staffing, lack of equipment and reagents. In agreement with this findings, [23] Schroeder et al. [22] also identified high cost of treatment, human resource, infrastructural gaps as obstacles to availability and access to quality essential health care services in Africa.

If PHC was the “heart” of UHC, then quality, a reliable PHC laboratory diagnostic service is the “soul” of clinical care, thus UHC by extension. For that reason, strengthening and increasing accessibility of diagnostic laboratory services at PHC, putting in place a working, efficient referral system across the levels of health care, educating, sensitizing, public involvement as well as making them aware of such a system at their proximity is critical. Most importantly, efforts to not only attract and but also to motivate and retain health-care workers in remote rural areas that include; offering adequate incentive e.g. monthly hardship allowances, provision of as well as improvement of the existing amenities such as housing, schools. In the absence of that, patients will continue disregarding the PHC for higher levels for even simple ailments, subsequently overcrowding them if availability and capacity for the basic ED cannot be assured. A key note in this study was that underlying majority of the

gaps in quality control and assurance management as well as drivers of low or slow uptake of certification and accreditation was basically the lack of an organizational structure or organogram with clear lines of accountability in majority of these facilities. By simple changes for instance redesigning of the organograms to incorporate quality assurance officer or manager, majority of the gaps could be addressed.

While the idea and objective of GOK medical equipment leasing programme (MELP) programme to bring services closer to the users by equipping at least two Hospitals in every county was brilliant; it might have the unwanted consequences of compromising the current referral system by promoting the prevalence of higher level health care, thus sustaining the current disregard of PHC and overcrowding in the national referral hospitals. A real inherent risk of this is highlighted by the current disregard of the PHC in favour of advanced levels of health care, even for basic ailments. For sustainability and posterity of UHC, a good balancing of the MELP with building capacities of PHC to equip them to provide reliable basic clinical care is equally important for UHC.

Just as the country required well-equipped national and county referral hospitals (Level 5 and 6 of health care), it is also equally important to revamp service delivery at PHC. If UHC is too critical to our country to fail, the failing at the basic level of PHC is calamitous. Worthwhile, the Ministry of Health (MOH)-Kenya approach to achieve UHC has been through waiver of user fees at all public hospitals and ensuring commodity security through Kenya medical supplies agency (KEMSA). Furthermore, about 80% of the funds for the UHC pilot programme have been allocated into the purchasing of drugs and basic medical equipment.

Though for a good measure the pilot UHC programme has been successful, notably, with some of the remarkable achievements including the overall increased patients’ numbers (of up to 300% surge), hospital deliveries as well as utilization of PHC facilities. Other notable achievements include the identification of gaps, infrastructural deficiencies, special challenges of under capacity of KEMPSA as sole supplier of medical requirements the current health insurance fund (NHIF) as well as delays in disbursement of UHC cards have been identified [25].

Nevertheless, with the current health financing gap of about USD 66 billion per year and majority of African countries allocating less than 5% of their gross domestic product (GDP), which is considered the minimum threshold for ensuring sufficient health coverage for at least 90% of country’s population to health care, new, creative and innovative measures are required. This study proposes three strategic intervention measures; the first one involves directing more infrastructural, technical and human resource investments to PHC. The advantage of this is the focus on PHC as the “engine” of UHC programme. The second approach is to strengthen the current referral system starting from PHC all the way to the national referral hospitals/Level

6, educate and create awareness of the users, thus change the current negative perception and disregard of PHC by the users in favour of advanced levels. Hence, investment in public involvement, participation, education and sensitization with the aim of changing their negative perceptions towards PHC is recommended. In readiness to a successful UHC programme implementation, across Kenya, capacity building, empowering of these facilities key enablers of reliable basic clinical care especially at PHC level, provision of the requisite knowledge, competencies, policies, guidelines, enactment of necessary legislations for the enforcement of consistent application, strict adherence or conformity to quality control and assurance management, their close monitoring as well as evaluation is paramount.

Some of the limitations of this study included; the health care service delivery or specifically UHC readiness index of the three counties was beyond the scope of this study whose focus was limited to laboratory services. Nonetheless, the findings from this study could be used as a basis for further studies that incorporate determination of the percentage availability of the 50 items considered essential for providing health-care (Service Readiness Index) by the WHO extending beyond the three study counties and subsequently adopting it for UHC readiness.

5. Conclusion and Recommendation

In summary, in terms of availability of WHO defined EDLs, there was low readiness of these facilities to support UHC at PHC level, low adoption of quality control, assurance management, certification and accreditation in the three counties. Hence, a dire need for defining and standardization of country-specific EDLs was noted. The main driving factors for these were the cost of the process, lack of or low knowledge and awareness levels accessibility. Hence, strengthening of the current referral system from PHC all the way to level 6, increasing investments in PHC to build capacities, empower them to provide the developed country-specific EDL for UHC at PHC, putting in place a basic requirement for the facilities an organizational structure (organogram) with clear line of accountability facilities at PHC, staff development programme, promotion of mandatory internal and external quality controls. Though, the findings of this pilot study might be applied to inform UHC programme implementation, future larger studies covering the entire country to identify gaps, deficiencies and shortcomings and to develop standardized country-specific EDL will be required. Other studies include ones to evaluate the real impact of UHC programme. Nevertheless, it is worthwhile to note that this pilot study was conducted before Covid-19 pandemic, which in addition to exposing significant infrastructural deficiencies in the Country's laboratory diagnostic testing services, has afforded a unique opportunity for their strengthening, especially at county and sub-county hospitals. Therefore, the level of preparedness might have changed for the better.

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