ASSOCIATION OF PATHOLOGY RESOURCES ON CERVICAL CANCER STAGING TRENDS BETWEEN 2018 & 2022: A RETROSPECTIVE STUDY AT MOI TEACHING AND REFERRAL HOSPITAL, WESTERN KENYA

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ABBREVIATIONS/ACRONYMS

MTRH: Moi Teaching and Referral Hospital

FIGO: International Federation of Gynecology and Obstetrics

NHSCSP: National Health Service Cervical Screening Program

WISN: Workload Indicators of Staffing Need

WHO: World Health Organization

ISO: International Standards Organization

EQA: External Quality Assessment

LMIC: Low- and Middle-Income Country

HIC: High-Income Country

TAT: Turnaround Time

SSA: Sub-Saharan Africa

HPV: Human Papilomavirus

ASCCP: American Society for Colposcopy and Cervical Pathology

KNH: Kenyatta National Hospital

AMPATH: Academic Model Providing Access to Healthcare

HIV: Human Immunodeficiency Virus

Table of Contents

List of Tables

List of Figures

Chapter 1 INTRODUCTION AND LITERATURE REVIEW

1.1 Burden of Cervical Cancer

Cervical cancer is a chronic illness resulting from persistent infection of the cervix by HPV types 16 and 18.[1] Over their life course, over 80% of women will develop at least one type of HPV infection, indicating its widespread ease of transmission.[1] In 2020, there were an estimated 604,127 annual cervical cancer cases globally, representing 3.1% of all cancer cases.[2] Approximately 84% of the newly reported cases and between 87% and 90% of the fatalities are concentrated in low-income and middle-income countries (LMICs).[3] These cases have been attributed to more than one-quarter million deaths yearly in LMICs due to inadequate screening, human papillomavirus (HPV) vaccination programs, and gross deficiencies in treatment efficacy.[2,4] In contrast, incidence and mortality rates have reduced by more than half during the past 30 years in high-income countries (HICs), due to the integration of structured screening initiatives.[4] The death rate is 18 times higher in these countries compared to poorer countries.[5,6] Due to the foreseeable population growth in most low-income countries, cervical cancer mortality rates are projected to increase by approximately 25% over the next ten years.[7]

1.2 Cervical cancer histopathology and laboratory resources

Histopathology and cytopathology have in recent years been the clinical and scientific foundation for cervical cancer prevention and treatment. These procedures classify microscopic patterns of biopsy tissue cells guiding histopathologists in the timely diagnosis and treatment of cancerous lesions.[8] This process however requires adequate histopathology resources to ensure early detection when cervical cancer is still within curable stages.[9] Among women with persistent low-grade abnormalities, such as HPV lesions and advanced cervical cancer lesions, histology plays a vital role in determining the extent of the abnormality.[10]

Inadequate pathology infrastructure for cervical cancer diagnosis can result in reduced access to screening, delayed diagnosis, and treatment among women.[11] As a result, the disease eventually progresses and limits treatment options impeding efforts to reduce cervical cancer morbidity and mortality.[11,12] A crucial setback to integrated cervical cancer care in sub-Saharan Africa (SSA) is its limited infrastructure and human capacity.[13] Pathologists play a critical role in diagnostics with an estimated 95% of clinical pathways relying on them.[14,15] Despite their role, they are significantly limited in low and middle-income countries, with only about 30% of patients accessing urgent pathology services.[16] WHO reports indicate that there is roughly one pathologist for every 15,000 people in high-income countries compared to most Sub-Saharan African countries whose ratio is as low as 1 pathologist for every 1 million people.[17] The United States and Canada boast 6.5 and 4.81 pathologists per 100,000 respectively compared to fewer than 3 pathologists per 100,000 in Sub-Saharan Africa.[14,15]

Recent studies indicate that HPV DNA testing is a more effective approach for age-appropriate screening of cervical cancer with higher sensitivity (100%) and specificity (90.6%). In comparison, the commonly used methods, cervical cytology (Pap smears) and Visual Inspection with Acetic acid (VIA) have a sensitivity of 78.2% and 31.6%; and specificity of 86.0% and 87.5% respectively.[18] However, in most developing countries that carry over 80% of the global burden of HPV-induced invasive cervical cancer (ICC), access to HPV DNA technological advancement has not been in grasp.[19,20] There are high costs of conducting HPV DNA tests limiting their access to women in need in low-income countries.[21,22] Pap smears, being the primary standard screening method, need a colposcopy examination and histopathology evaluation of cervical biopsies for complete diagnosis and reporting.[23] However, the service has been significantly hindered by the shortage of skilled technicians and well-

equipped laboratories in developing countries.[18,24,25 26] The American Society for Colposcopy and Cervical Pathology (ASCCP) provides guidelines related to the management of women with abnormal cervical cancer screening results.[27]

In November 2020, WHO drafted a global strategy to accelerate the elimination of cervical cancer by 2030 as a major public health concern, a triple-intervention strategy targeting to attain 90% HPV vaccination coverage by 15 years, 70% of women being screened twice at the ages of 35 and 45, and 90% of the women diagnosed having access to cervical cancer treatment.[28] However, this seemingly strikes as a pipedream for many developing countries due to the limited pathology facilities and skilled human resources.[19,28] Research by Hull et al. noted that while inadequate cervical cancer histopathology resources cannot be the sole factor contributing to the high burden of cervical cancer in LMICs, effective cervical cancer screening and provision of high-quality cytological testing greatly contribute to reduced incidence and mortality.[3] Population growth and increased screenings subsequently increase specimen volume requiring interpretation by skilled histopathologists.[29]

1.3 Problem Statement

In Kenya, cervical cancer is the second most common type of cancer among women after breast cancer.[30,31] Availability of quality cervical cancer pathology infrastructure and trained clinical staff vary across regions of Kenya with rural areas recording limited access to these services.[32] There has been a low pathologist-to-patient ratio and skilled laboratory technologists and histo-technicians to carry out histopathology tasks.[7] Additionally, patients tend to delay seeking screening, as a result, cancerous lesions are often detected at advanced invasive stages of cervical cancer resulting in a protracted illness upon diagnosis.[24,33,34] It is estimated that 5,236 women in Kenya are diagnosed with cervical cancer yearly, with close to 3,211 mortalities

occurring annually.[35,36] The ASCCP guidelines have been adopted by the Kenyan Ministry of Health to address the use of Pap smears, VIA/VILI, and HPV testing.[27] However, the unavailability of HPV testing at Kenyatta National Hospital (KNH) and Moi Teaching and Referral Hospital (MTRH), the major hospital in the country limits the scale-up and adequate implementation. Inadequate pathology resources have been identified as a significant barrier to timely and accurate diagnosis and treatment of cervical cancer. The timely detection and prompt initiation of treatment are critical for the effective management of cervical cancer cases.

1.4 Specific Aims

This study aimed to assess the progression of histopathology resources within the Moi Teaching and Referral Hospital healthcare system, identify potential associations with trends in cervical cancer diagnosis between 2018 and 2022, and suggest potential interventions that could improve the detection and treatment of cervical cancer. The specific aims of this study were*: 1) To map out pathology resources available for the detection of cervical cancer at MTRH* and *2) to compare the trends of cervical cancer staging associated with cervical cancer at MTRH over five years*.

1.5 Study Justification

The growing body of literature on cervical cancer has focused on the burden of cervical cancer, the factors influencing screening uptake, and the barriers to access to treatment in developing countries. However, there is limited research on the evolution of pathology infrastructure that is, the availability of skilled histopathology laboratory personnel and equipment and its association with trends of cervical cancer diagnosis over the years in Kenya. To address this gap, the study aimed to evaluate the state of histopathology infrastructure at Moi Teaching and Referral Histopathology Laboratory retrospectively to assess its association with

trends of cervical cancer staging between 2018 and 2022. This study is of significant public health importance, particularly in low-resource countries where cervical cancer remains a major health problem. This study's results contribute to the body of evidence supporting the significance of adequate histopathology resources in reducing the burden of cervical cancer. Moreover, this information can guide policymaking and practices aimed at improving cervical cancer screening and treatment services in low-income and resource-limited settings similar to Kenya.

Chapter 2 METHODS

2.1 Study Design and Setting

This thesis is based on primary and secondary data collected from Moi Teaching and Referral Hospital (MTRH) in Western Kenya using mixed methods of qualitative and quantitative data. MTRH is Kenya's second largest national referral health facility located in Eldoret town, the North Rift area of Western Kenya serving at least 22 counties with a bed capacity of about 1000 beds.[37] It serves at least 22 counties with an approximate catchment population of 25 million,[38] representing about 47% of the Kenyan population.[39] A purposive sampling method was used to select MTRH for this study due to its record of having maintained an inventory of cervical cancer tissue samples and a cancer registry for over ten years.

2.2 Sampling and study population

Primary data collection: We employed purposive sampling for the histopathology laboratory technologist and a census sampling to evaluate the inventory of all histopathology resources consisting of equipment, quality control measures, and personnel for the specified period of the investigation.

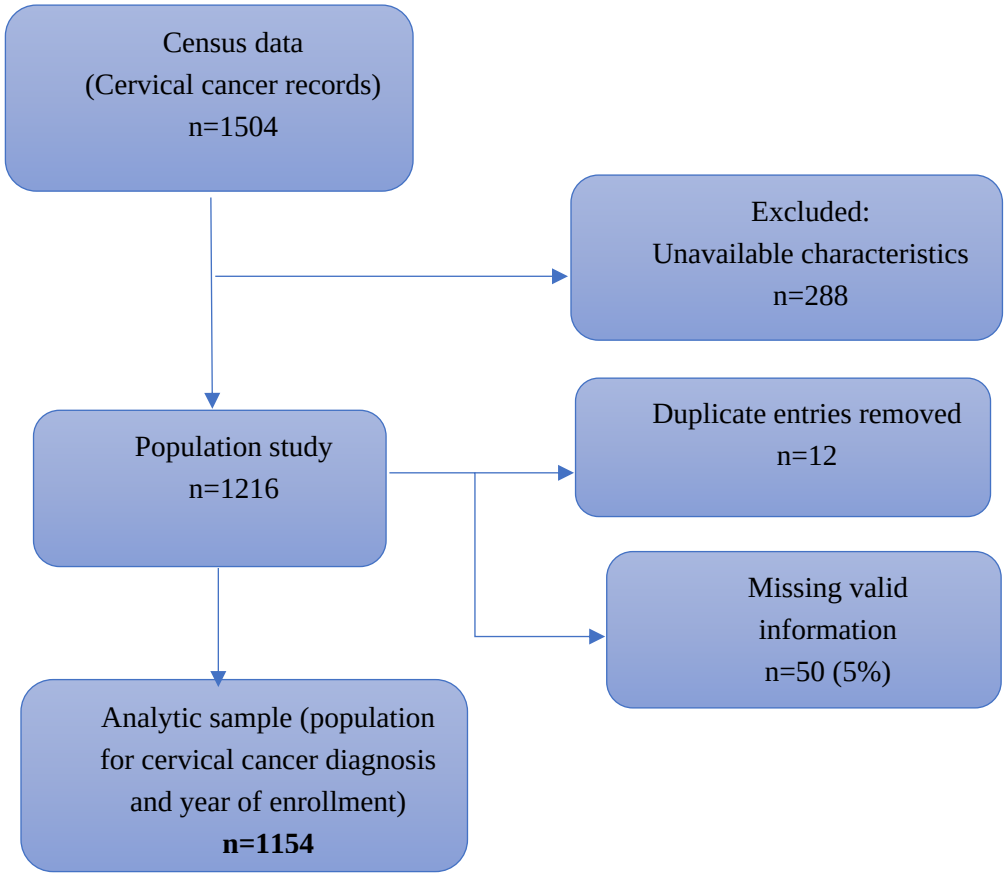
Secondary data collection: A census sampling technique was used to obtain data from medical records of eligible patients diagnosed with cervical cancer between 2018 and 2022.

2.3 Study Eligibility

Primary data collection (equipment inventory with histopathology laboratory technologist): The recruitment of a laboratory technologist followed the guidance of the histopathology department head. The laboratory technologist was recruited based on their expertise, experience, and knowledge about the histopathology resources at the facility over the past ten years.

Secondary data collection (patient medical record review): We included patient's medical records who: 1) were above 18 years old, 2) were diagnosed with cervical cancer between January 2018 to December 2022 at the referral health facility, and 3) had complete information on cervical cancer diagnosis at the time of the study. To limit the study findings to the specific population under investigation, we excluded records of patients who: 1) had a history of recurrent or concurrent cancer diagnosis beyond the study period, 2) were pregnant at the time of cervical cancer diagnosis, and/or 3) had missing key information on cervical cancer diagnosis.

Figure 1: Inclusion and Exclusion Outline for Analytic Sample for secondary data



2.4 Data collection

Data collection was done between October 2023 and February 2024 following pretesting of the instruments (*in Table 1 below*) within the hospital. Validation of the tools was done by a histopathology technician and a cervical cancer specialist to ensure they effectively captured the relevant information. The tools were operationalized in English as the data abstraction team was proficient in the language.

Primary data collection: The semi-structured interview guide comprised open-ended questions on 3 conceptual topics: essential pathology equipment, personnel, and quality control. Some of the interview questions included "How many pathology personnel are available at the histopathology laboratory (including roles) for each year?", "How often were on-job training for cervical cancer done?", "what were the essential pathology instruments available at this facility spanning 2018-2022?" and "Across the years, how often were quality control and evaluation (including servicing) done for the pathology equipment mentioned and personnel?". We classified the histopathology laboratory resources for each year as per the following standards: Trained personnel were compared to the World Health Organization's Workload Indicators of Staffing Need (WISN) tool for laboratory staffing with a guideline ratio of more than 2 pathologists and 2 histo-technicians per 100,000 population.[40] We assessed the equipment guided by the International Standards Organization's standards for medical laboratories, ISO 15189:2012 for quality and competence, indicating at least 2 pieces of equipment for critical function, for backup purposes.[41] Quality control was compared to the World Health Organization's (WHO) guideline of annual quality control performance for histopathology laboratories varying by workload.[42]. We assessed the Turnaround time (TAT) in line with the

United Kingdom's National Health Service Cervical Screening Program (NHSCSP) guidelines of 14 days for relaying biopsy tissues report to the patient.[43]

Secondary data collection: Using a standardized data abstraction form, the Kobo Collect platform was used to collect data from the patient's medical records for the years 2018-2022 from the AMPATH initiatives' cervical cancer database. Identifying information was anonymized. The data comprised patients' demographics, clinical information on diagnosis and staging, family history, comorbidities, and lifestyle factors. Collaboration between the research team and the oncology department during data collection was transparent developing trust in data use and ownership. Cross-checking was frequently done by the research team to ensure the credibility and reliability of data. Notes about the content and the procedures that occurred before, during, and after the interview were documented.

Table 1: Data collection techniques used to address study objectives

SPECIFIC OBJECTIVE	DATA COLLECTION METHOD
To map out pathology resources available for the detection of cervical cancer at Moi Teaching and Referral Hospital in Kenya, 2018-2022.	Qualitative Method: Histopathology inventory review (Standardized checklist)
To assess the trends of cervical cancer staging at the MTRH facility in Kenya from 2018-2022.	Quantitative Method: Medical records review (Pre-prepared standard data abstraction form)

2.4.1 Secondary Aim: Demographic and Socioeconomic Characteristics

We identified demographic and socioeconomic factors relevant to the outcome based on AMPATH's cervical cancer records. We first classified marital status into two groups: "Not married" which included single, widowed, and divorced women, and "Married". Education was grouped into two groups: "More than high school" and "less than high school". We grouped

parity defined as the number of children one has in two groups of “less than four” and “four of more” children.

2.4.2 Possible confounders

Studies have demonstrated that late-stage diagnosis of cervical cancer is associated with HIV-positive women due to immunosuppression compared to their counterparts.[44] Research has suggested that women who smoke and consume alcohol frequently are more likely to be diagnosed with cervical cancer.[45] Additionally, there is a positive correlation between diabetes and cervical cancer with most women presenting with late cancer burdened with type 2 diabetes.[46] We thus included covariates such as patient's HIV status, alcohol consumption, smoking habits, and diabetes to explore variations of cervical cancer diagnosis trends across these subgroups.

2.5 Statistical and Data Analysis

Primary data: Initially, we thoroughly reviewed the transcript and documenting observations as part of the audit trail cross-referencing it with inventory records. Thematic analysis was done using NVivo version 14 released in (March 2023). We then revisited the transcript and employed thematic content analysis to generate key themes.[47] We imported *apriori* codes into NVivo for this analysis and supplemented them with additional inductive codes tailored to the particular context. We conducted a comparative analysis of the interview, meeting notes, and observations from the inventory reports to identify patterns and recurring themes within and across the data about the availability of pathology resources.

Following a process of open coding and identifying and labeling relevant segments, codes were organized into more focused codes and then restructured to create descriptive codes. These codes captured key concepts and relationships between categories and subcategories. This

coding process enabled us to refine and revise emerging themes through an iterative process describing trends, and outcomes, as an abstract view of the findings.[48] In-vivo codes were linked to conceptual codes. We then merged and clearly defined each theme to better capture the essence of the data to provide a consistent interpretation of the interview and the observations.[49] We ensured the theoretical codes were closely linked to the focused codes, thus grounded in the data.[50] The themes: *availability of pathology resources including the availability of trained personnel, equipment, and quality control* checks across the five years were then quantitatively categorized upon standardization focusing on the adequacy of pathology resources based on the following predetermined criterion.

Secondary data collection: For the **second aim**, data was captured in Kobo Collect platform using a standardized data abstraction form and analyzed by descriptive and inferential statistics using Microsoft Excel and STATA version 17.[51] We conducted cross-tabulations of the dependent variable with the independent variable and covariates to examine associations and identify patterns and characteristics within various subgroups. This analysis allowed us to examine how the distribution of cervical cancer trends over the years, providing insights into potential temporal patterns or changes in the outcome of interest.

Results from the qualitative aim and descriptive analysis of the histopathology laboratory resources were then compared with the results from the medical records to explore potential associations across the five years.

2.6 Ethical Approval

Approvals were obtained from MTRH/Moi University (no. 0004537) and Brown University Institutional review boards (no. STUDY00000244) after which permission was sought from the hospital's oncology and histopathology laboratory heads of the department before data collection

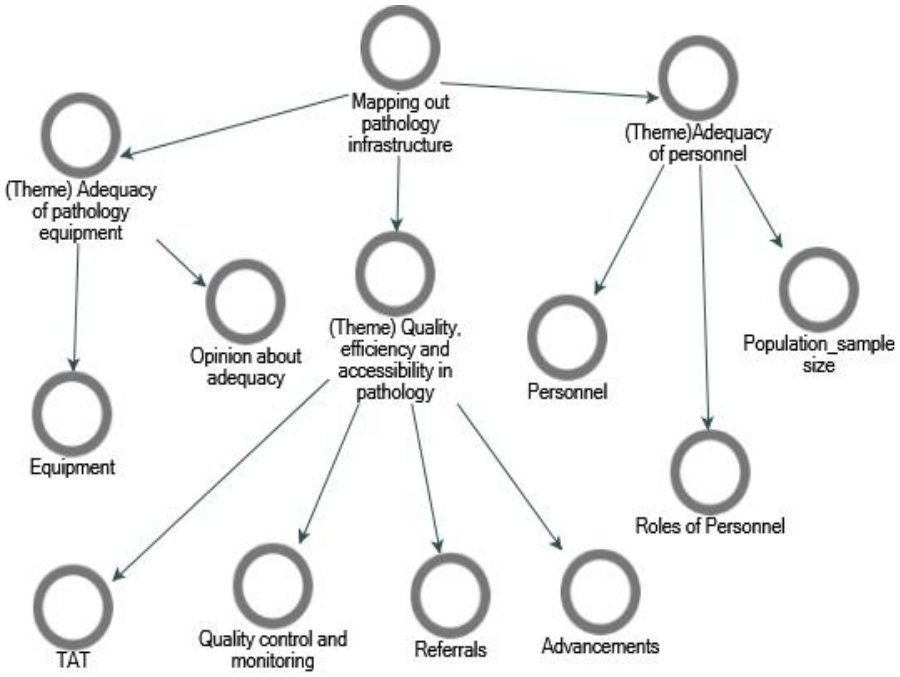
commenced. The departments were informed on the purpose of the study, how the data would be used, and the impact of data collection on the usual operations of the hospital activities. The Data Protection Act 2019, The Health Act 2017 of Kenya, and the data privacy policy of the United States were strictly followed during the process.

Chapter 3 RESULTS

3.1 Evolution of histopathology laboratory resources

The findings elaborate the inventory of the available histopathology resources from 2018 to 2022 noting the changes throughout the period retrospectively.

Figure 1: Flow diagram of emerging themes from the interview and inventory



3.1.1 Laboratory staffing

The interview highlighted key details about staffing adequacy and its impact on providing quality services across the years at the MTRH histopathology laboratory. As shown in the table below, in 2020, there was an increase in the number of personnel at the histopathology laboratory; the addition of two pathologists, one records personnel, and one office administrator. Consequently, over the years, the number of biopsy tissues examined increased from 3000 in

2020 to approximately 7000 in 2022, with approximately 8% and 9.5% being cervical cancer biopsies in each respective year.

According to the MTRH Health Records and Information Services Department, between 2018 and 2022 the hospital provided care to approximately 350,000 and 500,000 patients annually respectively. Comparing this patient population served by MTRH to the laboratory staff, there was a decreasing trend in the histopathology personnel-to-population ratio over the period, from 1.5 pathologists and 2.7 histo-technicians per 100,000 in 2018 to 1.4 pathologists and 1.8 histo-technicians per 100,000 in 2021.

Table 2: Pathology personnel at the MTRH histopathology laboratory

	2018	2019	2020	2021	2022
Pathologists	5	5	6	7	7
Lab technologists	9	9	9	9	8
Records personnel	0	0	1	1	1
Office Administrators	1	1	2	2	2
Lab assistants	1	1	1	1	1
MTRH patient census	**331,036**	**393,594**	**397,399**	**507,502**	**493,780**
Ref: Workload Indicators of Staffing Need (WISN) tool used to assess the adequacy of staffing levels in healthcare facilities by WHO guideline ratio, more than 2 pathologists and histo-technicians per 100,000 patient population.					
Personnel: patient ratio	Shortage	Shortage	Shortage	Shortage	Shortage
*The pathologist and histo-technicians to patient ratio was computed by dividing the number of the respective personnel by the total number of inpatients and outpatients.					

Figure 2: Bar graph and stacked bar chart showing trends of cervical cancer trends vs histo-technicians: patient ratio

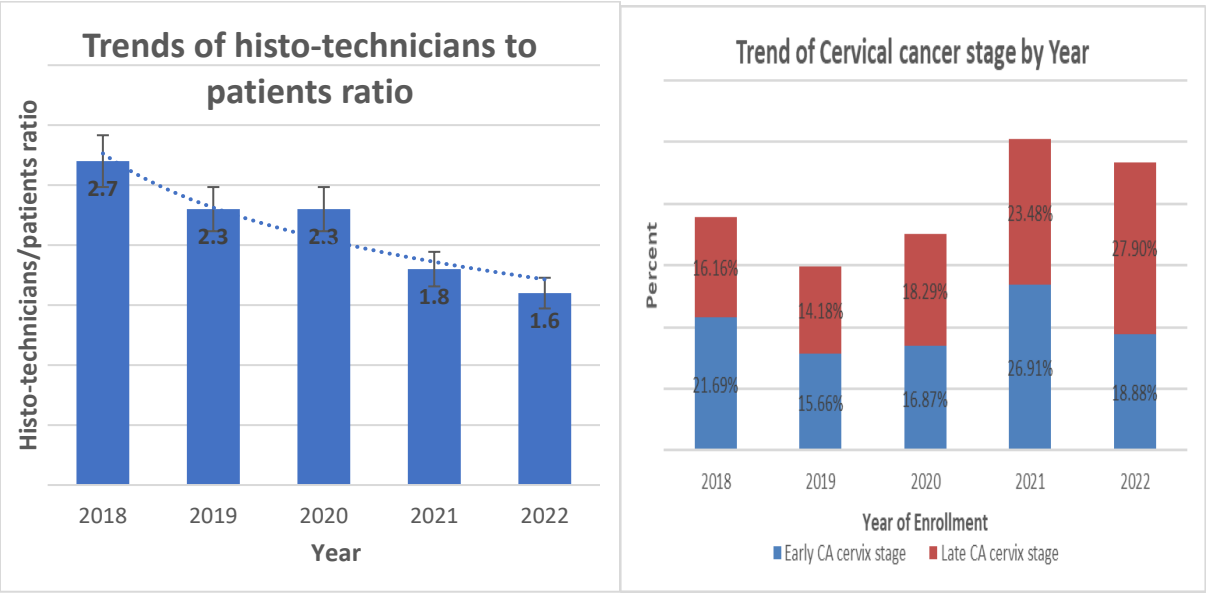
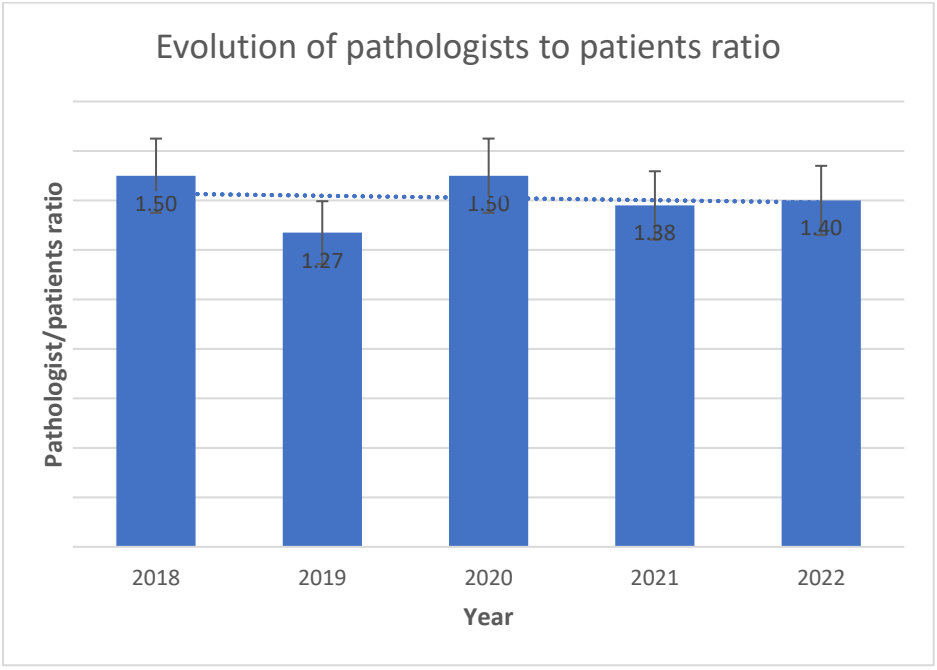


Figure 3: Bar graph showing evolution of pathologists-patient ratio



3.1.2 Histopathology equipment

From the interview, all the equipment acquired at the commissioning of the histopathology department in 2012 were manually operated including the centrifuge currently in use. However,

over the years, additional equipment such as an automatic microtone, automatic tissue processor, embedding machine, and an immunohistochemistry machine were acquired as shown in the table below:

Table 3: Inventory of Equipment

	2018	2019	2020	2021	2022
Cytology centrifuge (manual)	1	1	1	1	1
Automatic tissue processor	1	1	1	2	2
Embedding machines	1	1	1	1	2
IHC machine	1	1	1	1	1
Microtones	2	2	2	2	2

Ref: According to Medical laboratories' international standards, ISO 15189:2012, a histopathology laboratory should have at least 2 pieces of equipment for the same function, that is, a main machine and a backup for the same.

There was an addition of an automatic tissue processor in 2021 and the replacement of two microtones in 2022 that facilitated the efforts of tissue processing. However, there was diminished capacity in 2020 when a microtone machine broke down leading to reverting to the manual one acquired in 2012. This impeded the efforts of tissue examination which the hospital later purchased:

"…The AMPATH Cervical Cancer Program donated an automatic microtome in 2018, which we used until last year (2022) when it malfunctioned due to overload. The hospital immediately replaced them with two new ones."

The interview also emphasized the need to have backup equipment for the histopathology examinations more so automatic backup equipment. The participant indicated that the manual types are prone to measurement errors when processing high workloads.

"*Immunohistochemistry… Yes, one is enough,* ***but we like a backup such that in case there's a breakdown*** *we don't go back to manual because manual is subject to a lot of errors. So going forward when we get a backup, we would be comfortable*."

3.1.3 Quality control and measures

The MTRH histopathology laboratory was registered for the External quality assessment (EQA) in 2018 which is key in the quality assurance of the laboratory operation. The EQA program permits laboratories to determine the accuracy and precision of their equipment by testing samples with known characteristics such as concentration levels and other physical properties.

Table 4: Histopathology laboratory quality control

	2018	2019	2020	2021	2022
Quality checks	EQA Done	EQA Done	EQA Done	EQA Done	EQA Done
Referrals	Mostly lymphomas	Only Upon request	Only Upon request	Only Upon request	Only upon request
Turnaround time	14 days	14 days	14 days	14 days	14 days
Ref: According to the NHSCSP Guidelines the TAT from the date the sample is taken to when the patient receives the biopsy report within 14 days					
Overall rating	**Inadequate**	**Inadequate**	**Inadequate**	**Inadequate**	**Adequate**

Annual evaluation for all pathology equipment, personnel standards, and quality in the laboratory is done by the MTRH Department of Biomedical Engineering.

"…We have an annual evaluation for all equipment in the laboratory by the Dept. of Biomedical Engineering…. Equipment servicing is done annually by those given the contract to supply these equipment." "…Over 80% of biopsy specimen results are done in 14 days."

From the interview, it was reported that the turnaround time for pathology laboratory results to be reported back to the patient takes an average of 14 days (2 weeks).

3.2 Trends of Cervical Cancer Diagnosis

For aim 2, the dependent variable cervical cancer stage was operationalized in two categories of early (stage I & stage II) and late stage (stage III &stage IV) based on the International Federation of Gynecology and Obstetrics (FIGO) staging system.[52] The staging was then compared against the state of pathology resources over the years at MTRH.

Table 5: Description of MTRH Cervical cancer patients by Cervical cancer stage (n=1154), AMPATH records, 2018-2022

	Early Stage n=498 (43.15%)	Late Stage n= 656 (56.85%)
***CA Cervix Stage**		
2018	108 (21.69%)	106 (16.16%)
2019	78 (15.66%)	93 (14.18%)
2020	84 (16.87%)	120 (18.29%)
2021	134 (26.91%)	154 (23.48%)
2022	94 (18.88%)	183 (27.90%)
Education years		
At most Highschool	67 (13.45%)	81 (12.35%)
College+	15 (3.01%)	5 (0.76%)
*	416 (83.53%)	570 (86.89%)
HIV status		
Positive	123 (24.70%)	168 (25.61%)
Negative	253 (50.00%)	275 (41.92%)
*	122 (24.50%)	213 (32.47%)
***Smoking**		
No	431 (86.55%)	543 (83.87%)
Yes	1 (0.20%)	3 (0.46%)
*	66 (13.25%)	110 (16.77%)
Alcohol drinking		
Yes	2 (0.40%)	5 (0.76%)
No	72 (14.46%)	1 (0.55%)
*	424 (85.14%)	550 (83.84%)
***Diabetes**		
No	451 (90.56%)	577 (87.96%)
Yes	6 (1.20%)	11 (1.68%)
Parity		
<4	249 (50.00%)	311 (47.41%)
4+	249 (50.00%)	345 (52.59%)

Marital Status		
Not Married	331 (66.47%)	454 (69.21%)
Married	167 (33.53%)	202 (30.79%)

Overall, across the years, patients diagnosed with late-stage cervical cancer appear to be higher compared to those presenting early-stage with a respective significant difference of 27.90% and 18.88% in 2022. However, there was a steady rise in the distribution of patient enrollment in both groups except for a spike in early-stage cervical cancer cases in 2021.

Among the socio-demographic variables, most patients across all years had education levels of high school and below, with high proportions both in the late and late stage, 83.53% and 86.89% respectively. The distribution of parity was similar between early and late stages, with approximately half of the patients having less than four children and the other half having four or more children. A larger proportion of patients were unmarried in both the early (66.47%) and late (69.21%) stages. The proportion of patients with HIV-positive status dropped steadily from 2018 to 2022, with a notable decrease observed in 2022. Most patients were non-smokers across all years, although there was a notable decrease in the proportion of nonsmokers in 2022 compared to previous years. There was no significant difference between the proportion of patients who were HIV positive in both early (24.50%) and late stages (25.61%). There was quite a small percentage of patients who reported smoking and drinking alcohol, with slightly higher rates in the late stage (0.46%) and (0.76%) compared to the early stage (0.20%) and (0.40%) respectively. Most patients did not have diabetes, with slightly higher rates in the late stage (1.68%) compared to the early stage (1.20%).

Chapter 4 DISCUSSION

Our study found a progressive addition of pathology personnel and equipment, and an increasing trend in the number of patient visits at Moi Teaching and Referral Hospital, across the

investigated period. However, we also found a significant increase in the diagnosis of cases, especially late-stage cervical cancer, despite a decrease in the laboratory personnel-to-patient ratio. Our study findings offer profound insights and serve to improve cervical cancer diagnostics at MTRH and other hospitals in limited-resource settings.

4.1 Evolution of Pathology resources at the MTRH Histopathology laboratory

Our study identified an addition of pathology personnel and equipment at the MTRH histopathology laboratory across the five years. This study found that the laboratory staff-to-patient ratio decreased consistently in contrast to the fast-growing patient population, for instance, from 1.5 pathologists in 2018 to 1.4 pathologists per 100,000 in 2022. Similarly, there was a decrease in the ratio of histo-technicians to patients from 2.7 in 2018 to 1.8 in 2022. This is consistent with other reports that found a low pathologist-to-patient ratio.[7,14,15] Limited personnel impedes the carrying out of laboratory tasks in many Sub-Saharan African (SSA) countries.[7] While Abdulkareem et al.[53] reported that most countries in SSA have an average ratio as low as 0.1 pathologists per 100,000 people, our study revealed higher numbers of approximately 1.4 pathologists per 100,000 in 2022.

Our results show a lower pathologists-patient ratio than most High-Income Countries (HICs), which boast roughly 6.7 pathologists per 100,000 people.[17] The United States and Canada, for instance, have higher laboratory staff-patient ratios, recording 6.5 and 4.81 pathologists per 100,000, respectively, in 2019.[14,15] The numbers from our findings are lower than the WHO's WISN tool guideline for laboratory staffing which recommends having more than 2 pathologists and 2 histo-technicians per 100,000 population. This shortage likely posed a challenge in meeting the growing demand for histopathology services between 2018 and 2022.[40] Research indicates that such a low staff proportion leads to only 30% of patients having access to

urgent pathology services.[16,41] However, even with the ballooning population and more women seeking screening services, the effort by the pathology personnel to examine a higher number of tissue biopsies despite the low ratio is worth acknowledging.

Despite adding an automatic microtone, automatic tissue processor, embedding machine, and an immunohistochemistry machine across the five years, most of these malfunctioned due to overload. Our study identified a persistent challenge of relying on manual backup equipment, particularly for the immunohistochemistry machine and the centrifuge. Studies have shown that dependence on manually operated equipment in histopathology can lead to measurement errors, resulting in increased turnaround time and decreased efficiency in processing specimens.[54,55] The shortage of automated backup equipment places the MTRH histopathology laboratory below the required medical laboratories' standards of the International Standards Organization (ISO 15189:2012) benchmark.[41] These findings are consistent with a study done in 30 sub-Saharan African countries in 2016 reporting a shortage of laboratory equipment. This study reported that immunohistochemistry machines were available in 16 countries and molecular diagnostics were done in only two countries.[56] As reiterated by Thomas et al.[13], adequate pathology resources are key to ensuring early detection of cervical cancer in the curable stages. However, from our study, Kenya like many Low- and Middle-Income Countries (LMICs), faces a significant scarcity in diagnostic pathology facilities and staff.[13] These shortages have often been associated with staff burnout, culminating in poor-quality services that affect the turnaround time of patient diagnostics.[7] These shortages highlight the persistent disparities in histopathology equipment inventory between LMICs and HICs.

We found an average turnaround time (TAT) for surgical pathology at the MTRH histopathology laboratory to be 14 days across the investigated period. This TAT period and the

implementation of annual evaluation quality control measures closely align with the UK's National Health Service Cervical Screening Program (NHSCSP) guidelines of 10 -14 days.[43] Maintaining a 14-day TAT amidst a shortage of personnel-patient ratio is commendable and mirrors the lab's effective management of its processes over time to ensure timely diagnoses despite the surging numbers of tissue biopsies reported between 2020 and 2022. This quality measure positively contributes to operational effectiveness and patient satisfaction by reducing waiting times and anxiety.[57]

4.2 Trends of Cervical Cancer Diagnosis

Our study found a significant increase in the diagnosis of cervical cancer cases, especially across the years, despite a decrease in the laboratory personnel-to-patient ratio. However, this sequential increase in diagnosis cannot be entirely accounted for by the addition of laboratory resources over time. There are other possible explanations. For example, an increasing population over the years resulted in increased screening among women; hence more tissue biopsies examined.[58] Additionally, positive health-care-seeking behavior due to intensified awareness campaigns may have influenced the chance for higher diagnosis.[59] This observed upward trends in diagnosis, despite a decreasing personnel-to-patient ratio. In fact, we found an increased number of biopsy tissues examined, from 3,000 in 2020 to approximately 7,000 in 2022, with approximately 8% and 9.5% being cervical cancer biopsies in each respective year which we attribute to population growth. We also noted a spike in the number of cases seen in 2021, which might be due to a post-COVID-19 surge in hospital visits after the lockdown that had seen patient numbers reduce in 2019.[60] Even with the overall increased diagnosis trends, we observed higher cases of late-stage cancer diagnosis in 2021 and 2022. Other studies in SSA have reported a similar uptrend (approximately 68%) of late cervical cancer presentation upon

diagnosis despite expanded screening awareness programs.[61,62] This continuing increase in late-stage diagnosis has been linked to women presenting late for screening leading to the detection of cervical lesions at advanced stages.[63]

Yang et al.[64] and Fontham et al.[65], argue that the increase in registration and diagnosis of late-stage cervical cancer rates cannot be solely accounted for by decreased personnel-to-patient ratio or inadequate equipment. Nevertheless, this uptrend in cervical cancer diagnosis suggests a genuine increase in patients presenting with advanced stages during the investigated period. This uncertainty warrants the need for further research to elucidate the understand how inadequate staff and equipment contribute to late-stage diagnosis among women in Kenya and Sub-Saharan Africa (SSA). Unlike in developed countries that have reported declining cancer incidence since the 1970s, this study highlights a continuing disproportionate effect of decreased structural, and financial resources, in low-resource countries that limit early-stage cervical cancer diagnosis.[66]

4.3 Strengths and limitations of the study

The strengths of this study include employing mixed methods for retrospective data analysis to assess the histopathology laboratory resource inventory comprehensively. This method that used data over five years provided a holistic understanding of the evolution of the laboratory capacity and how it relates to the trends of cervical cancer diagnosis over time. Utilizing multiple data sources, including secondary data from the patient's medical records and an interview with laboratory staff, enhances the reliability and validity of the findings by corroborating information from different perspectives. While this study provides valuable insights into pathology resources and cervical cancer diagnosis trends, it is important to acknowledge certain limitations that may impact the comprehensiveness and generalizability of the results. Specifically, our study relied on retrospective secondary data hence subject to

limitations such as incomplete records, missing data, and potential biases.[67,68] To enhance the robustness of future research, we recommend conducting longitudinal cohort studies that track patients over time.[69] Following patients longitudinally can lead to a more accurate assessment of the trends of early and late-stage diagnosis trends and better relate these trends to the availability of pathology resources. Using a single interview with laboratory staff may introduce interviewer bias; however, cross-referencing the pathology laboratory inventory records over five years was essential for corroborating the information and ensuring comprehensive data analysis. We recommend implementing a comprehensive data management system at Moi Teaching and Referral Hospital's Cervical Cancer Department to ensure data integrity and facilitate efficient policy making.

Chapter 5 CONCLUSIONS AND RECOMMENDATIONS

The findings highlight an association between the evolution of histopathology resources and cervical cancer diagnosis at Moi Teaching and Referral Hospital. However, the nature of this relationship remains uncertain due to other factors that may influence it. The decline in the personnel-to-patient ratio underscores potential challenges in diagnosis calling for urgency in implementing comprehensive interventions to optimize early screening and diagnosis capacities. These shortages are bound to exacerbate further the laboratory's challenges in delivering timely and accurate histopathology services. This setback calls for the Kenyan Ministry of Health to allocate more funds to pathology infrastructure and personnel to improve access to essential services and reduce disparities.

We would like to acknowledge the ongoing efforts of the community health outreach teams in promoting screening for cervical cancer detection and treatment. These efforts have led to many women seeking cervical cancer screening services, even though they are still being diagnosed with advanced-stage cervical cancer. There remains a critical need to emphasize the

significance of early screening for effective treatment and management of the condition. We recommend intensified efforts to raise awareness and educate the public on the benefits of early cervical cancer screening. Additionally, the Kenyan Ministry of Health should enhance access to these screening services, especially among rural, and informal settlements in Western Kenya. We also recommend the Kenyan government and MTRH leverage international collaborations and partnerships to exchange knowledge, share best practices, and leverage resources that amplify efforts for effective early cervical cancer screening programs. There's a need for a holistic approach to resource management and healthcare delivery, emphasizing the need to address workforce and infrastructure gaps to improve patient care and histopathology outcomes within Moi Teaching and Referral Hospital and in similar LMIC settings.

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APPENDICES

A. Primary aim: Pathology resources inventory questionnaire

BROWN **Pathology resources inventory checklist:**		**Date**_____/_____/_____ __
Note taker (Initials):	**Facility name**:	**County/Country**:
Contact Info:	**Laboratory Department:**	
YEAR:		

A) EQUIPMENT AND QUALITY CONTROL

These questions are meant to get information for the investigation period between 2018 and 2022, Kindly only give information that spans these mentioned years.

1. Inventory of essential diagnostic and pathology instruments:

i) Pathology Equipment	**Time acquired (Month/year)**	**Time commissioned for use (Month/year)**	**Working Condition/Notes/Rating**
a. Cytology equipment			
b. Automatic tissue processor (ATP)			
c. Embedding machines			
d. Microtome			
e. Centrifuges			
f. Immunohistochemistry (IHC) machine			

2. How often were quality control and evaluation (including servicing) done for the pathology equipment mentioned?
1. Monthly 2. Quarterly 3. Semi-annually 4. Yearly 5. Other _____

3. Were there any pathology equipment that were non-functional or broken? (Please state reason for non-functionality and duration):

_____

_____

4. How long was the average duration between the collection of a sample/biopsy and the release of histopathology results from the lab?

1. <week 2. <month 3. 1-3 months 4. >3 months

B) PERSONNEL:

1. How many pathology personnel were available at the histopathology lab between 208-2022: (role+certifications). (*probe: How many technicians*)

Specialization	Number	Years of experience
Pathologists		
Lab Technologists		
Records persons		
Office Admin		
Lab assistants		

2. How often were On Job Trainings done? 1. Monthly 2. Quarterly 3. Semi-annually 4. Yearly 5. Other _____

3. a. Were continuous medical education (CME) for staff conducted? A) YES B) NO
   b. If Yes, How often and who is responsible _____

_____

4. How often was regular laboratory recertification performed, and who was responsible for it?

_____

C) REFERRAL SYSTEMS

1. How frequently were cases from the MTRH histopathology lab referred to other institutions for further testing?
   1. Rarely 2. Sometimes 3. Most times

2. Which cases were mostly referred if any? (list)

Obervation/Comments:_____

_____

Form Filled By: _____ **Assisting Provider #:** _____

B. Secondary aim: Cervical cancer diagnosis data abstraction form

BROWN **Medical records Data abstraction Form**: Cervical cancer Morbidity & Mortality		**Date** _____/___ /_____
Note taker (Initials):	**Facility name**:	**County/Country**:

Patient ID/code:	**Age _____ or Y.o.B _____**	
Year of enrolment _____	**Clinic:**_____ **Module** ☐1 ☐2 ☐3 ☐4	

1.Education:
1. ≤Primary (8 years)
2. ≤Secondary (12 years)
3. ≤College (14years)
4. College+

2. Monthly earnings:
1. <10000
2. <30000
3. <50000
4. >50000

3. Marital status
1. Single
2. Married
3. Widowed
4. Divorced

4. HIV Status: 1. Positive
2. Negative (skip to Q7)

5. CD4 Count if yes above _____

6. Receiving ARTs 1. Yes 2. No

7. Parity (No. children) _____

8. Prior cervical screening test 1. Yes 2. No

9. Screening test outcome 1. Positive 2. Negative **3. Suspicious** |Date_____

10. Type of screening/ Location _____
1. VIA/VILI
2. Pap smear
3. HPV test
4. Not Indicated

11. Type of CA cervix_____

12. Grade of CA cervix _____

12. Stage of cervical Cancer diagnosis
1 ☐ 2 ☐ 3 ☐ 4☐

13. Period between the date of cervical cancer diagnosis and the date of treatment initiation
1. <2 weeks 2. 2-4 weeks 3. 1-3 months 4.>3 months)

14. Cervical cancer Stage at start of treatment _____

15. Type of Treatment plan:
1. Surgery
2. Palliative Chemotherapy
3. Concurrent Chemo Radiation
4. Radiotherapy
5. Not Indicated

16.a) Duration of treatment_____

b) Date of withdrawal from treatment _____

17. Reason for withdrawal:

1. Death 2. Lost to follow up 3. Patient request 4. Medical judgement 5. Referral 6. Other _____

19. Diabetes status 1. Yes 2. No
20. Have hypertension 1. Yes 2. No
21. Have cancer of any other part of the body 1. Yes 2. No
22. Do you smoke cigarette? 1. Yes 2. No
23. If Yes, For how long have you been a smoker_____?
24. Do you drink alcohol? 1. Yes 2. No

25. If Yes, For how long?		
Comments:_____		
Form Filled By: _____ **Assisting Provider #:** _____		