

**ETHICAL CHALLENGES SURROUNDING HUMAN  
PAPILLOMAVIRUS VACCINATION AMONG STUDENTS,  
PARENTS, HEALTH CARE WORKERS, SCHOOL TEACHERS AND  
POLICY MAKERS IN UBUNGO MUNICIPALITY**

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**Master of Bioethics Dissertation  
Muhimbili University of Health and Allied Sciences**

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**Department of Bioethics and Health Professionalism**



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**By**

**Veronica Vicent Sisty**

**A Dissertation Submitted in Partial Fulfillment of the Requirements for Masters in  
Bioethics of Muhimbili University of Health and Allied Sciences**

**October 2021**

**CERTIFICATION**

The undersigned certify that, they have read and here by recommend for acceptance by Muhimbili University of Health and Allied Sciences a Dissertation entitled; **“Ethical Challenges Surrounding Human Papillomavirus Vaccination among Students, Parents, Health Care Workers, School Teachers and Policy Makers in Ubungo Municipality”**, in (Partial) fulfilment of the requirements for the degree of Master of Bioethics of Muhimbili University of Health and Allied Sciences

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Date:

**DECLARATION AND COPYRIGHT**

**I, Veronica Vicent Sisty**, declare that this Dissertation is my own original work, and that it has not been presented and will not be presented to any other University for similar or any other award.

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## **DEDICATION**

I dedicate this dissertation to my parents, Mr. Vicent Sisty (Late) and Mrs. Maria Vicent for their lovely care and raising me up, my beloved husband, Mr Patrick D. Geay and my lovely children Isdory, Benedict, Caroline and Careen.

## ABSTRACT

**Background:** Ministry of Health, Community Development, Gender, Elderly and Children (MoHC DGEC) has introduced Human Papilloma virus (HPV) vaccination into its immunization program. This program aimed at reducing the incidence and prevalence of HPV associated with cervical cancer in Tanzania. As to conform to the global accepted strategy for preventing cervical cancer and genital warts. However, the guideline for ethical adherence was not in place to reach adolescent school girls to implement the HPV Vaccination program.

**Objective:** The objective of this study was to explore ethical challenges surrounding vaccination in Tanzania: The Case of Human Papilloma Virus in Ubungo Municipality

**Methodology:** An exploratory study design, which employed Qualitative methodology was used in which fourteen (14) In-depth interviews and two (2) Focused group discussions were used to address the study objectives. This study was conducted in Ubungo Municipal, Dar es Salaam, Tanzania. Study subjects were vaccinated adolescent girls, Parents, Policy Makers for vaccination program from department of Policy and Planning in the Ministry of Health, Community Development, Gender, Elderly and Children (MoHC DGEC), School Teachers and Health Care Workers. Purposive sampling method was used to obtain study subjects where the saturation was reached at 14<sup>th</sup> participant and second FGD by learning no new information was generated and data collection stopped based on power of information. Data obtained were analyzed by thematic analysis with the help of the Computer- Assisted Qualitative Data Analysis Software (CAQDAS). The study duration scheduled for two consecutive months.

### Findings

The study revealed that, Parents and schoolgirls were not fully informed about the program of HPV Vaccination, that's includes the benefits and related side effects. The challenges in decision making in HPV vaccination investigated where informed consent among parents of vaccinated girls, informed consent among the vaccinated adolescent schoolgirls, mass vaccination in relation to person's autonomy and insufficient information in HPV vaccination were outlined.

**Conclusion and recommendation**

The findings from this study conclude that, during the HPV vaccination program as public program for specified age group without considering their environments and counterpart groups compromises the justice to the general population of concerned. In addition, the study found that some ethical principles were not observed during HPV vaccination program. For example in decision-making process where parents were poorly engaged to decide for their children and insufficient information to schoolgirls and parents which lead to mistrust of the program to the community. Therefore, the study suggest further study to explore more ethical issues in regard to mass vaccination.

**Key words:** Human papilloma Virus, autonomy, justices, discrimination



**LIST OF ABBREVIATIONS**

ASR	Age-standardized incidence rate
CAQDAS	Computer- Assisted Qualitative Data Analysis Software
DNA	Deoxyribonucleic acid
HBV	Hepatitis B virus
HCW	Health Care Workers
HPV	Human papillomavirus
IDI	In-depth Interview
IRB	Institutional Review Board
MBE	Master of Bioethics
MC	Municipal Council
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MUHAS	Muhimbili University of Health and Allied Sciences
VIA	Visual inspection of cervix with acetic acid
WHO	World Health Organization

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### DEFINITION OF KEY TERMS

<b>Adolescent</b>	Refers to a person aged between 09 to 15 years that require parental permission and their assent to participate in research (1)
<b>Assent</b>	Refers to an affirmative agreement to participate in vaccination program or research by person(s) who lack the legal capacity to make decision. Assent must be accompanied by a parental permission (6).
<b>Cervical cancer</b>	defined as a type of cancer that occurs in the cells of the cervix (the lower part of the uterus that connects to the vagina) (2)
<b>Discrimination</b>	Means unfair difference in the treatment of people because of their sex, race or socio-economic status (3).
<b>HPV Vaccination</b>	Refers to a safe and effective way of protecting Adolescent girls against cervical cancer disease (8).
<b>Human papillomaviruses</b>	Defined as small, double-stranded DNA viruses that infect the epithelium and cause abnormal tissue growth and other changes to cells in humans (4).
<b>Informed consent</b>	Means the moral contract between researchers and the study participants and setting the framework for the allowable to be involved in an intervention (5).
<b>Justice</b>	Defined as a fair distribution of scarce health resources to those in need at a specific time to protect them from disease burden (7).

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## CHAPTER ONE

### 1. INTRODUCTION

#### 1.1 Background

Human papillomaviruses (HPV) are small, double-stranded DNA viruses that infect the epithelium. More than 120 HPV types have been identified based on their differences in the genetic sequence of the outer capsid protein L1(4). Although there are many types of HPV, not all can cause diseases or infections. Type 6 and 11, are known to cause benign or low-grade cervical cell abnormalities, genital warts and laryngeal papilloma, while type 16 and 18 are the cause of approximately 70% of cervical cancers worldwide(4).

Cervical cancer is the fourth most common cancer in women globally, with over 500,000 new cases and an estimated 250,000 deaths each year(9). East Africa has the highest rate of cervical cancer in the world where age-standardized incidence rate (ASR) is estimated at 42.7 new cases per 100,000 women(10). Tanzania ranks second in the region with an ASR of 54.9/100,000 women in which, cervical cancer is the leading cause of cancer-related death among Tanzanian women. The report shows most of cases are diagnosed at a late stage of the disease (10). In response to this Tanzania introduced HPV vaccination into its immunization program through which over 600,000 adolescent girls, aged 9 to 14 years were vaccinated in 2018(9). However, in doing so, ethical principles were less followed concerning respect to person's autonomy, beneficence and justice.

This approach of using health-care workers to provide HPV vaccination to adolescent girls in schools, has been found to be a cost effective and efficient means to reach many girls(11). Despite the benefits of this vaccination strategy, it may be associated with ethical issues surrounding its implementation. Hence, it is important to explore the ethical challenges that may be associated with this innovative public health intervention aimed at reducing the incidence and prevalence of HPV associated cervical cancer.



## **1.2 Problem Statement**

It is the practice of many national vaccination programs, when an intervention is of public interest, that adherence to ethical principles such as individual autonomy, privacy, fairness and discrimination may be overlooked(12). Abiding to bioethical principles, any vaccination program requires that autonomy, privacy and confidentiality of the individual to be respected (13). However, often in cases of mandatory vaccination programs, there may be a large violation of bioethical principles such as violation of individual autonomy, right of an individual to accept or refuse medication and conflict between individual interest against those of public interest (14).

Ideally adolescent school girls involved in HPV vaccination programs are required to give out their assents, and, or legal guardians should consent on their behalf. In other words adolescent girls have the right to accept or to refuse an intervention even if its deemed for the good of the public(15). Autonomous agents, including adolescents are entitled to information about any health intervention involving them as a subject. Adolescents should freely be able to assent to participate, with the only exception to acquiring assent is if the person under the age of 18, and do not have full use of their mental ability to receive information and freely. In this case consenting to participate in a study and getting all information about the health in intervention becomes the responsibility of the parents or legal guardians(13). This study, therefore aims to reduce the knowledge gap by exploring ethical challenges surrounding HPV vaccination of Adolescent girls in Ubungu Municipal, Dar es Salaam, Tanzania.

## **1.3 Study's Rationale**

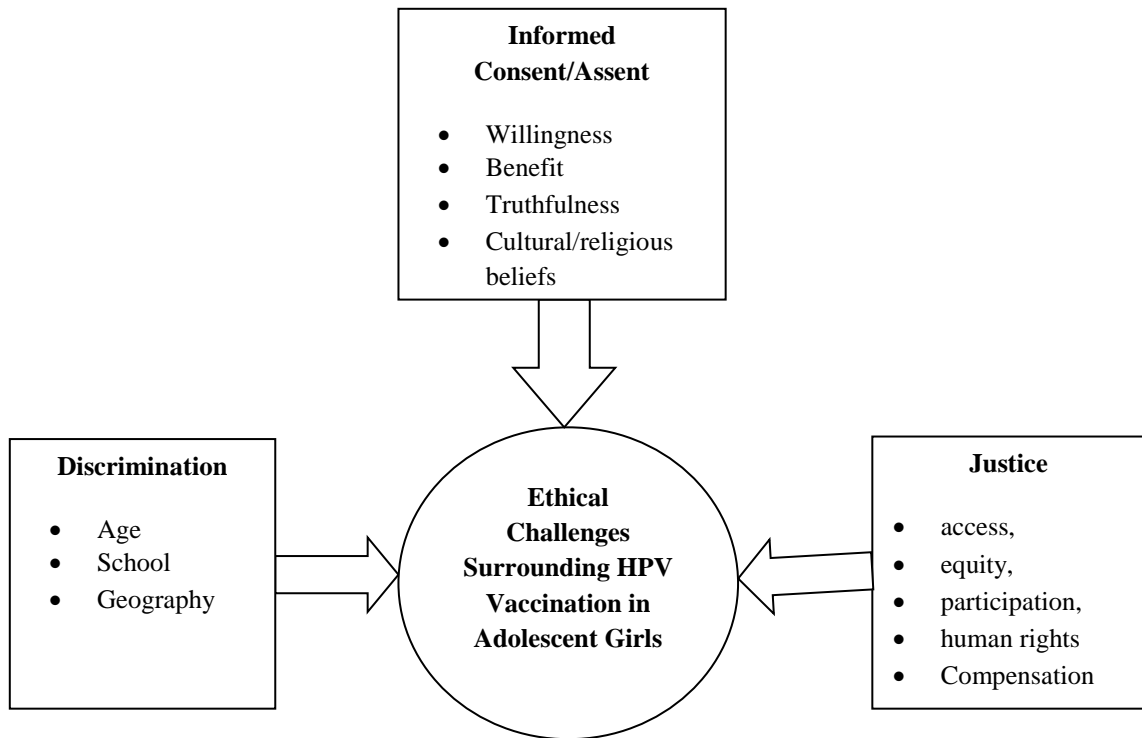
The findings of this study will be useful in providing information that can be used by policy makers, and health care workers to minimize the ethical challenges associated with national vaccination programs. But more importantly create awareness of ethical issues in vaccination programs and as such design HPV and other vaccinations program with reduced ethical challenges.

The study also will pave the way in line with universal health coverage to meet health for all as per sustainable development goals where ethical issues are indispensable.

This in turn may improve vaccination uptake and to minimize the negative socio-cultural and psychological perceptions towards HPV vaccination. We anticipate that this study will highlight ethical gaps in the national HPV vaccination program that will assist policy makers in the future to plan and implement a public health intervention in a more ethical manner.

#### **1.4 The Conceptual Framework**

A vaccine against human papilloma virus (HPV) is indicated to adolescent girls beginning age nine. Compared to other vaccine-preventable diseases, which are transmitted by either air or casual contact, HPV is primarily transmitted by sexual contact. To promote adolescents' participation in medical decision-making and advance policies that allow for independent consent to HPV vaccination. Ethical analysis theories, such as utilitarianism are needed to support policy development especially that not everyone is at risk. The concerns for autonomy, justice, and kinds of discriminations are revealed through exploration of ethical issues (16). This may in future support to empower adolescent girls in issues pertaining to their health and well-being as they will be more likely to explore and discuss information about HPV with others, and be able to make informed decisions or assent related to HPV vaccine(17).



**Figure 1: Conceptual Framework on Ethical Challenges Surrounding HPV Vaccinations**

Source: Adapted and modified by the Researcher (Zimmerman RK)

## **1.5 Research Questions**

### **1.5.1 Broad Research Question**

What are the ethical challenges surrounding HPV vaccination of adolescent girls in Dar es Salaam, Tanzania?

### **1.5.2 Specific Research Question**

- 1 How were the informed consent/assent process conducted among adolescent girls and their parents in taking HPV vaccination?
- 2 What are the elements of discrimination associated with HPV vaccination?
- 3 How was justice enhanced in HPV vaccination program among adolescent girls?

## **1.6 Research Objectives**

### **1.6.1 General Objective**

To explore ethical challenges surrounding HPV vaccination of adolescent girls in Dar es Salaam, Tanzania.

### **1.6.2 Specific Objectives**

- 1 To explore the informed consent and assent process during HPV vaccination of adolescent girls in Dar es Salaam, Tanzania
- 2 To explore discrimination associated to HPV vaccination of adolescent girls in Dar es Salaam, Tanzania.
- 3 To explore how justice was perpetuated during HPV vaccination of adolescent girls in Dar es Salaam, Tanzania.

## CHAPTER TWO

### 2 LITERATURE REVIEW

#### 2.1 Background

To-date there are vaccines available to protect against at least 20 diseases, including diphtheria, tetanus, pertussis, polio, influenza and measles(8). These vaccines have been shown to save lives of up to three million people every year(8).

Vaccination is considered a simple, safe, and effective way of protecting people against harmful diseases, before they come into contact with them(8). It uses body's natural defence resistance to specific infections and makes immune system stronger (8).

Even though vaccination is a very important and effective in public health intervention strategy, its administration is often associated with ethical issues. Vaccination associated ethical issues, may include, infringement of personal decision-making, mandatory vaccination, discrimination, and injustice among others. In 2009, during H1N1 influenza pandemic, the number of ethical issues was violated from its development to distribution. Among the ethical issues identified in this vaccination campaign included, disclosure failure of the risks of the vaccine, equitable distribution of the vaccine and the concept of mandatory vaccination (18). Similarly, other studies on national school-based HPV vaccination programs conducted in Singapore and Nigeria were highly associated with violation of ethical principles, such as autonomy, social justice and equity, and gender equality. Basically, these HPV school-based programs were found, among other effects, to create potential stigma among students from lower income families(3)(19).

Furthermore, other studies have indicated that, in many HPV school-based vaccination programs, ethical issues of informed consent is violated as the vaccination is administered without the presence of parents or legal guardians. The ultimate decision to vaccinate or not to vaccinate their children should be taken by their parents to ensure parental autonomy(15)(20). For example, in Finland and Sweden, it was found that most public funded HPV vaccination programs were only targeting girls only(13). This approach

violates the ethical principles of gender inequity in childhood immunization, despite that HPV causes diseases in both females and males.

## **2.2 Informed consent process in vaccination**

Consent is the principle wherein individuals must give their permission before receiving a medical intervention or procedure(5). According to the laws and regulations in place in most countries, consent is required for a range of medical interventions or procedures, from a simple blood test to organ donation, to vaccination (5). In only very few, well-described circumstances, such as life threatening emergencies, consent may be waived(5). Consent derives from the principle of autonomy and forms an important part of medical and public health ethics, as well as international law(5). According to WHO directives, where parental consent is required, health workers should allow older children and adolescents to provide assent to the vaccination(5).

Although, in some cases, it has been explicitly elaborated informed consent process may not be adequately observed. For example, studies in Southern Italy, have found that there is inadequate information to parents about infant vaccination (21)(22). Similarly in Sweden, the polio vaccination campaigns had information which were not well communicated to the public and some information was withheld from public(23). As a result, in Sweden, polio vaccination was highly objected by the public and the public lost trust in the vaccinations as result of the adverse effects resulting from polio vaccination. Likewise during the H1N1, vaccination conducted in Sweden in 2009, researchers reported that vaccine a safe and accurate. However, a group of adolescents developed narcolepsy as side effect which provider of the vaccine did not communicate to the adolescents(23)(24). The study conducted in United States explored ethical issues of consenting process during administration of HPV vaccine among adolescent girls and found that the adolescents self-consent was insufficient and cannot be ethically justifiable(25).In these instances, it cannot be ethically justified for health-care workers to waiver parental consent who is the legal guardian of the adolescent (25).This also led to lot of discussions and debate of whether HPV vaccine is that sensitive enough to the extent of exempting parental consent and adolescent accent(4). In Bangladesh, they waived parental consent

where children were sent to the vaccination session were assumed to have gotten parental consent. There was assumption that parents or guardians were informed about imminent vaccination through social mobilization and communication and this was sufficient (20). Similarly, in South Africa, yellow fever vaccination was associated with several ethical issues, including the segregation and isolation of those who refused to take vaccination and foreigners who entered South Africa were vaccinated yellow fever vaccine by force(26). Likewise in Nigeria, there was mass riot against polio vaccination program due to insufficient information about polio vaccination(27).

In Tanzania, it was reported that the HPV vaccination program reported lack of community engagement and which give little chance to decision making(28). And therefore, all these study findings clearly suggest that there is a need to investigate ethical issues associated with informed consent in mass vaccination campaigning

### **2.3 Discriminations associated with HPV vaccination**

In a study conducted in Nigeria, HPV vaccination was found to be discriminatory. Apart from being discriminatory between schools girls, HPV vaccination in Singapore left out-of-school young girls who were exposed to higher risks of being affected by HPV (3). HPV vaccination conducted in Singapore was discriminatory which led to segregation and stigmatization to those who were not vaccinated (3). This was due to the fact that adolescent had to pay for the vaccine which was very expensive and made only those from wealthier families to get vaccinated and leave out those from poor communities(19)(29). In South Africa, it was reported that vaccination program adopted in South Africa included screening for HPV, exclusion of young males and demanded of girls who had not yet participated in sexual acts(29). As it was reported by Harries in her study the HPV vaccination policy adopted in South Africa had concerns on ethical issues.

A Global and Public Health Group study conducted in England found that, men and women were equally affected by HPV which led to different types of cancer(30). However, Current HPV vaccination campaigns discriminate against men.

In Tanzania, there is no documented information about ethical issues associated with vaccination programs which have been conducted. However, a study conducted on Hepatitis B Virus (HBV) vaccination to health care workers, showed that there were

discrimination ethical issues associated with the vaccination program(31). HBV vaccination in Tanzania is mainly provided to health care workers because of the cost of vaccination. In addition to be selective to health care workers, it was also reported that not all health care workers were provided with HBV vaccination but those who were in tertiary hospitals and health care workers in other hospitals were left out while they were all in high risk of contacting the diseases(31).

A study conducted in South Africa proposed that, HPV vaccination should be done to women who had not been affected by HPV and not to adolescent only (29). Some girls acquired HPV very early in life which make the vaccination to be helpless to them(29). In this account, discrimination as an ethical issue is therefore important to be explored following HPV vaccination program.

#### **2.4 Justice in HPV vaccination**

Justice requires there is fair allocation of limited resources to different groups of people who need the resource regardless of their socioeconomic status. This applies to basic items such as shelter, food and potable water, as well as vaccines that are in limited supply. Allocation decisions are relevant to all countries regardless of socioeconomic status or experience of humanitarian emergencies. There is a shared global vulnerability to humanitarian emergencies, although this is more pronounced in poor countries and regions because poverty hampers resilience. If rural populations were systematically excluded, however, this would be considered inequitable since those adolescent in rural setting are also vulnerable to disease incidence. The role of justice is to specify social and economic conditions that determine whether certain inequalities should be seen as unfair(7). This means that if there is inequality in medical intervention, it has to be justified with valid ethical reasoning.

In a study conducted in Canada, it was shown that there was HPV vaccination that was in progress was for adolescent school girls only(32). However in Canada, the prevalence of cervical cancer among marginalized groups of women, especially recently immigrated and Aboriginal women is much higher than that of the general population(33). The study



findings suggest that justice is not adhered to in these vaccination campaigns by leaving these vulnerable groups out. Likewise, in a study conducted by WHO in Jordan, more than 60% of the children who were eligible for vaccination missed the opportunity for vaccination because of their geographical location and their financial status(24). These findings reveal that in Jordan there was injustice in vaccination program just because omitting girls, just because of their geographical location or financial status.

According to the study conducted in USA revealed that in vaccination programs there is often injustice to adolescents and are often not considered to express themselves(34). These included those in detention camps who have higher risks of being affected by HPV than those who are in normal life(34). Hence, this denial of access to vaccination is explicitly a form of injustice. WHO report on vaccination programs in Africa indicates that in most African countries, vaccination uptake is higher rate among children living in towns than those living in rural areas(3)(35). Town and big cities dwellers, have access to good health facilities and high number of health workers. In addition, parents who were in towns had more knowledge of vaccination than those in rural areas. But, those in villages had low rate of vaccination uptake due to lack of health facilities, shortage of health workers and poor knowledge of vaccines (35)(28). Moreover it has also been noted that, vaccine uptake varied with social economic situations. In both towns and in rural areas, those with better economic life had higher vaccination uptake than those with poor socioeconomic status (32)(28). Based on this report, it is obvious that there is injustice in vaccination among town and village dwellers depending on social economic status.

It is quite clear from the presented studies that mass vaccination campaigns may have a lot of ethical issues. However, whether these issues are associated with mass vaccination campaigns in Tanzania is difficult to establish, due to the scarcity of literature from Tanzania. We therefore embarked on study to explore ethical issues surrounding mass vaccination in campaigns In Tanzania, using the HPV program as a case study.

## CHAPTER THREE

### 3 MATERIALS AND METHODS

#### 3.1 Study Design

An exploratory qualitative study design was adopted to assess the ethical challenges surrounding the HPV vaccination program among adolescent girls in selected secondary schools

#### 3.2 Study Duration

Data collection, analysis and Report Writing was done for a period June to September after getting ethical clearance

#### 3.3 Study Area

The study was conducted in selected public and private secondary schools and health care centres at Ubungo municipal in Dar es salaam, Tanzania. The study area was selected based on HPV vaccination coverage data. In 2019 there were two HPV campaigns namely, HPV1 and HPV2. Coverage as a result of the HPV1 campaign was as follows; Ilala Municipal Council (MC) 64%, Kinondoni MC 96%, Temeke MC 128%, Kigamboni District Council 99% and Ubungo MC 80%. In 2021 Ubungo MC had lowest coverage of HPV<sub>1</sub> in with only 42% compared to Kigamboni (96%), Kinondoni (90%), Temeke (83%) and Ilala (54%), (region report 2020 unpublished). Selection of study area was due to lowest coverage of HPV<sub>1</sub> vaccinees compared to other districts in Dar es Salaam.

#### 3.4 Study population

The study conducted among adolescent school girls involved in HPV Vaccination program with respective age (09-15) of their participation. The parents, health care providers, schools teachers and policy makers selected based on their involvement in vaccination program. The population was selected because was able to provide their experience to fit study objectives(36).

### **3.5 Sample size**

The participants purposively selected to suit the study design. Twenty-four (24) participants were involved, it includes ten (10) adolescent girls in two (2) focus group discussion and fourteen (14) for in-depth interviews. Among the fourteen (14): five (5) were parents whom their children were vaccinated, two (2) policy makers, three (3) were healthcare providers and four (4) teachers whom participated in HPV vaccination program in selected secondary schools. The sample size of the participants reached after satisfaction with their information using the concept of “power of information” as the way of determining the sample size in qualitative studies(37)

### **3.6 Sampling Techniques**

The study used purposive sampling method by approaching the eligible participants with experience with HPV vaccination who fit the profile of the research objective (38). The permission obtained from Regional Administrative Secretary (RAS), District Administrative Secretary (DAS), District Educational Officer (DEO) and District Medical Officer (DMO) as well as Heads of school. Researcher contacted individual Participants, and obtain oral informed consent and in written form by signing the informed consent form. For those who consented, the Researcher negotiated with them appropriate time for interview.

### **3.7 Data collection tool**

Data collected using a semi-structured interview guide and focus group discussion prepared in English and translated into Swahili.

### **3.8 Data collection procedure**

A focused group discussion (FGD) was conducted among adolescent schoolgirls. Two separate focus groups of six (6) and four (4) students based on selected schools at respective central location; in-depth interviews (IDI) were conducted for parents, health care workers, policy makers and teachers in selected public schools and health care centre in Ubungo Municipal Dar es salaam Tanzania. With permission from the study participants the interview between a researcher and a study participant was audio taped using digital audio recorder and field notes were taken to capture the facial expressions, gestures and

other subtle but relevant cues. This helped in analysis and discussion of the findings. Each interview expected to last for maximum of 45 minutes.

### **3.9 Data Analysis**

The responses collected from the participants transcribed verbatim. After the transcription of the interviews, a thematic analysis method was used to analyze the data collected according to the analysis of qualitative health research(34). The method is used to analyze data by identifying and organizing relevant themes and sub themes. The method was beneficial in this research study due to the flexibility and rigor it offered (35). Five steps were used during data analysis with the assistance of Nvivo 10 software to identify the themes as adopted from five interactive phases of thematic analysis by Labra et al (36). The steps include;

#### 1 Familiarization with the collected data

The transcribed findings were repeatedly read to understand the content.

#### 2 Generating initial codes

The transcripts read line by line to generate meaningful codes.

#### 3 Searching for themes

The codes combined to make sub themes.

#### 4 Reviewing sub themes

Sub themes reviewed and make themes with the assistance of my supervisors, themes were merging and reduced to six themes from eight.

#### 5 Defining and naming themes

The reviewed themes re-named to enhance clarity.

An inductive approach of reasoning used in data analysis because of the exploratory nature of the study design to assist in identifying emerging themes (39).

### **3.10 Pretesting of data collection tools**

Prior to the main fieldwork, the instruments were pretested to five (5) respondents with characteristics of the population. The tools pretested at Ubungo Municipal Council and respondents purposively selected. The Pretesting also assessed estimates time required for each interview and help to modify questions. The Pre-testing of the instruments was

necessary to ensure clarity, suitability and flow of the questions uncovered doubt or ambiguity in questions(40).

### **3.11 Trustworthiness**

In ensuring the quality of the data collected, concerns about the trustworthiness of a research is inevitable. Four criteria were used to assess trustworthiness, they included; credibility, transferability, dependability and Conformability.

Credibility is defined as the confidence or the truth-value that can be placed in the research finding by ensuring the data collected from the research is a representative of the participant(41). In this study, credibility achieved through ensuring that data saturation reached through prolonged engagement.

**Transferability** defined as the extent to which the description provided by the researcher can be applied or understood by the reader in his or her own setting by providing description of the characteristics of the participant and the research process. In this research, information about the sampling procedure and characteristics of the participants have been described succinctly so that the reader can appreciate the significance of the sample selected to the problem of the research.

Dependability ensures there is consistency in data interpretation with the recommended standard of the research design chosen. This achieved through an audit of the findings collected. Conformability ensures that data and interpretations of the findings are not fabrications of the researcher's imagination but clearly derived from the data. This was achieved by proving enough quotations from the participants.

### **3.12 Ethical Consideration**

Ethical clearance to carry out this research was obtained from Muhimbili University of Health and Allied Sciences (MUHAS) Research and Publication Committee under IRB. Whereas permission to conduct the research was sought requested from the head of selected health care centres and secondary schools in Ubungo municipal Dar es Salaam.

Written informed consent obtained from parents, teachers, policymakers and the healthcare providers prior to interview. Participants also consented for their interview to be recorded.

An assent was obtained from adolescent schoolgirls prior to interview. Adolescent schoolgirls also consented for their interview to be recorded. All collected data kept confidential by the principal investigator and no identifiers have been used.

### **3.13 Study Limitation and Mitigation**

The data from in-depth interviews were subject to potential bias from participants. Of concern, was the adolescent population who were uncomfortable giving answers which they deem 'undesirable' because of the nature of the questions that required them to give their views on the parental permission during the consenting process. To address this limitation, the adolescent's girls were guaranteed confidentiality and privacy of any information they provided and the interviews were conducted in a private room where they were comfortable.

Another methodological limitation was the use of the explorative descriptive study design whose generalizability was limited to the specific population chosen. However, the limitation was not significant enough because the results from these studies are potential for other researchers to consider or provide recommendation in light of their study area and the results can help to address the ethical challenges that adolescent girls face when being involved in HPV vaccination.

## CHAPTER FOUR

### 4 RESULTS

#### 4.1 Introduction

Data analysis has generated several themes that respond to the original research objectives. Qualitative data was collected with the aim of exploring ethical challenges surrounding vaccination in Tanzania as the case of human papilloma virus in Ubungo Municipality. Themes were developed according to study specific objectives. The developed themes were decision making in HPV vaccination with subthemes; informed consent among parents of vaccinated girls, informed consent among the vaccinated adolescent school girls, mass vaccination in relation to person's autonomy and insufficient information in HPV vaccination. Second one is , discrimination in HPV vaccination with subthemes; age limitation and HPV vaccination sex and HPV vaccination, and locality and HPV vaccination. Lastly, fairness in HPV Vaccination, with subtheme shortage of vaccine, human rights in relation to HPV vaccination, accessibility of HPV vaccines, and poor follow up during second vaccination.

#### 4.2 Socio-Demographic Characteristics of Study Participants

The section presents a demographic characteristics of the interviewed study participants; parents, adolescent girls, healthcare workers, teachers and policy makers.

**Table 1: Showing characteristics of adolescent schoolgirls, Parents, Teachers, Health Care Policy Makers for In-depth Interviews**

<b>Identifier</b>	<b>Sex</b>	<b>Age</b>	<b>Education</b>
Adolescent 1	Female	14	Form Two
Adolescent 2	Female	15	Form Three
Adolescent 3	Female	15	Form Three
Adolescent 4	Female	15	Form Three
Adolescent 5	Female	16	Form Three
Adolescent 6	Female	15	Form Two
Adolescent 7	Female	15	Form Two
Adolescent 8	Female	17	Form Four
Adolescent 9	Female	17	Form Four
Adolescent 10	Female	16	Form Three
Parent 1	Female	40	Form Four
Parent 2	Female	39	Diploma in Education
Parent 3	Female	42	Bachelor degree in Education
Parent 4	Female	51	Standard seven
Parent 5	Male	40	Form Four
Teacher 1	Male	49	Degree
Teacher 2	Female	39	Master Degree
Teacher 3	Female	45	Degree
Teacher 4	Female	48	Degree
Health Care Worker 1	Female	38	Diploma in Nursing
Health Care Worker 2	Female	32	Diploma in Nursing
Health Care Worker 3	Female	35	Diploma in Nursing
Policy Maker 1	Female	37	Master Degree
Policy Maker 2	Female	40	Degree



**Table 2: Showing summary of developed themes and sub-themes**

<b>Theme</b>	<b>Main Theme</b>	<b>Sub-Theme</b>
#1	Decision making in HPV vaccination	Informed consent among parents of vaccinated girls
		Informed consent among the vaccinated adolescent school girls.
		Mass vaccination in relation to person's autonomy
		Insufficient information in HPV vaccination
#2	Discrimination in HPV vaccination	Age limitation and HPV vaccination
		Sex and HPV vaccination
		Locality and HPV vaccination
#3	Fairness in HPV Vaccination	Shortage of vaccine
		Human rights in relation to HPV vaccination
		Accessibility of HPV vaccines
		Poor follow up during second vaccination

### **4.3 Decision making in HPV vaccination**

Under the theme of decision-making, four subthemes emerged namely: Informed consent among parents of vaccinated girls, Informed consent among the vaccinated adolescent school girls. Mass vaccination in relation to person's autonomy and insufficient information in HPV vaccination

#### **4.3.1 Informed consent among parents of vaccinated girls**

Any medical intervention or procedure should have the clients informed about that procedure; during HPV vaccination the information about the vaccine was compromised.

The following quotes shows this

*“...In vaccination there is no any consent that a child or a parent should fill because it is very clear according to the government laws.” (Policy Maker 1)*

Another participant reacted to the subject matter saying:

*“...the only information I heard is from my daughter that they have already been vaccinated.”(parent 3)*

#### **4.3.2 Informed consent among the vaccinated adolescent schoolgirls**

The findings reveal that adolescent girls cannot consent on their own because they are not yet aged enough to consent. It is important for them to have guardian who decides for them. During the HPV vaccination program in Ubungo Municipality, they relied on the adolescents assent with no parental decision. during the interview, when asked who granted the permission for them to be vaccinated, one of the student said;

*“Yes the teacher is the one who advised us to be vaccinated and convinced us that the vaccination had no side effects and that’s when we got injected” (Student 6)*

Similarly, another to the student, the teacher agreed to the above statement by saying;

*“...it reaches a point that we have to convince the children that the vaccines are beneficial and if they do not vaccinate then it will bring the problem. So, it is to help their health. You know children of nowadays start engaging in sexual activities very early.” (Teacher 4)*

#### **4.3.3 Mass vaccination in relation to person’s autonomy**

According to Tanzania national immunization schedule HPV vaccination is mandatory to the targeted group but the question is should the program transgress or waive the informed

consent while it is not an emergence. The following quotes show the claims over the informed consent in respect to vaccination program as given below:

*“We did not make decision because that day she came with a card showing she was already vaccinated and we were not involved at all” (Parent 1)*

*“...the child just came back already vaccinated. ... I could not tell her to not go for vaccination.”(Parent 3)*

#### **4.3.4 Insufficient information in HPV vaccination**

Among the parents interviewed pinpointed clearly that they have to receive comprehensive information about the vaccine especially when they are to make decision on behalf of their kids in as far as HPV vaccination is concerned. One of the participants could not hide it all and said that:

*“No I have not yet gotten the information about the vaccine program ....the local government offices have so many people in the office who would help to pass the information to the parents and children.” (Parent 4)*

Another respondent reacted on the same subject matter with the following given illustrative quote:

*“The only information I got about the vaccination is just from hearing people talk about a vaccine on cervical cancer but I never got any official information.” (Parent 2)*

Another respondent on the same issue claimed that:

*“... if you get vaccinated you can lose your life ... the most important thing is the fear of becoming infertile.” (Parent 5)*

#### **4.4 Discrimination in HPV vaccination**

During vaccination, there were adolescent girls who were given the vaccine and others who were not given the vaccine. During this study this yield to ethical issues such as discrimination based to age limit and HPV vaccination, locality and HPV and sex and HPV vaccination.

#### 4.4.1 Age limit and HPV vaccination

During HPV vaccination they planned the vaccine to be given to adolescent school girls aged 14 years only while other who were eligible for the vaccination program were left out.

This is substantiated by the following illustrative quotes:

*“...They only considered the age...14 and 15 years my daughter told me.”*  
(Parent 3)

Another respondent said:

*“...adolescent girls aged 9 to 14 years were the ones we gave the vaccine.”*  
(Policy maker 2)

#### 4.4.2 Locality and HPV vaccination

During the vaccination program locality as placement of the targeted population was used as criterion in allocating the vaccine to those who were vaccinated. The following key informants' quotes clarify this:

*“...We used the criteria of considering schools with many students and that was recommended by the District Immunization and Vaccine officer”*  
(Health Care Worker 1)

On responding to similar question, the participant said:

*“...The only children who were given vaccine were only children who were in school. So the people administering the vaccines never provided it in our homes for adolescent girls who are out of the school.”*(Parent 3)

Also the following respondent responded to it as shown below:

*“...for example in Tanzania, the pilot study area was Kilimanjaro region where it was chosen because of the large number of children that go to school, so it did help us to a large percent to get the specific group of children who go to school ”* (Policy Maker 2)

#### 4.4.3 Sex and HPV vaccination

The vaccination program in Tanzania was targeted for adolescent schoolgirls who presumed not yet been engaged with sexual affairs. Nevertheless, the program did not include boys as the targeted group like girls regardless of being at equal chance of being affected. The following quotes illustrate the claim:

*“...there is something that does not add up....If the vaccine is given to the girls what about the boys. Does it mean they cannot get the cancer? And why does it consider girls who have not yet engaged in sexual affairs?”(Parent 3)*

Another respondent reacted to the same matter saying:

*“...it is difficult to give the vaccine to the boys because we have global shortage of the vaccine ... insufficient fund to invest in the vaccine as a country.” (Police maker 2)*

#### **4.5 Fairness in HPV vaccination**

Fair allocation of the vaccine during the program of HPV vaccination was inevitable; but during the study, it was shown to be contrary as portrayed under the sub-themes below:

##### **4.5.1 Shortage of vaccine**

During the study, the informants had their claims concerning with the subject matter as substantiated by the quotes below:

*“...we got an age criteria of 9 to 14 years during pilot study, but when we started rolling out the vaccine to the whole country, the eligibility criteria was just 14 years due to the shortage of vaccine.”(Policy Maker 2)*

Another respondent responded that:

*“...reason for providing for only this group is because there is shortage of the HPV vaccine in the world market because every country has started improving their production so the production reduces.” (Policy Maker 1)*

##### **4.5.2 Poor follow up during second vaccination**

HPV vaccination was two doses for HIV negative and three doses to HIV positive clients. After the adolescent school girls had gotten the first dose they were to get the second one or second and third so as to complete the dosage. The follow up for the second vaccination was very poor and sometimes could not be done at all. The following key informants' under quotes illustrate that

*“...most students were not given the second dose of the vaccination after transferring to different schools especially when they were done with their standard seven education...some travelled to other regions and others did not pass their standard seven hence they remained home.” (Health Care Worker 3)*

*“...poor empowerment of the facilitators during vaccination both financial and education...they don't make follow up since they are not paid and have no enough education on the program.”(Teacher 1).*

#### **4.5.3 Accessibility of HPV Vaccines**

During the program there were adolescent girls who were eligible for vaccination according to guideline but they could not get vaccinated due to age criteria of the targeted group. The following key informants substantiated this in the following quotes:

*“... all children who were eligible could not access the vaccine... they followed the age criteria and economic constrains that is why those who are out of school could not get the vaccine.” (Parent 2)*

On the same matter, another informant said:

*“...the accessibility to street children and other adolescent school girls in the peripheral was hard.” (Policy maker 2)*

#### **4.5.4 Human Rights in relation to HPV Vaccination**

Every adolescent girl had a right to be vaccinated if she is eligible no matter she is out of school or within the school. During HPV vaccination program some disparities emerged whereby priority was given to school girls of a certain age. The following key informants' quotes substantiate this:

*“... it was not all adolescent girls had engaged into sexual affairs...others were very genuine but aged 15, 16 and 17 yet they were denied their right to get the vaccine.” (Teacher 2)*

*“... the government limited with that age...but referring to the human rights and rights of children even those with 16, 17 and even 18 if had met the criteria were to be vaccinated.”(Health care worker 1)*

## CHAPTER FIVE

### 5 DISCUSSION

#### 5.1 Discussion

This chapter will interpret my study findings and contextualize the contribution of my findings to what other studies have shown from the literature review. The discussion focused to the developed themes from the findings. Themes developed include decision making in HPV vaccination; discrimination in HPV vaccination; and fairness in HPV Vaccination, with subtheme shortage of vaccine, human rights in relation to HPV vaccination, accessibility of HPV vaccines, and poor follow up during second vaccination.

##### 5.1.1 Decision Making Process during HPV Vaccination

Under this main theme, the following subthemes are detailed discussed: informed consent among parents of vaccinated girls; informed consent among the vaccinated adolescent school girls; mass vaccination in relation to person's autonomy; and insufficient information in HPV vaccination.

##### 5.1.1.1 Informed Consent among Parents of Vaccinated School Girls

Decision-making young individuals to undergo medical care need agreement from the parents or legal guardians. However, most studies on HPV school-based vaccination programs, shows that, ethical issues of informed consent are violated as the vaccination is administered without the presence of parents or legal guardians(15)(20). These findings are in line with this study, which found that Parents were poorly involved in decision-making. Thus, in this study, parents showed the concerns that, the ultimate decision to vaccinate or not to vaccinate their children should be taken by their parents to ensure parental autonomy.

Excluding parents in medical care such as Vaccination program is considered unethical since HPV vaccine is that sensitive enough to the extent of not exempting parental consent and adolescent accent(4).



In addition, it should not be waived as parental consent where children who were sent to the vaccination session were assumed to have gotten parental consent. There was the assumption that parents or guardians were informed about imminent vaccination through social mobilization and communication which is not valid(20).

#### **5.1.1.2 Informed Consent among Vaccinated School Girls**

Exploration of the ethical issues of consenting process during the administration of HPV vaccine among the adolescent girls, found that the adolescents self-consent was insufficient and cannot be ethically justifiable(25). And also, it cannot be ethically justified for health-care workers to waiver the parental consent who is the legal guardian of the adolescent (25).

Although, parents and legal guardians such as Schoolteachers have a legal authority to decide for their children but this found that Children need to be sufficiently informed so as they can give their assents. These findings are similar to other studies conducted in various places which found that Children need to provide their assents. For example, by WHO directives, parental consent is required, but health workers should allow older children and adolescents to provide assent to the vaccination(5).

#### **5.1.1.3 Mass Vaccination in relation to Person' autonomy**

Vaccinations with public interest especially among children are enclosed with unethical issues as when decision-making is required. Like in other study(29), that was done in Tanzania which found that, during HPV vaccination program there was lack of community engagement and which give little chance to decision making(28).With these findings, show that Parents, schools teachers and school girls were not well engaged to decide whether to take HPV vaccine or not as a requirement for respecting persons' autonomy. The findings in my study are also correlate with the results from the studies conducted in Southern Italy, which found that there was inadequate information to parents about infant vaccination (21)(22). Similarly in Sweden, the polio vaccination campaigns had information which were not well communicated to the public and some information from public(23). With this regards, the vaccination programs need to ensure community is presented with complete information to allow persons' autonomy to public services.

#### **5.1.1.4 Insufficient information on HPV Vaccination**

The findings of this study revealed that there was insufficient information on HPV Vaccination to adolescent girls and their parents from the concerned stakeholders about the program. Key participants reported that, if someone does not really know what the program entails and its risks and benefits, it is when they fear to accept the HPV program believing that it may cause death and infertility since they rely on speculation. Similar studies proposed that lack of comprehensive information decreases the degrees of vaccine acceptance. For example, studies in Southern Italy, have found that there is inadequate information to parents about infant vaccination (21)(22). Similarly in Sweden, the polio vaccination campaigns had information which were not well communicated to the public and some information from public(23). As a result, in Sweden, polio vaccination was highly objected by the public and the public lost trust in the vaccinations as a result of the adverse effects resulting from polio vaccination. Likewise, during the H1N1, vaccination conducted in Sweden in 2009, researchers reported that vaccine is safe and accurate. However, a group of adolescents developed narcolepsy as a side effect which the provider of the vaccine did not communicate to the adolescents(23)(24).

However, many of the interviewed healthcare workers and teachers tried to express how lack of understanding of the concept affects the implementation of HPV vaccine program. Although to-date there are vaccines available to protect against at least 20 diseases, including diphtheria, tetanus, pertussis, polio, influenza and measles(8). These vaccines have been shown to save lives of up to three million people every year(8). Therefore whenever there is a vaccination program all stakeholders require comprehensive information to avoid the mentioned ethical challenges.

#### **5.1.2 Discrimination in HPV Vaccination**

Discrimination in HPV vaccination as a main theme is further divided into subthemes; age limitation and HPV vaccination; sex and HPV vaccination; and locality and HPV vaccination.

### **5.1.2.1 Age Limitation and HPV Vaccination**

The finding shows that vaccination was discriminatory to some extent due to age limit set by the government that adolescent school girls with age 14 was vaccinated and those below and above the age limit (16,17,18) but sharing the same environment though may be eligible for vaccination was left out. Similarly the study conducted in South Africa proposed that, HPV vaccination would involve women who had not been affected by HPV and not to adolescent only (29). This means there is need of screening before vaccination of both, girls and women because the HPV vaccination is not effective to a person who has been affected by HPV (29). Some girls had

acquired HPV in their lower age which made the vaccination to be helpless to them(29).Likewise in Singapore, HPV vaccination left out-of-school young girls who were exposed to higher risks of being affected by HPV (3). HPV vaccination conducted in Singapore was discriminatory which led to segregation and stigmatization to those who were not vaccinated (3).

### **5.1.2.2 Sex and HPV Vaccination**

The findings of this study show the concerns of involving both male and female in provision of HPV vaccination. But, the implemented program as per this study concur with the study conducted in Canada, that showed there was HPV vaccination for adolescent school girls only(32).

The act of neglecting boys during HPV vaccination was interpreted as discrimination of boys since the findings from the research found that men and women were equally affected by HPV which led to different types of cancer(30). Although, the study conducted in South Africa which proposed that, HPV vaccination would involve women who had not been affected by HPV and not to adolescent girls only (29). However, such findings differ from this study where girls were vaccinated without screening. This means there is need of screening before vaccination of both, however, the girls and women or boys and men because the HPV vaccination is not effective to a person who has been affected by HPV where its impacts is for both sex(29). Therefore, vaccinating adolescent girls only does not predict the HPV free generation.

### **5.1.2.3 Locality and HPV Vaccination**

The finding revealed that schools with many students were given priority especially in towns compared to rural areas where coverage is low this finding concur with HPV vaccination in Singapore which left out-of-school young girls who were exposed to higher risks of being affected by HPV (3). HPV vaccination conducted in Singapore was discriminatory which led to segregation and stigmatization to those who were not vaccinated (3). Similarly, the current HPV Vaccination Program is based to secondary school girls of age of 14 only and this program is mandatory for the targeted group since it's a part of national immunization schedule of the United Republic of Tanzania of 2018. This currently implemented program by the Government of Tanzania is mostly delivered as vertical programs. Moreover, the coverage of the programs is limited to particular areas due to limited financial and human resources, logistic constraints, and limited community engagement (42). The dispersed groups of out-of-school girls of the same age, or those in the street or prisons are left out. This in turn, raises the ethical challenge of discrimination and justice among this group

### **5.1.3 Fairness in HPV vaccination**

Fairness in HPV Vaccination as a main theme under this study categorized into four subthemes as following: shortage of HPV vaccine; human rights in relation to HPV vaccination; accessibility of HPV vaccines; and poor follow up during second vaccination.

#### **5.1.3.1 Shortage of HPV vaccine**

The study findings **show** that justice was not adhered in these vaccination campaigns by leaving these vulnerable groups out. Likewise, in a study conducted by WHO in Jordan, more than 60% of the children who were eligible for vaccination missed the opportunity for vaccination because of their geographical location and their financial status(24). This reveals that, in Jordan there was injustice in vaccination program just because omitting girls, just because of their geographical location or financial status. Furthermore limitation in finances, human resource, logistic constraints and lack of community engagement may promote segregation of out of school adolescent girls(42). Furthermore the role of justice is to specify social and economic conditions that determine whether certain inequalities should be seen as unfair(7). This means that if there is inequality in medical intervention, it

has to be justified with valid ethical reasoning. Likewise, the currently implemented program by the Government of Tanzania is mostly delivered as vertical programs. Moreover, the coverage of the programs is limited to particular areas due to limited financial and human resources, logistic constraints, and limited community engagement (42)

### **5.1.3.2 Human Right in relation to HPV vaccines distribution**

The findings from this study show that not all eligible adolescent girls with criteria received HPV vaccination. Based on human rights, people of similar characteristics should be treated equally (38). All adolescent girls regardless of their circumstances has the rights to get vaccinated, though their out of the targeted group but still they are innocent.

HPV Vaccination Program conducted at Ubungo municipality was based to secondary school girls of age of 14 only and the program did not consider the autonomy of school girls of whether to accept or deny the HPV vaccine service. As per participants responses, participation was revealed as mandatory for the targeted group since it's a part of national immunization schedule of the United Republic of Tanzania of 2018.

The study also shows similar information that. the coverage of the programs is limited to particular areas due to limited financial and human resources, logistic constraints, and limited community engagement (42). The out-of-school girl groups of the same age, or those in the street or prisons were left out. Therefore, it can be said that excluding some groups from the service because of their age, location or due budget constrains is a kind of violating their rights.

### **5.1.3.3 Accessibility of HPV Vaccines**

This vaccination was conducted in the basses of equality in which all girls had equal chance for vaccination regardless of levels of risks(14) However, the current HPV Vaccination Program is based to secondary school girls of age of 14 only and this program is mandatory for the targeted group since it's a part of national immunization schedule of the United Republic of Tanzania of 2018.This currently implemented program by the Government of Tanzania is mostly delivered as vertical programs. Moreover, the coverage

of the programs is limited to particular areas due to limited financial and human resources, logistic constraints, and limited community engagement (42). Similarly study done in USA also revealed that in vaccination programs there is often injustice as adolescent who were in juvenile justice facilities are often not considered(34). These included those in detention camps who have higher risks of being affected by HPV than those who are in normal life(34). Hence, this denial of access to vaccination is explicitly a form of injustice. WHO report on vaccination programs in Africa indicates that in most African countries, vaccination uptake is higher rate among children living in towns than those living in rural areas(3)(35).

#### **5.1.3.4 Poor follow up during second vaccination**

The findings of this study revealed that, Poor follow up during second vaccination. Some of the interviewed health care workers and teachers expressed the main challenge was most of the students were not given the second dose of the vaccination. The reason behind was due to the challenge of transferring to different schools especially when they are done with their standard seven education since currently implemented program by the Government of Tanzania is mostly delivered as vertical programs. Moreover, the coverage of the programs is limited to particular areas due to limited financial and human resources, logistic constraints, and limited community engagement (42) Similarly, other studies on national school-based HPV vaccination programs conducted in Singapore and Nigeria were highly associated with violation of ethical principles, such as autonomy, social justice and equity, and gender equality. Basically, these HPV school-based programs were found, among other effects, to create potential stigma among students from lower income families(3)(19).

## CHAPTER SIX

### 6 CONCLUSION AND RECOMMENDATION

#### 6.1 Conclusion

The findings from this study conclude that, during the HPV vaccination program as public program for specified age group without considering their environments and counterpart groups compromises the justice to the population of concerned.

In addition, the study found irregularities in decision-making process where parents had no chance to consent for their children. There were insufficient information to schoolgirls and parents which lead to mistrust of the HPV Vaccination program to the community.

#### 6.2 Recommendations

- Ubungo Municipal government should review their intervention strategies for providing the HPV vaccine to ensure there is equity in provision of Vaccination program in adolescent girls.
- Parents should be well involved and given chance to offer informed consent about the HPV vaccination program for their children.
- Policy makers should be knowledgeable about the ethical issues when implementing public health intervention to reduce ethical challenges and dilemmas among the community members.
- Furthermore, Ubungo Municipal government should ensure community involvement through mass communication and education promotion to create awareness about the HPV vaccination program to minimize fear and misconception.

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## **APPENDICES**

### **Appendix I: Interview Guide for Teachers and Nurses**

#### **Informed Consent process**

1. How much do you know about HPV Vaccine?

Probe: how were you involved in HPV vaccine?

Probe: how did you perceive the program?

2. How did you receive the information about HPV vaccine program before?

Probe for type of information

-To probe for any perception of fear, attitude/religious beliefs about the program.-Were there chances for student to withdraw or refuse the service? If yes/no how was the procedure? What do you think are the consequences of refusing taking HPV vaccine?

-If you have child, would you consent for the HPV Vaccine? Why or why not?

#### **Discrimination associated with HPV**

3. How was the vaccine given to the adolescents within the selected schools?

-Which criteria were used in selecting the adolescents and schools that were involved in the vaccination program?

Probe: was it accessible to everyone? How about schools that are in the peripheral were they considered in the vaccination program?

Probe: How did you consider the age while giving the vaccine? Was everyone given without discriminating those who had above the age limit you selected and had all the criteria for receiving the vaccine?

-How about those who were not in school during the vaccination? Was the vaccine targeting a certain group of girls in the community while leaving others? How and why?

-How do you think others in your community feel about HPV vaccine? Probe for any kind of discrimination associated with HPV vaccine?

**Justice in HPV vaccination**

4. How justice was exercised during HPV vaccine program? Do you have any idea about the program?

Probe for a justice distribution among adolescent girls in Dar Es Salaam Schools

Also probe on re-consultation services

5. What do you think to be the right way of exercising HPV vaccine program among adolescent girls in Dar Es Salaam?

6. If it was just why were adolescent boys not enrolled into the vaccination program?

Thank you for your participation

**Kiambatisho Namba II: Mwongozo wa Mahojiano kwa Walimu na Wauguzi**  
**Ridhaa**

1. Unajua nini kuhusu chanjo ya virus vya papiloma?

-Ulihusishwaje kwenye hiyo chanjo?

-Unaichukuliaje huo mchakato wa chanjo?

2. Ulipokeaje taarifa kuhusu chanjo ya virusi vya papiloma?

-Uliza kuhusu taarifa alizopata

-uliza kuhusu hofu yeyote kuhusu chanjo hiyo, Labda kwa upande wa imani za kidini au kitamaduni?

-Kulikuwa na uwezekano wa wanafunzi kujiondoa katika ushiriki au kukataa kabisa kushiriki? Kama ndio au hapana utaratibu ulikuwaje? -

uliza pia: Unafikiri kuna matokeo gani ya kukataa au kushiriki katika chanjo hiyo? Kama una watoto, ungetoa ridhaa ya wao kushiriki katika chanjo hiyo? Kwa nini ndio au hapana?

**Ubaguzi unaohusihwa na chanjo ya HPV**

3. Chanjo ilitolewaje kwa wasichana katika shule hizo zilizokuwa zimechaguliwa?

-Ni vigezo gani mlivyotumia katika kuchagua shule hizo pamoja na wasichana waliopewa chanjo hiyo?

-Ilikuwa inapatikana kwa wote? Vipi kuhusu shule zilizopo pembezoni mlizipa nazo kipaumbele katika chanjo hii?

-Mlichukuliaje kigezo cha umri wakati wa utoaji chanjo? Kila mtu alipewa bila kuwabagua wale waliokuwa na vigezo vya kupewa chanjo ila umri wao ulikuwa tofauti na ule uliokuwa umepangwa?

-Je, vipi kuhusu wale ambao hawakuwepo shuleni wakati wa utoaji chanjo? Chanjo hii iliwalenga wasichana wa kundi Fulani tu katika jamii ikiwaacha wengine? Kivipi na kwa nini?

-Unafikiri wengine katika jamii wana hisia gani juu ya chanjo hii? Hawaoni kama inafanyika kibaguzi?

**Usawa katika chanjo ya HPV**

5. Usawa ulifanyikaje wakati wa utoaji chanjo? Una uelewa wowote juu ya hili?

-Iitolewa kwa usawa miongoni mwa wasichana waliokwisha balehe katika shule za sekondari mkoani Dar es Salaam?

6.Ni nini ambacho unafikiri kitakuwa njia sahihi ya ufanyaji wa zoezi la utoaji chanjo miongoni mwa wasichana waliokwisha balehe kwa Dar es Salaam?

-Kama ilikuwa na usawa kwa nini wavulana barubaru nao hawakuhusishwa kwenye chanjo?

**Ahsante kwa ushiriki wako**

## **Appendix III: Interview Guide for Parents**

### **Informed Consent process**

1. How much do you know about HPV Vaccine?

Probe: were you involved in HPV vaccine?

Probe: When your children were vaccinated who decided? How was the decision made?

Were you and your children given a chance to make decision?

2. How did you receive the information about HPV vaccine program? What information was provided to you before HPV vaccination?

-To probe for any perception on fear, attitude/religious beliefs about the program.--Were you willing to allow your child to participate in HPV vaccine? How were you involved to decide on your child participating in HPV vaccine? Were there chances to withdraw or refuse the service? If yes/no how was the procedure??

### **Discrimination associated with HPV**

3. How did you see the vaccination program?

Probe: Do you think it was discriminatory? How?

What things concern or worry you or make you less willing about your child get having HPV vaccine? -To probe if they can mention them... -If necessary, to probe also for potential concerns: fear, potential for future discrimination, insecurity, no benefit, no information

4. How do you think others in your community feel about HPV vaccine? Probe for any kind of discrimination associated with HPV vaccine?

### **Justice in HPV vaccination**

5. How justice was exercised during HPV vaccine program? Do you have any idea about the program?

Probe for a justice distribution among adolescent girls in Dar Es Salaam Schools

Also probe on re-consultation services

6. How do you think is the right way of exercising HPV vaccine program among adolescent girls in Dar Es Salaam?

-How do you concerned about the age limit for HPV vaccine?



Thank you for your participation

### **Kiambatisho Namba IV: Mwongozo wa Mahojiano kwa Wazazi**

#### **Ridhaa**

1. Ni kwa kiasi gani unauielewa kuhusu chanjo ya virusi vya Papiloma?

-Ulihusishwa katika huo mchakato wa chanjo?

-Pale watoto wako au motto wako alipopewa chanjo ni nani aliyefanya maamuzi? Maamuzi yalifanyikaje?

-Wewe na

mwanao mlipewa nafasi ya kufanya maamuzi?

2. Ulipataje taarifa kuhusu chanjo ya virusi vya papilloma? Ni taarifa gani zilizotolewa kwako kabla ya chanjo kutolewa kwa binti yako?

-Kuna hofu yeyote, imani za kidini au tabia vinavyohusiana na chanjo hiyo?

-Uliridhia mwenyewe kwamba mwanao ashiriki kwenye chanjo? Ulihusishwaje kwenye kufanya maamuzi juu ya ushiriki wa mwanao katika chanjo hiyo? Kulikuwepo na uwezekano wa kujitoa au kukataa kushiriki katika chanjo hiyo? Kama ndio au hapana mchakato mzima ulikuwaje?

#### **Ubaguzi unaohusiana na chanjo ya HPV**

3. Uliuonaje mchakato mzima wa chanjo?

-Unafikiri ilikuwa ya kibaguzi? Kiaje?

4. Ni hofu gani iliyokufanya usitamani mwanao apewe chanjo? Unaweza kuzitaja? Labda ni hofu ya kubaguliwa baadae? Kukosekana kwa usalama? Kutokuwa na faida?

-Unafikiri wengine kwenye jamii wana hisia gani kuhusu chanjo hiyo? Kuna aina yeyote ya kubaguliwa inayohusiana na chanjo hiyo?

#### **Usawa katika chanjo ya HPV**

5. Haki ilitendekaje wakati wa zoezi la utoaji wa chanjo? Una wazo lolote kuhusu hili?

-Vipi kuhusu usawa katika utoaji wa chanjo miongoni mwa wasichana wa shule?

6. Unafikiri njia sahihi ya kutoa chanjo ya HPV kwa wasichana waliokwisha balehe kwa shule za Dar es Salaam?

-Unalionaje la ukomo wa umri katika utoaji wa chanjo?

-Kuna lolote ambalo hatujalijadili ambalo ungependa kutuambia au unalohisi tunapaswa kulijua?

**Ahsante kwa ushiriki wako**

## **Appendix V: Interview Guide for School girls**

### **Informed Consent process**

1. How did you receive information about HPV vaccine?

Probe for kind of information

-To probe for any perception on fear, attitude/religious beliefs about the program.

2. Were you willing to participate in HPV vaccine? How were you involved to decide on participating in HPV vaccine?

-Who decided for you?

-Were your parents involved in decision?

-Were there chances to withdraw or refuse the service? If yes/no how was the procedure.

-What do you think are the consequences of refusing taking HPV vaccine?

3. If you were given chance to make decision, would you agree for the HPV Vaccine? Why or why not?

### **Discrimination associated with HPV**

6 What do you think are risks of receiving HPV vaccine?

Probe for any complications

7 How do you think others in your school feel about HPV vaccine?

Probe for any kind of discrimination associated with HPV vaccine?

### **Justice in HPV vaccination**

8 Was HPV vaccine program fair?

Probe for distribution among adolescent girls within the School

Probe for compensation for adverse effect if any

### **Thank you for your participation**

## **Kiambatisho Namba VI: Mwongozo wa Mahojiano kwa Wanafunzi**

### **Ridhaa**

1. ulipokeaje taarifa kuhusu chanjo ya HPV?

-uliza aina juu ya taarifa alizopewa

- uliza kuhusu mtazamo juu ya hofu, dini yako au tabia katika mchakato mzima wa chanjo?

2. Uliridhia mwenyewe kushiriki kwenye chanjo ya virusi vya papilloma?

Uliza pia: Ulihusishwaje kwenye kufanya maamuzi juu ya uushiriki wako?

Ni nani aliyeamua kwa ajili yako? Wazazi wako walihusishwa?

Ulikuwa na nafasi ya kutokushiriki au kukataa kushiriki? Kama ndio ilifanyikaje?

3. Ulizi pia kama Unahisi kuna madhara yeyote yakukubali/kukataa kushiriki katika chanjo hiyo?

Kama ungepewa nafasi ya kufanya maamuzi, je, ungekubaliana na chanjo ya HPV? Kwa nini ungekubali au ungekataa?

### **Ubaguzi unaohusiana na chanjo ya HPV**

4. unafikiri kuna madhara ya kupata chanjo ya HPV?

-ulizia kama kuna changamote zozote

5. Unafikiri wengine shuleni kwako wana hisia gani kuhusu chanjo ya HPV?

-uliza kama kuna aina yeyote ya ubaguzi wowote unaohusiana na kupata chanjo ya HPV?

### **Usawa katika chanjo ya HPV**

6. Unafikiri kulikuwa na Usawa katika mpango huu wa chanjo ya HPV?

-Uliza kuhusu mgawanyo au utoaji wa chanjo kwa wasichana ndani ya shule

Uliza kama kulikuwa mpango wa fidia kwa madhara

**Asante kwa ushiriki wako**

## **Appendix VIII: Interview Guide for Policy Makers**

### **Discrimination associated with HPV**

1. How was the vaccine given to the adolescents within the selected schools?
2. Which criteria were used in selecting the adolescents and schools that were involved in the vaccination program?

Probe: was it accessible to everyone? How about schools that are in the peripheral were they considered in the vaccination program?

Probe: How did you consider the age while giving the vaccine? Was everyone given without discriminating those who had above the age limit you selected and had all the criteria for receiving the vaccine?

3. How about those who were not in school during the vaccination? Was the vaccine targeting a certain group of girls in the community while leaving others? How and why?
4. How do you think others in your community feel about HPV vaccine? Probe for any kind of discrimination associated with HPV vaccine?

### **Justice in HPV vaccination**

5. How justice was exercised during HPV vaccine program? Do you have any idea about the program?

Probe for a justice distribution among adolescent girls in Dar Es Salaam Schools

Also probe on re-consultation services

6. What do you think to be the right way of exercising HPV vaccine program among adolescent girls in Dar Es Salaam?
7. If it was just why were adolescent boys not enrolled into the vaccination program?

**Thank you for your participation**

**Kiambatisho Namba IX: Mwongozo wa Mahojiano kwa Watunga Sera**

**Ubaguzi unaohusiana na chanjo ya HPV**

1. Uliuonaje mchakato mzima wa chanjo?

-Unafikiri ilikuwa ya kibaguzi? Kiaje?

2.Ni hofu gani iliyokufanya usitamani mwanao apewe chanjo? Unaweza kuzitaja? Labda ni hofu ya kubaguliwa baadae? Kukosekana kwa usalama? Kutokuwa na faida?

3.Unafikiri wengine kwenye jamii wana hisia gani kuhusu chanjo hiyo? Kuna aina yeyote ya kubaguliwa inayohusiana na chanjo hiyo?

**Usawa katika chanjo ya HPV**

4.Haki ilitendekaje wakati wa zoezi la utoaji wa chanjo? Una wazo lolote kuhusu hili?

-Vipi kuhusu usawa katika utoaji wa chanjo miongoni mwa wasichana wa shule?

5.Unafikiri njia sahihi ya kutoa chanjo ya HPV kwa wasichana waliokwisha balehe kwa shule za Dar es Salaam?

6.Unalionaje la ukomo wa umri katika utoaji wa chanjo?

7.Kuna lolote ambalo hatujalijadili ambalo ungependa kutuambia au unalohisi tunapaswa kulijua?

**Ahsante kwa ushiriki wako**

**Appendix X: Informed Consent Form for In-Depth Interview (IDIs) – English version**  
 MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED HEALTH SCIENCES



INFORMED CONSENT FORM

DIRECTORATE OF RESEARCH AND PUBLICATIONS

ID-NO.....

**Consent to Participate in a Study:** Greetings! My name is VERONICA SISTY, a Masters Student at Muhimbili University of health and allied sciences (MUHAS). I am working on a research with the objective of exploring your views on the “Ethical challenges surrounding HPV vaccination of adolescent girls in Dar es salaam, Tanzania”

**Purpose of the study:** Informed consent provides you with detailed information about the research study so that you can make a voluntary choice to participate in the study after understanding all the details in the study. The purpose of this research is to explore your views /and the views of your child on the ethical challenges surrounding HPV vaccination among adolescent girls in Dar es salaam, Tanzania.

**What Participation Involves:** This research will involve your participation in an in-depth interview where you will be audio-recorded and the interview will take about 30 to 45 minutes.

**Confidentiality:** Confidentiality is guaranteed by ensuring that the information you will provide in this study is not shared to any unauthorized third party but will be kept private. Any information about you will have a number instead of your name and only the researcher is the only one who will know what your number is.

**Risks:**We do not have any anticipated risks in this study but in case you may be asked some personal or private information by chance, or that you may feel uncomfortable talking about during the interview you are free not to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you feel uncomfortable.

**Right to withdraw from the study and Alternatives:**Your participation in this research is purely voluntary and you are guaranteed the right to withdraw from the research without any threat of loss of any benefit that you are entitled to obtain from the research and that the discontinuation from the study will not involve any form of penalty.

**Benefits:**There will be no direct benefit to you, but your participation will help us to find out more about your views on how HPV vaccination of adolescent girls has presented as an ethical challenge in Dar es salaam, Tanzania so that we can prepare a guideline that will help address those challenges.

**Who to Contact**

If you ever have questions about this study, you should contact the study Principal Investigator, **VERONICA SISTY, 0784-664288**; Muhimbili University of Health and Allied Sciences (MUHAS), reg no. HD/MUH/T.526/2019, P.O. Box 65001, Dar es Salaam. Dr Renatha Joseph, Head, Bioethics Department(MUHAS) mobile no. 0759-935-505).Also you may contact the Chairperson of the Research and Publications Committee, MUHAS, P.O. Box 65001, Dar – Es- Salaam -Tanzania, Tel +2552150302-6.

Signature:

Do you agree?

Participant agrees ..... Participant does NOT agree.....

I ..... have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant .....

Signature of PI or designee.....

Date of signed consent .....



**Appendix XI: Fomu ya ridhaa****CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI****KURUGENZI YA TAFITI NA MACHAPISHO**

NA.....

Ridhaa ya kushiriki katika tafiti: Salaam! Naitwa VERONICA SISTY ambaye ni mwanafunzi wa chuo kikuu cha tiba na sayansi shirikishi (MUHAS). Nafanyia utafiti tafiti yenye lengo la kupata maoni yako kuhusiana na changamoto za kimaadili na kivitendo za kupata ukubali na ruhusa ya mzazi wakati wa kutoa chanjo ya kuzuia saratani ya shingo ya kizazi kwa wasichana wa rika la balehe Tanzania

**Madhumuni ya Utafiti:**Fomu ya ridhaa hukupatia wewe taarifa toshelezi kuhusu tafiti ili kuweza kufanya uchaguzi wa hiari kushiriki katika tafiti baada ya kuelewa vipengele vyote katika tafiti.Dhumuni la tafiti hii ni kutathimini maoni yako / na maoni ya mtoto wako katika namna ambavyo changamoto za kimaadili zinavyojitokeza katika utoaji wa chanjo ya kuzuia saratani ya shingo ya kizazi kwa vijana wadogo wa kike katika mkoa wa Dar es salaam.

**Ushiriki:** Tafiti hii itahusisha ushiriki wako katika mahojiano ya kina ambapo utarekodiwa na mahojiano yatachukua kadri dakika 30 mpaka 45.

**Usiri:** Usiri umezingatiwa kwa kuhakikisha kuwa taarifa utakazozitoa katika tafiti hii hazitolewi kwa mtu yeyote yule asiyehusika lakini zitatunzwa kama taarifa binafsi. Taarifa yoyote ile kukuhusu wewe itakuwa na namba baadala ya jina lako na mtafiti pekee ndiye pekee ambaye atajua namba yako.

**Madhara:**Hakuna madhara yoyote ambayo tunayategemea katika tafiti hii lakini iwapo unaweza kuulizwa taarifa binafsi kwa bahati mbaya, au kwamba unaweza usijisikie kuongea wakati wa mahojiano uko huru kutokujibu swali lolote lile au kuhusika katika mahojiano kama utaona kwamba swali au maswali ni binafsi zaidi au kuyaongelea itakufanya usijisikie vizuri.

**Haki ya kujitoa kushiriki katika tafiti na mbadala:** Ushiriki wako katika tafiti hii ni wa hiari kabisa na umehakikishiwa haki ya kujitoa kushiriki katika tafiti bila kitisho chochote kile cha upotevu wa faida yoyote ile ambayo unastahili kuipata kutoka katika tafiti na kwako kujitoa katika tafiti hakutakuwa na aina yoyote ile ya adhabu.

**Faida:**Hakutakuwa na faida za moja kwa moja kwako, lakini ushiriki wako utatusaidia sisi katika kutafiti zaidi kuhusu maoni yenyu kwa namna gani utoaji wa chanjo kuzuia saratani shingo ya kizazi kwa vijana wadogo wa kike imezingatia kanuni na taratibu za kimaadili katika utoaji wa chanjo ili tuweze kufanya maboresho katika utoaji wa chanjo siku za usoni.

**Mtu wa kuwasiliana nae:**Ikiwa una maswali yoyote kuhusu tafiti hii, wasiliana na Mtafiti mkuu, **VERONICA SISTY 0784-664288**; Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, na.ya usajili HD/MUH/T.526/2019,S.L.P 65001, Dar es Salaam. Pia unaweza wasiliana na Mwenyekiti Kamati ya Tafiti na Machapisho (MUHAS),S.L.P 65001 Dar Es Salaam (Simu. na. +2552150302-6).

Saini:

Unakubali?

Mshiriki anakubali ..... Mshiriki hakubali.....

Mimi ..... nimesoma na kuelewa yaliyomo katika fomuu hii. Maswali yangu yamejibiwa. Nakubali kushiriki katika tafiti hii.

Saini ya mshiriki .....

Saini ya Mtafiti mkuu au mteule wake.....

Tarehe ya kusaini ridhaa .....

IDI Na.....

Mahali pa mahojiano .....

Namba Mahojiano .....

Tarehe.....

Muda wa kuanza .....

Muda wa kumalizia .....

**Tarifa za Mshiriki**

Jinsia .....

Umri .....

Elimu .....

Dini .....

**Appendix XII: Assent Form for Focus Group Discussion (FGD) - English Version**  
**MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED HEALTH SCIENCES**



**ASSENT FORM**

**DIRECTORATE OF RESEARCH AND PUBLICATIONS**

ID-NO.....

**Consent to Participate in a Study:**Greetings! My name is VERONICA SISTY, a Masters Student at Muhimbili university of health and allied sciences (MUHAS). I am working on a research with the objective of exploring your views on the “Ethical challenges surrounding HPV vaccination of adolescent girls in Dar es salaam, Tanzania”

**Purpose of the study:**Informed consent provides you with detailed information about the research study so that you can make a voluntary choice to participate in the study after understanding all the details in the study. The purpose of this research is to explore your views on the ethical challenges surrounding HPV vaccination of adolescent girls in Dar es salaam, Tanzania

**What Participation Involves:** This research will involve your participation in an in focus group discussion where you will be audio-recorded and the interview will take about 30 to 45 minutes.

**Confidentiality:** Confidentiality is guaranteed by ensuring that the information you will provide in this study is not shared to any unauthorized third party but will be kept private. Any information about you will have a number instead of your name and only the researcher is the only one who will know what your number is.

**Risks:**We do not have any anticipated risks in this study but in case you may be asked some personal or private information by chance, or that you may feel uncomfortable talking about during the interview you are free not to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you feel uncomfortable.

**Right to withdraw from the study and Alternatives:**Your participation in this research is purely voluntary and you are guaranteed the right to withdraw from the research without any threat of loss of any benefit that you are entitled to obtain from the research and that the discontinuation from the study will not involve any form of penalty.

**Benefits:**There will be no direct benefit to you, but your participation will help us to find out more about your views on how HPV vaccination of adolescent girls has presented as an ethical challenge in Dar es salaam, Tanzania so that we can prepare a guideline that will help address those challenges.

**Who to Contact:**

If you ever have questions about this study, you should contact the study Principal Investigator, **VERONCA SISTY 0784-664288**; Muhimbili University of Health and Allied Sciences (MUHAS), reg no. HD/MUH/T.526/2019, P.O. Box 65001, Dar es Salaam. Dr Renatha Joseph, Head, Bioethics Department (MUHAS) mobile no. 0759-935-505).Also you may contact the Chairperson of the Research and Publications Committee, MUHAS, P.O. Box 65001, Dar – Es- Salaam -Tanzania, Tel +2552150302-6.

Signature:

Do you agree?

Participant agrees ..... Participant does NOT agree.....

I ..... have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant .....

Signature of PI or designee.....

Date of signed consent .....

Interview site.....

Interview No .....

Date.....

Start time.....

End time.....

**PARTICIPANT'S DEMOGRAPHIC INFORMATION**

- Sex \_\_\_\_\_
- Age \_\_\_\_\_
- Education level \_\_\_\_\_
- Religion \_\_\_\_\_
- Tribe \_\_\_\_\_

**Appendix XIII: Fomu ya ukubali****CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI****KURUGENZI YA TAFITI NA MACHAPISHO**

NA.....

**Ukubali ya kushiriki katika tafiti:**Salaam! Naitwa VERONICA SISTY ambaye ni mwanafunzi wa chuo kikuu cha tiba na sayansi shirikishi (MUHAS). Nafanyia utafiti tafiti yenye lengo la kupata maoni yako kuhusiana na "changamoto za kimaadili na kivitendo za kupata ukubali na ruhusa ya mzazi wakati wa tafiti zinazohusisha vijana wadogo Tanzania".

**Madhumuni ya Utafiti:**Fomu ya ridhaa hukupatia wewe taarifa toshelezi kuhusu tafiti ili kuweza kufanya uchaguzi wa hiari kushiriki katika tafiti baada ya kuelewa vipengele vyote katika tafiti. Dhumuni la tafiti hii ni kutathimini maoni yakokatika namna ambavyo changamoto za kimaadili zinavyojitokeza katika utoaji wa chanjo ya kuzuia saratani ya shingo ya kizazi kwa vijana wadogo wa kike katika mkoa wa Dar es salaam.

**Ushiriki:** Tafiti hii itahusisha ushiriki wako katika mahojiano ya kina ambapo utarekodiwa na mahojiano yatachukua kadri dakika 30 mpaka 40.

**Usiri:** Usiri umezingatiwa kwa kuhakikisha kuwa taarifa utakazozitoa katika tafiti hii hazitolewi kwa mtu yeyote yule asiyehusika lakini zitatunzwa kama taarifa binafsi. Taarifa yoyote ile kukuhusu wewe itakuwa na namba baadala ya jina lako na mtafiti pekee ndiye pekee ambaye ataijua namba yako.

**Madhara:** Hakuna madhara yoyote ambayo tunayategemea katika tafiti hii lakini iwapo unaweza kuulizwa taarifa binafsi kwa bahati mbaya, au kwamba unaweza usijisikie kuongea wakati wa mahojiano uko huru kutokujibu swali lolote lile au kuhusika katika mahojiano kama utaona kwamba swali au maswali ni binafsi zaidi au kuyaongelea itakufanya usijisikie vizuri.

**Haki ya kujitoa kushiriki katika tafiti na mbadala:** Ushiriki wako katika tafiti hii ni wa hiari kabisa na umehakikishiwa haki ya kujitoa kushiriki katika tafiti bila kitisho chochote kile cha upotevu wa faida yoyote ile ambayo unastahili kuipata kutoka katika tafiti na kwako kujitoa katika tafiti hakutakuwa na aina yoyote ile ya adhabu.

**Faida:** Hakutakuwa na faida za moja kwa moja kwako, lakini ushiriki wako utatusaidia sisi katika kutafiti zaidi kuhusu namna gani utoaji wa chanjo kuzuia saratani shingo ya kizazi kwa vijana wadogo wa kike imezingatia kanuni na taratibu za kimaadili katika utoaji wa chanjo ili tuweze kufanya maboresho katika utoaji wa chanjosiku za usoni..

Mtu wa kuwasiliana nae: Ikiwa una maswali yoyote kuhusu tafiti hii, wasiliana na Mtafiti mkuu, **VERONICA SISTY 0784-664288**; Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, na.ya usajili HD/MUH/T.526/2019, S.L.P 65001, Dar es Salaam. Pia unaweza wasiliana na Mwenyekiti Kamati ya Tafiti na Machapisho (MUHAS), S.L.P 65001 Dar Es Salaam (Simu na. +2552150302-6).

Saini:

Unakubali?

Mshiriki anakubali ..... Mshiriki hakubali.....



Mimi ..... nimesoma na kuelewa yaliyomo katika fomu hii. Maswali yangu yamejibiwa. Nakubali kushiriki katika tafiti hii.

Saini ya mshiriki .....

Saini ya Mtafiti mkuu au mteule wake.....

Tarehe ya kusaini ridhaa .....

Mahali pa mahojiano .....

Namba Mahojiano .....

Tarehe.....

Muda wa kuanza .....

Muda wa kumalizia .....

**Tarifa za Mshiriki**



Jinsia .....

Umri .....

Elimu .....

Dini .....

**Appendix IX: Ethical Clearance**

	<p><b>UNITED REPUBLIC OF TANZANIA</b>          MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY          MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES  <b>OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS</b></p>	
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Ref. No.DA.282/298/01.C/	Date: 10/06/2021
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MUHAS-REC-06-2021-679

Veronica Vicent Sisty,  
 Master of Bioethics,  
 School of Public Health and Social Sciences,  
 MUHAS.

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED:  
 "ETHICAL CHALLENGES SURROUNDING VACCINATION IN TANZANIA,  
 THE CASE OF HUMAN PAPILLOMA VIRUS"**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

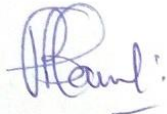
APPROVAL DATE: 10/06/2021  
 EXPIRATION DATE OF APPROVAL: 10/06/2022

**STUDY DESCRIPTION:**  
**Purpose:**  
 The purpose of the study is "to explore ethical challenges surrounding HPV vaccination of adolescent girls in Dar es salaam, Tanzania."

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:  
<https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20605.pdf> and in the MUHAS archives.

**The PI is required to:**

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
8. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
9. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website <https://drp.muhas.ac.tz/>.



Dr. Bruno Sunguya  
**Chairman, MUHAS Research and Ethics Committee**



Cc: Director of Postgraduate studies,  
 MUHAS

## Appendix X: Introduction

### The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
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Dr. Bruno Sunguya  
Chairman, MUHAS Research and Ethics Committee



Cc: Director of Postgraduate studies,  
MUHAS

**Appendix XI: Permission Letter**

THE UNITED REPUBLIC OF TANZANIA  
PRESIDENT'S OFFICE  
REGIONAL ADMINISTRATION AND LOCAL GOVERNMENT

UBUNGO DISTRICT  
Telephone No.

022 – 2926340/5  
Please reply quote

Ref. No: AB.66/213/01"D"/11



DISTRICT COMMISSIONER'S OFFICE  
2 MOROGORO ROAD,  
P.O. Box 55064,  
UBUNGO,  
14882 - DAR ES SALAAM.

22<sup>nd</sup> June, 2021

Municipal Director,  
**UBUNGO.**

**RE: RESEARCH PERMIT**

Mrs. VERONICA VICENT SISTY is student/researcher from **Muhimbili University of Health and Allied Sciences**. She has been permitted to undertake field work research on "ETHICAL CHALLENGES SURROUNDING VACCINATION IN TANZANIA THE CASE OF HUMA PAPILOMA VIRUS" from 17<sup>th</sup> June, 2021 to 10<sup>th</sup> June, 2022.

I kindly request your good assistance to enable him to complete his research.

Beatrice L. Mbawala

For: DISTRICT ADMINISTRATIVE SECRETARY  
**UBUNGO**

Copy to: Researcher.

For: DISTRICT ADMINISTRATIVE SECRETARY  
P. O. Box 55064  
UBUNGO