

**THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PHD)**

**EVALUATION OF CERVICAL CANCER PREVENTION POLICIES IN  
EAST AFRICAN COUNTRIES**

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## **LIST OF ABBREVIATIONS**

CDC:	Centers for Disease Control and Prevention
DRC:	Democratic republic of Congo
GAVI:	Global Alliance for Vaccines and Immunizations
GCP:	Gross County Product
GDP:	Gross domestic product
HIV/AIDS:	Human Immunodeficiency Virus/ Acquired Immunodeficiency syndrome
HPV:	Human Papilloma Viruses
INRB:	National Institute for Biomedical Research
LMICs:	Low middle income countries
SSA:	Sub-Saharan Africa
UK:	United Kingdom
UNICEF:	United Nations Children's Fund
USA:	United States of America
VIA:	Visual inspection with acetic acid
VILI:	Visual inspection with Lugol's iodine
VLPs:	Virus like particles
WHO:	World Health Organization

## **CHAPTER 1: INTRODUCTION**

All over the world, cancer is a major public health burden. 19.3 million was the estimated number of new cases of cancer and nearly 10 million deaths from cancer globally [1,2]. Cancer burden is apparent all over the world; however, the low middle income countries (LMICs) have an upward prevalence in the number of new cases and deaths from cancer for example the Sub Saharan countries[3]. The occurrence of cancer is characterized by unregulated proliferation of cells after the failure of the mechanisms that regulate normal cell growth in so doing invading and destroying the tissues and organs that are adjacent then dissemination to the other parts of the body[4]. World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) have enumerated obesity, alcohol consumption, family history of cancer, Human Papilloma Viruses (HPV), Human Immunodeficiency Virus/ Acquired Immunodeficiency syndrome (HIV/AIDs), lifestyle and tobacco smoking have been linked as the major risk factors for cancer[5,6]. Among the leading cancers that have been implicated to have a high morbidity and mortality worldwide in women of all ages are cancer of the breast, cancer of the lung and cancer of the cervix[7]. Inadequate primary health care, compromised screening procedures, delayed histology results, little or no resources, follow up hitches, lack of awareness and limited treatment opportunities have marred the diagnosis and detection of cancer in the developing countries hence the cancer is discovered late and at an advanced stage[8,9]. Ineffective implementation of policies for control of cancer, overwhelmed health demands and poor monitoring through population registries is a great contributor to the long term problem of cancer of the cervix facing sub-Saharan Africa(SSA)[10-12]. This has been the typical picture in most of these developing regions[13]. In contrast, the incidence and mortality from cervical cancer have decreased in developed countries, attributable to organized and consistent cervical screening programs rather than opportunistic screening

programs and HPV vaccination [2], well-structured national health care systems, affordable high quality cancer treatment for all and prioritized health care spending hence the low mortality to incidence ratios[14].

Cancer of the cervix has been linked to HPV and evidence strongly shows that it is the main causative agent[15], 99% of cervical cancers are caused by HPV. HPV types 16 and 18 cause approximately 70% of cervical cancers worldwide[4, 5][16]. Invasive cervical cancer is more frequently related with high risk Human Papilloma Virus (HR-HPV) types 16 and 18 than with other types[17]. Of all the diseases transmitted sexually by mucosa to mucosa contact in the reproductive tract, HPV is the most frequent infection [18]. There are a variety of HPV genotypes. These group of viruses are sexually transmitted[19]. There are oncogenic and non-oncogenic types. Their prevalence ranges from different geographic locations and populations [20-22], the most prevalent HPV oncogenic or high risk types are HPV 16 and 18 [23,24]. The 10 most frequent high risk HPV types are HPV 16, 18, 31, 35, 39, 45, 51, 52, 56 and 58. The 10 most frequent low risk HPV types are HPV 6, 11, 32, 40, 42, 43, 44, 54, 57 and 61[25]. The diversity among continents and countries and the heterogeneity of the HPV types has affected the efficacy of HPV vaccination[26], hence these two factors ought to be taken into account when developing of vaccines and of screening tests [27]. Based on this heterogeneity, no one HPV vaccine has the ability to provide full protection against all the HPV types[28]. Effective programs and interventions facilitating early screening of women and increased availability of HPV vaccinations will greatly contribute to reduction of mortality from cervical cancer as it is preventable[29]; this will maximize the chances of successful treatment of precancerous lesions[30]. In his address, Dr Tedros, reiterated that “CC is a Non-Communicable Disease (NCD) that we can overcome. He

added that if no action is taken women will continue dying from CC, and the rates will rise by almost 50% by 2030 [31]. “

## **1.1 BACKGROUND**

### **1.1.1 The burden of cervical cancer (CC)**

Globally, in 2020, cancer of the cervix was ranked fourth as the cancer with high incidence among females of all ages, with a total of 604,127 new cases which translates to 6.5% of the total percentage of new cases [32]. Comparing these global statistics to the African continent, in 2018, a significant proportion is from African countries with 19 of its countries being amongst the 20 top countries globally with the highest incidence of CC [33]. Narrowing it down to SSA, cervical cancer incidence is on the rise, and currently the second most frequent cancer and responsible for women deaths [34]. The highest age standardized incidence rate of CC worldwide is from the south of Africa, Malawi (43.1 per 100,000)[35]. In the SSA, CC has been implicated for the cause of death among women in SSA as evidenced by its high (21.7%) percentage as compared to other mortalities from the other types of cancers [34].

This alarming morbidity and mortality in the low resource settings has left countries desperate for an intervention. The WHO has made strategies that will hasten the eradication of CC as a public health concern by setting targets for countries to achieve by 2030; 90% full vaccination for girls before their 15th birthday, high precision screening for 70% women and 90% women diagnosed with CC to receive treatment and care[36]. High level advocacy translated to vaccination against HPV and routine mass screening is the intervention urgently needed in SSA to curb this public health burden[34,37]. Underscreening and inadequate follow up are some reasons for the increasing burden of CC in some populations[38].

## **1.1.2 Public health policies for reducing disease burden**

### **1.1.2.1 Policy mapping**

Policy mapping is a process of examining the prevalence, distribution and characteristics of adopted policies across jurisdictions to provide evidence on some effective interventions and highlights the modifications of health policies[39]. For a while now , it has been noted that policy mapping applies a methodology towards bringing clarity to the laws in health and it has become a popular practice [40]. Mapping policy is essential because it provides very useful perspectives and reveals conceptual gaps in laws that affect health and can facilitate starting points to make amendments[41].

Countries cannot be able to achieve their public health program goals effectively without laws; it is mandatory that legal and regulatory instruments are established and executed [42]. Under legal mapping studies, laws, regulations and policies are the frequent legal instruments utilized. Legally binding policies are classified as legislations, regulation and litigation[43]. Briefly, laws and regulations are policies; policy is broadly used to refer to laws and regulations that are expected to accomplish certain objectives, they articulate the government's intentions to address priority public issues and the actions to be taken[44]. However, the enforcement and consequences of noncompliance differs for policies and laws[45]; laws are to govern behaviors and regulation is the use of various instruments to implement socioeconomic policies or law[46]. The laws are crucial to efforts to achieve public health aims of a population. For instance, decreasing the prevalence of CC in a country counter reduces the burden of CC. The rules that are passed by the parliament are referred to as Acts and they are a type of law. To establish public health agencies, assign them core functions, apportion funding and demarcate their actions to protect the human rights is a function

of a legal regulation[45]. Some national authorities and agencies take a further role to develop and publish by to further guidelines or strategies and other non-binding policy statements to elucidate how existing laws and regulations ought to be understood and implemented; they provide a detailed description of the actions that have been recommended therein. It is worth noting that the guidelines and policy statements aforementioned do not provide mandatory instructions except if they are incorporated into a regulation under terms and conditions of an agreement[47]. These national policies, strategies and plans are fundamental legislative tools for protecting populations against threats from health calamities like cancer of the cervix among other diseases[48]. In the past decade, international health commitments have been established enabling countries to legally bind themselves to oblige to implement national health policies[49].

Strategy is a form of the policy statements, hence the link with the term policy. A strategy is a non-binding plan detailing the clear purpose, measurable objectives and actionable approaches and tangible specific programs whose responsibility is to achieve the government's ultimate goal [50]. It is crucial to set up national cancer control policies [51] as it is a demonstration of the state's commitment to facilitate and provide the direction for the implementation and realization of the cancer control programs which have proved that indeed public health policies enhance positive clinical outcomes[52]. In the management and control of cancer, cancer policies provide the visibility that elevates interventions to address the burden of cancer leading to tangible gains, for instance lung cancer incidences reduction due to strengthening the implementation of smoke free laws and tobacco control policies[53-55].

### **1.1.3 Cervical Cancer policies and guidelines**

Policies and guidelines for CC should address the affected population which is girls and women, the programs and structures crucial in the control of CC covering the full continuum from prevention to treatment and management of CC[56]. In 2018, the WHO made a worldwide call to action to eliminate and end the suffering from curable and preventable cancer[31]. The comprehensive CC control guideline by WHO broadly outlines the components for effective CC programs. These are the primary and secondary prevention, diagnosis of CC, treatment modalities and palliative care [57]. The main objective of this international guide was to provide a uniform direction to governments to enable them establish, implement and update their CC guidelines and protocols[6]. There have been great public health achievements whose success can only be pointed to policy amends[43].

National policies on cervical cancer ought to be tailored for countries especially the LMICs recognizing the social disparities among the populations[48]. Specifically the national cervical cancer screening programs have fallen short because they have failed to favor different groups of disadvantaged and marginalized women [58] because evidence has shown that in SSA, the huge gaps in health care systems have hindered implementation of cervical cancer policies[59]. These countries have the highest CC burden, lowest rates of crude and effective CC screening, lowest availability of skilled personnel and inadequate diagnostic and treatment facilities[60] in contrast with the countries that have established guidelines whose screening rates are high with low disease burden [61]. Effective CC policies are a fulfilment of the human rights of women and are a foundation for their empowerment[62].

#### **1.1.4 Prevention of cervical cancer**

CC is considered a highly preventable cancer due to the highly effective HPV vaccine (primary) and early screening (secondary) prevention methods[1]. There are several cervical cancer screening protocols adopted worldwide with just slight modifications providing alternative screening intervals. All these protocols are helpful in detecting cervical precancerous lesions and cancer. According to the American College of Obstetricians and Gynecologists (ACOG), they recommend three options for cervical cancer screening in people aged 30 to 65: these are, cervical cytology alone every three years, primary HrHPV testing every five years or co-testing with cytology and hrHPV testing every five years[63].

The United States Preventive Services Task Force (USPSTF) 2018 recommendations on screening for cervical cancer discourage against screening of women below 21 years and women above the age of 65 who have had regular cervical cytology screening without a history of any abnormalities in the last 10-20 years. It further recommends that women between age 21 to 29 be screened for cervical cancer every 3 years by cervical cytology alone, then every 5 years with HrHPV testing alone or a combination of cervical cytology and HrHPV testing for women between the age of 30 and 65[64].

The American Society for Clinical Pathology (ASCCP) and the Society of Gynecologic Oncology (SGO) both endorsed the USPSTF's cervical cancer screening guideline[65].

Early detection by early screening for HPV, Pap smear testing, HPV vaccination and the treatment of precancerous lesions are the strategies to control and prevent CC[66]. In order to identify cervical precancerous deviations, CC screening is recommended for all women aged between 25 and 65 years [67]. Age appropriate high quality cytology test the Papanicolaou test (Pap smear) is the ideal screening examination highlighted in the guidelines for prevention and early detection of CC[6,68]. Although cytology tests produce a false negative result for conventional smears, they are the most common used method for cervical cancer screening in many countries. Currently, the HrHPV testing is the most effective way for detecting precancerous cervical lesions and age appropriate cytology testing is



recommended [69]. Primary HPV screening has several advantages, including increased sensitivity in detecting precancerous lesions, improved reassurance with a negative test, and the ability to reasonably prolong screening intervals[70]. The existence of cytology false negatives and inadequate screening contribute to the failure of cervical cancer screening[71]. The use of primary HPV testing will greatly reduce the rate of false negative rate of cytology[72].

Vaccination against the high risk and most common HPV types 16 and 18 prevent the problem of CC amongst women in SSA in the future [73,74]. Affordable, effective screening programs designed based on the poor resource settings' needs will greatly lower the incidence of CC as data shows that screening has been associated with reduction in the incidence and mortality of CC in United Kingdom (UK) and Australia[75]. The screen and treat approach is more practical, safe and reduces the chances of having increased prevalence of high grade CC precursor lesions in low resource setting because of its high sensitivity of 100%, its ability to give immediate results and requires less intense training [76]. Screen and treat approach is achieved by visualizing the cervix through inspection then any dysplasia noted then treated using cryotherapy[77]. Visualization is done through visual inspection with acetic acid (VIA) and visual inspection with Lugol's iodine (VILI)[76]. A study in Cameroon on HPV-based screen-and-treat approach revealed that VIA/VILI had a sensitivity and specificity of 80 percent and 44 percent, respectively, in identifying CIN2+ among HPV positive women this is proof that the screen and treat approach does not have a 100% sensitivity and is a feasible approach in low resource settings [78,79]. The main benefit of the "screen and treat" approach for at-risk women in low-resource settings is the possibility of reducing loss to follow-up, which has an influence on cervical cancer control.[80]

HPV DNA testing has been found to have higher sensitivity as compared to cytology tests [81]. It is however pricier and as such due to the inadequate infrastructure[82] in the low resource settings the cytology testing is more efficient as the primary method of screening[83]. Although evidence

shows screening rates are low, there is proof that screening provides substantial protection against CC[84]. To maximize on the effective screening technologies and approaches, outreach programs are necessary to empower women in the communities to go for screening[85].

### **1.1.5 Human Papilloma Virus Vaccine**

2006/2007 was the year HPV vaccines were first launched worldwide[86]. Quite a number of countries expressed remarkable interest and embraced the idea by adopting it in their national immunization schedules[87]. WHO recommends Cervarix, Gardasil and Gardasil 9 HPV vaccines. Cervarix is a bivalent vaccine targeting the high risk HPV types 16 and 18, while Gardasil offers protection against both HPV 6 and 11 in addition to HPV 16 and 18[88]. In 2016 the United States Food and Drug Administration (FDA) approved Gardasil 9 is a nonavalent HPV vaccine (9vHPV) which protects against more cancer causing HPV types 16, 18, 31, 33, 45, 52, and 58, and also prevents genital warts caused by HPV types 6 and 11[89,90]. Gardasil 9 is the only HPV vaccine that provides protection against HPV types causing cervical cancer in women and other HPV-associated anogenital cancers in both men and women[91]. Further reduction of HPV related cancers will be possible in effective vaccination programs with Gardasil 9 [92].

These vaccines contain virus like particles (VLPs) of HPV[93]. VLPs are multi-protein structures that mimic authentic native viruses like HPV in how they are made but they lack the viral genome hence rendering them safe and cheaper[94]. HPV vaccination provides prophylactic efficacy against cervical pre-cancer in vaccinated adolescent girls and women consequently reducing the incidence of cervical cancer[95]. It is predicted that high vaccine coverage of girls will eliminate CC in most LMICs[74]. The HPV vaccines according to literature can provide nearly 100% protection against the HPV types included in the vaccines if they are given in adolescent age for prevention [96]. HPV vaccination may offer the added benefit of lowering the prevalence of HPV

infection caused by types not covered by the vaccines though there is some evidence of cross protection [97,98].

Evidence has shown that HPV vaccination has played a major role in elimination of cervical cancer and it is projected that HPV-related cancers will tremendously decline[99]. A meta-analysis documented a 83% reduction in prevalence of HPV types 16 and 18 in girls aged 13–19 years when at least 50% coverage was achieved[100]. Because HPV vaccines do not protect against all HPV types that can cause cancer, women who have been vaccinated are advised to follow the same screening recommendations as unvaccinated women. There could be future changes in screening recommendations for vaccinated women.[101]

HPV vaccination has been handled as a public health priority by many countries as studies provide evidence of its gains and efficiency The recommended age for vaccination is girls between 9 and 14 years since it is assumed that at this age the girls are not sexually active nor prior exposure to HPV and also because higher immunity can be generated in this age group[6].

A prediction modelling study confirmed that HPV vaccination will impact positively in the elimination of CC in LMICs in the next century[74]. In developed countries where CC incidences are reduced like UK, United States of America (USA), Australia and Europe which have achieved high vaccination coverage[99,104,105], there have been recommendations for gender neutral vaccinations since there have been occurrences of HPV attributable cancers in men[106-108]. It is also presumed that these gender neutral vaccines would provide significant cost-effective benefits[109]. There is an urgent need to introduce HPV vaccination in the developing countries due to the high burden of CC[110-114].

Globally, the uptake of HPV vaccines is suboptimal [115] and available research shows that low levels of awareness [116,117], poor compliance to the HPV vaccination program[118], irrational

parental reservations and misinformation[119], cultural and religious reasons [120]. Data has shown that the costs of HPV vaccine and lack of prioritization are some of the challenges associated with coverage and uptake of the HPV vaccine in the LMICs[121]. Recommendations that have been proposed include coming up with strategies that can be operationalized at the different populations in the diverse country levels[70]. Over half of all the deaths from CC can be significantly controlled employing crucial strategies like providing comprehensive public health education on HPV vaccination to communities [103], giving prophylactic HPV vaccination and conducting mass screening for CC [34].

There are several factors that distinguish HPV vaccine from the other pediatric vaccines in that the mode of transmission which is sexually, the adolescents who are the target population, the fact that most HPV associated cancers affect the females and the nature of time lag between getting an infection and the onset of cancer[86]. A large percentage of HPV-related malignancies occur in men for example oropharyngeal cancer anal, head and neck cancers [122]. Anal cancer in men is most commonly associated with HPV type 16, and is more common in men who have sex with men. As in women, HPV types 6 and 11 cause the majority of male genital warts[6].

Kenya conducted a HPV pilot program in 2013-2015 [123] whose success influenced the introduction of HPV vaccine countrywide in October 2019 with an objective to immunize 800,000 girls annually[124]. Through the support of Global Alliance for Vaccines and Immunizations (GAVI) and the WHO the vaccines were available at no cost. The United Nations Children's Fund (UNICEF) publicized relevant public health messages highlighting the advantages, safety and effectiveness of HPV vaccine [125].

As with any undertaking, increasing awareness and publicizing the HPV vaccine will improve the knowledge on all aspects of HPV and its prevention, this includes addressing the concerns of

parents and children who are involved in HPV vaccination as this will enhance the uptake[126]. Compliance to vaccination ought to be accepted by the stakeholders for it to be successful[127]. In Kenya, communities' opinions regarding HPV vaccination are related to apparent mistrust towards new vaccinations[119], deficient knowledge about the HPV infections and the vaccination[120,127], insufficient information due to fragmented training of stakeholders[128]. In Kitui, Kenya, besides there being evident low knowledge levels, the community gave a positive reception to the HPV vaccine regardless of some hindrances like girls' absenteeism, inaccessibility to school and irrational fears of side effects [119]. A study among mothers of adolescent girls in western Kenya revealed that there was a positive desire to accept the HPV vaccination regardless of obvious low levels of knowledge[129]. It is advantageous when simple knowledge on the natural history of CC is available and disseminated to the communities as this greatly contributes to the efforts of its prevention and control[130].

Little is known about the uptake of HPV vaccine in different regions of Kenya. The views of the populace are fragmented and marred with a lot of misinformation. This is what informed this research as it sought to bring an insight on the progress of the HPV vaccination program and the opinions towards the introduction of the vaccine for the 10 to 11-year-old boys and girls two counties at the coast of Kenya (Mombasa and Tana-River).

## **1.2 OBJECTIVES**

### **1.2.1 Part 1**

1. To identify and content analysis of policies for prevention and management of cancer of the cervix of East-African countries
2. To determine the compliance of the policies from East-African countries with the comprehensive cervical cancer control guide to essential practice by WHO.

### **1.2.2 Part 2**

1. To assess the knowledge and attitude of HPV vaccination among school boys and girls, parents and other key informants comprising of head teachers, health workers and community leaders regarding HPV vaccination.
2. To assess the position of HPV vaccination programs in Mombasa and Tana-River counties in Kenya and potential improvements.

## **CHAPTER 2: METHODOLOGY**

### **2.1 PART 1: National Policies to Prevent and Manage Cervical Cancer in East African Countries: A Policy Mapping Analysis**

#### **2.1.1 Systematic searching**

A thorough systematic document search for health policies on CC prevention and management from East African countries i.e. Burundi (BI), Comoros (KM), Democratic Republic of Congo (DRC), Djibouti (DJ), Eritrea (ER), Ethiopia (ET), Kenya (KE), Madagascar (MG), Rwanda (RW), Somalia (SO), Uganda (UG), and Tanzania (TZ) [131] [132]. The search was uniformly conducted from the 12 national or government websites, national health ministry/department or related websites, national cancer institute sites, international LexisNexis and Westlaw legal databases, national legal databases, the African legal information institute, the international cancer control partnership portal, and the WHO non-communicable disease document repository. A comprehensive list of all the websites and databases is found in the appendix 1. Depending on the filtering options of the different websites, different search terms were used. For the national databases, cervical cancer or cancer was used without any restrictions. This was because different countries had different titles for the documents. For the international databases, country name and cervical cancer or cancer were used. The comprehensive search was conducted from February to June in 2019.

#### **2.1.2 Document screening**

A documents searched criteria was formulated. The documents of interest were any legal instruments i.e. guidelines, strategies, plans, policies, regulations, and acts of parliament. The eligible documents included; all national legal documents published under the health ministry,

health-related ministries, governmental institutions, national cancer institutes, or parliaments. All national legal instruments that described the aspects of the prevention, management, and control of cervical cancer. The documents that were excluded lacked information on cervical cancer e.g. national non-communicable disease policies because they contained generalized information about cancer instead of highlighting the particular aspects of cancer of the cervix. Documents that were non-legal texts like articles or grey literature were also excluded. Data screening and the process of selection for every country is illustrated in PRISMA flow charts. The charts are available in appendix 2.

### **2.1.3 Data coding and analysis**

The data that was found were in different languages. These languages were English, Kiswahili, and French. The documents that were in Kiswahili and French were translated into English. The QRS Nvivo 12 Plus software package for content analysis of unstructured qualitative data was used for the processing of the data. All the legal documents were in PDF format and thus were uploaded into the Nvivo software. Data was coded using a content analysis approach. A codebook was developed through the collaboration of the two coders according to the WHO national cancer control programs, policies, and managerial guidelines [133]. The process was document analysis of the contents of the policies to find out if they contained the elements highlighted by the WHO guide. Inductive thematic analysis was used to analyze the data while identifying key themes emerging from the data following the coding process. The data categories were coded in two stages, with the second stage taking a more refined approach. A series of consensus discussions were undertaken to review, refine and confirm the main themes and codes; data that was related was selected and put into nodes.



#### **2.1.4 Quality appraisal**

Quality appraisal of the documents was conducted using a validated assessment tool that had a response scale. The tool provides the relationships between policy determinants and expected outcomes[134,135]. Each policy was independently evaluated based on seven domains. These domains represent critical information used to evaluate a policy. These include background, goals, resource considerations, monitoring and evaluation, public opportunity, obligations, and potential for public health impact. The scoring was based on a 3-point nominal scale with ranges 0 to represent not fulfilled or weak, 1 represented room for improvement and 2 represented fulfilled. Two independent reviewers carried out a systematic assessment of each policy and gave scores for each domain according to the information that was in the text or legal documents. The contradictions that came up between the two reviewers were resolved by way of open discussions. An interrater reliability using Cohen's kappa (k) inter-rater reliability statistic was determined using SPSS statistics for Windows version 25.0. The inter-rater reliability is the extent to which two or more raters or reviewers agree. Each domain and each document were assessed. The result was based on Fleiss' kappa coefficient thresholds [136,137].

## **2.2 PART 2: Knowledge, Attitude and Practice of Main Stakeholders towards Human Papilloma Virus Infection and Vaccination in Mombasa and Tana-River Counties in Kenya: A Qualitative Study**

### **2.2.1 Study setting**

Kenya is a country in East Africa with coastline on the Indian Ocean, with a population of approximately 52.5 million people[138]. The study population was from Mombasa and Tana River

counties which are located on the Indian Ocean coast. To the best knowledge, there is no similar survey that has been carried out in this region before. The two counties are distinct in that they have diverse socio-economic outlook which can permit a comparison of the results. Mombasa is situated in an urban locality. Mombasa County is the second largest city after Nairobi the capital of Kenya with a population of 1.2 million people. Mombasa county is among the counties with highest Per Capita Gross County Product (GCP) of 271,039 Kenya shillings in 2013-2017 [139]. GCP is the measure of how much each county contributes to the gross domestic product (GDP) of Kenya, it can be loosely interpreted as the “County GDP”. Mombasa county has a cosmopolitan population, characterized by a relatively high proportion of foreigners, hence a bedrock for tourism. Tana River county is in a rural locality with a population of 315,943 people. The major ethnic groups comprise of the Somali, Pokomo and Orma. Tana River county is one of the underdeveloped counties in Kenya, among the counties with the lowest Per Capita GCP of 106,894 Kenya shillings in 2013-2017[139]. The county is dry and prone to drought and the communities have ethnic and land conflicts [140,141]. These two counties are advantaged since they depend on the Indian Ocean for their social and cultural security[142] and the marine resources due to their location on the Kenyan coast.

### **2.2.2 Study design and sampling**

Individual interviews were conducted by purposively selecting the participants using a maximum variation sampling strategy. Maximum variation sampling is when the researcher selects a small number of subjects that maximize the diversity relevant to the research question for examination and analysis. In this descriptive qualitative study, the inclusion criteria were composed of at least a boy or a girl aged between 9–13 years, a parent, a head teacher, a community leader and a health worker who was engaged in the HPV vaccination exercise. The principal researcher identified the

potential participants from Mombasa and Tana River counties. The first participants were picked randomly from the list of schools then the participants were asked to volunteer or suggest other participants who would be eligible to be give the interviews. This was repeated until data saturation was reached in all the interest groups. A community leader is any member of the community appointed or selected and has strong influence on the decision making for community agenda and also mobilizes the community members by working together with the local government authorities. In this study these are the chiefs, village elders, community health workers and religious leaders. The interviewees were drawn from diverse populations in both Mombasa and Tana-River counties.

### **2.2.3 Data collection**

A total 103 interviews were conducted. Semi-structured interviews were the mode of data collection. An interview guide was developed with focus on three comprehensive themes, these were: the level of the interviewee's knowledge that is related to cervical cancer, the interviewee's attitude towards cervical cancer prevention and the interviewee's opinions on possible means to tackle the barriers in current practice. The semi- structured interview guide is available in appendix 4.

The effectiveness of the vaccination exercise highly depends on these factors that are covered in these themes. In generating the interview guide, the WHO guideline for essential practice for control of the cancer of the cervix was used as a point of reference[6]. The guideline highlights the implementers of the HPV vaccination programs as the community health workers and the primary and secondary level health care providers.

A semi-structured interview guide was developed with questions that were related across the different groups of interviewees, however there was slight modifications to suit each of the participant groups. All the semi-structured interviews were carried out by the researcher who has

significant experience in qualitative research. The interviews were held uniformly in a friendly environment that was convenient to the participant or for the children in a shielded environment in the vicinity of the parents or, in the case of the adult informants, in their offices or secluded part of the classrooms. For all the boys' and girls' apart from a few that were interviewed from the comfort of their homes or at the health centers, the interviews were conducted in their schools, either at the head teacher's office or in a private separated part of the classroom. The interviews were captured by recording using a digital voice recorder, observations and notes were taken.

Data collection was conducted between September 2020 and February 2021. The interviews were conducted in both English and Kiswahili depending on the language that the interviewees were comfortable to communicate or their individual preference. On average the interviews lasted for 30 minutes.

#### **2.2.4 Data transcription, coding and analysis**

All the audio files were transferred from the digital recorder to the computer in an MP3 format. Then uploaded into the QRS Nvivo 12 Plus software package for content analysis of unstructured qualitative data. Folders were generated to cater for the two counties and the different participant groups then all the audio files were assigned different numbers in a random manner to assure confidentiality of the participants. Transcription was done verbatim by two researchers. The assistant transcriber was trained and transcribed some the English audio files. The Kiswahili audio files were transcribed by the principal researcher who also collected the data. The original list of codes was established based on the research questions and review of literature. Content was analyzed in themes, then indexed and then coded inductively for emerging similar themes. The initial open codes were sorted into sub-themes based on their similarity. These subthemes were

clustered and refined to form broad themes. Open discussions were carried out to arrive at agreements regarding the themes.

Based on current evidence, knowledge node responses were categorized into three. These were: accuracy of the response either it was correct, lacked an answer or severe misunderstanding. Under attitude nodes, the opinion of others was classified depending on the nature of the attitude as supportive, opposing or neutral. Throughout the process of data collection, analysis and reporting the Standards for Reporting Qualitative Research (SPQR) guideline were followed [143]. The guide is available on appendix 5.

During the preparation of the protocol, creation of the coding system, interrater reliability and data analysis, consistency was observed guided by the Guba and Lincoln's criteria for determining rigor in qualitative research[144,145]. For each group, two interviews were coded by two researchers to determine the degree of similarity by doing an interrater reliability statistic using the Nvivo software. A sample (10%) of the interviews were coded by one researcher, then all by the principal researcher. The sample (n=10) was randomly selected and the criteria was to have a similar proportion of interviews drawn from each county and each stakeholder group. After satisfactory reliability was confirmed, the principal researcher proceeded to code the remaining data independently [48]. According to the Cohen's Kappa score interpretation, values  $\leq 0$  point toward lack of agreement, values 0.01-0.20 point toward no or little agreement, values 0.21-0.40 point toward fair agreement, values 0.41-0.60 point toward moderate agreement, values 0.61-0.80 point toward substantial agreement, and values 0.81-1.00 point toward nearly perfect agreement[146]. The Kappa score result per theme was: knowledge 0.79, attitude 0.83, and practice 0.75.

### **2.2.5 Ethical issues pertaining human subjects**

University of Eastern Africa, Baraton (UEAB) Research and Ethics Board in Kenya approved the study and permission to conduct the research was granted by award of a research permit from National Commission for Science, Technology & Innovation (NACOSTI) the License number was NACOSTI/P/20/6514. Each participant was presented with pertinent information about the study then all questions answered. Only after this the consents were requested. All the adult participants gave a written informed consent prior to the start of the interview while the parents and teachers signed the informed consent on behalf of the minors.

## CHAPTER 3: RESULTS

### 3.1 PART 1: National Policies to Prevent and Manage Cervical Cancer in East African Countries: A Policy Mapping Analysis

#### 3.1.1 Description of policies

After a thorough search, for the eligible documents, policies, plans, guidelines, acts and strategic documents from Kenya, Uganda, Tanzania, Burundi, Rwanda, Eritrea, Ethiopia, Madagascar, DRC and Comoros made the sample with the exception of Somalia and Djibouti where no relevant documents were found. 24 documents were included and the comprehensive list is as shown below in Table 1. There were only 4 acts of parliament which are legally binding out of all the 24 legal documents that were identified. Kenya had the most documents with Uganda having the second most.

**Table 1. List of policy documents by counties, title and the year of publication**

Country	Title of Policy	Type	Year of publication	Reference
Burundi	National Health policy	Policy	2016	[127]
Democratic Republic of Congo	National strategy to combat the cancer of the uterine neck and breast	Strategy	Not available	[128]
Eritrea	Health Sector Strategic Development plan	Strategy	2016	[129]
Ethiopia	Guideline for cervical cancer prevention and control	Guideline	2015	[130]
	National Cancer Control Plan	Plan	2015	[131]
Comoros	Reproductive health policy	Policy	2002	[132]
Madagascar	National Strategic Plan to fight against cervical cancer	Strategy	2016	[133]
	National cancer policy	Policy	2010	[134]
	Cervical cancer screening guide	Guideline	Not available	[135]
Uganda	Uganda Cancer Society Strategic Plan	Strategy	2016	[136]
	Cervical Cancer strategic Plan	Strategy	2010	[137]
	Cancer Institute Act	Act	2017	[138]
	Uganda cancer institute treatment guidelines	Guideline	2017	[139]
Tanzania	The ocean road cancer institute	Act	1996	[140]
	National cancer strategic plan	Strategy	2013	[141]
	Cervical cancer strategic plan	Strategy	2011	[142]
Rwanda	Ministry of Health strategic plan	Strategy	2018	[143]
Kenya	Cancer prevention and Control (Amendment Bill)	Act	2016	[144]
	Cancer prevention and Control Act	Act	2012	[145]
	National Cervical Cancer Prevention Plan	Plan	2012	[146]
	National Guidelines for Prevention and management of Cervical Breast and Prostate Cancers	Guideline	2012	[147]
	National Cancer Treatment Guidelines	Guideline	2013	[148]
	National Cancer Control strategy	Strategy	2011	[149]
	National Cancer Control strategy	Strategy	2017	[150]

The table shows 24 legal instruments from 10 countries, with their legislative type i.e. policies, plans, guidelines, acts and strategic documents.

### 3.1.2 Quality appraisal

The interrater reliability of the sum of scores for the policy documents that were retrieved was determined by using the Intraclass Correlation Coefficient (ICC). The mean of the sum of scores for internal validity was 7.63 (95% Confidence Interval (CI): 5.85–9.40). The scores were from 0–13 as seen in appendix 3, tables 1 to 3. The ICC was high with a score of excellent and a value of 0.947 (95% CI: 0.876–0.977). The Kenya National Cancer Prevention Strategy 2017–2022, Kenya national cervical cancer prevention plan Final Feb 2012 and Ethiopia Guideline for cervical cancer prevention and control had the highest scores with 13 while the Uganda cancer Act has the lowest with a score of 0. Out of the 7 domains, public opportunity had the highest score among all the policy documents with a mean of 1.33 (95% CI: 1.01–1.65) while resource considerations had the lowest score with a mean of 0.79 (95% CI: 0.51–1.07). Using the SPSS software package, the Cohen’s kappa ( $k$ ) inter-rater reliability statistic was calculated for each domain. These results as seen on Table 2 demonstrate the level of agreement/disagreement of the two raters for the policies that were obtained. The scores for each domain and each document between the two raters were discussed and disagreements were solved with open discussion.

**Table 2. Inter-rater reliability for the domains of internal validity**

	No agreement	Slight	Fair	Moderate	Substantial	Excellent	Almost perfect agreement
Domain	$k (\leq 0)$	$k$ (0.01-0.20)	$k(0.21-0.40)$	$k(0.41-0.60)$	$k(0.61-0.80)$	$k (>0.75)$	$k(0.8-1.00)$
Background and case' for change					0.645		
Goals					0.67		
Resources					0.714		
Monitoring and evaluation				0.515			
Public opportunities				0.467			
Obligations			0.263				
Potential for public impact			0.262				

[The table shows inter-rater reliability was expressed by Cohen’s kappa ( $k$ ). Calculation is based on the internal validity scores, available in Table 2 and 3 of appendix 3.



### 3.1.3 Overview of themes

The data was grouped into the contents that were frequently occurring. These emerging concepts were grouped into parent nodes. Then the nodes were further categorized into themes. Global burden, justification for regulation, epidemiology, risk factors, validity period, edition year, target group, screening, treatment, mitigation efforts, diagnosis and prevention were the parent nodes (See table 3 below). The child nodes were grouped into themes which were screening, prevention, diagnosis and treatment, challenges and solutions. These themes are comprehensively described below.

**Table 3. Code Book with the files and references**

<b>Parent Nodes</b>	<b>Files</b>	<b>References</b>
Challenges	17	100
Diagnosis	10	27
Edition Year	19	30
Epidemiology	17	67
Global Burden	14	40
Justification for regulation	23	67
Mitigation efforts	17	78
Prevention	13	75
Risk Factors	15	70
Screening	15	96
Target group	12	21
Treatment	13	105
Validity period	11	11

The table shows the parent nodes that were used to code the data

### 3.1.3.1 Screening theme

This theme covered the all the ideal features that are involved in effective and systematic application of approaches of examining women to detect any suspicious lesions that may be suggestive of cervical cancer then need refer them for further investigation[57]. In this theme, the goal of cervical screening and the recommended techniques was elaborated. There were 7 child nodes with 96 references (the number of relevant text parts that were coded at a node) from 15 files. These child nodes were: cytology using Pap smear test, early screening and detection, HPV DNA tests, single visit see and treat (SVA) approach, VIA combined with cryotherapy, VIA and VILI. Early screening and detection had 5 files and 9 references coded, the Ethiopian National Cancer Control Program expressed its objective as, “Some cancers like breast and cervical can benefit from early screening and detection and treating the disease before it grows into an advanced stage”. Cytology with Pap smear test was mentioned severally in most of the documents, in 9 files with 19 references, for instance, Kenya National Cervical Cancer Prevention Plan underscored it as a limitation, “*Pap smear is the most commonly used method for cervical cancer screening, but its availability is limited to the urban areas. The long waiting time between screening and obtaining results leads to many clients getting lost to follow up*” [147]. For HPV DNA testing had 10 files with 15 references coded while SVA 4 files with 8 references. VIA combined with cryotherapy, VIA and VILI. VIA was discussed in 12 files with 25 references while VILI appeared in 10 files with 17 references. These two methods, VIA and VILI were the most commonly discussed by the legal documents in majority of the countries as illustrated by Table 4 below.

**Table 4. Coding presence for the different modalities of screening among the East-African countries**

Country	Cytology by Pap smear test	Early screening and detection	HPV DNA tests	SVA	VIA combined with cryotherapy	VIA	VILI
Burundi	No	No	No	No	No	No	No
Comoros	No	No	No	No	No	No	No
DRC	No	No	Yes	No	No	Yes	Yes
Eritrea	No	No	No	No	No	No	No
Kenya	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ethiopia	No	Yes	Yes	No	Yes	Yes	Yes
Madagascar	Yes	Yes	Yes	No	Yes	Yes	Yes
Rwanda	No	No	No	No	No	Yes	No
Tanzania	No	Yes	Yes	Yes	Yes	Yes	Yes
Uganda	No	Yes	Yes	Yes	No	Yes	Yes

Table 4 shows that Kenya, Ethiopia, Madagascar, Tanzania and Uganda have most screening modalities in the legal instruments as compared to the rest of the countries.

DRC- Democratic Republic of Congo, HPV DNA-Human papillomavirus DNA test, SVA- Single visit see-treat-approach, VIA- visual inspection with acetic acid, VILI-visual inspection with Lugol's iodine

### 3.1.3.2 Prevention theme

There were 11 nodes with 75 references from 13 files coded for prevention. This theme was mainly inclined towards providing modalities that would abate exposure to the causes of CC and reduce individual susceptibility to the consequences of these causes therefore offering the definitive potential public health control of cancer which are efficient and cost effective[148]. The 11 nodes included: abstinence from sexual exposure, adoption of healthy lifestyle, advocacy, being mutually faithful, capacity building, consistent condom use, creating awareness on cancer and reproductive health education, promote male circumcision, discouragement of tobacco use, VIA combined with cryotherapy and HPV vaccination. Creating awareness on cancer and reproductive health education, HPV vaccination and advocacy had the vast majority of concern from the legal documents as it shown in Table 5.

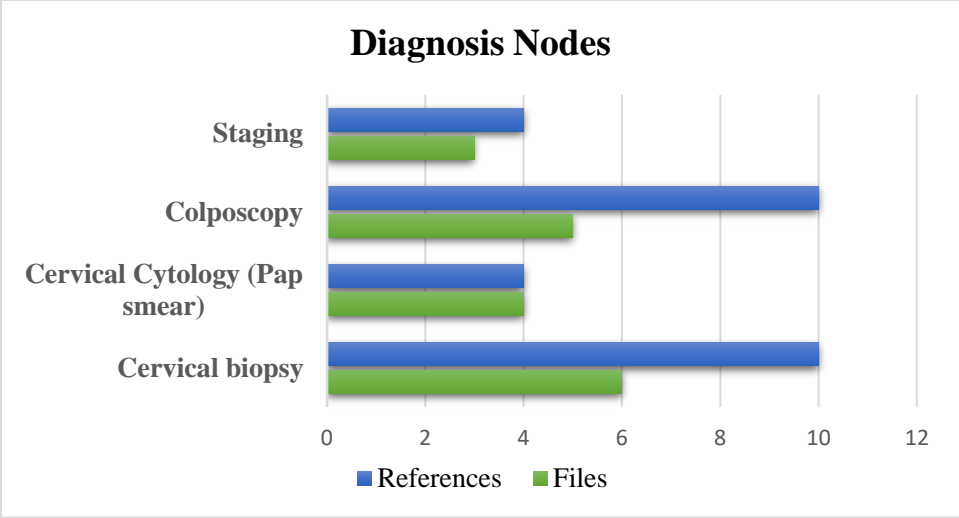
**Table 5. Prevention nodes against the East-African countries**

	BI	KM	DRC	ER	ET	KE	MG	RW	TZ	UG
Abstinence from sexual exposure	0	0	0	0	1	2	0	0	0	0
Adoption of healthy lifestyle	0	0	0	0	0	0	6	0	0	0
Advocacy*	0	0	3	0	2	4	1	0	1	3
Being mutually faithful	0	0	0	0	1	2	0	0	0	0
Capacity building	0	0	0	0	1	0	0	0	1	0
Consistent condom use	0	0	0	0	1	2	0	0	1	1
Creating awareness on cancer and reproductive health education*	0	0	3	0	3	6	3	0	2	8
Discouragement of tobacco use	0	0	1	0	0	1	1	0	1	0
HPV vaccination**	0	0	2	0	1	5	3	0	3	2
Promote male circumcision	0	0	0	0	0	2	0	0	0	0
VIA combined with cryotherapy	0	0	0	0	1	0	0	0	0	0

The table shows how the usage of prevention nodes among the countries. \*Highlights the main intervention plans to reduce cervical cancer in East-African countries. \*\* Prophylactic vaccination against HPV is yet to be included in the national immunization schedules. The rows represent the prevention nodes while the columns represent the countries, Burundi (BI), Comoros (KM), Democratic republic of Congo (DRC), Eritrea (ER), Ethiopia (ET), Kenya (KE), Madagascar (MG), Rwanda (RW), Uganda (UG) and Tanzania (TZ)

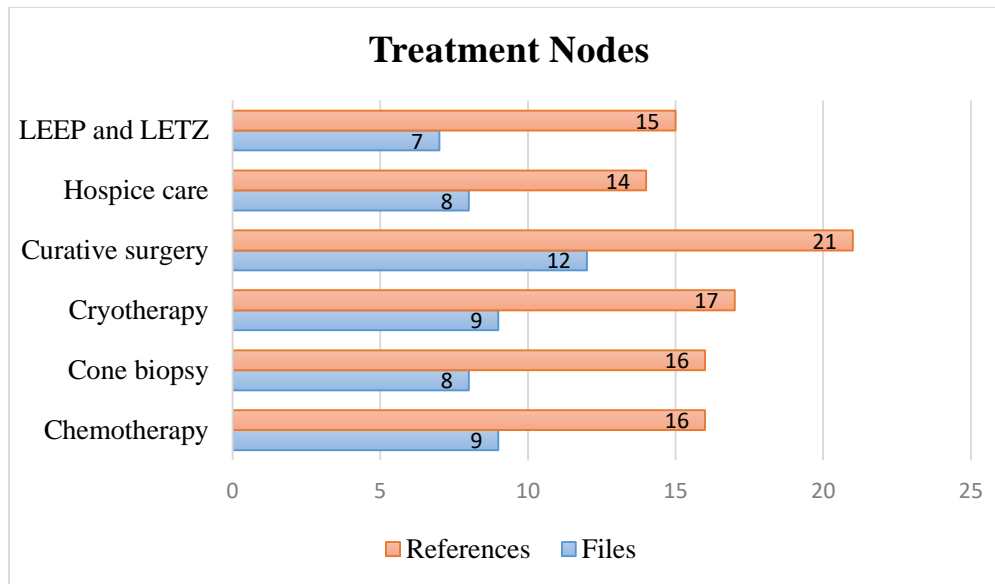
### 3.1.3.3 Diagnosis and Treatment theme

In CC prevention and control, diagnosis and treatment are pivotal components of secondary prevention to aid in reduction of the incidence and prevalence of CC and the mortality that is associated by interrupting progression to invasive cancer from pre-cancer[6] and the techniques that are used to confirm certainty of CC and the interventions geared towards reducing vulnerability. In this theme, 4 nodes were identified with 27 references from 10 files for diagnosis theme and 7 nodes for the treatment theme with 104 references from 13 files. The 4 nodes in the diagnosis theme were: colposcopy (n=5), cervical biopsy(n=6), cervical cytology (Pap smear) (n=4) and staging (n=3) as shown on figure one below.



**Figure 1. Diagnosis nodes, files and references**

The treatment nodes were chemotherapy (n=9), cone biopsy (n=8), cryotherapy (n=9), curative surgery (n=12), hospice care (n=8), radiotherapy (n=13) and loop electrosurgical excision procedure (n=7) as shown below on Figure 2. DRC, Madagascar, Kenya, Uganda and Ethiopia cited cervical biopsy, colposcopy and endo-cervical curettage as the most commonly used diagnostic tests for cervical pre-cancer. The Kenya National Guidelines for Prevention and Management of Cervical, Breast and Prostate Cancers highlighted that a confirmation of a diagnosis is an essential step thereby recommended colposcopy and cervical biopsy. Out of the 12 countries, only legal documents from Tanzania, Uganda, Kenya, Madagascar, Ethiopia and DRC mentioned the 7 nodes for treatment. Figure 1 and 2 below shows the diagnosis and treatment nodes.



**Figure 2. Treatment nodes, files and references**

### 3.1.3.4 Challenges and solutions theme

This theme was characterized by the challenges or limitations and obstacles facing the actualization to reducing the burden of CC. The coded items were from 100 references and 17 files under 11 nodes. On the other hand, some solutions or measures came out as suggestions to decrease the burden of CC. 77 references were coded from 17 files incorporated under 8 nodes. For the challenges theme the nodes included: late stage detection (n=15), high cost of treatment (n=9), chronic diseases (n=3), lack of information (n=7), poor infrastructure (n=10), long waiting time (n=1), scanty records (n=6), low screening rates (n=2), socio-cultural issues (n=3), poor funding (n=3), uncoordinated screening services (n=2), lack of capacity (n=8) and lack of regulation (n=1).

Late stage or advanced stage at detection had the highest citations from countries. Poor infrastructure for prevention and control of cervical cancer was also vastly mentioned referring to lack of capacity and uncoordinated screening services. Kenya, Madagascar, DRC, Uganda and

Ethiopia severally pointed out high cost of treatment and lack of information. The Madagascar National policy for cancer, reiterated, “The stakes of the fight against cancer in Madagascar are summed up by a lack of information to the general public on the issue, the physical and financial inaccessibility of support services that are concentrated in the capital, a reference system against faulty reference, and helpless patients who rely heavily on alternative medicines.”

For the solutions, the nodes were, initiation of prevention, screening and management of reproductive organ cancer at all levels (n=6), development and implementation of a national cervical cancer prevention and control programs (n=6), establishment of appropriate surveillance strategies and integration of other national policy documents (n=6), training up of health officers on screening and treatment and deploying them (n=6). There were additional and unique nodes mentioned one or two times like the scale up of screening and treatment of cervical cancer (n=5), coordination of activities and resource mobilization (n=4), cancer education and community mobilization strategies (n=2), and the continuation of the previous strategy (n=1).

### **3.1.4 Comparison of the national policies from East-African countries to the WHO Comprehensive Cervical Cancer Control guide to essential practice.**

WHO recognizes the challenge of CC, the goal of the CC prevention and control policies is to accelerate the reduction of the incidence, prevalence, morbidity and mortality of cervical cancer. Countries are called upon to step up and develop national policies and protocols as guided by the WHO guide for ideal practice in controlling cancer of the cervix. For any cervical cancer prevention and control policy document there are certain elements that must be addressed. These are HPV vaccination, screening, treatment for precancerous lesions, treatment for invasive cancer

and a functioning referral system. A majority of the East-African countries to be precise, Kenya, Uganda, Tanzania, Madagascar, Rwanda, Ethiopia, Burundi and DRC had adhered to the requirements. However, it was noted that the countries are yet to include HPV vaccination into their national immunization programs. Somalia, Eritrea, Comoros and Djibouti did not have any information on HPV vaccination. In 2011, Rwanda was the only African country that had the HPV vaccination program included in its national immunization schedule [149]

Majority (n=9) of the countries had regular screening programs, however the link to treatment was a challenge. Slightly more than half (n=7) countries regulate the procedures for the treatment for precancerous lesions while only 6 countries had mentioned the treatment of invasive cancer. Our findings highlight that only 6 countries had referral mechanisms for patients with cancer of the cervix. Table 6 below illustrated how the legal documents compared to the WHO guide.

**Table 6. Adherence to the WHO recommendations by countries**

Countries	HPV vaccination	Screening	Treatment for precancerous lesions	Treatment for invasive cancer	Referral system
Kenya	Yes	Yes	Yes	Yes	Yes
Uganda	Yes	Yes	Yes	Yes	Yes
Tanzania	Yes	Yes	Yes	Yes	Yes
Madagascar	Yes	Yes	Yes	Yes	Yes
DRC	Yes	Yes	Yes	No	No
Rwanda	Yes	Yes	Yes	Yes	Yes
Eritrea	No	No	No	No	No
Ethiopia	Yes	Yes	Yes	Yes	Yes
Burundi	Yes	Yes	No	No	No
Comoros	No	Yes	No	No	No
Djibouti	No data	No data	No data	No data	No data
Somalia	No data	No data	No data	No data	No data

This table demonstrates how the cervical cancer legal documents from the different countries had adhered to five essential requirements by the WHO Comprehensive Cervical Cancer Control guide to essential practices. **Yes** means that the legal documents in a country fulfilled the essential elements, **No** means lack of information in the national legal documents, while **No data** means lack of any relevant legal documents from a country.



## **3.2 PART 2: Knowledge, Attitude and Practice of Main Stakeholders towards Human Papilloma Virus Infection and Vaccination in Mombasa and Tana-River Counties in Kenya: A Qualitative Study**

### **3.2.1 Participants characteristics**

From the sample analyzed majority of the respondents were women. Out of the 76 adults who were interviewed, 53 were women. From the different cohorts, among the parents, there were 9 women out of 10. Among the health workers, the nurses were exclusively female. From the community leaders out of the 22, 15 were female. Amongst the head teachers, 14 were women out of 23. The age ranges of the boys and girls was from 10 to 13 years, parents and health workers between 30 and 45 years while community leaders between 35 and 60 years. Table 7 below illustrates a summary of the participants. The religious leaders interviewed were drawn from the Christian and Muslim faiths.

**Table 7. Interviews from both Mombasa and Tana-River counties**

	Mombasa County	Tana-River County
Health worker	11	10
Community leaders	11	11
Head teachers	12	11
Parents	6	4
Girls	11	9
Boys	2	5
Total	53	50

The table shows a summary of all the interviews from both counties.

### **3.2.2 Emerging themes**

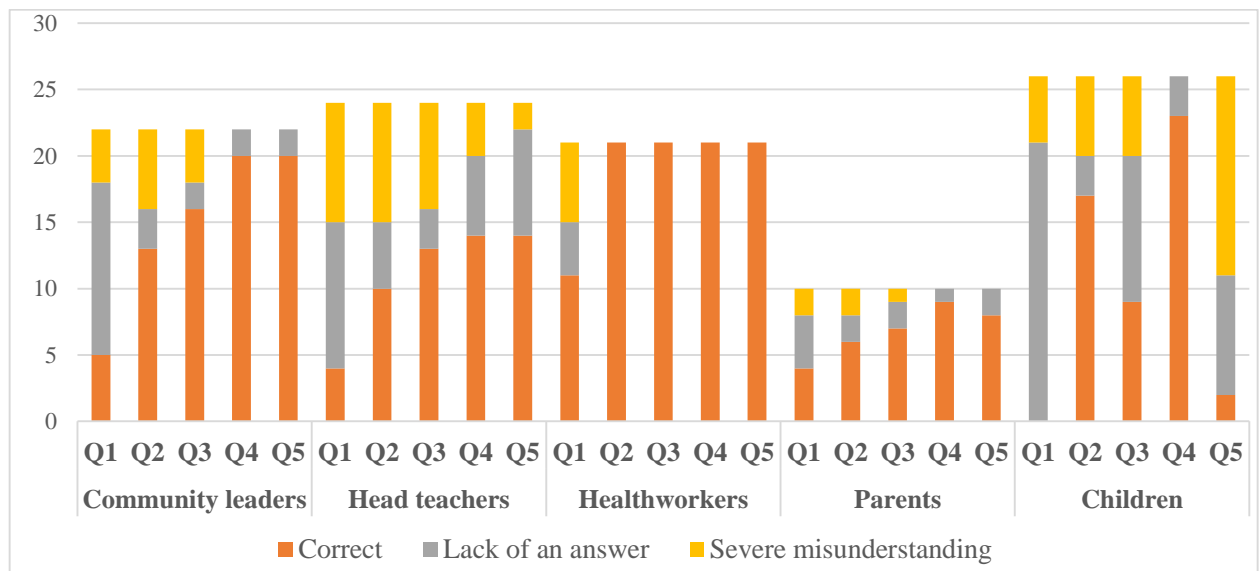
The nodes were divided into 3 main categories knowledge, attitude and recommendations. The child nodes in the different categories are discussed below under 4 broad themes. Burden of CC, Knowledge on CC, HPV and HPV vaccination knowledge, attitudes towards HPV vaccination and recommendations to improve the uptake of HPV vaccination.

### **3.2.3 Burden of cancer of the cervix**

The CC burden was evaluated among the community leaders and health workers. Both groups uniformly reported that there was a widespread diagnosis of CC at an advanced stage and the associated mortality rates were very high: “...*Yes, cervical cancer is a real problem in my community. We have had cases of several women who get diagnosed at very late stages and end up losing their life and practically we lost one of the community health volunteer to cervical cancer because it was diagnosed at a very late stage*”. (Participant 32, a health worker). Further to that, there was a steep increase in the incidences of positive results after screening for cervical cancer: “...*Yeah it is, well of late we are getting cases because we have been encouraging people to do cervical cancer screening, and I think we got some few cases, so cervical cancer it is real in our community*”. (Participant 57, a health worker). There was an upward trend and sharp increase in the number of women dying from CC: “...*Yes, it is rampant. So many people die with cervical cancer*”. (Participant 19, a head teacher). It was noted that CC is relatively a disease that is unknown: “...*It is a very serious problem, because, in the past, we did not understand the disease, but this time, we have seen women; it has become very challenging, because many are suffering from the disease. Before it is known, the mother loses her life, she dies* “. (Participant 10, a community leader).

### 3.2.4 Cervical cancer, HPV and HPV vaccination knowledge

Knowledge was summarized by 7 nodes which predominantly answered questions about knowledge. These questions were what is HPV, what is the goal of HPV vaccination, how is CC and HPV prevented, risk of catching HPV or cervical cancer, what is cervical cancer, what is cervix and what is the goal of Pap smear. The responses to these questions were considered as correct, lack of an answer and severe misunderstanding. Health workers gave correct answers while the children had the highest percentage of lack of an answer or severe misunderstanding. It was quite noticeable that the children lacked suitable biological knowledge to respond to some of the questions (see Figure 3). The questions on the risks of catching HPV and CC, prevention of HPV and CC and the goal of HPV vaccination had high percentages of correct replies from the groups combined.



**Figure 3. Knowledge on Human Papilloma Viruses (HPVs) infections, HPV vaccination and cervical cancer.**

The figure shows the number of participants in each category (y axis) and their responses (correct in orange, lack of an answer in grey and severe misunderstanding in yellow) to the questions asked to assess their knowledge. Q1-Question 1: What is HPV Q2-Question 2: Goal of HPV vaccination Q3- Question 3: Prevention of Cervical cancer and HPV Q4- Question4: Risks of catching HPV Q5- Question 5: What is cervical cancer.

Substantial proportion of reactions had severe misinterpretation for instance the question on what is HPV, 37% of head teachers, what is the goal of the HPV, 26% of the community leaders and what is CC, 57% of the children. For instance, a response on the goal of HPV vaccination: “...I don’t think it’s important at this point because I have never heard of a young child having the cervical cancer or something”. (Participant 23, a head teacher). There seemed to be mixed understanding and confusion about the goal of HPV vaccine: “...if she received this vaccine, even if she goes to get married, if she meets the man who is infected with the HPV virus, they do not get it. She will be safe”. (Participant 40, a parent). The question on how to prevent HPV and CC received satisfactory responses in most of the groups i.e. 99% and 74% from the health workers and community leaders respectively. Conversely, the other groups showed inadequate knowledge on this question. Below are 3 responses that demonstrated this finding: “...I can’t tell the prevention because I don’t know what is cervical cancer”. (Participant 11, a community leader)

A parent conveyed that: “...Preventing will be by giving medicine, try to prevent it by giving medicine that will prevent it from happening”. And “...prevention mmmmmh mainly this disease we can prevent by your lifestyle maybe. The food you eat, that is your lifestyle”. (Participant 1 community leader)

Many respondents struggled to respond to what is HPV. On the knowledge on the threat of catching HPV and CC, the responses were acceptable across all the groups. For example, this quote was uttered alluding that the interviewee knew about Human Immunodeficiency Virus (HIV) instead of HPV: “...All I know is the one that is associated with HIV”. (Participant 33, a health worker). Another serious misinterpretation was demonstrated in the following quote: “... acidic food actually, kind of thinking is a bit, delays it to the feelings of papilloma because once you eat this thing you feel some changes and then you relate it to papilloma”. (Participant 23, a head teacher)

On what is cervical cancer, answers received were correct from majority of the adult respondents. The children (78%) stayed silent and were shy to respond. A few (19%) of the head teachers did not give correct responses. A boy retorted: “...*I have heard it is a terrible disease that is killing people*”. Some interviewees refrained from responding to some questions claiming that they had no background health knowledge: “...*Yeah, you know I don't have knowledge of health, otherwise I have heard about it.*” (Participant 56, a head teacher).

The question on objective of a Pap smear, from the questioned groups, the responses showed a moderate reaction from parents (66%), head teachers (63%) and community leaders (30%). All the respondents with the exception of health workers for obvious reasons were asked what is a cervix. More than half (61%) of the community leaders provided an accurate answer. Majority (78%) of the children went silent while the proportion of accurate responses from the others were head teachers (43%), parents (36%) and children (20%)

### **3.2.5 Attitudes towards HPV vaccination**

This theme had 6 nodes which included, access to information, efficacy, safety, opinion of others, cultural and religious beliefs. Except opinion of others, these child nodes were connected to the attitudes and perceptions of the individual participants. In detail, the opinion of others depicted how the interviewee perceived the children, parents, class teachers, health workers and community leaders hence informing their responses on these people in relation to HPV vaccination. To define the magnitude of these opinions, there was a further classification according to the nature of the attitude i.e. supportive, opposing or neutral. When asked on how the community's perception towards the introduction of the HPV vaccination, its acceptance and the inclination to participate in the HPV vaccination exercise, different reactions sufficed. The participants expressed that there was insufficient availability of information and poor access to the information. This is evidenced

by the quotes below: “...they still need to be educated because the information they have is still low” (Participant 42, a community leader). Low literacy (n=11) was underscored as a barrier to the acceptance and uptake of the HPV vaccine. A minority (n=13) of participants made reference to having no confidence in the efficacy of the HPV vaccination to prevent CC: “...am not quite sure if it can work, because I have heard many controversies about it. There have been uncertainties of whether it can actually work” (Participant 60, a parent). A significant (n=72) number of participants have no faith in the ability of the HPV vaccine’s efficiency in boys owing to the fact that boys have no cervix: “...it doesn't relate to the boys or do they also have ovaries”. (participant 20, a head teacher. Another interviewee reiterated: “...it something that they cannot get because maybe they don’t have a uterus”. (Participant 2, a community leader)

There were numerous concerns about safety which consequently heavily influenced the attitudes as evidenced by the high number of references to it. From both counties, there was a uniform pattern of significant percentages of mentions about birth control misconceptions from all the participants including the children. Table 8 below illustrates how the Tana-River County groups as compared to Mombasa county groups recorded greater proportions on the birth control misconceptions. On the issue of side effects, from both counties, the children mentioned acute side effects while the parents voiced fear of the unknown.

**Table 8. Safety nodes from both counties**

	Absence of actual side effects	Birth control misconceptions	Fear of the unknown
Parents	6% (6/10)	45% (10/10)	49% (7/10)
Health workers	16% (10/21)	51% (7/21)	34% (7/21)
Head teachers	22% (20/23)	64% (14/23)	14% (5/23)
Community leaders	8% (20/22)	64% (16/22)	28% (11/22)
Children	59% (10/26)	28%(3/26)	13%(1/26)
Tana-River County	13% (35/50)	74% (26/50)	13% (6/50)
Mombasa County	14% (41/52)	50% (32/52)	36% (27/52)

The table shows how the safety nodes were distributed in the different groups and from each county.

Referring to how the community reacted, the following quote captured this opinion: “...*they rejected and sent false messages that the vaccines are for family planning and it would affect their children in many ways*”. (Participant 6, a community leader)

Just like the majority of the participants on the misconception on the association of HPV vaccine and birth control in reference to what other girls from her class said, a girl voiced that: “...*yes, some said they do not want to be injected. Others said, the vaccine spoils the womb of girls*”. (Participant, a girl). There was a high frequency of expressions of fear of the unknown (n=33) from a substantial number of participants: “...*so far I myself also, have fear of unknown. What if you're taking it as a prevention then eventually you come into contact with cervical cancer as a result of you being vaccinated and then you get cervical cancer then what would be the repercussion of this vaccine, Is it 100 effective?*” (Participant 31, a health worker). The issue of fear was highly articulated by the grown-ups, some conveyed excessive great fears as compared to children. The undesirable opinions and novelty of the HPV vaccine amongst most of the community members was the genesis of some of these fears. From an apprehensive parent: “...*Yes. I have fear because, as a parent, I am at risk of getting the cancer, and my baby is also at risk of getting this cancer*”. (Participant 62, a parent). Majority of the girls expressed their fear of the injection. As demonstrated by a quote from a girl as she spoke about the other girls during the vaccination exercise: “...*Some said they were scared. Others when their turn to be injected came, they moved backwards*”. (Participant, a girl). None of the participants gave an account of having observed actual side effects after vaccination however, it was mentioned severally that there were actual side effects. When asked if they had encountered or heard of any common or severe side-effects from HPV vaccination: “...*From the girls who have received the jabs and come for the follow-up vaccination we've not yet seen any side effect*”. (participant 32, a health worker)

When participants gave their perspective on the opinions of the others, the cultural and religious beliefs received many references as being a contributor of the opposition towards the HPV vaccination exercise. This was consistent in both counties. There was an observation that the culture of the locals was a great obstacle to the success of the HPV program: “...*in our community, culture, that is, is the biggest factor that has hindered. Because, they believe, the HPV vaccine, is to limit children, child bearing, that is, as in a child when she is older, they give her the vaccine so that, she does not have more children in the future*”. (Participant 37, a community leader). The religious beliefs were a hindrance to acceptance of the HPV vaccination. Some participants expressed that accepting the vaccine was going against their faith: “...*Religious reasons. Some have faith say that no medication to them should be administered right from birth, they should just live like that and only Jesus Christ would save them. Such faith becomes really a challenge to us*”. (Participant 46, a head teacher). The concern about faith was uniform and acknowledged by the different religious groups: “...*you know mostly the people who are living in this locality are Muslims, family planning is prohibited in the holy Quran that is their perception*”. (Participant 58, a community leader)

Additionally, a ridiculous account around the opinions rumored in the community was given by a parent when asked on the goal HPV vaccination: “...*They also say that you are being injected so that you join Illuminati*”. (Participant 63, a parent). When asked on the reasons why some girls did not manage to finish two dosages as required, the responses were to some extent in an opposing tone. The reasons were not convincing: “...*maybe after getting the first dose, maybe a parent was misled by someone maybe in the community that don't repeat this*”. (Participant 52, a head teacher) From Table 9 below, participants in both counties uniformly felt that a bigger ratio of the



community members and parents were against the HPV vaccine, conversely the community leaders, teachers, health workers, children and the media were in full support.

**Table 9. Opinions of others towards the HPV vaccination program**

	Neutral	Opposing	Supportive
<b>Children</b>	14% (5/36)	19% (7/36)	78% (28/36)
<b>Community leaders</b>	27% (6/22)	23% (5/22)	82% (18/22)
<b>Community members</b>	21% (14/67)	79% (53/67)	39% (26/67)
<b>Healthcare workers</b>	26% (10/38)	39% (15/38)	82% (31/38)
<b>Media</b>	0%	17% (2/ 12)	67% (8/12)
<b>Parents' opinions</b>	12% (8/66)	71% (47/66)	52% (34/66)
<b>Teachers</b>	13% (3/23)	4% (1/23)	83% (19/23)

The table shows the opinions of others (these are the thoughts that the participants randomly made about the children, community leaders, community members, healthcare workers, media, parents' opinion and teachers) to the HPV vaccination program categorized into neutral, opposing or supportive.

### 3.2.6 Recommendations to improve the uptake of HPV vaccine

This theme was classified into 7 nodes which comprised of consent process, COVID-19 pandemic, inclusion into the national immunization schedule, pre-vaccination preparedness, building capacity for health workers and community leaders, community involvement and sensitization.

On involvement of children, health workers and parents in the procedure to obtaining an informed consent, 37 interviews confirmed that these groups participated autonomously well-versed giving their approval to participate in the HPV vaccine exercise. It was evident that the girls were given information and their parents were engaged in the consent process: “...the students were called and they were told to bring their parents and their parents were talked to and they were given consent forms to sign which there are others that refused.” (Participant 12, a head teacher).

The COVID-19 pandemic gravely affected the continuance of the HPV vaccination exercise following the abrupt closure of schools as directed by the government. This was similarly reported

by the health workers in both counties: “...Before the COVID we had already arranged to go to certain schools so that we can give them there.” (Participant 29, a health worker). All scheduled vaccination calendars in the health centers and county hospitals in collaboration with the primary schools were interrupted leading to delays in the consequent dose for the girls that had received the first dose: “...the COVID pandemic drew us back again because when we were in top gear trying to do dissemination of information that's when lockdowns came in, people are basically afraid to come to the hospitals”. (Participant 66, a health worker)

Recommendations to promote sensitization drives was a suggestion given by many participants. A concerned parent articulated this: “...it would be good for the community to be sensitized so that they know the importance of the vaccine”. (Participant 70, a parent). Some participants endorsed the inclusion of the HPV vaccination to the national immunization program. They emphasized that this would potentially increase the uptake of the HPV vaccine since it would be made compulsory for all the eligible children: “...the government make it compulsory for every child to receive this vaccination. So if after policy is in place it will be everybody abide by it to make sure that the child is given this vaccination”. (Participant 63, a health worker)

Pre- vaccination education is pivotal as some respondents emphasized. They argued that there was need for provision of intensive education together with community mobilization and capacity building for health workers and community leaders who were at the fore front in implementation of the HPV vaccination exercise: “...We will also like to involve the politicians, the spiritual leaders because they are the people who influence most of the peoples' decisions, so if we involve them at least to create a positive impact when it comes to the vaccination and also if the ministry of education works together with the ministry of health to ensure that each and every girl gets the jab; at least no girl is left behind”. (Participant 32, a health worker).

## **CHAPTER 4: DISCUSSION**

### **4.1 PART 1: National Policies to Prevent and Manage Cervical Cancer in East African Countries: A Policy Mapping Analysis**

#### **4.1.1 Summary of findings**

1. There was a low number of binding and old policies.
2. There were discrepancies to the WHO international guideline and discordance between evidence and policy
3. There was scarcity of data reporting on the morbidity and mortality as evidence for policy making.
4. The majority of East African countries have not established screening registries that incorporate individuals' screening data with cancer registry, as is required.
5. There are financial, logistical, and sociocultural constraints that are hindrances that have contributed to a poor disclosure of policies and the implementation of screening programs, contrary to high income countries

#### **4.1.2 Comparison of findings with literature**

Great strides have been made by the East-African countries in the effort to eradicate CC. This was as evidenced by the prevention and control policies for cancer of the cervix that this research analyzed. It is quite impressive to note that since 1996, there was already a cancer act of parliament in Tanzania [150]. Eighty-three percent was the extent to which the countries addressed issues of CC as recommended by the WHO blue print for prevention programs for cancer of the cervix.

Screening women is the primary means to detect if a woman has any suspicious lesions then refer them for follow up to further examine if it is indeed a case of pre-cancer or CC[148]. Colposcopy,

cytology with Pap smear test, HPV DNA tests, SVA, VIA and VILI screening and treatment techniques as recommended by the WHO guideline for essential practice for control of the cancer of the cervix were echoed and emphasized by majority of the policy documents from the countries. For example, the Strategic Plan for Cervical Cancer Prevention and Control in Uganda accredited that, *“Screening for the screen-and-treat approach can include visual tests. With screening tests that provide immediate results, such as VIA and VILI, screening and treatment can be provided during a single hospital visit”*. These practices have been proven to have effective and efficient ability to lower the incidence of pre-cancerous lesions and CC[6,151]. Literature has severally recommended use of VIA and VILI, because of their simplicity and promptness of availing instant results and needing less training to be able to utilize in the disadvantaged settings that have limited resources [76,152,153]. For low-resource settings, visual inspection approaches have a potential to be effective cervical cancer screening tools contributing to the reduction of cervical cancer incidence and mortality in these the low resource countries[154-156].

SVA relies on visual inspection and as such is part of VIA and VILI hence scalable by women [157]. Hospitals that have limited or few services known as low level hospitals can be able to implement VIA and VILI because their low-cost and non-invasive nature. The characteristic prolonged and delay in results while using cytology tests and HPV DNA techniques resulting in fragmentation of the link between screening and treatment contribute to the wide use of VIA and VILI in low resource settings. In these settings treatment by cryotherapy is done immediately in the event there is a case of suspicious or precancerous lesions [158,159]. The 2015 DRC National strategy to combat cancer of the uterine neck and breast in Democratic Republic of Congo acknowledged that HPV DNA testing was unavailable throughout the country, though just two specialized structures i.e. National Institute for Biomedical Research (INRB) and pathological

laboratory of University Clinics of Kinshasa, since they had the infrastructure and capacity to conduct the test, emphasizing that these two remain the national reference structures to implement the HPV DNA tests, on the other hand the Tanzania Cervical Cancer Strategic Plan 2011 declared the introduction of cervical cancer screening using VIA with colposcopy across the country and HPV DNA testing in pilot sites. Several researches conducted in Africa [160] [161] have demonstrated that HPV DNA testing is largely costly however it is highly recommended owing to its sensitivity which is far much better than the one produced by cytology [85]. The expensive laboratory infrastructure necessary to have the ideal results poses the use of HPV DNA scarce in the limited in low resource settings [162]. Catarino et al. acclaimed introduction of point-of-care HPV testing to facilitate prompt results hence making screening more feasible and reducing the infrastructural requirements that pose challenges in implementing screening programs in low-, and middle-income countries [159].

The fact that CC is a potentially preventable NCD, its prevention should be accentuated in the LMICs and under developed countries grappling with the CC menace[163]. As a primary prevention for CC, HPV vaccination has proven to significantly reduce the CC burden and as such WHO has fervently advised countries to prioritize HPV vaccination programs and consequently include it in the national immunization schedules along with the other childhood immunizations [164]. An Australian study on the impact of 10 years HPV vaccination, following the successes of vaccinating 11 to 13-year-old girls, the vaccination was later extended to include boys aged 11 to 12 years [165]. Several researches have made suggestions to make HPV vaccination compulsory because there is evidence of its efficacy as such with the mandatory directive, there is a guarantee in increased vaccine uptake, reduced healthcare costs, decline in HPV related disease, and also an opportunity to save lives [166-169]. Madagascar, Tanzania, Kenya, Ethiopia, Uganda and DRC out

of the 12 East African countries had plans to introduce the HPV vaccine to prevent cervical cancer. With advancement of great lessons and experiences globally, there is a lot of hope for countries in terms of adopting HPV into their national vaccination programs[170]. Building capacity of health workers is critical because it cushions from wastage and capitalizes on execution of cost-effective cancer prevention and control approaches[171]. From the analysis, most legal documents from the data set underscored that empowerment is essential by means of conducting collaborative seminars and workshops, pursuing medical education, training health practitioners, continuous updates and conducting research [172,173]. Promoting cancer awareness and prioritizing sensitization of CC by mobilizing the masses and lobbying were some of the means recommended by most of the countries as they are vital components in cancer control programs [37,174]. The policies emphasized on improving the knowledge and perception of CC by creating public awareness aiding in motivation of the populations in taking action as it also plays a big role in prevention[175].

Depending of the stage of CC the treatment options include surgery, radiotherapy and chemotherapy according to rising stages. International Federation of Gynecology and Obstetrics (FIGO)staging is based on clinical examination. Based on the FIGO cancer report, for stage I/IA1/IA2 cervical cone biopsy is done to determine depth and width of the lesion. For stage IB, radiotherapy with concurrent chemotherapy or radical hysterectomy and pelvic lymph node dissection which is determined by the size of the lesion whether it is greater or less than 4cm. For stage II/IIA/IIB/III/IIIA/IIIB the primary mode of treatment is radiation with concurrent chemotherapy. For stage IV/IVA/IVB the treatment is radiation and/or chemotherapy, tailored for the individual disease pattern. For recurrence after primary surgical treatment, if the lesion is localized, radiotherapy or chemoradiation are treatment options. If the recurrence is after primary radiation treatment and the lesion is localized, the treatment options include surgical/exenterative

therapy[176]. In women with locally advanced cervical cancer, neoadjuvant chemotherapy where chemotherapy drugs are administered before surgical extraction of the tumor may be used to prevent disease progression. Neoadjuvant chemotherapy is also an option in low resource settings.[176,177]

The diverse infrastructure and scarce resources has led to a great discrepancy between the developed and Africa countries. The developed countries have accessible advanced technology and personnel to implement the recommended and ideal treatment for CC while the countries in Africa where CC burden is high, are contending with vaccination and screening. Diagnostic and treatment advancement is still a distant attainment[178]. Tanzania Cervical Cancer Strategic Plan echoed the scarcity of personnel, that in all of Tanzania, there are only 15 pathologists and majority are based in its capital at Muhimbili University of Health and Allied Sciences (MUHAS) and Muhimbili National Hospital(MNH). Woman in the distant parts of Tanzania have limited access to diagnostic and treatment services[179].

From the findings of this research indicate that the treatment for pre-cancerous lesions in Africa are curative surgery which is hysterectomy and cone biopsy whereas for invasive CC is radiation, surgery and palliative care; this aligns with the conclusions of a study on the perspective of CC in the SSA countries[180].

#### **4.1.3 Challenges and solutions towards addressing the burden of cancer of the cervix**

Lack of information about CC and the shortage of preventive services are the main causes of late stage diagnosis of CC in SSA[151] and as such, the late stage diagnosis was linked to low survival rates despite interventions with radiotherapy and surgery[181]. Poor infrastructure that is characterized by unapproachability to the health centers for preventive and curative services,

insufficient drugs and poor screening facilities[12]. The poor screening facilities have inadequate human resource hence the low percentage rates of screening seen in these developing countries [182]. Further lack of information also contributed to the low screening rates [183]. The advanced stage diagnosis has been associated with the prolonged cytology results which causes a lapse and ultimately a loss to follow up of patients [184], effective referral systems prevent the many cases of loss to follow up. As seen in the legal documents and evidence from literature, most countries cited lack of funding as a barrier to measures geared at preventing and controlling CC[151,185].

The solutions that were vastly highlighted by the East-African countries insisted on initiation of prevention, screening and management of reproductive organ cancers at all levels of health care. Concerted efforts to develop and implement national cervical cancer prevention and control programs and integration of other national policy documents will greatly contribute towards the reduction of CC burden[66]. Establishment of surveillance systems and empowerment of health workers through comprehensive training on screening and treatment then deploying them is a key contributor in scaling human resource for health [159]. All the countries echoed that training new and existing health workforce is very critical in the control of CC because the staff will be more competent to handle activities in the cancer control programs [186]. Undoubtedly reversing the CC burden requires extensive advocacy to drive prioritization, allocation of budget, resource mobilization and collaborations with essential stakeholders for passably response to the cancer crisis [186].

#### **4.1.4 Need for evidenced-based health policies on cervix cancer prevention**

From the legal documents analyzed in this study, there were scanty binding policies and inconsistency with the international guide whose role is provide a basis for developing CC policy documents. Public health policies have a major function on provision of evidence based solutions



to overcome burden of CC. There was a uniform nonexistence or very limited data on morbidity and mortality of CC cancer from these countries hence the gap in making of policies that would strengthen the programs for prevention and control of CC. Capacity building for policy makers on integration of evidence to the agenda for health policy making to better inform the priority budget items touching on CC reduction hence narrowing the gap between evidence and policy[187]. Record keeping by having operational registries aids in monitoring and evaluation together with reinforced surveillance systems. Screening and cancer registries are yet to be established and linked to all the women's data [188,189], this was observed in majority of the East-African countries. Strengthened surveillance systems, detailed registries and data linkages contribute to prioritized resource allocation tailored to the needs of a particular population thereby improving cancer outcomes [190]. The scarcity of data across the East-African countries illuminates the unavailability of reliable data to assess the burden of cancer in the populations. In contrast to the developed countries, poor implementation of screening programs and poor disclosure of policies have been marred by gross financial, logistical and sociocultural constraints [191]. The policy makers in East-African countries need to urgently intensify transparency of legislature and give priority to developing and implementing CC policies and amending old policies that never worked and still remain in force in so doing widening the gap between what is necessary and what requires to be implemented[192]. From the findings, there were few policies, some outdated which mirrored the weaknesses in addressing the CC crisis, binding and non-binding policies are crucial in addressing the public health agenda, therefore there is need for scientifically sound policies and their executive laws for there to be evident change.

## **4.2 PART 2: Knowledge, Attitude and Practice of Main Stakeholders towards Human Papilloma Virus Infection and Vaccination in Mombasa and Tana-River Counties in Kenya: A Qualitative Study**

### **4.2.1 Summary of major findings**

1. A significant proportion of adults have limited knowledge of the subject, health workers were the most informed. Despite the fact that children are also involved in decisions about vaccination, children have very limited knowledge about HPV infection, HPV vaccination and cervical cancer.
2. Broad irrational fears and misinformation about HPV vaccination exist in society.
3. The vaccination of boys is not supported by the majority of the participants.
4. Parents and the community members in general are not in favor of HPV vaccination, while teachers, health workers and community leaders are.
5. A similar pattern of inadequate knowledge and strongly opposed attitudes was observed in Tana-River and Mombasa.

This study provides information on the factors that are leading to poor uptake of HPV vaccination in two counties in Kenya. It was worth noting with the exception of the health workers, a substantial percentage of the adult participants in this study had inadequate information and knowledge on the key issues that were being evaluated. Children had little or no knowledge about what CC and HPV infection and HPV vaccination however, it is important to note that the children were part of the process of obtaining a consent and making a choice on the vaccination. It was not surprising to hear of the numerous unreasonable and illogical fears and distorted information prevailing among the community members. A high proportion of the participants were not in favor and did not support boys being a target for the HPV vaccination. In general, the parents and

community members who are great influencers for positive feedback to the vaccination exercise did not express solidarity. On the other hand, head teachers, health workers and community leaders voiced their full support and expressed recommendations to improve the uptake of the vaccine and mend the negative impression among community members. From both Mombasa and Tana-River counties, there was a uniform observation in most of the emerging themes such as scanty knowledge and intense opposing attitudes.

#### **4.2.2 Integration with prior work, implications, transferability and contribution to the field**

From a majority of the interviewees, their experience was that they had previously heard a thing or two about CC or HPV; but when it came to recalling and giving answers, they vaguely responded or said they do not recall what they had learnt. Some participants also uttered that they hardly heard about Pap smear. A good proportion of participants were cognizant of the fact that the HPV vaccine confers protection against cancer of the cervix. On the risk of catching HPV infection and CC, the participants were acquainted with the knowledge that there was a high probability of catching both, particularly for the reason that there is early onset of commencement of sexual activity and having several sexual partners. This finding corresponds with Yamaguchi et al [193,194]. There is an urgent need to carry out awareness drives and make the vaccines readily available to attain the desirable levels of vaccine acceptability; since the introduction of HPV vaccines in 2006/2007, great support has been accorded to the LMICs to empower women by educating them [24,117,195,196]. Some health workers demonstrated gaps in knowledge, however from our findings, there was proof of information that was obtainable through seminars and workshops that the health authorities facilitated. The information provided to the parents and girls was substandard [197]. For the effective implementation of the HPV vaccination program, it is commended that a series of trainings and information dissemination campaigns be accelerated.

Promoting training and communication of health workers significantly contributes to the effectiveness of the vaccination campaigns [198].

A high proportion of the participants implied and associated the HPV vaccine as a means of birth prevention or depopulation purporting that it was laced with contraception to sterilize the young girls. This was the most common misinformation about the HPV vaccine among the community members and highly hindered the uptake of the vaccine. Another misleading information was that the vaccine itself introduced the virus that causes CC to the girls. Some religious leaders who are highly influential in the community propagated this erroneous information initiating extremely hostility when it came to passing the accurate information on HPV vaccination to the community members; this finding is in line with Otieno et al [199,200]. These ambiguous and biased information is detrimental as it gives the health workers the double task to drive the correct HPV vaccination messages to the populace [201].

A number of children were not vaccinated or did not complete the doses. Diverse explanations were fronted comprising of unreasonable fear of the unknown vaccine, deviance from culture, non-conformity to traditional customs, negative influence from the community members, husbands giving stern warnings to their wives not to vaccinate the girl child, bizarre beliefs for example the vaccine was an indoctrination to illuminati. This study concluded that the HPV vaccination landscape has extremely been informed by the religious and cultural beliefs and endorses wiggle et al. and Grandahl et al. [195,202].

On condition that the HPV vaccine assured protection to the girls against a diagnosis of CC later in life, a huge number of parents were willing to have their daughters immunized [197]. These fears are understandable and can be addressed through proper education to the parents [203] by

conducting community led awareness campaigns steered by the village elders, community and religious leaders especially in the well hemmed community like the Kenyan one[198].

Predictably, the concerns about the safety of the efficacy of the HPV vaccine were conveyed as fear of the side effects, fear of death of their children and injection phobia despite there being no evidence of any link of the HPV vaccine with those adverse effects[204]. There is evidence to prove that the HPV vaccine is safe and has been publicized to have little or no adverse effects [205].

Contrasting reactions were received when it came to the issue to vaccinate boys or not. Grandahl et al on their study on “I also want to be vaccinated!” validated the expression by one of the boy’s desire to also receive the HPV vaccine [202]. A substantial proportion of the participants articulated their disapproval in vaccinating the boys citing the anatomy of the boys has no cervix nor CC a disease affecting men therefore it was useless to vaccinate the boy child. Some participants responded with a question whether the boys had a cervix or a uterus. These responses portrayed insufficient knowledge base concerning HPV infections and the diseases it causes as revealed in a research in the UK probing on HPV vaccination in boys[206]. Another proportion recommended the HPV vaccination to be prioritized to the girls then at a later opportunity expand the program to involve the boys; this finding corresponds with an exploration on the knowledge and intentions among parents of boys and girls in US shared their thoughts that it was crucial to vaccinate girls than the boys [207]. Generally the responses on vaccination in boys were opposing and many participants connected the HPV vaccination with the girls owing to its goal being to exclusively prevent cancer of the cervix; as indicated in literature, this is a common observation among the community members[108,208,209].

By and large in both counties, the parents and members of the community uniformly opposed the HPV vaccination exercise. This trend has commonly been observed in some studies where the

vaccination controversy was conspicuous among community members have alluded their disapproval to inexplicable fears and apprehensions. Addressing these concerns and arguments by competent health workers by steering vigorous community discourses heavily involving the community members[130,210], these dialogues will be successful only after building the capacity of health workers and community leaders as these stakeholders are the drivers of distributing health messages to the community another reason is that they are already known in the community and have built trust and created rapport with the members of the community.

The findings of this research indicated that the parents and children were actively part of the consent process. The nurses reported that the adolescent girls displayed no hesitancy on being vaccinated; this somewhat is in agreement with a South African study on factors influencing vaccine uptake however in contrast the nurses had no struggles starting conversations surrounding sex with the adolescent girls as compared to the findings of this research [211].

The COVID-19 pandemic severely interfered with the implementation of the HPV vaccination exercise. The challenges affecting the acceptability of the COVID-19 vaccine because of the safety concerns were a great contributor. The lockdowns and interruption of health care preventive activities saw a complete halt in continuation of the scheduled HPV vaccination exercise[95,212].

From the participants, the girls who had received the first dose experienced delays for the second dose while others missed it altogether. There were many plans in collaboration between the primary schools, health centers and the county hospitals to realize as many girls as possible but unfortunately the lockdown terminated these plans because the children had to stay at home. This was observed all over the world therefore the health authorities have been advised to map out new ideas to revive the HPV vaccination exercise in order to evade long term negative consequences[213]. The HPV vaccine is yet to be incorporated into the national immunization

schedule. The health workers expressed it as a concern that would greatly drive the HPV vaccine agenda in the community curtailing the forgetfulness to return for the second doses and hostile reception. From literature it was recommended that nations expand their national immunization budgets to cater for the adoption of the HPV vaccine to the routine immunization programs [214].

Vaccine acceptancy will highly benefit from involving the community and organizing pre-vaccination preparedness[215]. This was highly recommended by the participants especially the community leaders and health workers whose responsibility was to enlighten the population about the HPV vaccination exercise.

#### **4.2.3 Implications and limitation of the study**

From this study findings, the hurdles that are ailing the HPV vaccination acceptability from two counties in Kenya. The uniform patterns observed from the two counties can be generalized to the entire country because the sample was a representative of the composition of the Kenyan population which is not too diverse. The recommendations by the health workers and community leaders to have concerted strategies to sensitize the community and also involve them in the HPV vaccination awareness drives was an optimistic gesture.

Having conducted the interviews in only two counties of Kenya owing to budget and time constraints this was a limitation of this study. Selection bias is a characteristic of this study due to the nature of the methodology used hence the may affect the interpretation of the data. The groups had a handful number of interviewees and this is because a minimum sample of 12 reaches saturation of data. Although the overall inter-rater reliability result falls into the moderate category, there were domains that fell into the fair agreement category to be taken into account for the reliability of the coding.

## **CHAPTER 5: RECOMMENDATIONS AND CONCLUSIONS**

This research adds its voice to the existing body of knowledge on the state of CC policies in East African countries and the low HPV vaccination uptake in Kenya.

Governments make knowledgeable decisions for health on the basis of gaps identified from policy mapping. Legal mapping in the health sector is crucial as it is a pointer of the gaps in the health system impeding the realization of the objectives to reduce the burden of cancer in SSA and also provides beneficial information to the stakeholders of policy making. There is an urgent need to perform periodic reviews of old and outdated cervical cancer policies to incorporate new innovations and latest evidence based best practices[61] additionally, guaranteeing transparency to legal information in the East African countries. Lack of capacity remains an important challenge to implementing the programs to prevent and control cancer of the cervix in these countries and as such the mismatch between policy and practice needs to be looked into. East African countries need to combine their efforts in fighting the CC scourge by prioritization in budgeting, enhanced accountability and pooling of funds to sustain the HPV vaccination and CC prevention and control programs. HPV vaccination drives will be successful with rigorous community involvement in creating awareness by modifying the negative attitudes and promoting vaccine perceptibility. Utilization of specialists and their attendance in grassroots mobilization will aid in the credibility of the disseminated information and appeal the community members to willingly accept the HPV vaccination thereby improving the uptake of the HPV vaccination. Strengthening the surveillance system will contribute to availing information on the vaccination coverage and automatically inform policy. Campaigns to reach the children, parents and teachers are vital because they are the implementers and promoters of the HPV vaccine; their perception is very important as it shapes the vaccination landscape and they are the point of contact to the children and often they are in



opposition of the vaccination based on the many fears indicated in chapter 3. Studies in the future should pay attention to large scale awareness creation and education on HPV infections, HPV vaccination and CC and innovative techniques to deliver the critical information to the populace.

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# ACADEMIC PUBLICATION LIST



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Registry number: DEENK/525/2021.PL  
Subject: PhD Publication List

Candidate: Diana Wangeshi Njuguna  
Doctoral School: Doctoral School of Health Sciences  
MTMT ID: 10068755

## List of publications related to the dissertation

1. **Njuguna, D. W.**, Mahrouseh, N., Isowamwen, O. V., Varga, O.: Knowledge, Attitude and Practice of Main Stakeholders towards Human Papilloma Virus Infection and Vaccination in Mombasa and Tana-River Counties in Kenya: a Qualitative Study. *Vaccines*. 9 (10), 1-16, 2021.  
DOI: <http://dx.doi.org/10.3390/vaccines9101099>  
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## List of other publications

3. Mahrouseh, N., Andrade, C. A. S., Kovács, N., **Njuguna, D. W.**, Varga, O.: Diabetes Mellitus and Associated Factors in Slovakia: results from the European Health Interview Survey 2009, 2014, and 2019. *Nutrients*. 13 (7), 1-11, 2021.  
DOI: <http://dx.doi.org/10.3390/nu13072156>  
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4. Lovas, S., Mahrouseh, N., Bolaji, O. S., Nellamkuzhi, N. J., Andrade, C. A. S., **Njuguna, D. W.**, Varga, O.: Impact of Policies in Nutrition and Physical Activity on Diabetes and Its Risk Factors in the 28 Member States of the European Union. *Nutrients*. 13 (10), 1-17, 2021.  
DOI: <http://dx.doi.org/10.3390/nu13103439>  
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5. Akinsolu, F. T., Nemieboka, P. O., **Njuguna, D. W.**, Ahadji, M. N., Kölesné Dezső, D., Varga, O.:  
Emerging resistance of neglected tropical diseases: a scoping review of the literature.  
*Int. J. Environ. Res. Public Health.* 16 (11), 1-14, 2019.  
DOI: <http://dx.doi.org/10.3390/ijerph16111925>  
IF: 2.849

**Total IF of journals (all publications): 25,344**

**Total IF of journals (publications related to the dissertation): 11,061**

The Candidate's publication data submitted to the iDEa Tudóstér have been validated by DEENK on the basis of the Journal Citation Report (Impact Factor) database.

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## APPENDIX 1: LIST OF DATABASES AND WEBSITES

Republic of Burundi: Available online: <http://minisante.bi> (accessed on 29 June 2019)

African Legal Information Institute: Available online: <https://africanlii.org/liisearch?keyword=cancer> (accessed on 04 March 2019)

International cancer control partnership: Available online: <https://www.iccp-portal.org/> (accessed on 05 March 2019)

Country planning cycles Database (WHO): Available online: <http://www.nationalplanningcycles.org> (accessed on 05 March 2019)

Republic of Rwanda: Available online: <http://www.moh.gov.rw/index.php?id=188> (accessed on 18 March 2019)

Democratic Republic of Congo: Available online: <http://sante.gouv.cd> (accessed on 19 March 2019)

Union of the Comoros: Available online: <https://www.gouvernement.km> (accessed on 14 June 2019)

Republic of Kenya: Available online: <http://www.health.go.ke> (accessed on 25 March 2019)

Kenya Law : Available online: <http://kenyalaw.org:8181/exist/kenyalex/index.xql> (accessed on 25 March 2019)

Kenya Hospices and Palliative Care Association: Available online: <http://kehpc.org/publications/> (accessed on 26 March 2019)

WHO Health law by countries: Available online: <https://www.who.int/health-laws/countries/en/> (accessed on 28 March 2019)

Federal Democratic Republic of Ethiopia: Available online: <http://www.moh.gov.et> (accessed on 08 April 2019)

Ethiopia Law: Available online: <https://www.abysinnialaw.com/> (accessed on 09 May 2019)

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Republic of Madagascar: Available online: <http://www.sante.gov.mg> (accessed on 29 April 2019)

Republic of Uganda: Available online: <https://health.go.ug/> (accessed on 13 May 2019)

Uganda Legal Information Institute: Available online: <https://ulii.org/search/ulii/cancer> (accessed on 11 March 2019)

Uganda Cancer Society: Available online: [www.ugandacancersociety.org](http://www.ugandacancersociety.org) (accessed on 01 March 2019)

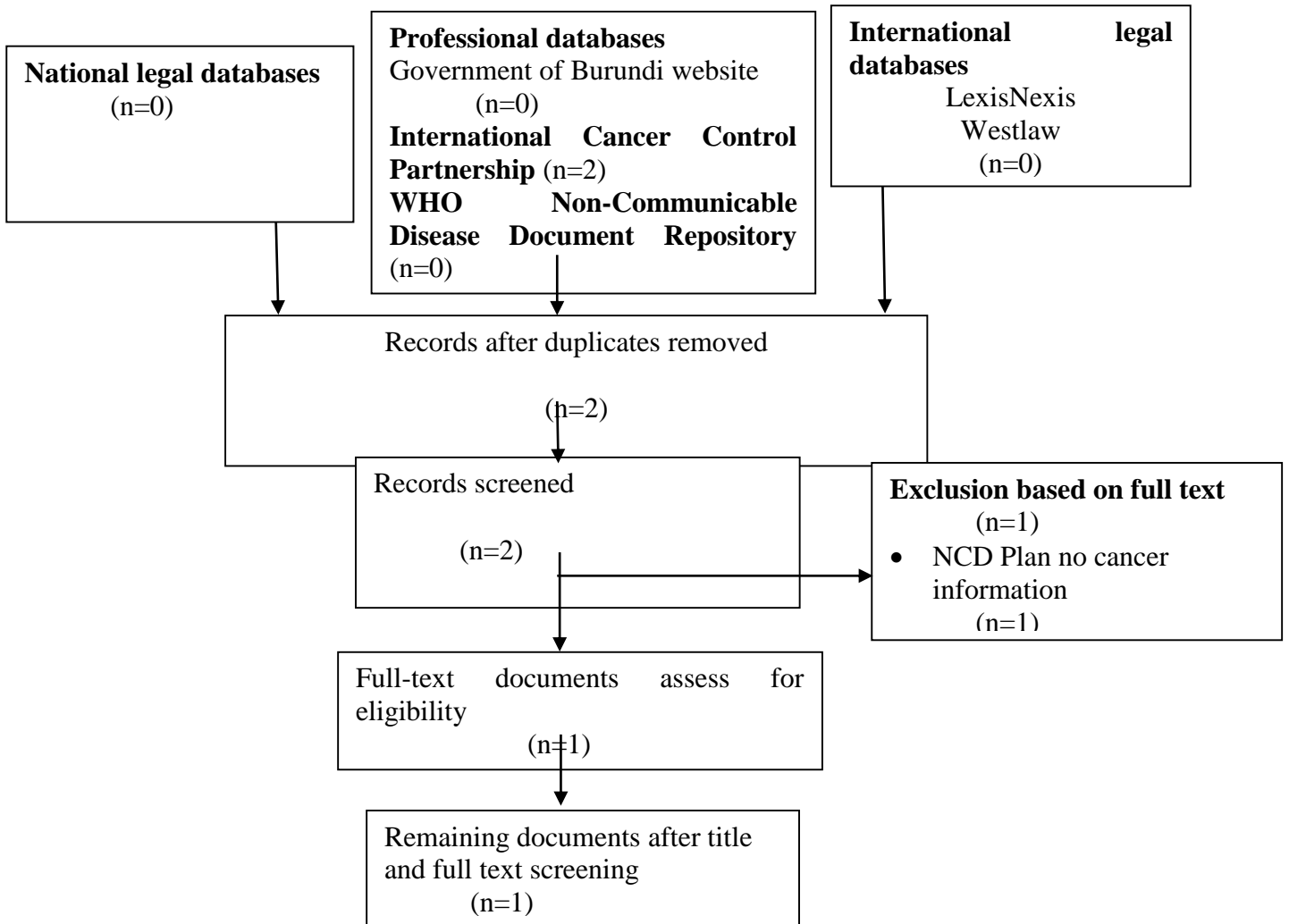
Uganda Cancer institute: Available online: <https://www.uci.or.ug/> (accessed on 03 June 2019)

Federal Republic of Somalia: Available online: <http://moh.gov.so/en/> (accessed on 24 April 2019).

Non-communicable Disease Document Repository. Available online: <https://extranet.who.int/ncdccs/documents/db> (accessed on 14 June 2019)

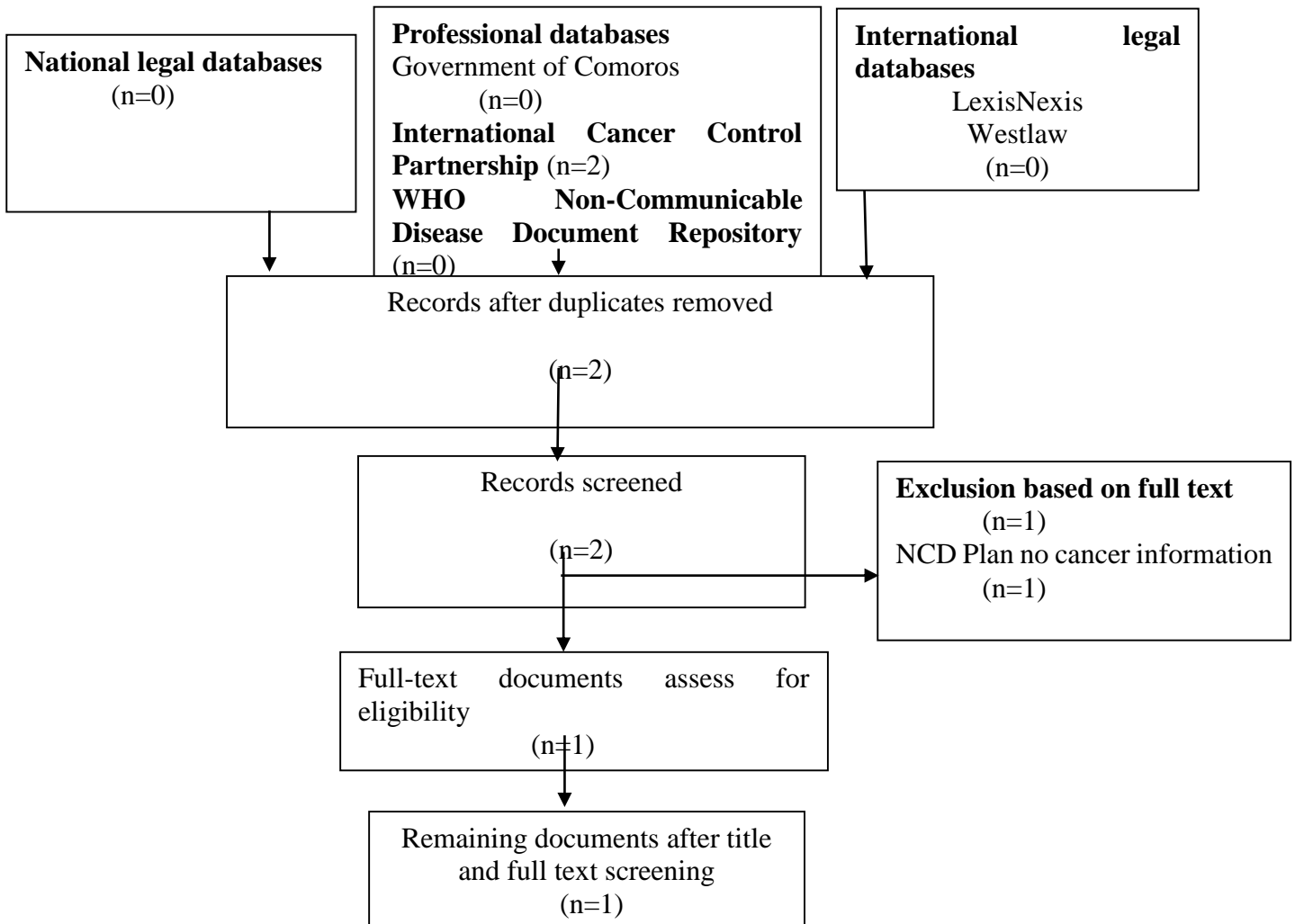
## APPENDIX 2: PRISMA FLOW CHARTS

### BURUNDI

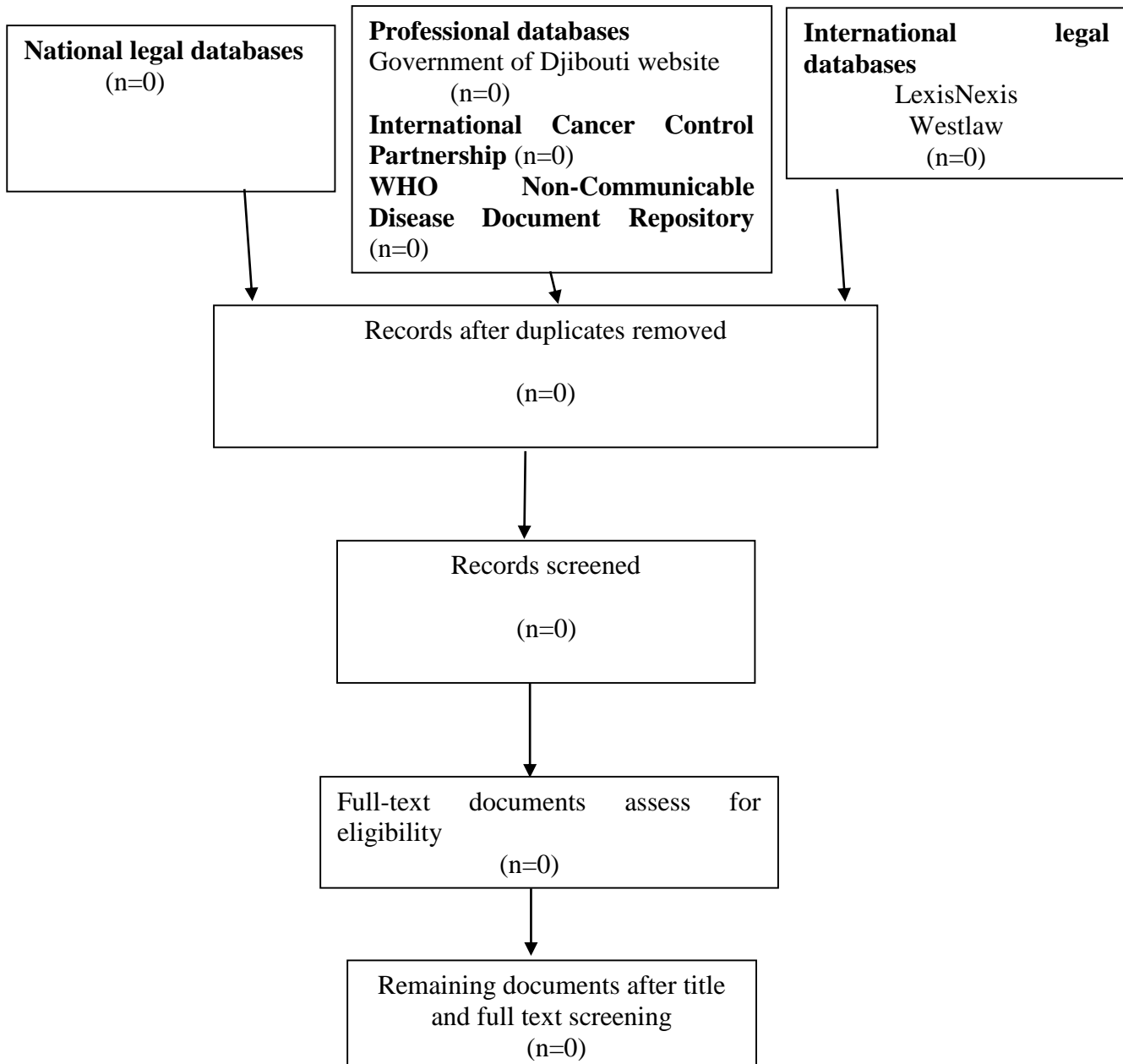




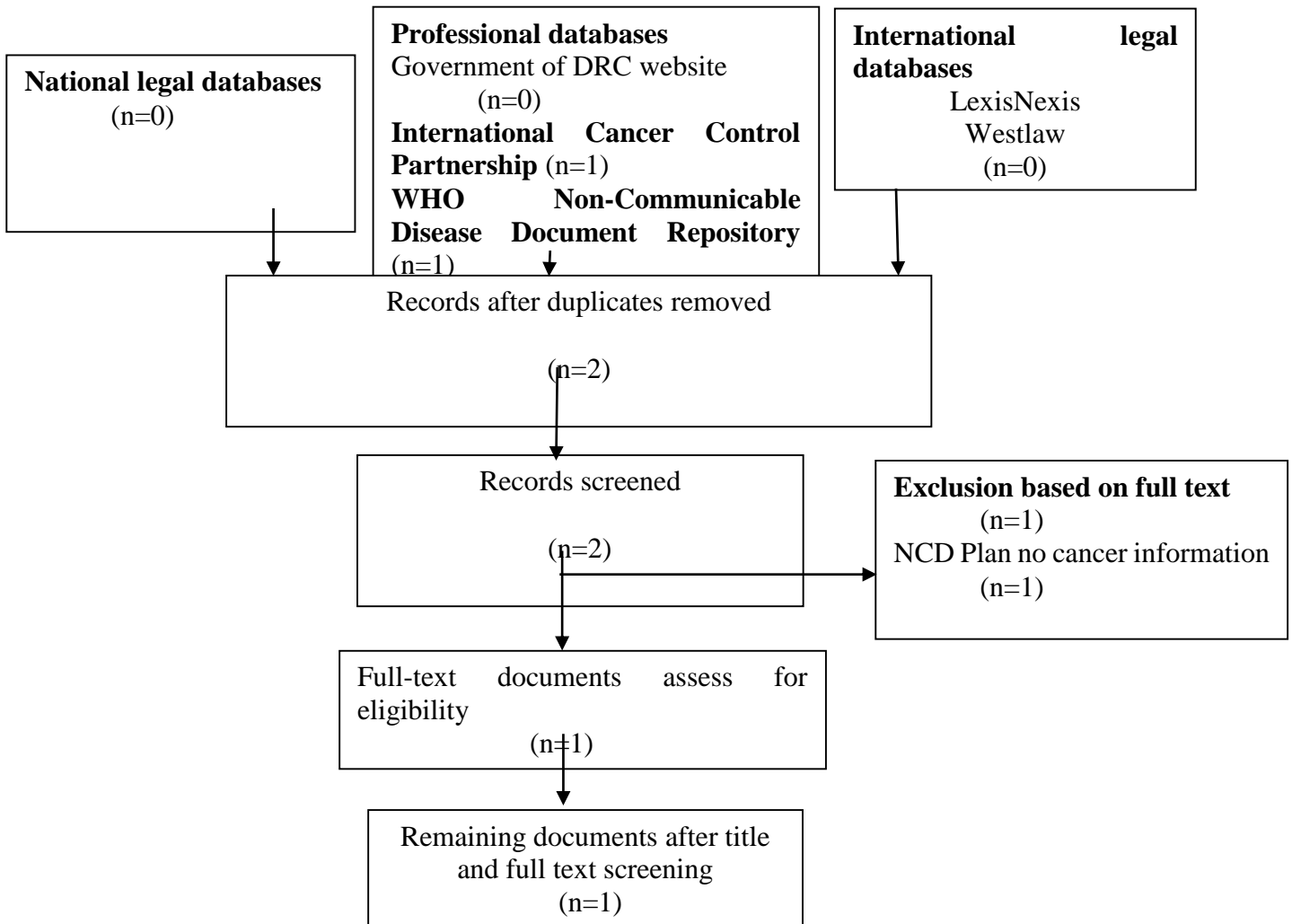
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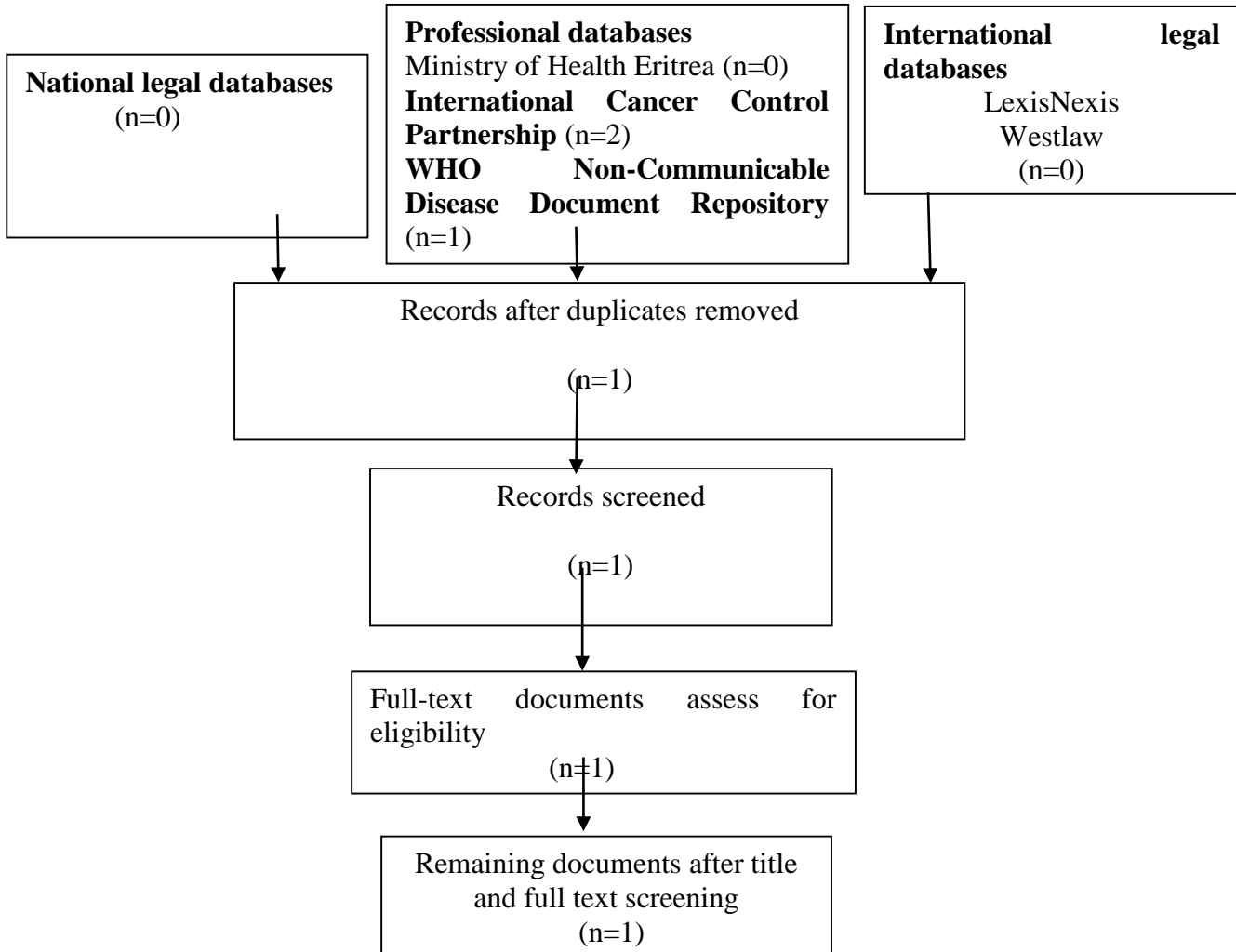
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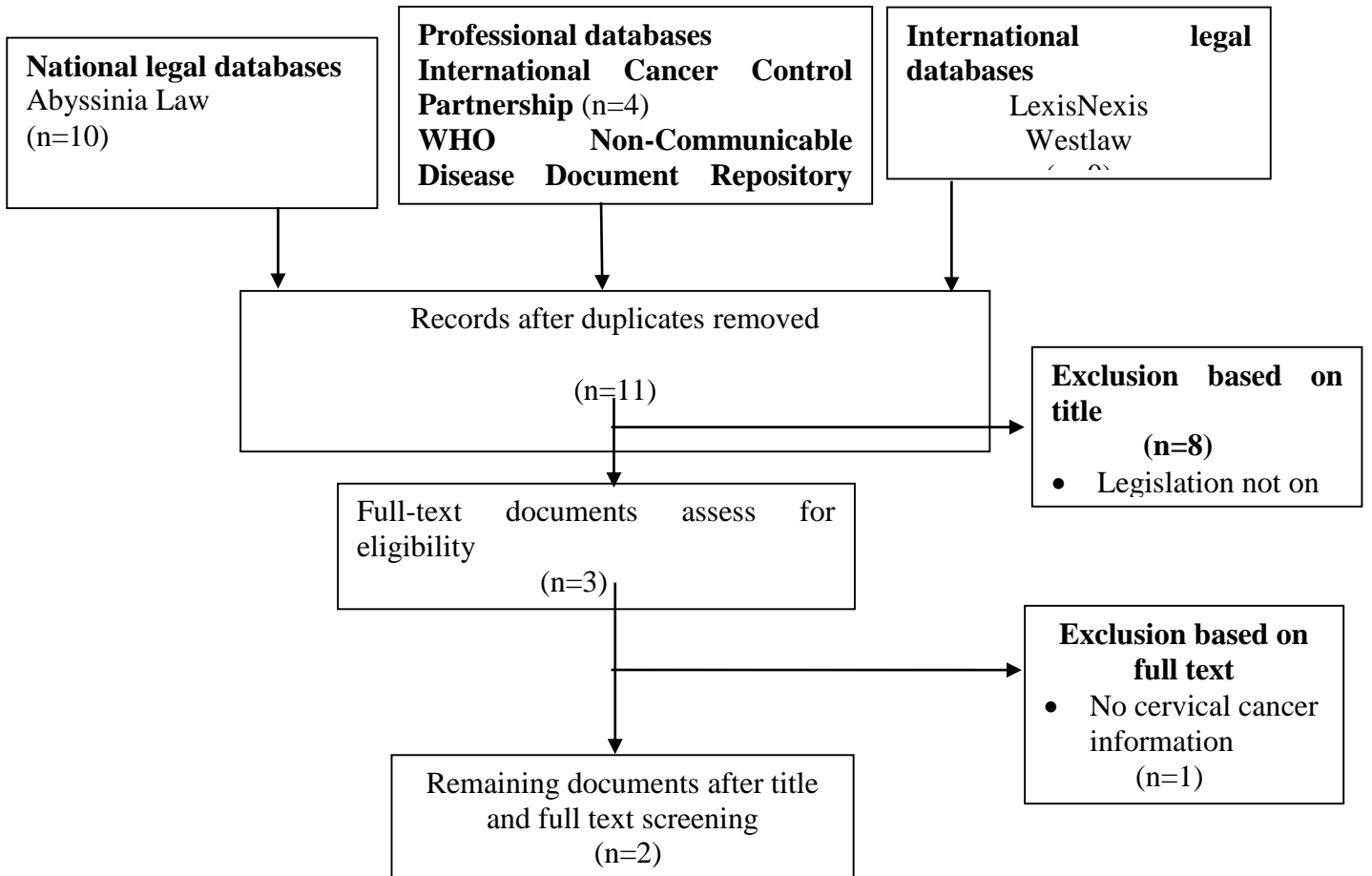
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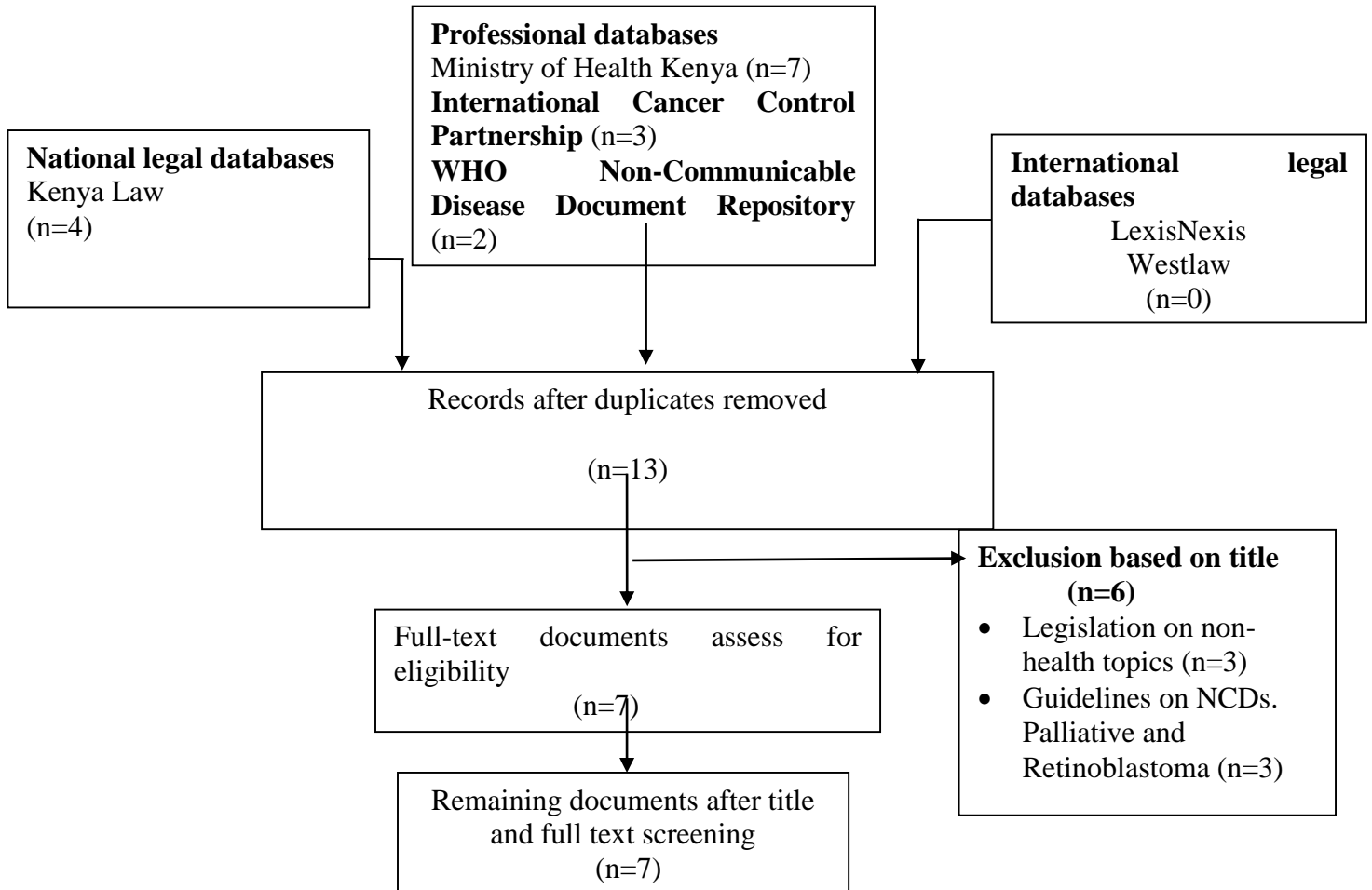
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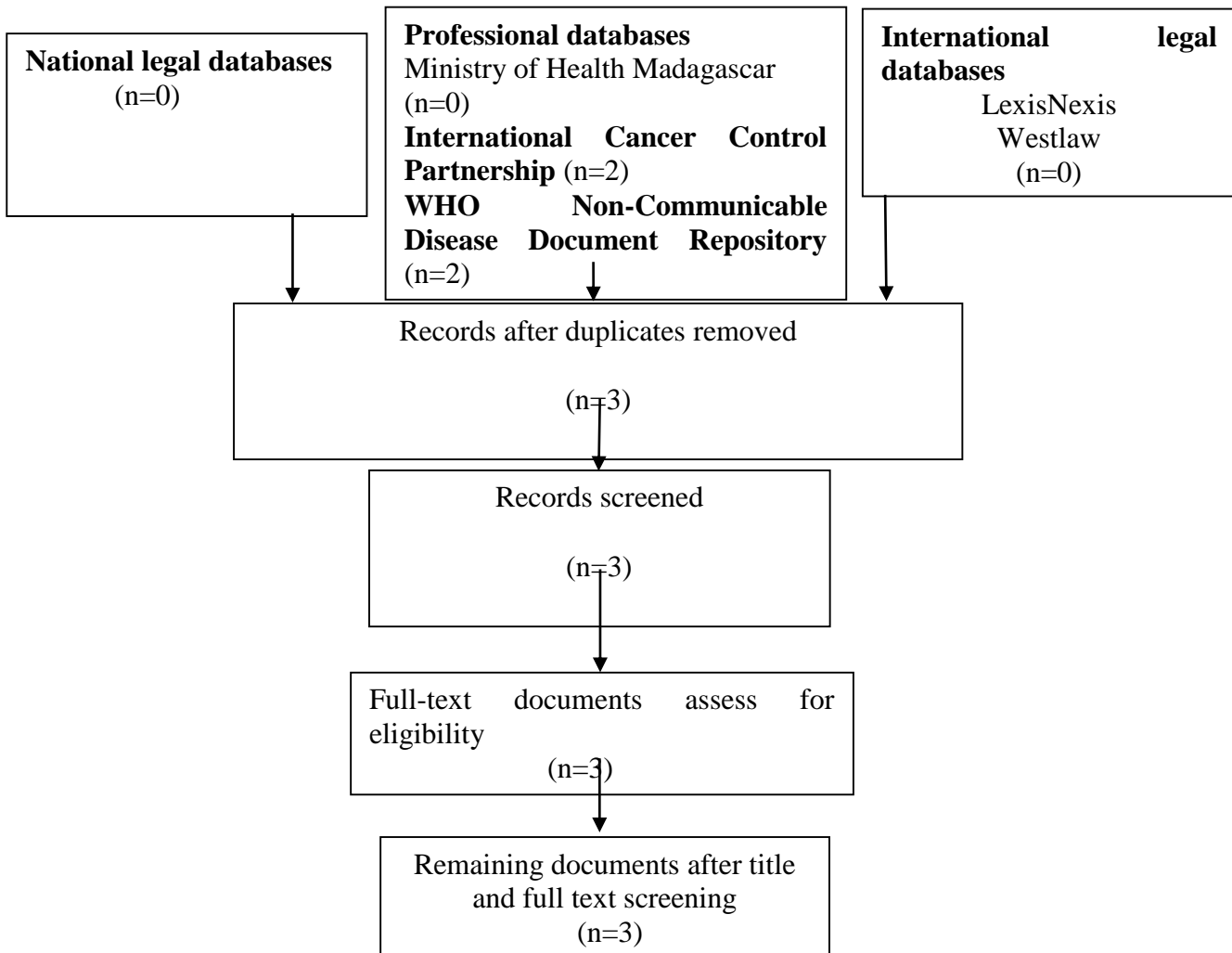
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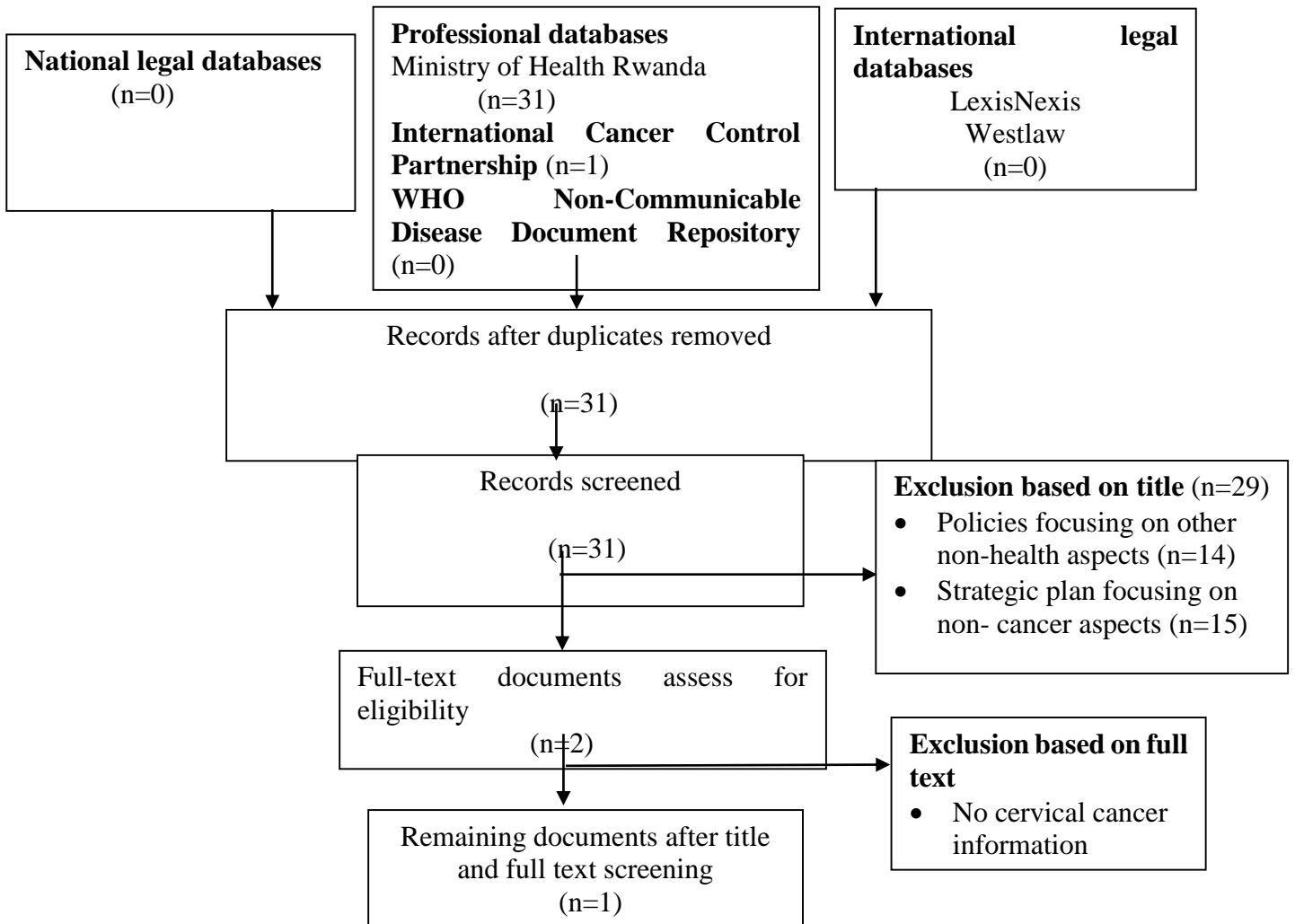
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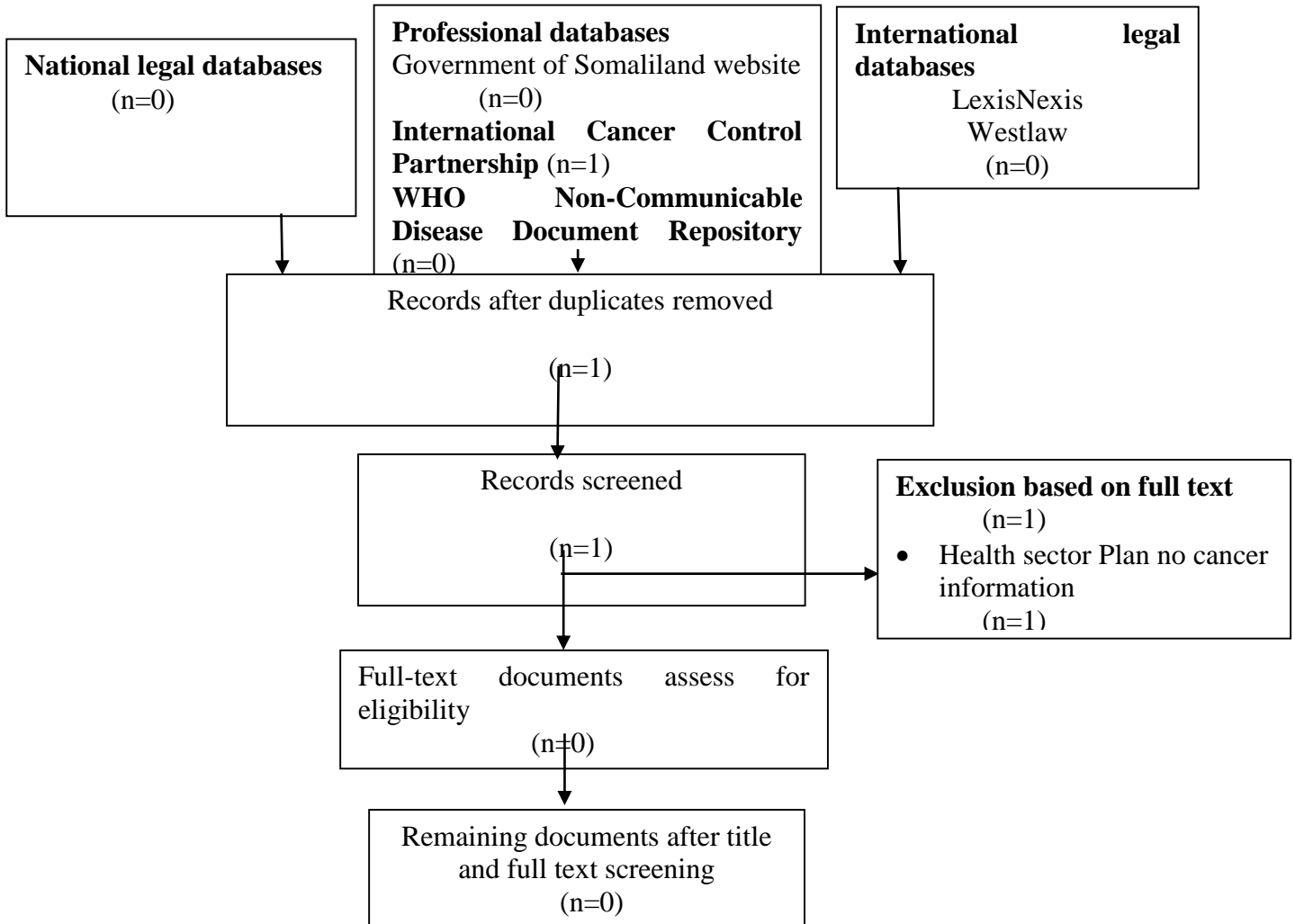


# RWANDA

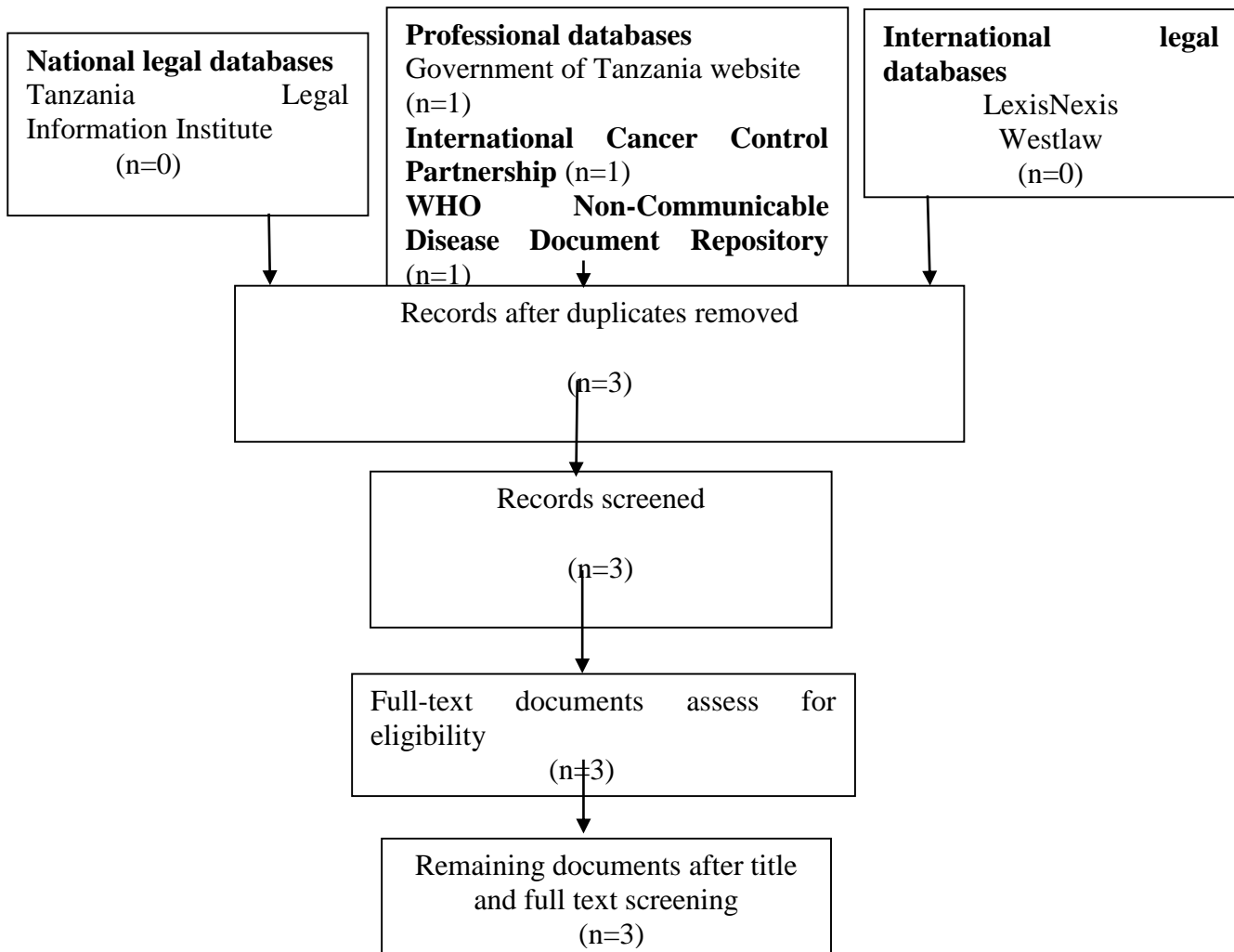




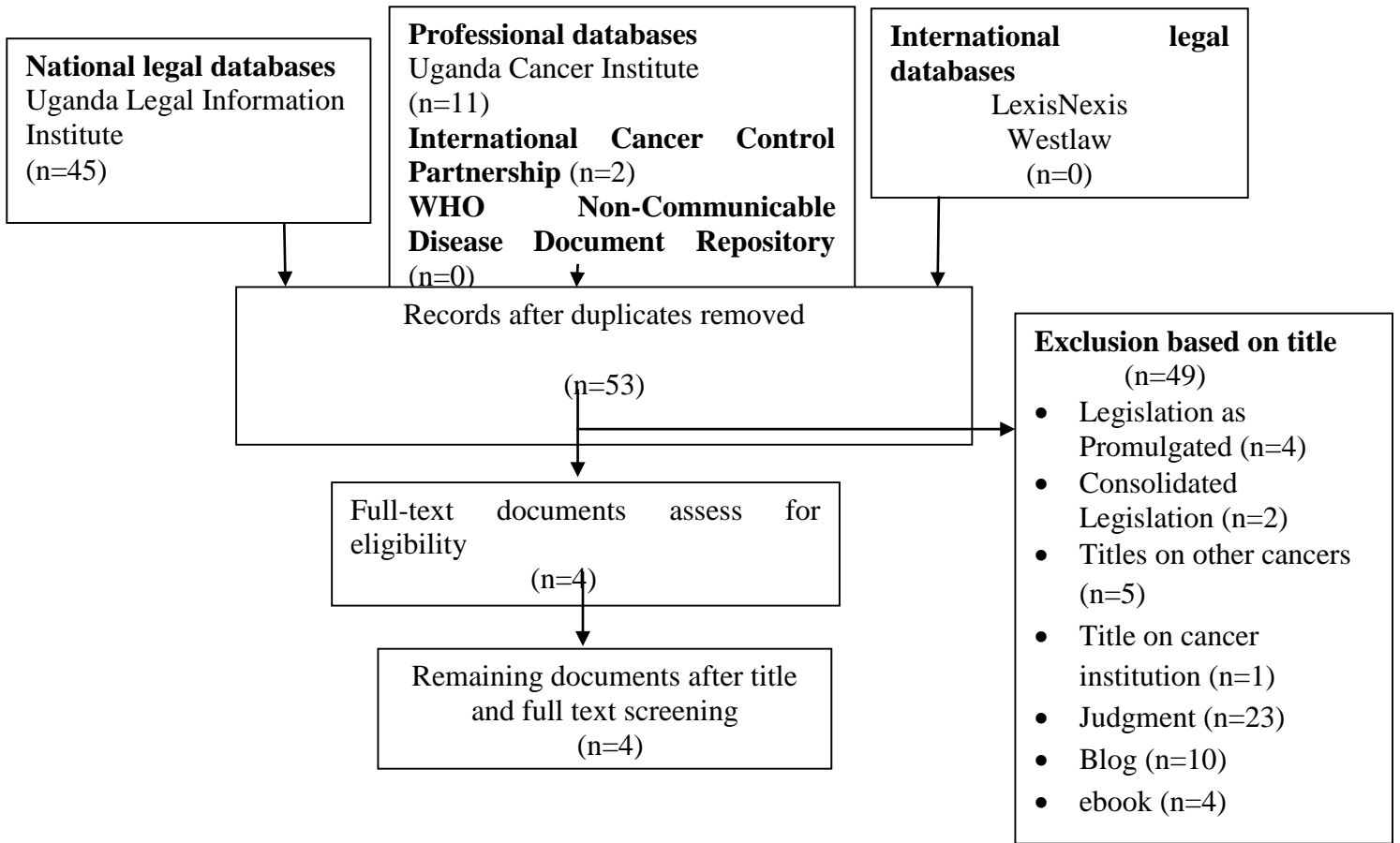
# SOMALIA



## TANZANIA



# UGANDA



## APPENDIX 3: INTERNAL VALIDITY ASSESSMENT FOR THE INCLUDED LEGAL DOCUMENTS

**Table 1: Internal validity assessment for the included legal documents, by domains**

Countries		Kenya							Uganda			Tanzania			Ethiopia		Eritrea	Madagascar			Rwanda	Comoros	DRC	Burundi	
*Policy document		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Criteria																									
Background and case for change	Fulfilled	2	2		2	2		2	2	2			2	2		2				2	2			2	
	Room for improvement																	1		1					1
	Not fulfilled			0			0				0	0		0				0				0	0		
Goals	Fulfilled	2			2	2				2						2	2				2				
	Room for improvement		1	1			1		1	1			1	1	1			1		1		1		1	





**Table 2: Internal validity assessment for the included legal documents, by domains, by**

**Reviewer 1**

Countries		Kenya							Uganda				Tanzania			Ethiopia		Er itrea	Madagascar			Rw anda	Co mos ros	D R C	Bu run di	
*Policy document	Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
Policy background	Fulfilled	2	2	0	2	2		2	2	2			2	2		2	2		2	2	2			2		
	Room for improvement																	1				1		1		
	Not fulfilled				0		0				0	0		0							0					
Goals	Fulfilled	2			2	2			2	2			2	2		2	2							2		
	Room for improvement		1	1	0		1				1			1				1		1	1	1				
	Not fulfilled							0			0								0			0			0	
Resources	Fulfilled	2											1				2									

	Room for improvement		1	1	1	1			1	1	1			1	1	1			1		1	
	Not fulfilled						0	1				0					0	0	0		0	0
Monitoring and evaluation	Fulfilled	2		0	2	2		2		2			2	2		2	2		2			1
	Room for improvement								1										1		1	
	Not fulfilled		0		0		0				0	0			0			0	0			0
Public opportunities	Fulfilled	2	2		2	2		2	1	2			2	2		2	2		2			2
	Room for improvement										1							1		1	1	1
	Not fulfilled			0			0					0			0			0				
Obligations	Fulfilled	2			2	2		1		2			2	2		2			2			2
	Room for improvement			1				1		1					1	1						
	Not fulfilled		0									0					0	0	0		0	0



Potential for public health impact	Fulfilled		2		2	2		2		2	2		2			2	2	2				0	
	Room for improvement	1										1		1						1	1		
	Not fulfilled			0			0		0			0			0				0			0	
Total		1	3	8	3	1	1	3	3	2	1	0	8	1	3	6	0	1	3	2	3	1	2

**Table 3: Internal validity assessment for the included legal documents, by domains, by**

**Reviewer 2**

Countries		Kenya							Uganda				Tanzania			Ethiopia		Er itrea	Madaga scar			Rw an da	Co mo ros	D R C	Bu run di
*Poli cy docu ment		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Criteria																									
Back groun d and case for chang e	Fulfil led	2	2		2	2		2	2	2			2			2				2	2			2	
	Room for impr ovem ent												1			1				1					1
	Not fulfil led			0			0				0	0			0			0				0	0		
Goals	Fulfil led	2			2	2				2						2	2				2				
	Room for impr ovem ent		1	1						1		1	1	1					1		1	1		1	
	Not fulfil led							0	0			0							0				0		0
Reso urce	Fulfil led	2											2			2					2				



Potential for public health impact	Fulfilled	2	2					2	2		2												2											
	Room for improvement				1	1								1	1	1	1			1	1	1												
	Not fulfilled			0			0			0	0						0				0	0		0										
Total		1	2	9	3	1	1	2	1	1	1	0	0	0	6	0	0	1	0	9	6	3	9	5	4	9	1	3	3	3	3	1	0	3

\*Legend policy documents given a number from 1 -24 in the order listed below.

1. Kenya national cancer prevention strategy 2017-2022
2. Kenya national cancer treatment guidelines
3. Kenya cancer prevention and control act 2012
4. Kenya national cervical cancer prevention plan Final Feb 2012
5. Kenya National Cancer Control strategy 2011- 2016
6. Kenya Cancer Prevention and Control Amendment Bill 2016
7. Kenya National Guidelines for Prevention and Management of Cervical Breast and Prostate Cancers
8. Uganda Cancer Society Strategic Plan 2016-2021
9. Uganda cervical cancer strategic plan 2010-2014
10. Uganda 2017 UCI treatment guidelines
11. Uganda cancer Act
12. Tanzania national cancer control strategy
13. National Cervical cancer prevention and control Strategic plan
14. The Ocean Road Cancer Institute Act 1996
15. Ethiopia Guideline for cervical cancer prevention and control
16. Ethiopia National Cancer Control Plan final

17. Eritrea Health Sector Strategic Development plan
18. Madagascar cervical cancer screening guide
19. National policy for cancer
20. Madagascar National Strategic Plan to fight against cervical cancer
21. Rwanda ministry of health strategic plan
22. National reproductive health policy
23. National Strategy to combat cancer of the uterine neck and breast
24. Burundi Politique Nationale Sante 2016 2025

## APPENDIX 4: SEMI-STRUCTURED INTERVIEW GUIDE

### Semi-structured interview guide

Interview guide

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#### Interview guide for girls and boys and parents/guardians and key informants comprising of school teachers.

Questions for all.

Questions only for parents/guardians and key informants comprising of school teachers.

Questions only for girls and boys.

Main theme	Main question and source	Follow-up check list of topics
Cervical cancer	<p>Do you know what is the cervix?</p> <p>Do you know what is cervical cancer?</p> <p>How can cervical cancer be prevented?</p> <p>Do you think your daughter could get cervical cancer anytime in her life?</p> <p>Have you ever had a Pap smear? Do you know what it is for? How often do you have one? From what age?</p>	<p>Do you know where the cervix is located and the parts of the cervix?</p> <p>Do you know what is the cause of cervical cancer?</p> <p>Have you ever heard about cervical cancer screening? Do you know how cervical cancer is screened?</p> <p>Do you think you or anybody in your family got or can get cervical cancer?</p> <p>Have you heard about Pap smear? If not, short explanation is given.</p>
HPV	<p>What do you know about HPV?</p> <p>How do you get it? How can it be prevented?</p> <p>Do you think you could get HPV?</p> <p>Do you think your daughter or son could get HPV?</p> <p>What consequences could it have in males and females?</p>	<p>What information have you received so far about HPV?</p> <p>What do you know about the association between sexual habits and HPV?</p> <p>How is HPV transmitted? Who is at risk of infection? Who can get infected of HPV?</p> <p>Do you think that your children can get infected during their life?</p> <p>What diseases can HPV cause?</p>
HPV vaccination	<p>What are the benefits of HPV vaccine?</p>	<p>What do you know about HPV vaccine?</p>

	<p>What consequences (negative) can the vaccination have?</p> <p>Who should be vaccinated against HPV?</p> <p>What do you think about the fact that in Kenya HPV-vaccination is not offered to boys?</p> <p>Do you think your daughter needed the HPV vaccine?</p> <p>Has anyone told you that your daughter should get HPV vaccination? Who told you, how?</p> <p>What fears about HPV vaccine have you heard in the community?</p> <p>Have you heard teachers talk about the HPV vaccine? What have they said? What do you think they believe about the vaccine?</p> <p>Have you ever heard a doctor or a nurse talk about the vaccine? What have they said?</p> <p>How do you discuss/talk about HPV vaccination among your friends?</p>	<p>Do you have any fears for HPV vaccination?</p> <p>Do you think boys can get infected with HPV?</p> <p>What are the most important reasons to vaccinate boys (or not to vaccinate boys)?</p> <p>Who informed you about the HPV vaccine? Please describe your feelings about the HPV vaccination. Have you ever heard a doctor or a nurse or anybody else talk about the vaccine? What have they said? And how did they explain it?</p> <p>What is public opinion? What are the concerns about HPV vaccination?</p> <p>Who informed you about the HPV vaccine? Please describe your feelings about the HPV vaccination.</p> <p>Have you ever heard any information about the HPV vaccine?</p> <p>Do your friends have any concerns about HPV vaccine?</p>
Decision making	<p>Do you have the necessary information to make a consent decision?</p> <p>What are the reasons for which your daughter was not vaccinated or did not complete the vaccination schedule?</p> <p>In matters related to the health of your daughter (like vaccines and medical procedures) who do you think should decide what to do? Herself? her father? the doctor?</p>	<p>What information would you need to make a decision regarding vaccination?</p> <p>Would you want to be vaccinated if you were offered HPV vaccination free of charge? What would motivate you to vaccinate your daughter or to complete the vaccination schedule?</p> <p>Do you think that your child can decide on their own if they want to take up vaccines or medical procedures?</p>
Conclusion	<p>Is there anything more you would like to say which I didn't ask you about?</p>	

## Interview guide for health workers and community leaders

Main theme	Main question and source	Follow-up check list of topics
Cervical cancer	Do you think that cervical cancer is real problem in your community?	How many people have cervical cancer in your community?
HPV	<p>What do you know about prevention of HPV infection?</p> <p>How do you decide when to begin discussing sexual health with patients?</p>	<p>What do you know about HPV viruses? Do you know more about these viruses than others?</p> <p>HPV vaccination is connected to issues of sexuality. Tell me how you manage discussions related to sexuality with your adolescent patients.</p>
HPV vaccination	<p>What do you think people understand to be the benefits and risks of HPV vaccination?</p> <p>What prompts you to discuss/offer vaccination to your patients? How often do they follow your advice for vaccinations?</p> <p>How would you describe the initial reaction of the community to the introduction of the HPV vaccination?</p> <p>To what extent were the girls and parents/ guardians willing to be participate in the vaccination exercise?</p> <p>Have you talked about your experiences with HPV vaccination with your colleagues? What have their experiences been? Do you feel that they are different or similar to yours? Why?</p> <p>Have you encountered or heard of any common or severe side-effects from HPV vaccination?</p> <p>Right now we know boys do not receive the HPV vaccine. What do you think about this?</p>	<p>Is HPV vaccination necessary?</p> <p>What has your experience been with offering the HPV vaccine?</p> <p>Do you have any concerns about the short-term or long-term safety of the vaccine? Have your colleagues mentioned any concerns? Are there any fears about the HPV vaccine or vaccines in general? Did you have to always coerce the girls and parents/guardians to take the HPV vaccine?</p> <p>Do you feel that they are different or similar to yours? Why?</p> <p>Have you encountered or heard of any severe reactions?</p> <p>Do you think that boys should be vaccinated?</p>



Decision making	<p>Do parents ever seem reluctant to have their daughters vaccinated? [IF YES (and assuming rather frequent “yes” responses)] What have they said? What have their reasons been?</p> <p>What about the adolescent girls themselves? How do they feel about getting vaccinated against HPV?</p> <p>Can you think of any cases where you did not (or would not) offer HPV vaccination to a patient but did (would) offer another vaccine?</p> <p>HPV vaccination entails follow up visits to ensure effectiveness. Are there problems with follow up, or anticipated follow up, ever considerations for you?</p>	<p>How do parents feel about having their daughters vaccinated against HPV? Tell me examples, why parents or girls are hesitant.</p> <p>Do the girls look like they are fearful to receive the vaccine?</p> <p>Have you encountered incidences where you could not give the HPV vaccine?</p> <p>Have you experienced loss to follow up for consequent doses?</p>
Conclusion	Is there anything more you would like to say which I didn’t ask you about?	Do you have any ideas for improving compliance with HPV vaccination recommendations?

## APPENDIX 5: STANDARDS FOR REPORTING QUALITATIVE RESEARCH (SRQR) CHECKLIST

Section
<b>Title and abstract</b>
<b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
<b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
<b>Introduction</b>
<b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
<b>Purpose or research question</b> - Purpose of the study and specific objectives or questions
<b>Methods</b>
<b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., post positivist, constructivist/ interpretivist) is also recommended; rationale**
<b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
<b>Context</b> - Setting/site and salient contextual factors; rationale**
<b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**
<b>Ethical issues pertaining to human subjects</b> - Documentation of approval

by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
<b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**
<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts
<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**
<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**
<b>Results/findings</b>
<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and <del>findings</del> ); might include development of a theory or model, or integration with prior research or theory
<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
<b>Discussion</b>
<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of

application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field
<b>Limitations</b> - Trustworthiness and limitations of findings
<b>Other</b>
<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed
<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting

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## **APPENDIX 6: PROJECT SUMMARY-SHARED WITH PARTICIPANTS**

### **Project summary**

**Title:** Perceptions of Human Papilloma Virus Vaccination among school girls/boys, parents/guardians and key informants comprising of school teachers, health workers and community leaders in Kenya: A qualitative study

**Study authors:** Diana Wangeshi Njuguna and Orsolya Varga

### **Introduction**

Cervical cancer is one of the leading causes of cancer deaths in women globally majority of these occurring in the developing countries. Cancer of the cervix is largely a preventable cancer and evidence has shown that access to screening and early detection is very essential to maximize on the chances of successful treatment of precancerous lesions or suspicion of cervical cancer.

There is high evidence to show that HPV vaccination prevents the incidence of cervical cancer by providing a prophylactic efficacy against cervical pre-cancer in adolescent girls and women who received the HPV vaccination. HPV vaccination contributes to prevention of cervical cancer hence is a public health priority.

The effectiveness and benefits of the HPV vaccine has been demonstrated in several countries as there is a high level of interest to reduce the burden of cervical cancer. Comprehensive HPV vaccination and public education could significantly prevent over half of all cervical cancer deaths.

We are conducting this research work to explore

1. The knowledge and acceptance of HPV vaccination among school girls, boys, parents/guardians and key informants comprising of school teachers, health workers and community leaders.
2. The attitudes and concerns of school girls, boys, parents/guardians and key informants comprising of school teachers, health workers and community leaders regarding HPV vaccines and HPV vaccination.
3. The willingness of the school girls' and their parent's/guardian's to participate in the HPV vaccination program.

To meet these objectives, we wish to conduct explorative qualitative semi-structured interviews.

## APPENDIX 7: INFORMED CONSENTS

### Informed consent form - children

#### Consent Form for Children

**Research Title:**

Perceptions of Human Papilloma Virus Vaccination among school girls, parents/guardians and key informants comprising of school teachers, health workers and community leaders in Kenya: A Qualitative Interview

**Researchers' Name:** Diana Wangeshi Njuguna, Orsolya Varga

I have read the participation information sheet and have had the opportunity to ask the researcher any further questions I may have had. I understand that my participation in this research is voluntary and I may withdraw at any time from the study without affecting my access to healthcare services in any way. I understand that the risks to me are minimal in this study and have read the information sheet and asked any questions I may have about the risks. I understand that I will be asked during an interview which takes approximately 30 minutes. The interview will be audio recorded. Following the transcription, the audio file will be destroyed, the text anonymized making impossible identification of participants. Thus, names of participants will not be used.

If I have any concerns or complaints regarding the way, the research is or has been conducted I can contact the University of Eastern Africa, Baraton Ethics Review Committee.

By signing below, I am consenting to participating in the interview. I understand that information from me will be used for the PhD thesis of Diana Wangeshi Njuguna and possibly other published studies and I consent for it to be used in this manner.

I give permission for my child \_\_\_\_\_ to participate in this research. (child's name)

Parent/ Guardian Signature \_\_\_\_\_ Date \_\_\_\_\_

Name (please print) \_\_\_\_\_

Child's signature \_\_\_\_\_

## **Informed consent form - adults**

### **Consent Form for Adults**

**Research Title:**

Perceptions of Human Papilloma Virus Vaccination among school girls, parents/guardians and key informants comprising of school teachers, health workers and community leaders in Kenya: A Qualitative Interview

**Researchers' Name: Diana Wangeshi Njuguna, Orsolya Varga**

I have read the participation information sheet and have had the opportunity to ask the researcher any further questions I may have had. I understand that my participation in this research is voluntary and I may withdraw at any time from the study without affecting my access to healthcare services or work in any way.

I understand that the risks to me are minimal in this study and have read the information sheet and asked any questions I may have about the risks. I understand that I will be asked during an interview which takes approximately 30 minutes. The interview will be audio recorded. Following the transcription, the audio file will be destroyed, the text anonymized making impossible identification of participants. Thus, names of participants will not be used.

If I have any concerns or complaints regarding the way, the research is or has been conducted I can contact the University of Eastern Africa, Baraton Ethics Review Committee

By signing below, I am consenting to participating in the interview. I understand that information from me will be used for the PhD thesis of Diana Wangeshi Njuguna and possibly other published studies and I consent for it to be used in this manner.

Name (please print) \_\_\_\_\_

Caregiver/parents' signature \_\_\_\_\_

Date\_\_\_\_\_





## Ethical Board Approval



OFFICE OF THE DIRECTOR OF GRADUATE STUDIES AND RESEARCH  
UNIVERSITY OF EASTERN AFRICA, BARATON  
P.O. BOX 2500-30100, Eldoret, Kenya, East Africa

B0218082020

August 18, 2020

TO: Diana Wangeshi Njuguna  
Department of Preventive Medicine, Faculty of Public Health  
Debreceni Egyetem  
4032 Debrecen Egyetem ter 1

Dear Diana,

**RE: Perceptions of Human Papilloma Virus Vaccination Among School Girls, Parents/Guardians and Key Informants Comprising of School Teachers, Health Workers and Community Leaders in Kenya: A Qualitative Study**

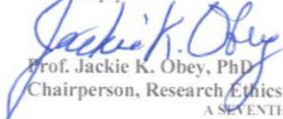
This is to inform you that the Research Ethics Committee (REC) of the University of Eastern Africa Baraton has reviewed and approved your above research proposal. Your application approval number is UEAB/REC/02/08/2020. The approval period is 18<sup>th</sup> August, 2020 – 17<sup>th</sup> August, 2021.

This approval is subject to compliance with the following requirements:

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by the Research Ethics Committee (REC) of the University of Eastern Africa Baraton.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to the Research Ethics Committee (REC) of the University of Eastern Africa Baraton within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to the Research Ethics Committee (REC) of the University of Eastern Africa Baraton within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to the Research Ethics Committee (REC) of the University of Eastern Africa Baraton.

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

Sincerely yours,

  
Prof. Jackie K. Obey, PhD  
Chairperson, Research Ethics Committee



County Government Approval

Mombasa County



DEPARTMENT OF HEALTH SERVICES  
OFFICE OF THE CHIEF OFFICER, PUBLIC HEALTH

Email : [chiefofficerpublichealth2020@gmail.com](mailto:chiefofficerpublichealth2020@gmail.com)

When replying please quote;

Ref. MCG/COPH/RSCH. /061

Diana Wangeshi  
University of Debrecen  
**HUNGARY.**

P. O. BOX 90441 - 80100  
Msanifu Kombo Street  
**MOMBASA.**

**Date: 27<sup>th</sup> October, 2021**

Dear Sir/Madam,

**RE: AUTHORIZATION TO CARRY OUT A STUDY IN MOMBASA COUNTY**

The Mombasa County department of Health Services is in receipt of your request to conduct a study titled "Perception of Human Papilloma Virus Vaccination among school girls, boys, parents/guardians and key informants comprising of school teachers, health workers and community leaders in Kenya" that received ethical approval from National Commission for Science Technology & Innovation, and University of East Africa, Baraton.

The department is glad to grant you authorization to conduct your study over a period 12 months (expires **17<sup>th</sup> August, 2021**) in **Mombasa County** in line with the approved study protocol.

Upon completion of study, you are required to share your findings and recommendations with department of Health services, Mombasa County.



**PAULINE OGINGA**  
**A.g CHIEF OFFICER PUBLIC HEALTH**  
**DEPARTMENT OF HEALTH SERVICES**  
**COUNTY GOVERNMENT OF MOMBASA**



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**THE PRESIDENCY  
MINISTRY OF INTERIOR AND CO-ORDINATION OF  
NATIONAL GOVERNMENT**

Telegrams:  
Email: countycommissionertanariver@gmail.com  
Telephone: HOLA (046)62448 and 6221  
When replying please quote

OFFICE OF THE COUNTY COMMISSIONER  
TANA RIVER COUNTY  
P.O. BOX 1- 70101  
**HOLA**

**REF. NO. TCC/ADM.37/147**

**DATE: 11<sup>TH</sup> JANUARY, 2021**


DIANA WANGESHI NJUGUNA  
DEPARTMENT OF PREVENTIVE MEDICINE. FACULTY OF PUBLIC HEALTH  
DEBRECENI EGYETEM  
4032 DEBRECEN EGYETEM  
**NAIROBI.**

**RE: RESEARCH AUTHORIZATION**

Reference is made to a letter from the National Commission for Science, Technology and Innovation Ref. No. NACOSTI/P//20/6514 dated 9<sup>TH</sup> September 2020 on the above subject.

This office wish to state that, it has no objection in your undertaking research activities as stated in the above referenced letter. We further wish you a good stay and success in your research endeavors.

Thank you.

  
**GEOFFREY M. MWACHOFI  
FOR: COUNTY COMMISSIONER  
TANA RIVER COUNTY.**

**CC.**  
**DEPUTY COUNTY COMMISSIONERS**  
**TANA RIVER SUB COUNTY.**

**THE COUNTY DIRECTOR OF EDUCATION  
TANA RIVER COUNTY.**