STRATEGIES TO PROMOTE THE PREVENTION AND CONTROL OF HUMAN PAPILLOMA VIRUS INFECTION AND ITS SEQUELA AMONG ETHIOPIAN WOMEN

By

TADESSE FIKRE LEMA

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SUPERVISOR: Prof. MM Moleki

CO-SUPERVISOR: Dr. A Mosalo

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DEDICATION

I DEDICATED THIS THESIS TO WOMEN WHO LOST THEIR LIVES TO CERVICAL CANCER

Student number: 14113007

D E C L A R A T I O N

I declare that **STRATEGIES TO PROMOTE THE PREVENTION AND CONTROL OF HUMAM PAPILLOMA VIRUS INFECTION AND ITS SEQUELA AMONG ETHIOPIAN WOMEN** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

Tadesse Fikre Lema

February, 2024

Date

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STUDENT NUMBER: 14113007
STUDENT: TADESSE FIKRE LEMA
DEGREE: DOCTOR OF PHILOSOPHY IN NURSING
DEPARTMENT: HEALTH STUDIES, UNIVERSITY OF SOUTH AFRICA
SUPERVISOR: Prof. MM Moleki
CO-SUPERVISOR: Dr. A Mosalo

ABSTRACT

Human Papilloma Virus (HPV) is the most common viral infection of the reproductive tract and is the cause of precancerous cervical lesions that may progress to cancer. Cervical cancer (CC) is the second most common cancer in women and the second leading cause of cancer deaths in Ethiopia. The two most effective strategies to prevent and control HPV infection and CC are high coverage of HPV vaccination and CC screening.

The purpose of this study was to develop strategies to promote the prevention and control of HPV infection and CC among Ethiopian women.

The research was conducted on 383 women in Adama, Ethiopia. The Health Belief Model (HBM) guided the study. Explanatory sequential mixed methods research was employed, which included an initial quantitative survey followed by qualitative interviews. Descriptive cross-sectional and an exploratory descriptive and contextual study designs were employed in the quantitative and qualitative phases, respectively. Data in the quantitative phase were collected via a systematic sampling technique and analysed statistically using SPSS version 26, while via a purposive sampling technique and analysed thematically using content analysis in the qualitative phase. Methodological triangulation was employed to integrate the quantitative and qualitative strands. The e-Delphi technique was applied to achieve common viewpoints from experts.

The prevalence of HPV infection was 26.6%. The most oncogenic HR-HPV genotypes; HPV16 and HPV18 were found at significant proportions of 22.5% and 5.9% respectively. ‘’Other HR-HPV’’ genotypes altogether accounted for the highest proportion of HPV infection, 63.7%. Risk-factors, identified as having a statistically significant association with HPV infection were being divorced, post-coital bleeding, early sexual debut, having multiple sexual partners, STI, and being HIV-positive. The prevalence of precancerous cervical lesions was 12.5%, and most risk-factors mentioned above had significant association to development of precancerous lesions too.

There was low perceived-susceptibility but high perceived-severity towards HPV infection and CC among women. Perceived-benefits of CC screening were early diagnosis and treatment of symptoms before they turned into cancer. Fear of results and negative peer pressure were perceived-barriers identified not to get screened.

Strategies and education programmes pertaining to HPV infection and CC should be organised and implemented.

KEY CONCEPTS

Cervical cancer; Ethiopian women; human papilloma virus; infection; prevention; promote; strategies; sequela.

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AOR	Adjusted Odds Ratio
ART	Antiretroviral Therapy
CC	Cervical Cancer
CIN	Cervical Intraepithelial Neoplasia
CIS	Carcinoma In Situ
CKC	Cold Knife Conization
COR	Crude Odds Ratio
DNA	Deoxyribonucleic Acid
FGD	Focus Group Discussion
FMOHE	Federal Ministry of Health Ethiopia
GAVI	Global Alliance for Vaccine and Immunization
HBM	Health Belief Model
HSIL	High-grade Squamous Intraepithelial Lesion
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HR-HPV	High-risk Human Papilloma Virus
ICC	Invasive Cervical Cancer
ICCPA	International Cervical Cancer Prevention Association
ICO	Catalan Institute of Oncology
LEEP	Loop Electrosurgical Excision Procedure
LLETZ	Large-Loop Excision of the Transformation Zone
LR-HPV	Low-risk Human Papilloma Virus
LSIL	Low-grade Squamous Intraepithelial Lesion
NCC	Normal Cervical Cytology
OR	Odds Ratio
PHR-HPV	Probably high-risk Human Papilloma Virus
SPSS	Statistical Package for Social Science
STI	Sexually Transmitted Infection
UNFPA	United Nations Population Fund
UNISA	University of South Africa
VIA	Visual Inspection with Acetic acid
WHO	World Health Organisation

CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

There are more than 400 types of Papillomaviruses (PV) identified, among these, nearly 218 types of Human Papillomavirus (HPV) have been isolated and identified as causing infections in humans at the present time (Magalhães, Vieira, Garcia, Ribeiro De Carvalho-Leite, Guedes & Araújo 2021:1-16). About 45 types of the HPVs are implicated in infections of the genital tract, while others cause skin disease like cutaneous warts which include common warts, flat warts, and palmoplantar warts (Magalhães et al 2021:1-16).

HPV is a small (approximately 8,000 base pairs), non-enveloped, double-stranded deoxyribonucleic acid (DNA) virus belonging to the Papillomaviridae family (Bakir, Alacam, Karabulut, Beka, Ozluk, Yilmazbayhan & Agacfidan 2021:44). It replicates in the nucleus of squamous epithelial cells. The genetic material is enclosed by an icosahedral capsid composed of major and minor structural proteins, L1 and L2 respectively (World Health Organization [WHO] 2017:241-268).

The HPVs are classified phylogenetically according to DNA sequence homology in the L1 gene which encodes the structural L1 capsid protein into five genera: Alpha, Beta, Gamma, Mu, and Nu (Della Fera, Warburton, Coursey, Khurana & McBride 2021:321). The genus gamma includes 99 types, followed by the genera alpha 65 types, and beta 54 types, and the genera Mu and Nu include only 3 and 1 types of HPV respectively (Gheit 2019:2). Each genus has evolved to adapt to distinct ecological niches within their host. Specifically, viruses within the Beta, Gamma, Mu, and Nu genera infect the cutaneous epithelium, whereas viruses within the Alpha genus infect both cutaneous and mucosal epithelia (Della Fera et al 2021:321).

HPVs are known to be implicated in the development of about 5% of all human cancers which can be divided into three subtypes of HPV based on the clinical prognosis of their associated lesions: These are high-risk types (HR-HPVs), probably high-risk types (PHR-HPV), and low-risk types (LR-HPV) (Acquaviva, Visani, Sanza, De Leo, Maloberti, Pierotti, Crucitti, Collina, Chiarelli Olivari, Pession, Tallini & Biase 2021:29).

HPV infection is now a well-established cause of cervical cancer (CC) and there is growing evidence of HPV being a relevant factor in other anogenital cancers (anus, vulva, vagina, and penis) as well as head and neck cancers (Catalan Institute of Oncology (ICO) 2019:30; Obeid, Almatrrouk, Alfageeh, Al-Ahdal & Alhamlan 2020:1304).

HPV infections are asymptomatic in most women and do not develop cancer (Bakir et al 2021:44). However, some women will experience a persistent infection with certain HPV genotypes that go on to cause abnormalities in infected cells. These changes are called 'precancerous' because they can develop into invasive CC. Persistent HPV infection is defined by the presence of type-specific HPV DNA on repeated clinical biological samples over a period of time, usually six months, although this time period is not universally accepted (WHO 2017:241-268).

The WHO's report on CC, February 22 (WHO 2022) posits that it takes 15 to 20 years for CC to develop in women with normal immune systems, while it takes only 5 to 10 years in women with weakened immune systems, such as those with untreated HIV infection. The presence of high-risk HPV genotypes was demonstrated in 99.7% of CCs worldwide (Menon, Broeck, Rossi, Ogbe, Harmon & Mabeya 2016:2567–77).

HPV is also responsible for other diseases such as recurrent juvenile respiratory papillomatosis and genital warts, (ICO 2019:30; Obeid et al 2020:1304). In other circumstances, most HPV infections are harmless, and almost 90% of these infections are cleared spontaneously by the immune system within one to two years of acquiring it (del Valle-Mendoza, Becerra-Goicochea, Aguilar-Luis,

Pinillos-Vilca, Carrillo-Ng, Silva-Caso, Palomares-Reyes, Taco-Masias, Aquino-Ortega, Tinco-Valdez, Tarazona-Castro, Sarmiento-Ramirez & del Valle 2021:1-7).

There are no treatments for persistent HPV infections but the resulting precancerous lesions can be easily removed using simple and effective outpatient procedures so they will not progress to CC (United Nations Population Fund (UNFPA)/International Cervical Cancer Prevention Association (ICCPA) 2021:7). However, since these precursor lesions do not cause any clinical symptoms, they can only be found by cervical screening.

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

1.2.1 Background to the Research Problem

HPV is the most common viral infection of the reproductive tract and is the cause of a range of conditions in both men and women, including precancerous lesions that may progress to cancer (WHO 2017:241-268).

At present, there is a relatively clear picture of HPV infection's natural history, oncogenic properties, screening, and prevention algorithms. However, HPV infection rates continue to persist, especially in developing countries, where CC incidence and prevalence are still high (Chan, Aimagambetova, Ukybassova, Kongrtay & Azizan 2019:1-11).

Almost all women are infected with HPV shortly after initiating sexual activity (WHO 2014:39). In addition to having penetrative sexual intercourse, the virus can also be transmitted by skin-to-skin contact in the genital regions close to the penis and vagina. Seven out of 10 of all CC cases reported throughout the world are caused by only two high-risk types of HPV-16 and 18 (WHO 2014:39). Another four high-risk HPV types: 31, 33, 45 and 58 are less commonly found to be associated with CC, with particular types being more prevalent than others in certain geographical areas. Infection with other low-risk HPV types causes

warts in the genital area or around the anus (Bergman, Buckley, Villanueva, Petkovic, Garritty, Lutje, Riveros-Balta, Low & Henschke 2019:7). The two known HPV types that cause most genital warts or condylomas are HPV6 and 11 (WHO 2014:39).

1.2.1.1 Prevalence and Genotypes of Human Papillomavirus

Based on a meta-analysis, the HPV prevalence world-wide among women with normal cytological findings is estimated to be 11.7% (WHO 2017:241-268). The highest prevalence was in sub-Saharan Africa (24%), Latin America and the Caribbean (16.1%), Eastern Europe (14.2%), and South-east Asia (14%). However, country-specific adjusted HPV prevalence in cervical specimens ranged from 1.6% to 41.9% worldwide (WHO 2017:241-268). HPV-16 and HPV-18 genotypes together are responsible for 71% of cases of cervical cancer globally (WHO 2017:241-268). More specifically, 60.6% of cases are attributed to HPV-16 and 10.2% to HPV-18, whilst HPV-31 accounts for 3.7%, HPV-33 for 3.8% and HPV-45 for 5.9%, HPV-52 for 2.8% and HPV-58 for 2.3% of CC cases. HPV types 16, 18, 45, 31, 33, 52, and 58 account for approximately 90% of the squamous-cell carcinomas which are positive for HPV DNA. Women infected with one HPV type may be co-infected or subsequently infected with other types as well.

1.2.1.2 Pre-cancerous Cervical Lesions

Cervical pre-cancer is a distinct change in the epithelial cells of the transformation zone of the cervix marked by the cells developing in an abnormal fashion in the presence of persistent or long-term HPV infection (WHO 2014:39). The Transformation Zone (T- Zone) is the portion of the cervix between the new and original squamo-columnar junction (SCJ) where squamous metaplasia has occurred. According to the Federal Ministry of Health Ethiopia (FMOHE) national cervical cancer prevention training package participant manual (2015), an estimated 10% will develop pre-cancerous changes in their cervical tissue out of women infected with HPV. These pre-cancerous lesions are observed most

frequently between the ages of 30 and 40. About 8% of the women who develop these changes will develop pre-cancer limited to the outer layers of the cervical cells (carcinoma in situ [CIS]), and about 1.6% will develop invasive cancer unless the pre-cancerous lesion or CIS is detected and treated. The progression from premalignant lesions to CC takes place over a period of 10 to 20 years. Although rare, some pre-cancer lesions become cancerous over a year or two, such as in those patients with untreated HIV infection (WHO 2014).

According to Pathfinder International (2013), the development of CC usually occurs after a prolonged phase of pre-cancerous lesions in the cervix. Therefore, early identification and treatment at its pre-invasive stage may benefit the patients and decrease the burden of morbidity and mortality resulting from CC. Visual Inspection with Acetic Acid (VIA) is one of the screening modalities for cervical pre-cancerous lesions (FMOHE 2015).

1.2.1.3 Prevention of Human Papillomavirus through Vaccination

HPV is one of the vaccine preventable infections. The goal of vaccination is to prevent invasive CC by preventing infection with major oncogenic types of HPV (Lei, Ploner, Elfström, Wang, Roth, Fang, Sundström, Dillner & Sparén 2020:1341). Since the first licensure of HPV vaccines in 2006, the HPV vaccines: Bivalent (Cervarix® provides protection against high-risk oncogenic genotypes HPV-16 and 18), quadrivalent (Gardasil4®) provides protection against HPV-6, 11, 16 and 18 genotypes), and nine-valent (Gardasil9®) provides protection against HPV-6, 11, 16, 18, 31, 33, 45, 52 and 58 genotypes) have proven to be safe, highly immunogenic and to induce strong direct and indirect protection against HPV and its sequelae (Gallagher, Lamontagne & Watson-Jones 2018:1-7).

According to the Centre for Disease Control and Prevention (CDC) (2021), since HPV vaccine was first recommended in the United States in 2006, infections with HPV types that cause most HPV cancers and genital warts have dropped by 88% among teen girls and 81% among young adult women. HPV vaccination

has also reduced the number of cases of precancers of the cervix in young women.

As of June 2020, 107 (55%) of the 194 WHO Member States were considered to have introduced HPV vaccination nationwide or partially as per WHO definition. Whilst it took less than a decade for 80% of High-income countries (HICs) to introduce the HPV vaccine, low- and middle-income countries (LMICs) only started introducing the HPV vaccine later, and at a slower pace. They are also more than twice as many LMICs as HICs, so they still lag far behind, with only 41% of LMICs having introduced by the end of 2019 (Montoliu, Bruni, Saura-Lazaro, Brotons, Alemany, Diallo, Afsar, LaMontagne, Mosina, Contreras, Velandia-Gonzalez, Pastore, Gacic-Dobo & Bloem 2021:2).

HPV vaccine was introduced in Ethiopia in December 2018, targeting 14-year-old girls (WHO 2021:1-4). This age group was targeted in Ethiopia because the WHO recommended that adolescents, girls aged between 9 - 14 years, should receive two doses of HPV vaccine six months apart to prevent infection with HPV (WHO 2021:1-4).

1.2.2 The Source of the Research Problem

Cervical cancer is the most commonly diagnosed cancer in 23 countries and is the leading cause of cancer death in 36 countries. Most of these countries are in sub-Saharan Africa, Melanesia, South America, and South-Eastern Asia (WHO 2021). According to the WHO (2021) report, in 2020, an estimated 604,000 women were diagnosed with CC worldwide and about 342,000 women died from the disease.

The researcher, in his many years of professional career in clinical areas, observed that cytology (pap smear) positive cases and precursor lesions found by cervical screening (that is commonly done in Ethiopia using visual inspection with acetic acid (VIA)) were on the increase. As a result, women are dying from cervical cancer more than ever.

A report from ICO/IARC HPV Information Centre shows that the annual number of CC cases and deaths in Ethiopia which are related to persistent HPV infection has been increasing from time to time (Bruni, Albero, Serrano, Mena, Gómez, Muñoz, Bosch & de Sanjosé 2021:1-15). According to this report, it was estimated that in the year 2018 about 6,294 new CC cases were diagnosed, and 4,884 CC deaths occurred annually in Ethiopia (Bruni et al 2019:1-15), which escalated to 7,445 and 5,338 respectively in the year 2020 (Bruni et al 2021:1-15). This confirms the researcher's observations over many years in clinical areas during his career.

1.3 RESEARCH PROBLEM

According to the WHO guideline for screening and treatment of pre-cervical cancer lesions and CC prevention (2021), CC is a leading cause of mortality among women. Persistent HPV infection with high-risk genotypes is a well-established cause of CC (Obeid et al 2020:1304; ICO 2019:30), and it was demonstrated that high-risk HPV genotypes were present in 99.7% of CC cases worldwide (Menon et al 2016:2567). Annual estimates of new CC cases in the African continent reach 119,284 per 100,000 women per year. Of these, Eastern African countries share the highest burden of the region 52,633 followed by Western African countries, which is 31,955 (ICO, 2019:23). An estimated number of 111, 632 new cases of invasive cervical cancer (ICC) occur annually in sub-Saharan Africa and it is responsible for almost one-quarter of all female CCs in the world (ICO, 2019:23). Invasive CC incidence in Africa is one of the highest in the world with an estimated overall Age-Standardised incidence Rate (ASR) of 27.6 per 100 000 women and varies by region with 43.1 in Southern Africa, 40.1 in East Africa, 26.8 in Central Africa, and 29.6 in Western Africa. In contrast, the ASR is 7.2 in Northern Africa and 11.2 in Europe and the Americas (ICO, 2019:23).

The annual number of new cases of CC has been projected to increase from 570,000 to 700,000 between 2018 and 2030, with the annual number of deaths projected to increase from 311,000 to 400,000 (WHO 2020:1-3). More than 85%

of those affected are young, under-educated women who live in the world's poorest countries. The majority are also mothers of young children whose survival is subsequently truncated by the premature death of their mothers (WHO 2020:1-3).

Cervical cancer is the second most common female cancer, and the second leading cause of cancer deaths in women aged 15 to 44 years in Ethiopia (Bruni et al 2021:1-15). About 7,445 new CC cases are diagnosed, and 5,338 CC deaths occur annually in Ethiopia (estimations for 2020) (Bruni et al 2021:1-15).

The WHO (2020:1) states that there is a need for strategic, urgent, and bold action to scale up and sustain the implementation of HPV vaccination and CC screening to prevent cancer development of the cervix. In Ethiopia, coverage of immunisation services has steadily expanded over the last two decades, but substantial gaps have remained at both level and distribution among different segments of the population. These considerable coverage gaps have persisted and led to a heavier vaccine-preventable disease (VPD) burden among poorer households.

The Ethiopian Ministry of Health started vaccinating schoolgirls aged 14 years using Gardasil-4™ (A quadrivalent HPV vaccine that provides protection against highly prevalent HR HPV genotypes HPV-16 and 18, and low-risk oncogenic genotypes related to the appearance of 90% of genital warts HPV-6 and 11) since December 2018 (Derbie et al 2022b:1-8). Ethiopia has delivered an HPV vaccination campaign targeting 2.4 million 14-year-old girls across the country in two cohorts in 2021 (WHO 2021:1-4). Two doses of HPV vaccine are required for this age for full protection against the HPV which causes CC (WHO (2022:1). The country continued vaccinating over 1.8 million 14-year-old girls in nine regions against HPV in 2022 (WHO 2022:1). The vaccines were administered in schools and health facilities for two cohorts. More than 866,000, 14-year-old girls took the first dose of the vaccine while 970,000 who received the first dose in January 2021 took the second one. Vaccinating girls using Gardasil-4™ and screening women for cervical lesions using HPV16/18 oncoproteins significantly

reduce the number of girls who might be protected, and women who might be missed by screening, respectively.

Despite this significant improvement, women aged 15 years and above are beyond the targeted age for receiving the HPV vaccine though teens and young adults through age 26 years need to have been vaccinated, as they are more likely to have been infected with HPV, which puts them at risk of developing invasive CC. In addition, the Gardasil-4^{TM} vaccine that Ethiopia uses to immunise girls targets only four HPV genotypes. This implies that some proportion of the population who might be infected with other high-risk genotypes are left unprotected. In other words, the existing vaccination will not shield women against CC who may have other high-risk HPV genotypes other than HPV-16 and HPV-18. In contrast, most developed countries are currently using the nine-valent Gardasil®9 vaccine that targets close to 90% of all HR-HPVs, which is an ideal type of vaccine for Ethiopians. Yet, Ethiopia has been working on CC screening using VIA for more than a decade despite the fact that the services are not as widespread in the country as they should be. In addition, the services are not integrated with the HPV vaccination programme.

Even though HPV screening and vaccination are complementary preventive options for CC, they are often implemented as separate and non-coordinated public health programmes in the country.

Therefore, it is crucial to have baseline prevalence estimations of HPV infection, genotype distribution, and risk factors, which are invaluably essential in choosing the appropriate type of HPV vaccine and monitoring the impact of HPV vaccination campaigns among the target population. Unfortunately, not many studies have been conducted regarding these critical issues in the current study area and across the country in general. In addition, the prevalence of pre-cancerous cervical lesions, risk factors and treatments offered, as well as risk perception of women towards HPV infection and CC, and perception of women regarding CC screening and HPV vaccination are not well studied and documented in the entire country. This limits the implementation of HPV prevention programmes.

It is from this background and problem statement that the study sought to develop strategies to promote the prevention and control of HPV infection and its sequala CC among Ethiopian women and also to answer the following research questions.

1.3.1 Research questions

The research questions were posed in accordance with the study phases using a mixed method quantitative and qualitative research design.

1.3.1.1 Phase 1: Quantitative Phase

1. What is the prevalence of HPV infection among women who participated in the study?
2. What are the HPV genotypes among women identified as having HPV infection?
3. What are the risk factors for HPV infection among women who participated in the study?
4. What is the prevalence of pre-cancerous cervical lesions among women identified as having HPV infection?
5. What are the risk factors for pre-cancerous cervical lesions among women who participated in the study?
6. What are the treatments offered to women identified as having pre-cancerous cervical lesions?

1.3.1.2 Phase 2: Qualitative Phase

1. What are the risk perceptions of women who participated in the study about HPV infection and CC?
2. What are the perceptions of women who participated in the study regarding CC screening?
3. What are the perceptions of women who participated in the study pertaining to HPV vaccination?

1.3.1.3 Phase 4: e-Delphi

1. What strategies should be developed to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women?

1.4 AIM/PURPOSE OF THE STUDY

The main purpose of this study was to develop strategies that promote the prevention and control of HPV infection and its sequela CC among women in Ethiopia.

1.5 RESEARCH OBJECTIVES

The research objectives in this study are described below according to the phases.

1.5.1 Phase 1: Quantitative Phase

- To assess the prevalence of HPV infection among women who participated in the study.
- To assess the genotypes of HPV among women identified as having HPV infection.
- To assess the risk factors for HPV infection among women participated in the study.
- To assess the prevalence of pre-cancerous cervical lesions among women identified as having HPV infection.
- To assess the risk factors for pre-cancerous cervical lesions among women who participated in the study.
- To identify treatments offered for women identified as having precancerous cervical lesions through VIA test.

1.5.2 Phase 2: Qualitative Phase

- To explore and describe the risk perceptions of women who participated in the study about HPV infection and CC.
- To explore and describe the perceptions of women who participated in the study about CC screening.
- To explore and describe the perceptions of women who participated in the study about HPV vaccination.

1.5.3 Phase 3: Meta Inferences

- To integrate findings from quantitative and qualitative strands of mixed methods research.
- To develop an overall conclusion, explanation or understanding through an integration of the inferences obtained from phase 1 and phase 2 studies.

1.5.4 Phase 4: e-Delphi

- To solicit consensus and information for planning and prediction purpose among the expert panel members for the development of strategies that promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

1.6 SIGNIFICANCE OF THE STUDY

The information obtained from this study will help achieve a better understanding of the prevalence and genotypes of HPV infection involved in diseases such as pre-cancerous cervical lesions and CC cases, and risk factors that expose women to this infection across the country. Accordingly, the researcher developed strategies to promote the prevention and control of HPV infection and its sequela CC. Furthermore, the output of the study provides objective evidence that could be used to develop appropriate guidelines, design policies, and conduct further HPV-related research based on the findings and

recommendations obtained from this study. Furthermore, the study findings play significant role in the prevention and control of HPV infection and ensure that CC deaths are no longer be public health problems in the country.

1.7 DEFINITION OF KEY TERMS

For the purpose of this study, the following terms are used and defined as stated below:

Human papillomavirus: Human papillomavirus is a small, non-enveloped, double-stranded DNA virus belonging to the Papillomaviridae family (Bakir et al 2021:44). It is the most common viral infection of the reproductive tract. In this study, HPV was regarded as a virus that causes infections in women which resulting in conditions such as pre-cancerous cervical lesions and CC.

Cervical cancer: Cervical cancer is a cancer that develops in a woman's cervix (the entrance to the uterus from the vagina) (WHO 2023). Almost all CC cases (99%) are linked to infection with high-risk HPVs, an extremely common virus transmitted through sexual contact (WHO 2023). Cervical cancer begins when healthy cells on the surface of the cervix change or become infected with HPV and grow out of control, forming a mass called a tumour. Long-term infection of HPV on the cervix can result in cancer, leading to a mass or tumour on the cervix (American Society of Clinical Oncology [ASCO] 2022). In this study, CC was regarded as a cancer arising from the cervix due to persistence infection with certain types of HPVs (HR-HPVs) specially HPV-16 or HPV-18.

Cervical cancer screening: Screening means checking for a disease before there are symptoms. Screening is a public health intervention used on a population at risk, or target population (FMOHE 2015). Screening is a process that includes a system of informing and inviting the target population to participate; administering the screening test; following-up with test results and referral for further testing among those with abnormal test results; and ensuring timely pathologic diagnosis, staging and access to effective treatment with

routine evaluation to improve the process (Taplin, Dash, Zeller & Zapka 2006:317-340).

Cervical cancer screening is the systematic application of a test to identify cervical abnormalities in an asymptomatic population. For screening programs to have an impact on the incidence of CC, they need to screen as many women as possible. In this study, two different CC screening modalities were considered. The first modality was HPV DNA testing which was regarded in this study as the process of identifying the presence of HPV-16, HPV-18 and other high-risk HPV genotypes in women residing in the study area using internationally acceptable HPV detecting procedures. The second modality was visual inspection with acetic acid (VIA), a naked-eye examination of the uterine cervix which was regarded in this study as looking for the presence of aceto-white reaction in 1 minute after application of 5% acetic acid solution on the cervix, to detect the presence of any precancerous lesions of the cervix in women who were tested positive for HPV DNA test.

HPV Vaccines: Vaccines are critical to the prevention and control of many communicable diseases and therefore underpin global health security (WHO 2021:6). Three prophylactic HPV vaccines, directed against high-risk HPV types, are currently available for the prevention of HPV-related disease: the Quadrivalent (Gardasil4® provides protection against HPV-6, 11, 16 and 18 genotypes) vaccine was first licensed in 2006, the Bivalent (Cervarix® provides protection against high-risk oncogenic genotypes HPV-16 and 18) vaccine was licensed in 2007 and the Nine-valent (Gardasil9® provides protection against HPV-6, 11, 16, 18, 31, 33, 45, 52 and 58 genotypes) vaccine was licensed in 2014 (WHO position paper 2017:241–268). In this study, HPV vaccines were regarded as vaccines that helped to protect women against infection with certain types of HR-HPVs that could cause pre-cancerous cervical lesions and CC.

Strategies: Are careful plans or methods for achieving a particular goal usually over a long period of time (*Merriam-Webster Dictionary* 2020, sv “strategy”). In this study, strategies were regarded as plans or methods developed by the

researcher that would help promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

Prevention: According to (*Merriam-Webster Dictionary* 2021, sv “prevention”) prevention means the act or practice of preventing or hindering something. In this study, ‘prevention’ was regarded as the action of preventing Ethiopian women from HPV infection and its sequela CC.

Control: According to (*Merriam-Webster Dictionary* 2021, sv “control”) to control means to reduce the incidence or severity of specially to innocuous levels. Control implies regulating or restraining in order to keep within bounds or on a course. In this study, ‘control’ was regarded as regulating or restricting HPV infection and its sequela CC to the extent that they are no longer be public health problems among Ethiopian women.

Sequela: According to (*Collins English Dictionary* 2018, sv “sequela”) sequela means any abnormal bodily condition or disease related to or arising from a pre-existing disease. Sequela means any complication of a disease. In this study, sequela was regarded as CC that arises from complications of persistent HPV infection.

Women: The female human beings (*Collins English Dictionary* 2018, sv “woman”). In this study, women were regarded as females aged 15 years and above residing in the study area.

1.8 OPERATIONAL DEFINITIONS

Prevalence of HPV: The prevalence of HPV in this study tells us how widespread HPV infection is in the study area during the study period, meaning the total number of HPV-infected cases in Adama City during the study time. It was measured by dividing the total number of HPV-infected women during the study period to the total number of women who participated in the study.

Genotypes of HPV: In this study, the genotypes of HPV were regarded as the group of HPVs that share a similar genetic makeup. Some of the tests on the market provide information about specific HPV genotypes, such as HPV-16 and 18. According to the WHO 2021 Guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition, HPV tests are called partial genotyping when they report HPV-16 and 18 (including HPV-45 in some cases) and other carcinogenic types separately. Other HPV tests may provide extended genotyping, when they report additional types, or groups of types, such as HPV-31, 33, 35, 45, 52, and 56. In this study, the HPV testing called partial genotyping (i.e. the detection of HPV-16 and 18 versus other carcinogenic types), was applied to identify women at the highest risk of CC among those testing positive for HPV. It was determined by using an internationally acceptable Nucleic Acid test (NAT), i.e., HPV DNA detecting procedure, that was Abbott Real Time HR-HPV.

Risk factors of HPV infection: Risk factors are factors such as habits or environmental conditions that predispose or increase the chance of developing a particular disease. Risk factors of HPV infection in this research were regarded as having high-risk sexual behaviour that is the main risk factor associated with the acquisition and persistence of HPV infection which includes age of first vaginal sex and number of sexual partners. Infection with other STIs including HIV, a high number of lifetime sexual partners, early sexual debut and host susceptibility are documented risk factors for HPV infection. It was assessed through interviews with study participants against high-risk sexual behaviours listed above.

Pre-cancerous cervical lesion: Refers to changes to the cervical cells in the transformation zone. Pre-cancerous cervical lesions in this study were regarded as the occurrence of lesions on the cervix following persistent high-risk HPV infection that would lead to invasive cervical cancer if not detected and treated timely. It was determined by VIA test. A 5% of dilute acetic acid solution was applied to the cervix. A minute later, the presence of any aceto-white change or reaction in the cells covering the cervix (epithelial cells) was considered as VIA positive.

Treatment of pre-cancerous cervical lesions: Treatment of pre-cancerous cervical lesions in this study was regarded as the management of pre-invasive cervical lesions using Cryotherapy, Thermocoagulation, or Loop electrosurgical excision procedure (LEEP) services, according to the illegibility, providers skill and availability of the service.

Risk perception towards HPV infection and cervical cancer: Risk perception of HPV infection and CC in this research was regarded as the attitude or understanding of women towards the potential to be infected with HPV and possibly develop CC. It was assessed through focus group discussions (FGDs), which was guided by the Health Belief Model (HBM).

Perception regarding cervical cancer screening: Perception of cervical screening in this research was regarded as the attitude or understanding of women towards the importance of having screened for cervical cancer. It was also assessed through FGDs which was guided by the HBM.

Perception regarding HPV vaccination: Perception of HPV vaccination in this research was regarded as the attitude or understanding of women towards the importance of having vaccinated for HPV. It was assessed through FGDs which was guided by the HBM.

1.9 THEORETICAL FOUNDATIONS OF THE STUDY

1.9.1 Theoretical Framework

A theoretical framework is the ‘blueprint’ or guide for research (Grant & Osanloo 2016:12). This study was guided by the HBM theoretical framework.

1.9.1.1 Health Belief Model

The HBM is a social psychological health behaviour change model developed to explain and predict health-related behaviours, particularly regarding the

uptake of health services (Razmara, Aghamolaei, Madani, Hosseini & Zare 2018:380). This model is comprised of several components: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy (Razmara et al 2018:380). Health behaviours are influenced by a person's desire to avoid illness or to get well, and by their confidence that the recommended action will achieve this. The developers of the model assume that people are ready to act if they:

- Believe they are susceptible to the condition (perceived susceptibility).
- Believe the condition has serious consequences (perceived severity).
- Believe taking action would reduce their susceptibility to the condition or its severity (Perceived benefits).
- Believe that the costs involved in taking action are outweighed by the benefits (perceived barriers).
- Are confident in their ability to successfully perform an action (self-efficacy).
- Are exposed to factors that prompt action (cue to action)

When applying the HBM to planning health programmes, practitioners should ground their efforts in an understanding of how susceptible the target population feels towards the health problem, whether they believe it is serious, and whether they believe action can reduce the threat at an acceptable cost (Croyle 2005:20).

Therefore, the HBM was used to guide the study and to develop strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

1.9.2 Research Paradigm

Paradigm: - A paradigm is a general viewpoint or ideology (Perera 2018:1-8). A paradigm is a set of philosophical or theoretical concepts that characterise a particular way of viewing the world (Gray, Grove & Sutherland 2017:1075). Research paradigms are a set of common beliefs and agreements shared by

scientists on how problems can be understood and addressed (Perera 2018:1-8). A paradigm comprises four elements, namely, epistemology, ontology, methodology, and axiology.

According to Creswell and Plano Clark (2017:82), four worldviews are most useful for applying mixed methods research namely, Post-positivism, Constructivism, Transformative and Pragmatism. The research paradigm of focus in this study was the pragmatism.

Pragmatism: Pragmatic paradigm arose among philosophers who argued that it was not possible to access the 'truth' about the real world solely by virtue of a single scientific method as advocated by the Positivist paradigm, nor was it possible to determine social reality as constructed under the Interpretivist paradigm (Kivunja & Kuyini 2017:35).

The pragmatic paradigm advocates a non-singular reality ontology (that there is no single reality and all individuals have their own and unique interpretations of reality), a relational epistemology (i.e. relationships in research are best determined by what the researcher deems appropriate to that particular study), a mixed methods methodology (a combination of quantitative and qualitative research methods), and a value-laden axiology (conducting research that benefits people) (Kivunja & Kuyini 2017:35). Pragmatism draws on many ideas, including employing "what works," using diverse approaches, and valuing both objective and subjective knowledge (Creswell & Plano Clark 2017:86).

The following are pragmatisms' answers to philosophical questions according to (Creswell & Plano Clark 2017:86).

- Ontology (What is the nature of reality?): - Singular and multiple realities (e.g. researchers test hypotheses and provide multiple perspectives.

- Epistemology (What is the relationship between the researcher and that being researched?): - Practicality (e.g. researchers collect data by ‘what works’ to address the research question).

- Axiology (What is the role of values?): - Multiple stances (e.g. researchers include both biased and unbiased perspectives).

- Methodology (What is the process of research?): - Combining (e.g. researchers collect both quantitative and qualitative data and mix them).

In this study, pragmatism was adopted because the paradigm allowed the researcher to have a pluralistic stance of gathering all sorts of data to best answer the research questions. In essence, a pragmatist employs a mixed-methods design to follow one or multiple combinations of some of the prevalent researches. In a mixed-methods research design, quantitative approaches help derive objective findings by using tools such as surveys, whereas qualitative research approaches help understand the situation through indicative results by exploring through using tools such as participant observation and interviews.

1.10 RESEARCH METHODOLOGY AND RESEARCH DESIGN

1.10.1 Research Method

A research method is a rigorous and meticulous process of logically and systematically applying all steps, strategies and procedures for collecting and analysing data in a research study as directed by the research design (Burns and Grove 2015:41). The study was conducted in four phases. The research methods of each phase are briefly described**.**

1.10.2 Research Design

A research design is a plan and procedure for research that spans the decisions made in the research from broad assumptions to detailed methods of data collection and analysis. It involves the intersection of philosophy, strategies of

enquiry and specific research methods (Creswell 2012:5). This study employed an explanatory sequential mixed methods design (Quantitative → qualitative = explanation), which included an initial quantitative study design aimed at assessing the prevalence, genotypes and risk factors of HPV infection, and prevalence, risk factors and treatment of precancerous cervical lesions among women in Adama, and a follow-up qualitative interviews i.e. FGDs, design to explore and describe the risk perceptions of women towards HPV infection, and their perception towards CC screening and HPV vaccination. Priority was given to the quantitative phase. The qualitative results helped to explain the initial study results and built a better understanding of the significant and nonsignificant quantitative findings (Creswell & Plano Clark 2017:86).

1.10.2 1 Phase I: Quantitative Research Design

In Phase I, the researcher employed a cross-sectional descriptive study design to assess the prevalence, genotype distribution and risk factors of HPV infection among women in Adama.

1.10.2.2 Phase II: Qualitative Research Design

In Phase II, the researcher employed qualitative, exploratory, descriptive and contextual research design to explore and describe women's risk perceptions towards HPV infection and their perception about CC screening and HPV vaccination.

1.10.2.3 Phase III: Meta Inferences

In Phase III, the researcher mixed/integrated the data that was collected and analysed in phase 1 in the quantitative study with the data collected and analysed in the follow-up qualitative study in phase 2. The primary focus was to explain quantitative results by using qualitative data to explore certain results in more detail, or help explain unexpected results (e.g., using follow-up interviews to better understand the results of a quantitative study). Greater emphasis was given to the quantitative strand.

1.10.2.4 Phase IV: e-Delphi

According to Green (2014:1), e-Delphi is defined as a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with multiple challenges. The e-Delphi method allows experts to communicate and engage with one another online or in their own time in their vicinities to solve problems until a consensus is reached. In the e-Delphi process, reaching a consensus by experts cannot be resolved in a once-off discussion. As an iterative process, e-Delphi involves a chance for initial feedback, collation of feedback and distribution of collated feedback to participants for further review. Depending on the number of research questions and available time to reach consensus, the e-Delphi process includes three rounds, to prevent exhaustion and attenuation (Green 2014:1).

In Phase IV, the researcher applied three rounds of the e-Delphi technique to achieve a common viewpoint from experts using questionnaires, which finally helped the researcher develop strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

1.10.3 Study Setting

The study was conducted in Adama City, central Oromia region, Ethiopia. Adama forms a special zone of Oromia and is surrounded by East Shewa Zone. It is located at 8.54^{o}N 39.27^{o}E at an elevation of 1712 meters, 99km southeast of the capital city of Addis Ababa. The city sits between the base of an escarpment to the west, and the Great Rift Valley to the east. Based on the 2007 census conducted by the Central Statistical Agency of Ethiopia, the city has a total population of 220, 212, of whom 108,872 were men and 111,340 women. Currently, the total population size of the city is estimated to be more than 324,000. With regard to health facilities, the city has five private hospitals, two non-governmental reproductive health clinics, more than 90 private clinics, one public hospital (Adama Hospital), and eight health centres (Geda, Adama, Boku shenen, Hawas, Biftu, Dembela, Anole and Angatu). The study was conducted

at the three public health facilities in Adama City (Adama Hospital, Geda, and Adama Health Centres), where CC screening services are offered to women.

1.10.4 Study Population

1.10.4.1 Target population for Phase I

In Phase I, the target population was all women aged 25 - 49 years residing in the Adama City administration.

1.10.4.1.1 Inclusion criteria

Randomly selected women aged 25-49 years who had resided in Adama City for at least the past six months and attended the selected health facilities during the study period.

1.10.4.1.2 Exclusion criteria

Women beyond 25 - 49 years age range, confirmed CC cases; women at advanced stage of disease and too ill to participate, mentally unstable to consent for participation, and unable to communicate properly were excluded from the study.

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1.10.4.2 Target population for Phase II

In Phase II, the target population was all women aged 25 - 49 years residing in the Adama City administration.

1.10.4.2.1 Inclusion criteria

Purposefully selected women residing in Adama City for at least the past six months and attended the selected health facilities during the study period. The selection was based on the participants importance to the subject under study,

i.e., information-rich women believed to have some awareness about the topics to be discussed, and could have the ability to articulate their experiences clearly during the FGD.

1.10.4.2.2 Exclusion criteria

Women beyond 25 - 49 years age range, confirmed CC cases; women at advanced stage of disease and too ill to participate, mentally unstable to consent for participation, and unable to communicate properly were excluded from the study.

1.10.5 Sample Size

1.10.5.1 Sample Size for Phase I

The sample size for Phase I was calculated using Raosoft calculator on the internet by considering the following assumptions.

- Margin of error 5%
- Confidence level 95%
- Population size 96,432 (Women 15 years and above of age residing in Adama)
- Response distribution 50%

Accordingly, the sample size for Phase I was **383.**

1.10.5.2 Sample Size for Phase II

Qualitative research experts argue that there is no straightforward answer to the question of 'how many' and that sample size is contingent on several factors relating to epistemological, methodological and practical issues (Baker & Edwards 2012:1-8). Instead, the sample size depends upon data saturation. Samples of 20 and 30 (and multiples of 10) are the most common (Mason 2010), with 25-30 being a typical recommendation (Dworkin 2012:1319-1320). Undoubtedly, the most widely used principle for determining sample size and

evaluating its sufficiency is that of saturation. In this phase of the study, the researcher formulated three focus groups, each consisting of 10 members, altogether 30 study participants.

1.10.5.3 Sample Size for Phase IV

The group of experts participating in the Delphi method is called “panel” (McMillan, King & Tully 2016:655). The e-Delphi employs ‘experts’ as panel members (Taylor, Feltbower, Aslam, Raine, Whelan & Gibson 2016:2). In the panel selection, the tip for the panel consists of size, panel member features, and the response rate (Giannarou & Zervas 2014:65-82). There is a complete agreement on how to choose the participants. They are not randomly but purposively selected to enter the research to apply their knowledge and experience with respect to the problem (Giannarou & Zervas 2014:65-82). Although it is sufficient to reach an acceptable size of 10 experts, there is no agreed standard for the number of the participants (Avella 2016:305-321). In Phase IV of sample size determination, the researcher purposefully recruited 10 health professional expert panellists (consisting of Doctors, Radiologists, Nurses working in oncology clinics, university lecturers and other health experts) from different parts of the country, who were knowledgeable on the topic under study, and agreed to participate in the study. The researcher communicated with them through e-mail.

1.10.6 Sampling Technique

1.10.6.1 Sampling Technique for Phase I

In Phase I, the researcher employed systematic probability sampling technique which is defined as a sampling technique conducted when an ordered list of all members of the population is available and involves selecting every K^{th} individual on the list, starting from a point that is selected randomly (Gray et al 2017:1093). The systematic sampling technique was used to assess the prevalence, genotypes and risk factors of HPV infection as well as the

prevalence and risk factors of precancerous cervical lesions associated with the development of CC among women who attended selected health facilities in Adama.

1.10.6.2 Sampling Technique for Phase II

In Phase II, the researcher used a purposive sampling technique which is a judgmental or selective sampling method that involves conscious selection by the researcher of certain subjects or elements to include in a study (Gray et al 2017:1081). The purposive sampling technique was used to explore and describe the risk perception of women regarding HPV infection and CC, and their perception towards CC screening and HPV vaccination.

1.10.6.3 Sampling Technique for Phase IV

In Phase IV of the sampling technique, the researcher employed the purposive sampling technique to select 10 expert panellists from different parts of the country. The recruited experts were health professionals who agreed to participate in the study and had expert knowledge of the topic under study. The researcher communicated with them through e-mail.

1.10.7 Data Collection Methods and Procedure

1.10.7.1 Data Collection for Phase I

The data collection for Phase I was accomplished through a face-to-face interview using a pretested structured questionnaire adapted and modified from different related literature. A systematic sampling technique was employed with every third respondent among women who visited selected health facilities during the study period for family planning service, for antiretroviral therapy in case of HIV-positive women, and for gynaecological and other reproductive health services.

1.10.7.2 Data Collection for Phase II

In Phase II, a common approach in a qualitative study, the interview method, was employed to collect data from the study participants. In this phase of the study, the researcher purposefully recruited participants among women who had already taken part in the quantitative phase of the study and believed to have an awareness of the issues to be discussed in the qualitative phase. Focus group discussions were conducted in private rooms at each selected health facility where the information between the discussants could not be overheard. The researcher asked the study participants to describe their risk perception towards HPV infection and CC, and their perceptions concerning CC screening and HPV vaccination. Upon the permission of the study participants, the discussions were audio-recorded, and then transcribed by the researcher.

1.10.7.3 Data collection for Phase IV

In this Phase of the study, data were collected from expert panellists using a questionnaire stating the strategies drawn from Phase III through the e-Delphi method. An 80% agreement between panellists was considered a consensus.

1.10.8 Data Analysis

1.10.8.1 Data Analysis for Phase I

In Phase 1, quantitative data analysis was conducted to obtain the prevalence, genotypes, and risk factors of HPV infection among women residing in the study area. All data generated were revised, checked for completeness, and coded for computerized data entry and entered into the Epi Info 7 software programme. The data were then exported, re-coded and analysed using statistical package for social science (SPSS) version 26. Descriptive and summary statistics with frequency, proportion and odds ratio were used to describe the study population, prevalence, genotype distribution, and the risk factors of HPV infection among

women at selected health facilities in Adama. Discrete variables were presented with the use of tables and percentages.

1.10.8.2 Data Analysis Phase II

Phase II of the study was a qualitative approach. The researcher employed a six-step process of thematic analysis to analyse the risk perception of women towards HPV infection and CC, and their perception towards CC screening and HPV vaccination. The steps of thematic analysis, namely, familiarisation, coding, generating themes, reviewing themes, defining and naming themes, and writing up were followed in the process of data analysis in this particular phase of the study.

1.10.8.3 Data Analysis Phase IV

In this Phase, the data analysis involved the analysis and careful management of quantitative data. Data collected from this initial stage were analysed through using frequency and percentile, central tendencies (mean, median, and mode) and levels of dispersion (standard deviation and the inter-quartile range). In subsequent rounds, participants were asked to rank/respond to the analysed options from the previous round. A Likert scaling technique was applied. Between rounds, the group's responses were analysed, summarised, and communicated back to them, a process called controlled feedback. This approach was repeated for three rounds until a consensus was reached on each strategy.

1.10.9 Ethical Considerations

1.10.9.1 The Study Participants/Respondents

Ethics in social research refers to the researcher's moral deliberation, choices and accountability throughout the research process and it involves ethical decisions made from the time the topic of the study was identified until the

findings of the study are disseminated (Miller, Birch, Mauthner & Jessop 2012:14). In studies, when the study subjects are human beings, care must be taken to ensure that their rights are protected. Accordingly, participation in this study was on a voluntary basis by obtaining informed consent (Annexure E) from each participant after being informed about study and risk anticipated and how it will be addressed. All ethical principles had been considered to ensure that the rights of study participants were protected.

1.10.9.1.1 Autonomy

Autonomy denotes that the researcher should have respect for the other people, respect for their dignity and their self-worth**.** The participants' right to self-determination was ensured by explaining the purpose and significance of the study to them, and informed consent was obtained from each participant. The researcher explained that participation was purely voluntary. Participants were informed that they had the right to withdraw from the study at any time without any penalty.

1.10.9.1.2 Anonymity, Confidentiality and Privacy

Anonymity was assured as no names of study participants were written on the questionnaire. Confidentiality was achieved by keeping the data in strictest confidence under lock and key. Privacy was assured by carrying out the interview in a private room where no information could be overheard.

1.10.9.1.3 Beneficence

Doing well for others and promoting others' interest and well-being. Related to this principle is the right to protection from discomfort (Grove et al 2015:37).

1.10.9.1.4 Non–maleficence

Non-maleficence is the principle of avoiding harm or doing as little harm as possible (De Vos et al 2011:115). Participants were assured that their

participation and the information they provided would not be used against them in any way. The physical and psychological discomfort that the participants might face during the examination were kept minimised by all means possible like by making the screening procedure women-friendly.

1.10.9.1.5 Justice

Justice is the principle that entails the individual's rights for fair treatment (Grove et al 2015:37). The participants were selected fairly for reasons directly related to the problem being studied. The selection was free of bias, study subjects were recruited randomly using the selection criteria, and all the participants had a known chance of participating in the study.

1.10.9.2 The Institutions

Permissions from the institutions participating in the study must be obtained in advance before any data collection activities are commenced. In this study, the researcher obtained ethical approval from the Research Ethics Committee of the Department of Health Studies at the University of South Africa (UNISA) (Annexure A). Permission was also obtained from Oromia Health Bureau (Annexures B2 and B3), Adama City Heath Office (Annexures B4 and B5), and the heads of the selected health facilities.

1.11 SCOPE OF THE STUDY

Mixed methods research is the type of research in which a researcher combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, and inference techniques) for the broad purposes of breadth and depth of understanding and corroboration (Johnson, Burke, Onwuegbuzie & Lisa 2007:123). A mixed method draws on the strengths of both qualitative and quantitative research. The qualitative results help explain the initial study results and build a better understanding of the significant and non-significant quantitative findings. The e-

Delphi method allows the use of a “committee” with fewer drawbacks (scheduling, travel/space requirements, lengthy discussions).

Anonymity reduces the impact of dominant individuals, helps reduce peer pressure to conform and allows opinions to be considered in a non-adversarial manner. Responses are weighted equally so no one person can shift the opinions of the group. Providing controlled feedback on the group opinion reduces noise and allows participants to reconsider based on others’ rankings (Hsu & Sandford 2007:10). Since this study was conducted in Adama City, it is not possible to generalise the findings to the wider national population.

1.12 STRUCTURE OF THE THESIS

The study consists of 8 chapters. Table 1.1 shows the structure of the thesis, indicating outline of the chapters.

Chapter 1: The chapter presented the introduction and background information about the research problem. The statement of the research problem, aim of the study, the significance of the study, definition of key terms, operational definitions, theoretical foundations of the study, research design, method, and scope of the study are also discussed.

Chapter 2: Presented the literature review of the study. The prevalence, genotypes, and the risk factors of HPV infection are discussed in detail.

Chapter 3: Discussed the research design and methodologies used in the study. Population, sampling, data collection, ethical considerations, data analysis, and rigour of the study are also discussed in detail.

Chapter 4: Discussed the data management and analysis, and presented the research results and overview of the quantitative research findings.

Chapter 5: Presented the data collection, management and analysis of qualitative study. The findings of the qualitative study are discussed in detail.

Chapter 6: Presented the meta-inferences, integration of quantitative and qualitative findings, and the triangulation of Phase I and Phase II study findings.

Chapter 7: Presented the development and validation of the strategies in detail.

Chapter 8: Presented the conclusions, recommendations and contribution of the study. The limitations of the study, and concluding remarks are also provided.

Table 1.1: Structure of the thesis indicating outline of the chapters

Chapters	Titles
Chapter 1	Orientation to the study
Chapter 2	Literature review
Chapter 3	Research design and method
Chapter 4	Analysis, presentation and description of quantitative research
Chapter 5	Analysis, presentation and discussion of qualitative data
Chapter 6	Integration of quantitative and qualitative findings
Chapter 7	Strategies development and validation
Chapter 8	Conclusions and recommendations

1.13 SUMMARY

This chapter presented the introduction and background information of the research problem. The statement of the research problem, aim of the study, significance of the study, definition of key terms, operational definitions and the theoretical foundations of the study, the research design and method, as well as the scope of the study, are also discussed. This chapter gives both an overview and serves as an introduction to the study. Most of the contents are presented in more detail in the subsequent chapters of the thesis.

The next chapter, Chapter 2, reviews the literature related to the study.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

The literature review of a research report is an interpretative, organized, and written presentation of what the researcher has studied (Aveyard 2014:113). The purpose of conducting a literature review is to discover the most recent and the most relevant information about a particular phenomenon (Gray et al 2017:201). The literature review provides an answer to the question “What is known on this topic?”. The literature review may be a synthesis of research findings, an overview of relevant theories, or a description of knowledge on a topic (Paré, Trudel, Jaana, & Kitsiou, 2015:63).

The researcher in this study used primary sources, books and an international online data base such as Google Scholar to manage a review of different recently conducted scholarly literature across the world consisting of the most relevant information about the researcher’s topic of study. Google Scholar is a freely accessible web search engine that indexes the full text or metadata or scholarly literature across an array of publishing formats and disciplines. Released in beta in November 2004, the Google Scholar index includes peer-reviewed online academic journals and books, conference papers, theses and dissertations, preprints, abstracts, technical reports, and other scholarly literature.

The keywords used for the online database search were; HPV, prevalence, genotype, risk factors, cervical cancer screening, HPV vaccination, pre-cancerous cervical lesion, and Ethiopian women.

2.2. DISCOVERY OF HUMAN PAPILLOMAVIRUS

Previously, the discovery of herpes-simplex 2 virus (HSV-2) DNA in CC tumour cell samples led scientists to hypothesise that HSV-2, an STI that commonly results in genital warts, caused CC (Grace, 2017:1-5). However, in 1976, a German Nobel Prize winner, Harald Zur Hausen, conducted experiments using nucleic acid hybridisation to search for HSV-2 DNA in CC tumour samples. During the experiments, he found inconsistent results that pointed out not all tumour samples contained HSV-2 DNA. This finding led him to question whether or not the HSV-2 caused the CC. After failing to produce evidence of HSV-2 DNA in tumour samples, Zur Hausen began investigating another STI, HPV, as the cause of CC (Grace, 2017:1-5). When he published his hypothesis in 1976, Zur Hausen theorised that HPV infections, which commonly result in genital warts, were the cause of CC. From 1977 onwards, Zur Hausen established his theory that HPV causes CC (Grace, 2017:1-5). From 1980 through 1982, Zur Hausen and his research team analysed genital wart samples and discovered two new types of HPV in the samples, HPV-6 and 11. After isolating and cloning, they searched for HPV-6 and 11 DNA in CC tumour samples to conclude that HPV-6 and 11 caused CC. However, they discovered that the DNA found in the sample was not abundant. Instead, Zur Hausen discovered two new HPV strains, HPV-16 and 18, in the CC tumour samples in 1983 and 1984. Once he identified these two new HPV types and found the prevalence of their DNA in CC tumours, other scientists confirmed that HPV caused CC and determined that HSV-2 was a co-factor to CC (Grace, 2017:1-5).

The continued investigation of this virus by Zur Hausen and his research team confirmed that HPV-6 and 11 were prevalent in genital wart samples. In contrast, HPV-16 and 18 were prevalent in CC samples (Grace, 2017:1-5).

The results of Zur Hausen's experiments on HPV led to improved diagnosis of CC and helped to identify many more HPV types, and were used as a template to develop the HPV vaccines, Gardasil and Cervarix. In 2008, Zur Hausen won

the Nobel Prize in Physiology or Medicine for discovering HPV-16 and 18, the two strains of HPV that cause CC.

2.2.1 Human Papillomavirus Genotypes

Epidemiological studies conducted over the last decade demonstrated that HPV is a common STI worldwide, affecting at least 50% of sexually active individuals of both sexes at some point during their lives (Kremer, van Zummeren, Heideman, Lissenberg-Witte, Snijders, Steenbergen, Dreyer & Meijer 2018:1-15; del Valle-Mendoza et al 2021:1-7).

Among the HPV genotypes identified, 19 are distinguished as high-risk HPV types associated with cervical intraepithelial neoplasia (CIN) 2/3, of which 13 are considered carcinogenic (HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) and 6 are possible carcinogenic (HPV-26, 53, 66, 69, 73, 82). Whilst 9 genotypes are low-risk HPV types associated with genital warts and low-grade squamous intraepithelial lesion (LSIL) (HPV-6, 11, 40, 42, 43, 44, 54, 61, 70) (Obiri-Yeboah, Akakpo, Mutocheluh, Adjei-Danso, Allornuvor, Amoako-Sakyi, Adu-Sarkodie & Mayaud 2017:3).

High-risk HPV genotypes HPV-16 and 18 are responsible for 60–80% of CCs and pre-cancerous cervical lesions among individuals aged 25 years to 40 years worldwide (de Almeida, Martins, Pontes, Corrêa, Montenegro, Pinto, Soares, Vidal, Félix, Bertoni, Szklo & Moreira 2017:1). HPV is epitheliotropic; once the epithelium is infected, the virus can either persist in the cytoplasm or integrate into the host genome. When HPV remains in an episomal non-integrated state, the result is a low-grade lesion. High-grade lesions and cancer may develop when the virus integrates into the human genome (FMOHE 2015).

HPV-16 is the most prevalent type found everywhere (Bruni 2020:12-15). The oncogenic potential of HPV-16 depends on the regulation of viral transcriptional factors. At the initiation of viral infection, the HPV-16 genome can be presented as an unintegrated small DNA molecule, also called episome, resulting in benign

or pre-cancerous lesions of the cervix. However, HPV-16 can integrate its genome into the host genome, which can lead to the development of cervical carcinoma and cervical intraepithelial neoplasia grade III (Chan et al 2019:1-11).

All HPVs contain at least seven early genes (E1 - E7) and two late genes (L1 and L2), E6 and E7 are the only viral factors necessary for the immortalisation of human genital epithelial cells. These two oncoproteins form complexes with host regulatory proteins (p53 and pRB) and facilitate the way to development of cancer in different ways. Integration of E6 with p53 impairs the normal function of DNA repair by degrading the p53 protein. Integration of E7 with pRB pushes the cell to the synthesis phase. Cells being pushed to the synthesis phase and programmed cell death and repair being impaired will lead to uncontrolled cell growth, namely, cancer (FMOHE 2015).

All viral genome integration in combination with dysregulation of the E2 protein, which is a repressor of the oncoprotein, contributes towards the carcinogenic process. These events cause overexpression of E6 and E7 proteins, eventually contributing to viral carcinogenesis by altering cellular apoptotic mechanisms (Chan et al 2019:1-11). Over-expression of E6 and E7 alone is insufficient to contribute to the carcinogenesis as other genetic and epigenetic factors also need to be established.

HPV-16 is the most carcinogenic HPV type, and 50% of all cervical cancers are associated with this genotype (Mirabello, Clarke, Nelson, Dean, Wentzensen, Yeager, Cullen, Boland, Schiffman & Burk 2018:80). In HPV16-positive cells, it is found that E6 and E7 viral genes are retained, and integrated into the host genome and expressed. E6 and E7 are small proteins of 150 and 100 amino acids without any known enzymatic activity, but they can influence the host cell activity by binding with cellular proteins.

E6, for example, binds with E6-associated binding protein (E6AP), a ubiquitin ligase leading to a structural change in E6 allowing it to bind with p53, the cell cycle control tumour suppressor protein to form a trimeric complex E6/E6AP/p53 (Chan et al 2019:1-11). This binding leads to the degradation of p53 and thus

leads to cell proliferation. E7, on the other hand, binds pRb (the other major tumour suppressor) causing its inactivation and degradation. Both the low-risk and high-risk E7 proteins have been shown to target the pRB family members, including p107 (RBL1) and p130 (RBL2), for degradation. pRb downregulates E2F, a transcription factor. As pRb is deactivated by E7, E2F is up-regulated and cell proliferation genes are activated (Chan et al 2019:1-11).

Similarly, Bakir et al (2021:45) states that the oncogenic potential of HPV16 and HPV18 relates to E6 and E7 which block tumour suppressor proteins p53 and retinoblastoma. As a result, a process that leads to the immortalisation of damaged cells begins, which continues to grow and divide out of control. Moreover, E6 and E7 are associated with changes in host DNA and DNA virus methylation. DNA methylation is a biochemical process where a DNA base, usually cytosine, is enzymatically methylated at the 5-carbon position (Harrison & Parle-McDermott 2011:74). E6 and E7 have been shown to bind DNA methyltransferases (DNMT), which impairs their activity, leading to hypermethylation of CpG islands, which can eventually lead to possible silencing of host tumour suppressors (Chan et al 2019:1-11).

An epigenetic modification associated with gene regulation, DNA methylation is of paramount importance to biological health and disease. Interactions of E6 and E7 with cellular proteins and DNA methylation modifications are associated with changes in key cellular pathways that regulate genetic integrity, cell adhesion, immune response, apoptosis, and cellular control (Zhang, Xu, Zhang & Qiao 2020:720-728).

According to Della Fera et al (2021:321), the development of HPV-mediated cancer is associated with long-term persistent infection; continual expression of the viral oncogenic E6 and E7 proteins nullifies cell cycle checkpoints, which finally inhibits immune detection. Consequently, the infected cells over proliferate and cellular mutations accumulate, leading to the formation of HPV-associated cancers.

2.2.2 Prevalence of Human Papillomavirus Infection

Globally, among women with normal cervical cytology (NCC), HPV prevalence was 10.4% and 11.7% in 2007 and 2010, respectively, adjusted to 9.9% in 2019 (Kombe Kombe, Li, Zahid, Mengist, Bounda, Zhou & Jin 2021:2). According to Bruni et al (2019:90-119) a summary report of Human Papillomavirus and Related Diseases in the World posted on 17 June 2019, the prevalence of HPV differs in different countries. It was found that Oceania (a geographic region that includes Australasia, Melanesia, Micronesia, and Polynesia) reported the highest prevalence of HPV at 30.9%, followed by Africa at 21.1%, Europe at 14.2%, America at 11.5%, and Asia 9.4%. In countries from Latin America, the prevalence of HPV type observed was 16.1% according to studies conducted in Trinidad and Tobago, Costa Rica, Honduras, Guatemala, Belize, Mexico, Argentina, Brazil, Chile, Colombia, Paraguay, and Peru (Sichero, Picconi, & Villa 2020:4).

Among Asian countries, adjusted HPV prevalence ranges from 6.2% in South-east Asia (Philippines, Thailand, Vietnam) to 13.6% in Eastern Asia (China, South Korea). Also, the prevalence of HPV in other Asian countries including Japan, Taiwan, and India was 7.0%, 7.0% and 7.5%, respectively (Jaehyun, Sangmi & Byeong-Sun 2020:182). In the general population subgroup in the Middle East and North Africa (MENA) region, the pooled HPV prevalence rate was 16%, with most prevalent HPV in the Northeast Africa region (Egypt) 21% and least prevalent in the Levant (Lebanon, and parts of Syria and Turkey) region 7% (Obeid et al., 2020:1306).

The WHO (2017:56) reported that in Africa, HPV infection prevalence is estimated at 21.3%, with significant variations from region to region, with 33.6% in East Africa, 21.5% in West Africa and 21% in Southern Africa. Across Sub-Saharan African countries, HPV prevalence ranges from 12% in South Africa to 46% in Gabon (Smith, Melendy, Rana & Pimenta 2008:56-57). Specifically, the prevalence of HPV in Nigeria was 14.7% (Gage, Ajenifuja, Wentzensen, Adepiti, Eklund, Reilly, Hutchinson, Wacholder, Harford, Soliman, Burk & Schiffman

2012:2111–2117). In Uganda, the prevalence of HPV was 19.2% (Safaeian, Kiduggavu, Gravitt, Gange, Ssekasanvu, Muroka, Sklar, Serwada, Wawer, Shah & Gray 2008:306–311). Mozambique reported HPV prevalence of 40.0% (Castellsague, Menendez, Loscertales, Kornegay, dos Santos, Gomez-Olive, Lloveras, Abarca, Vaz, Barreto, Bosch & Alonso 2001:1429-1430).

2.2.3 Prevalence and Genotype-Specific Distribution of Human papillomavirus

In a retrospective study conducted in Istanbul, Turkey, on Evaluation of human papillomavirus genotype distribution in cervical samples of 72 female patients, Bakir et al (2021:45-46) found that the prevalence of HPV infection was 35%. The most common HPV types detected in cervical specimens were HPV-16, HPV-51, and HPV-66, 10%, 8%, and 8%, respectively. According to this study, the prevalence of HPV is much higher than the worldwide HPV prevalence, which is 11.7%.

In a study of HPV screening for the detection of pre-cancerous cervical lesions and CC in Israeli women, Feinberg, Yehuda-Shnaidman, Wolf, Sandbank, Segal, Vaknin and Schejter (2021:494:500) found that from a total of 115,807 cervical samples tested for HPV presence, 10,582 (9%) were found positive for one or more of the 14 HR-HPV types tested. In the age group of 25-30, 3,104 (17.5%) women were found positive for HR-HPV (825 had HR-HPV types 16 and/or 18). The screening methods included HR-HPV for HPV-16, 18, and 12 HR-HPV types and the PAP LBC test.

Whilst, Obaid AL-Mawla, Khalil, Murshid and Ameen (2021:1-6), in a cross-sectional study on Prevalence and Genotype Distribution of Cervical High-Risk Human Papilloma Virus in women in Iraq found that the prevalence of HR-HPVs was 12.9%, which was more or less comparative to the worldwide prevalence of HPV 11.7%. HR-HPV genotypes detected during the study were HPV-18-45 (5%), followed by HPV-16 (4.4%), and HPV-11 (3.5%).

On the other hand, a population-based survey conducted between September and December of 2014 on prevalence, genotype distribution and risk factors of cervical HPV infection in Yangqu County of Taiyuan City, China, which enrolled 10,086 women shows that the overall prevalence of HPV infection was 8.9%. This was much less than the overall high-risk HPV infection reported rate among mainland Chinese women, which was 19.0% (Lie et al 2019:1030-1037). The five most common HPV genotypes detected were HPV-16, 52, 58, 53, and 66. HPV-18 was only the eleventh most common type in HPV-positive cases (Yang, Wang, Wang, Wang, Wang, Wang, Zhao, Li, Liu & Hao 2020:1645-1652).

Another cross-sectional study conducted from 11 August 2017 to 11 September 2018 on 12,628 outpatient participants aged from 19 to 84 years at the Third Xiangya Hospital of Central South University, Changsha, Hunan, China, investigated the characteristics and risk factors of HPV infection. The overall HPV infection rate was 13.9% which was lower than that of the overall HPV infection rate among mainland Chinese women (19.0%). The top 5 HPV subtypes detected were HPV-52 (28.01%), HPV-58 (14.83%), CP8304 (11.47%), HPV-53 (10.84%), and HPV-39 (9.64%). HPV-16 and HPV-18 were 9.3% and 3.5%, respectively (Gao, Liou, Yu, Zou, Li, Huang, Zhang, Xu & Zhao 2021:1-10).

According to a systematic review conducted in 2019 on the distribution and prevalence of HPV in Women in Mainland China, the overall high-risk HPV infection rate was 19.0% (95% CI, 17.1%-20.9%), which was higher than the worldwide prevalence of 11.7%. The top five HPV subtypes found were HPV-16, HPV-52, HPV-58, HPV-53, and HPV-18 (Li, Li, Song, Wang & Yin 2019:1030-1037).

Similarly, a cross-sectional study was conducted on the genotype-specific prevalence of HPV infection on 524 asymptomatic Peruvian women from September 2017 to July 2019. The overall prevalence of HPV was 19%. The high-risk HPV genotypes identified in the population studied were HPV-52, HPV-31 and HPV-16, which were 17.6%, 15.7%, and 12.9%, respectively. HPV-18,

another important oncogenic genotype, was only identified in one sample among all the positive women (del Valle-Mendoza et al 2021:2-3).

A study conducted on HPV type distribution in the general female population and in women diagnosed with CC across Western Kazakhstan from 2014 - 2017 shows that a total of 1,166 clinically healthy women, as well as 73 women diagnosed with CC were tested for HPV. The overall prevalence of HPV infection was determined as 25.0% (22.3;27.7 95% CI, p = 0.05). The top five leading HPV types identified were HPV-16 (26.4%), HPV-31 (10.1%), HPV-51 (9.4%), HPV-52 (9.0%), and HPV-6 (7.9%). From the total of 291 HPV-positive women, 236 (81.2%) of them were infected with HR-HPV types (Balmagambetova, Tinelli, Urazayev, Sakieva, Koyshybaev, Zholmukhamedova & Urazayeva 2019:1089-1096).

A population-based study on the prevalence and genotype distribution of cervical HPV infection in the pre-vaccination era was done in the Canary Islands. The study was conducted between 2002 and 2007 on a sample of women aged 18–65 years living in any of the two most populated Canarian Islands: Gran Canaria (GC) and Tenerife (TF). A total of 6,010 women participated in the study. The overall prevalence of HPV infection was 13.6% (CI 12.8%–14.5%) and 11.1% (CI 10.3%–11.9%) for high-risk types, which is more or less comparable to the worldwide prevalence. The most frequent HPV type was HPV-16 followed by HPV-51, HPV-53, HPV-31, HPV-42 and HPV-59 (Andujar, Roura, Torres, Vega, Pavcovich, Sanchez, Lubrano, Trujillo, Almeida, Santana, Hurtado, Arencibia, Benito, Medina, Carballo, Camacho, del Pozo, Quesada, Salido, de Sanjosé, Bruni, & the HPV Canary Study Group. 2020:1-12).

On the other hand, a community-based cross-sectional study titled HR-HPV prevalence and type distribution was conducted from January 2017 to May 2017 in Hurungwe district North-western Zimbabwe. This study, which incorporated 643 participants shows that the overall prevalence of HR-HPV was 17%. The most common types were HPV-16, HPV-18, HPV-35, HPV-52, HPV-58, HPV-68, HPV-18, and HPV-51 (Fitzpatricka, Dube Mandishorab, Katzensteinc, McCartye, Webera, Sahooa, Manasab, Chirenjef, & Pinskya 2019:24-25).

Another community-based study done on the prevalence and distribution of HPV genotypes among women in Kinshasa, the Democratic Republic of the Congo, between July 2015 and July 2017 reveals that among 1,870 samples collected from women at baseline, 27.8% of them tested positive for HPV. Out of this, 24.4% of them were HR-HPV positive. The most prevalent HPV types were HPV-68, HPV-58, HPV-52, HPV-53 and HPV-35 (Mutombo, Ina Benoy, Tozin, Bogers, Van geertruyden & Jacquemyn 2019:4-5).

Similarly, a population-based cross-sectional study which included 2002 women, was conducted on characterization of HPV prevalence and risk factors to guide CC screening in the North Tongu District, Ghana in 2019. The prevalence of high-risk HPV types was 32.3%, which was much higher than the worldwide prevalence. The five most common detected HPV types were HPV-16 (7.4%; 95%CI: 6.3–8.7), HPV-52 (7.2%; 95%CI: 6.1–8.5), HPV-35 (4.8%; 95%CI: 3.9–5.8), HPV-59 (4.7%; 95%CI: 3.8–5.8), HPV-56 (3.9%; 95%CI: 3.1–4.8). (Krings, Dunyo, Pesic, Tetteh, Hansen, Gedzah, Wormenor, Amuah, Behnkel, Hofler, Pawlita & KaufmannI 2019:1-20).

In contrast to other studies, a study conducted in the Eastern Cape Province of South Africa between April and May 2019 on High HPV prevalence among 213 high school females reveals an extremely high overall HPV prevalence rate, which was 76.06%. The most dominant HPV types were HPV-62 (16.4%), followed by HPV-61 (13.6%), HPV-59 (13.6%), and HPV-51 (10.8%). HPV-16 and HPV-18 accounted for only 8.5% and 8%, respectively. Prevalence of HR-HPV types 54.46% was as high as that of LR-HPV types 53.52% (Mbulawa, Somdyala, Mabunda & Williamson 2021:5). The prevalence of HPV in this study was 6.5-fold to the worldwide prevalence which was 11.7%.

Moreover, a cross-sectional study entitled with HPV types, cervical high-grade lesions and risk factors for oncogenic HPV infection among 3,416 Tanzanian women was conducted in existing CC screening clinics in Kilimanjaro and Dar es Salaam. The study included 609 HIV-positive women and 2,807 HIV-negative women. The overall HR-HPV prevalence was 18.9%, whereas the HR-HPV prevalence in women with high-grade squamous intraepithelial lesions (HSILs)

was 92.7%. Among HPV-positive women with HSIL, HPV-16 (32.5%) and HPV-58 (19.3%) were the most common types followed by HPV-18 (16.7%) and HPV-52 (16.7%) (Mchome, Kjaer, Manongi, Swai, Waldstroem, Iftner, Wu, Mwaiselage, & Rasch 2021:56-62).

2.2.4 Risk Factors Associated with Human Papillomavirus Infection

High-risk sexual behaviour is the main risk factor associated with the acquisition and persistence of HPV infection and development of HPV-associated cancers (Rettig, Kiess & Fakhry 2015:35-49). High-risk sexual behaviour is sexual activity that puts a person at risk for acquisition of STIs, such as human immunodeficiency virus (HIV), HPV, unplanned pregnancy, and being in a sexual relationship before a person is mature enough to know what makes a healthy relationship.

Teens and young adults are at higher risk than adults because they may not understand the concern about STIs and how they are transmitted, or they may not talk about safer sex practices with sex partners. Teens and young adults are not prepared or do not understand how to use protective measures to prevent STIs and may not also be aware of symptoms of STIs after they have been exposed to them. In addition, people within these age groups may not seek medical care for STI symptoms if occurred. On top of that, they may not have access to treatment or be able to afford treatment. The other serious part of these age groups' sexual activity is that they may use alcohol and drugs and have sex.

Drugs and alcohol impair judgment and make unsafe sex more likely. Infection with other STIs, including HIV, a high number of lifetime sexual partners, early sexual debut and host susceptibility are documented risk factors for HPV infection (Ndizeye, Vanden Broeck, Lebelo, Bogers, Benoy & Van Geertruyden (2019:2). The risk factors for acquiring HPV and CC include a weakened immune system; smoking; sexually-transmitted infection, Chlamydia infection; long-term use of oral contraceptives; having children at a young age; having

multiple sexual partners, and a family history of CC (Zhang, Xu, Zhang & Qiao 2020:722).

A cross-sectional study conducted from 11 August 2017 to 11 September 2018 on 12,628 outpatient participants aged from 19 to 84 years at the Third Xiangya Hospital of Central South University, Changsha, Hunan, China, investigated the characteristics and risk factors of HPV infection. Age (OR 1.01; 95% CI 1–1.01; $P < 0.05$) and alcohol consumption (OR 1.30; 95% CI 1.09–1.56; $P < 0.01$) were found to be risk factors for HPV infection. However, the presence of Candida in the vaginal flora was found to be a protective factor against HPV infection (OR 0.62; 95% CI 0.48– 0.8; $P < 0.001$) (Gao et al 2021:1–10).

Whilst, a population-based survey between September and December of 2014 enrolled 10086 women on Prevalence, genotype distribution and risk factors of cervical HPV infection in Yangqu County of Taiyuan City, China shows that low educational level, low income, smoking, age at first sexual encounter <23 years old, and number of births ≥3 times were potential risk factors for infection with HR-HPV cases (Yang et al 2020:1645-1652).

Andujar et al (2020:1-12), in a population-based study conducted on a sample of women aged 18–65 years living in any of the two most populated Canarian Islands; 3,847 from Gran Canaria and 2,163 from Tenerife shows that factors associated with an increased risk of HPV infection included young ages 18–29 years, the number of sexual partners throughout life, not being married, being a smoker, and having had previous cervical lesions or genital warts.

A cross-sectional study entitled HPV prevalence and risk-factors among HIV-negative and HIV-positive women residing in rural Eastern Cape, South Africa was conducted at a community health clinic. A total of 417 women aged 30–98 years were recruited for the study between September 2017 and August 2018. HIV-positive status (OR 2.52, 95% CI 1.63–3.90), having ≥3 lifetime sexual partners (OR 2.12, 95% CI 1.16–3.89), having ≥1 sexual partner in the last month (OR 1.89, 95% CI 1.21–2.92), ≥4 times frequency of vaginal sex in the past month (OR 2.40, 95% CI 1.32–4.35), and having a vaginal discharge

currently/in the previous week (OR 2.13, 95% CI 1.18–3.85) had increased the risk of acquiring HR-HPV infection. In the multivariate analysis, HIV positivity remained strongly associated with HR-HPV infection (OR 1.94, 95% CI 1.17–3.22) (Takua, Busingec, Mdaka, Phohlo, Basera, Garcia-Jardon, Meiring, Gyllensten, Williamson & Mbulawaa 2020:176-182).

After the multivariate logistical regression of the population-based cross-sectional study conducted on the characterisation of HPV prevalence and risk factors to guide CC screening in the North Tongu District, Ghana, only the factors of age, marital status and number of sexual partners appeared to have a high association for HPV infection. Younger age had a higher OR for infection. Being single (AOR: 2.6; 95%CI: 1.8–3.8; p-value: <0.001), having a steady partner but not living together (AOR: 2.2; 95%CI: 1.6–2.9; p-value: <0.001) and being divorced (AOR: 1.9; 95%CI: 1.2–3.0; p-value: 0.011) were highly associated with high-risk HPV positivity. Living with someone but not being married (AOR: 1.3; 95%CI: 1.0–1.7; p-value: 0.047) was also associated with infection. The more sexual partners a woman had, the higher the ORs for infections were (e.g., >3 partners AOR: 5.0; 95%CI: 1.7–14.6; p-value: 0.004). Interestingly, there was already a high association for infection with the first sexual partner (AOR: 3.3; 95%CI: 1.1–9.3; p-value: 0.027) (Krings et al., 2019:1-20).

A cross-sectional study entitled HPV types, cervical high-grade lesions and risk factors for oncogenic HPV infection among 3,416 Tanzanian women was conducted in existing CC screening clinics in Kilimanjaro and Dar es Salaam. The study included 609 HIV-positive women and 2,807 HIV-negative women. Factors associated with HR-HPV included younger age, increasing number of partners and early age at first intercourse. Similar risk factors were found among HIV-positive and HIV-negative women. In addition, among HIV-positive women, those with CD4 counts <200 cells/mm3 had an increased risk of HR HPV (OR 2.2; 95% CI 1.2 to 4.8) compared with individuals with CD4 count ≥500 cells/mm3 (Mchome et al 2021:56-62).

2.3 PREVENTION OF HUMAN PAPILLOMAVIRUS INFECTION AND CERVICAL CANCER

Globally, healthcare programmes have used two strategies to monitor and control HPV infection and CC: creating high-coverage vaccination programmes or high-coverage screening programmes (Obeid et al 2020b:1304-1313). However, perhaps the most effective strategy would be the use of both programmes together.

HPV vaccines are very effective at preventing infections and diseases related to the vaccine-specific genotypes in women with no evidence of past or current HPV infections. On the other hand, screening programmes have consistently been associated with a reduction in CC incidence and mortality, which are the consequences of HPV infection. In this regard, developed countries have achieved reduced incidence and mortality from CC over the past 40 years. This is largely due to the implementation of organised cytological screening and vaccination programmes. Despite the successful implementation of the HPV vaccination programme in many countries all over the world, problems related to HPV prevention and treatment of related diseases will continue to persist in developing and underdeveloped countries.

There are also apparent limitations and public health challenges in attempting to implement HPV vaccination programmes. These limitations and challenges include the vaccine's type specificity, required to be given prior to exposure, the three-dose schedule, ethical issues in targeting the age group of early adolescence, and potential communication challenges around HPV being an STI (Brotherton 2019:138-140).

Therefore, large groups of advanced-age women who have not received vaccination are still at the risk of CC development (Chan et al 2019:1-11). For instance, Ethiopia has a population of 33.7 million women aged 15 years and older who are at risk of developing CC (ICO/IARC 2021:1-2). Furthermore, CC screening and HPV vaccination are complementary preventive options often

implemented as separate and non-coordinated public health programmes. The HPV-FASTER protocols aim to address this disconnect by combining both strategies with the ultimate purpose of accelerating the reduction of CC incidence and mortality and making the programmes both cost-effective and sustainable (Faster 2018:1-5).

The proposal of the “HPV FASTER” protocol is to offer HPV vaccination to women in a broad age range of 9 to 45 years, irrespective of HPV status. In addition to the vaccination, women of any age above 25/30 years would be screened using a validated HPV test as part of their initial visit; women who test HPV-positive would be offered triage and follow-up diagnostic tests and treatment (Faster 2018:1-5). From the review given here, it is clear that the CC screening, along with the HPV vaccination programme, should be implemented and supported at a governmental level in developing countries with high incidence and mortality of CC. Unfortunately, the application of these programmes is still out of the economic reach of the developing countries, including Ethiopia (Obeid et al 2020b:1304-1313). HPV detection using DNA testing is beyond what many developing countries can afford. This is also a serious problem in Ethiopia.

The national approach to prevent CC in Ethiopia is the ‘Screen and Treat’ using a screening test that gives immediate results (like visual methods, VIA) followed by “on the spot” treatment (e.g. using cryotherapy) of detected lesions, without any further tests unless a suspected cancer is a preferred approach (FMOHE 2015). This is because it: can effectively identify most precancerous lesions, is non-invasive, easy to perform and inexpensive, can be performed by all levels of healthcare workers in almost any setting, provides immediate results that can be used to inform decisions and actions regarding treatment, requires supplies and equipment that are readily available locally.

To reduce the number of times a woman needs to visit the clinic, the “Single Visit” approach, “see-and-treat” approach is preferred for managing pre-cancerous cervical lesions. The “Single Visit” approach links VIA with treatment using cryotherapy. Using this approach, women with VIA-positive results and for

whom cryotherapy is indicated are offered treatment on the spot. The main advantage of this approach is that it reduces the number of women lost to follow-up. This loss often occurs when women have to return to the clinic for the screening test results, diagnostic follow-up and possible treatment.

In conclusion, the HPV FASTER protocol can be applied in Ethiopia with some modifications (since it is not currently feasible to make use of it all in all) integrated with the country's national strategy, which is 'Screen and Treat' approach as per the researcher's point of view. The approach is further discussed in Chapter 7 under the strategy development section.

2.3.1 Human Papillomavirus Vaccination

2.3.1.1 History of HPV Vaccine Development

Vaccines are critical to the prevention and control of many communicable diseases and, therefore, underpin global health security as they are widely seen as critical for addressing emerging infectious diseases, for example by containing or limiting outbreaks of infectious diseases or combating the spread of antimicrobial resistance (WHO 2021:6). Vaccination prevents an estimated 2.5 million deaths each year (WHO 2013:12). So that, immunisation is, and should be recognised as, a core component of human right to health and an individual, community and governmental responsibility.

After the identification of HPV as the primary cause of CC in the 1980s, work ensued to develop a vaccine (Markowitz & Schiller 2021:S367–78). In the 1980s and 1990s, studies in animal models demonstrated that animals could be protected against papillomavirus lesions using purified virions, neutralising antibodies was necessary and sufficient for protection against viral challenge, and protection was likely specific to the HPV type. Vaccine development focused on sub-unit approaches owing to the challenges in propagating papillomaviruses and because of the oncogenes contained in the viral genome (Markowitz & Schiller 2021:S367–78). All licensed HPV vaccines completed a

range of safety, immunogenicity and efficacy trials before licensure (Schiller, Castellsagué & Garland 2012:F123–38).

The first efficacy trials were randomised controlled trials (RCTs) among young women aged 15–26 years (Markowitz & Schiller 2021:S367–78). Although the target group for HPV vaccination programmes is preadolescents and young adolescents, efficacy trials were not feasible in that age group, primarily because it would take too long to accrue a sufficient number of STIs or lesions. HPV vaccines were licensed in young adolescents based on bridging immunogenicity trials and safety data (Markowitz & Schiller 2021:S367–78). Later, RCTs were conducted among women >26 years old and among men.

The first vaccine for prevention of morbidity and mortality attributable to HPV associated disease was licensed in 2006 (Kjaer, Dehlendorff, Belmonte & Baandrup 2021:1329-1335). The quadrivalent vaccine was first licensed in 2006, the bivalent vaccine in 2007 and the nonavalent vaccine in 2014 (WHO 2017:241-268).

Initial commercial development of HPV vaccines was under taken by 2 companies, GlaxoSmithKline Biologicals (GSK) and Merck & Co (Markowitz & Schiller 2021:S367–78). GSK developed a bivalent vaccine (Cervarix), composed of HPV16 and HPV18 VLPs. Merck developed a quadrivalent vaccine (Gardasil), with HPV-16 and HPV-18 as well as HPV-6 and HPV-11 VLPs. Merck later developed a nonavalent vaccine, Gardasil 9, similar to Gardasil but containing L1 VLPs of 5 addition oncogenic types HPV-31, 33, 45, 52, and 58 and so has the potential to provide type-specific protection against approximately 90% of CCs worldwide (de Martel, Plummer, Vignat & Franceschi 2017:664–670).

Human papillomavirus vaccines are the first vaccines to prevent infection by a mucosatropic sexually transmitted infectious agent and do so without specific induction of mucosal immunity. They are also the first sub-unit vaccines to consistently induce long-term (more than a decade) stable serum antibody responses (Markowitz & Schiller 2021:S367–78). Furthermore, they are among

the most effective prophylactic vaccines available and have established several essential landmarks in human vaccinology.

Prophylactic HPV vaccines contain virus-like-particles (VLPs), which consisting of self-assemble spontaneously from 72 pentamers of the L1 major capsid protein (Arbyn & Xu 2018:1085-1091). Because these vaccines are produced from a single virion protein, they are non-infectious and non-oncogenic (Markowitz & Schiller 2021:S367–78). The VLPs are morphologically similar to authentic viruses and induce high titres of virion-neutralising antibodies. Administration of these vaccines by intramuscular injection triggers the production of antibodies that are believed to prevent new type-specific infections and the subsequent development of cervical intraepithelial neoplasia. The ultimate goal of HPV vaccination is to prevent invasive CC by preventing infection with major oncogenic types of HPV (Lei et al 2020:1340-1348).

2.3.1.2 Strategies to Promote Provision of HPV Vaccine

Research findings from different countries in recent years show that the utilisation of HPV vaccines is very effective for preventing infection and disease related to the specific HPV genotypes. Hence, vaccination programmes have been successfully implemented in many countries all over the world (Chan et al 2019:1-11). For instance, in countries with long-standing screening programmes, catch-up vaccination cohorts and established registration have demonstrated reductions in the diagnosis of cervical intraepithelial neoplasia in screening women due to vaccination (Brotherton 2019:138-140). Additionally, researchers from Scotland show a reduction of low and high-grade CIN associated with high uptake of the HPV bivalent vaccine at the population level (Palmer, Wallace & Pollock, 2019:1161). Results from one of the studies from Japan demonstrated that women aged 20–24 years who received HPV vaccination had significantly lower rates of abnormal cervical cytology results compared to those who did not receive the vaccine (Tanaka, Shirasawa & Shimizu 2017:1597-1601).

A study from Australia found that the use of tetravalent (another term for quadrivalent) HPV vaccine, composed of HPV-16 and HPV-18 as well as HPV-6 and HPV-11 VLPs helps to reduce cases of high-grade and low-grade squamous intraepithelial lesions in females (Gertig, Brotherton, Budd, Drennan, Chappell & Saville 2013:227).

Although vaccination is an effective way to reduce CC, people's acceptance of vaccination remains a big challenge in developing countries (Perlman, Wamai & Bain 2014:e90912). HPV vaccination provides an opportunity for low-resource settings to reduce the burden of CC (Saqer, Ghazal & Barqawi 2017:1237). Vaccine hesitancy is complicated and context-specific. Thus, hesitancy is caused by individual, group, and discourse influences, yet as any vaccine-specific problems. Every country must take steps to understand the extent and nature of hesitancy at an area level on an unbroken basis. Consequently, every country ought to develop a strategy to extend acceptance and demand for vaccination that should embrace current community engagement and trust-building, active hesitancy hindrance, regular national assessments of considerations, and crisis response designing (Lane, MacDonald & Marti 2018:3861–3867).

In Ethiopia, misconceptions about the cause and prevention of CC are common due to a lack of awareness and poor health-seeking behaviour (Alene, Atnafu, Mekonnen & Minyihun 2020:8519–8526).

The HPV vaccine was introduced in Ethiopia in December 2018, targeting 14-year-old girls. The Ethiopian Ministry of Health has been leading the rollout and conduct of the HPV vaccination in collaboration with regional health bureaus and the education sector, key stakeholders, and different partners including WHO, UNICEF, CHAI, PATH, Jhpiego, Girls Effect and Save the Children (WHO Regional Office for Africa 2021:1-4). The vaccines are acquired through the support of GAVI, the Vaccines Alliance. The benefit of vaccinating girls against HPV infection is not even debatable. Advocacy, social mobilisation and consistent awareness creation activities should be conducted prior to the HPV

vaccination campaigns to scale up the uptake of HPV vaccination. Consistent broadcasting of the benefits of the HPV vaccine through national, regional and community media (TV and radio), and on educational TV channels as well as in schools should be strengthened to ensure high HPV vaccine uptake.

Development of comprehensive communication materials (guidebooks, leaflets, banners, and posters) and community sensitisation meetings with health workers should be held to raise awareness about HPV vaccination campaigns and address any questions. Intense advocacy efforts should also be undertaken to sensitize technical stakeholders, such as the government, state and district officials, local political leaders, and community leaders, using meetings and sensitisation workshops. This will ensure uniformity of messages disseminated among key stakeholders, who further act as advocates for the HPV vaccine in their communities. State public health officials should undertake sensitisation workshops with the representatives of major radio and print media outlets. Launching ceremonies should be conducted to ensure maximum dissemination of campaign messages to the community.

2.3.1.3 Provision of HPV Vaccine

According to Montoliu et al (2021:2), as of June 2020, 107 (55%) of the 194 WHO member states were considered to have introduced HPV vaccination nationwide or partially. High-income countries were the first to introduce HPV vaccination, and there remain disparities by income, with >85% of high-income countries having introduced vaccination, compared with only 30% of lower-income countries (Markowitz & Schiller 2021:S367–78). WHO has collected data and calculated coverage measures since 2010 for females and since 2019 for males. In general, countries with school-based vaccination programmes have achieved higher coverage (mean, 20% higher) than those with health facility-based programmes (Markowitz & Schiller 2021:S367–78). This is because; schools are the best places to get most adolescents together, they are well-positioned to integrate positive messages about the vaccination and decision-making for parents is influenced by school-based vaccinations.

Currently, 30 European countries have introduced HPV vaccination into their national immunisation programmes recommending vaccination for pre-adolescent females and 17 countries for males (Fallucca et al 2022:998).

Ethiopia launched the HPV vaccine for the first time with the support of the Global Alliance for Vaccine and Immunization (GAVI) in 2018 (WHO-Ethiopia 2018). The vaccine is currently being delivered primarily through a school-based approach to reach all eligible girls. Accordingly, Ethiopia should introduce HPV vaccination into its national immunisation programmes recommending vaccination for pre-adolescent females. According to (WHO 2021:1-4), Ethiopia had completed an HPV vaccination campaign targeting 2.4 million 14-year-old girls across the country in two cohorts. Recently, Ethiopia delivered a campaign which commenced on 10, January 2022 and ended on 22, January 2022, aimed to immunise over 1.8 million 14-year-old girls in nine regions against HPV (Derbie et al 2022b:1-8).

As stated in HPV vaccination (CDC 2021), HPV vaccines can be given starting at age 9 through 45 years who are not already vaccinated. However, the CDC recommends HPV vaccination for ages 11-12 years, and teens and young adults through age 26 years who have not already started or finished the vaccine. HPV vaccination is not recommended for ages 27 through 45 years as it provides less benefit, because more people in this age range have already been exposed to HPV. However, some adults in this age range who are not already vaccinated may decide to get an HPV vaccine after speaking with their doctor about their risk for new HPV infection and the possible benefits of vaccination for them. With regard to the doses, the CDC recommends that only two doses are needed if the first dose was given before the fifteenth birthday that would be received 6 to 12 months apart. Teens and young adults who start the series later, at age 15 through 26 years, need three doses of the HPV vaccine (CDC 2021).

Vaccination schedule: The current evidence supports the recommendation for a 2-dose schedule with adequate spacing between the first and second dose in

those aged 9–14 years. This schedule also has cost- saving and programmatic advantages that may facilitate high coverage (CDC 2021).

For HPV vaccines, a 2-dose schedule with a 6-month interval between doses is recommended for individuals receiving the first dose before 15 years of age. Those aged ≥15 years at the time of the second dose are also adequately covered by 2 doses. There is no maximum recommended interval between doses. However, an interval no greater than 12–15 months is suggested in order to complete the schedule promptly and before becoming sexually active. If the interval between doses is shorter than 5 months, a third dose should be given at least 6 months after the first dose. A 3-dose schedule (0, 1–2, 6 months) should be used for all vaccinations initiated ≥15 years of age, including in those younger than 15 years known to be immunocompromised and/or HIV-infected (regardless of whether they are receiving antiretroviral therapy). It is not necessary to screen for HPV infection or HIV infection prior to HPV vaccination (WHO 2017:241-268).

2.3.2 Cervical Cancer Screening

The other key aspect of the prevention of CC, which is a sequela of persistent infection with any of the high-risk HPV genotypes is the identification and treatment of the premalignant cervical lesion by CC screening (Getaneh, Tegene & Belachew 2021:775). Cervical cancer screening is an essential part of routine health care for anyone with a uterine cervix. It is well known that CC screening can reduce CC incidence and mortality (Chan et al 2019:1-11).

Routine CC screening has been shown to greatly reduce both the number of CC cases and deaths from the disease. Cervical cancer screening strategies are different among countries. Some countries have population-based programmes, whereby women in the target population are individually identified and invited to the screening. In opportunistic screening, invitations depend on the individual's decision or encounter with health care providers. Organised cervical screening programmes may achieve high participation at regular intervals with equal

access, and high-quality standards for diagnosis, thus potentially more effective than opportunistic screening (Bucchi, Baldacchini & Mancini 2018:1-10).

Three different types of screening are currently available: (1) Cytology-based screening (Conventional Pap smear (Pap), liquid-based cytology (LBC) and colposcopy + biopsy). (2) Visual inspection (Visual Inspection with Acetic Acid (VIA), Visual Inspection with Lugol's Iodine (VILI) and digital imaging approaches i.e Automated visual evaluation (AVE)). (3) Molecular (Nucleic Acid tests (NAT) includes HPV DNA (e.g., Abbott, Roche Cobas, Qiagen, Cepheid Xpert, and others) and mRNA (Hologic Aptima), and Protein biomarkers (HPV antibodies, oncoproteins e.g., OncoE6/QIAsure) testing for high-risk HPV types (FMOHE 2015).

For many years, cytology-based screening, known as the Pap test or Pap smear was the only method of screening. It has been reported that the Pap test can reduce the incidence rate and the mortality rate of CC by 79% and 70%, respectively (Patel, Hari, Bernstein, Farfel & Raman 2018:165). Since the introduction of the Pap smear cytology testing in the 1950s and 1960s, CC incidence and mortality have declined in the United States with organised CC screening programmes and screening rates of 83% (Virginia 2012:880-890). On the other hand, population coverage by screening programmes in developing countries ranges only between 6% and 8% (Chan et al 2019:1-11). There are many reasons mentioned as barriers against cervical screening in developing countries. These include shortage and underutilisation of screening facilities, lack of awareness and poor attitude towards CC and risk factors, beliefs about CC, feeling healthy, stigma, fear of the test results and fear of marital disturbance (Getaneh et al 2021:775).

The principles of molecular testing are as follows: To amplify HPV targets, a primer mix of three forward primers and two reverse primers targeting a conserved late protein (L1 region) is utilised. Fluorescently labelled probes are used to create a signal for high-risk (HR) HPV genotypes. Internal Control (IC) amplicons are produced using a primer set that targets an endogenous human beta globin sequence and identified using an IC specific probe. As a sample

validity control for cell adequacy, sample extraction, and amplification efficiency, the Abbott Real Time HR-HPV assay identifies the endogenous human beta globin sequence. Different fluorophores are used to mark probes for HPV-16, HPV-18, non-HPV 16/18 genotypes (Other HR-HPVs), and IC, allowing their signals to be distinguished in a single reaction (WHO 2014:1-15).

Ethiopia has been working on cervical screening using VIA for more than a decade and a new primary screening modality (HPV DNA test) was initiated in 2021 to screen women with HIV as a pilot (Bogale, Belay, Medhin & Ali 2020:179).

The current recommended CC screening method in resource limited settings like sub-Saharan Africa is a visual inspection of the cervix using acetic acid (VIA) (Kiros, Mesfin, Getu, Hailemichael, Esmael, Andualem & Geteneh 2021:719-725).

Visual inspection of the cervix with acetic acid is an effective, inexpensive, safe, non-invasive and acceptable screening test that can be combined with simple treatment procedures for early cervical lesions, provided by trained health workers that can save lives from CC even in remote areas with few resources like a health centre (Poli, Bidinger & Gowrishankar 2015:203–207). VIA is one of the visual inspection methods for CC screening, which is easy to perform and can be done by health professionals of all levels. It is performed by application of acetic acid to the cervix and looking for the presence of an aceto-white reaction to detect pre-cancerous lesions of the cervix.

The visual inspection is made after applying 3-5% acetic acid to the uterine cervix. If an abnormal load of cellular proteins is present in the cervical epithelium, the acetic acid coagulates the proteins conferring an opaque and white aspect of the concerned area. VIA sensitivity for detecting pre-cancerous lesions is comparable to or greater than even cervical cytology, while requiring fewer resources and is feasible to carry out in low-level health facilities. More importantly, VIA provides instant results, and those eligible for treatment can receive treatment of the pre-cancerous lesions using cryotherapy on the same

day and in the same health facility. This “see and treat” method ensures adherence to treatment soon after diagnosis, hence stemming the problem of failing to honour patient referrals.

The primary goal of screening is to identify abnormal cervical cells with severe cell changes (also called pre-cancerous lesions) caused by HPV, so they can be removed to prevent invasive cancers from developing. Most developed countries have well-organised strategies for organised screening, early detection, and successful treatment of pre-cancerous cervical lesions. A secondary goal is to find CCs at an early stage, when they can usually be treated successfully.

In Ethiopia, more than 200 health facilities are providing VIA screening followed by cryotherapy (ablative treatment technique) (Haile et al 2019:e16970). Moreover, Loop electrosurgical excision procedure (LEEP) service was scaled up from 5 to 15 hospitals and the Federal Ministry of Health (FMOHE) is working to expand VIA screening and cryotherapy into 823 districts. However, more efforts on other screening techniques are urgently necessary to scale up the CC screening coverage in Ethiopia. Besides, using rapid, easy to-use, and low-cost molecular tests; such as the OncoE6 test that directly detects the elevated levels of the E6 oncoprotein of HPV types 16 and 18 can be used as a preferred screening test.

2.3.2.1 Prevalence of Pre-cancerous Cervical Lesions

A cross-sectional study was conducted in a Tertiary Care Hospital in Bangalore, India, to determine the prevalence of pre-malignant and malignant cervical lesions among patients. A total of 516 women were screened by a single round of VIA testing with a positive rate of 11.2%, and 3.5% were biopsy-positive. Out of 516 women, VIA was positive in 58 cases (11.2%). Biopsy was done in 57 cases and biopsy was positive in 18 cases (3.5%). Biopsy reports showed 9 women with squamous cell carcinoma, 1 with adenocarcinoma, 1 with CIN1, 3 with CIN3, 4 with koilocytic atypia. The positive predictive value for VIA is 30%.

The prevalence of pre-malignant and malignant lesions of the cervix is 3.5% (Jagruthi & Hemavathi 2019:2758).

Another retrospective study entitled HPV Screening Test for the Detection of Pre-cancerous Cervical Lesions and Cervical Cancer in Israeli Women was performed in Maccabi HealthCare HMO from March 2017 to March 2019. Of 10,582 found positive for one or more of the 14 HR-HPV types tested, 3,916 (37%) showed abnormal PAP LBC results. In the age group of 25-30, 3,104 women were found positive for HR-HPV, of which, 1,293 (42%) showed abnormal PAP LBC results (Feinberg et al 2021:494-500).

According to a hospital-based cross-sectional study conducted from August to October 2017 in Bamenda, Cameroon on the prevalence of pre-cancerous cervical lesions in women attending Mezam Polyclinic, which included a total of 60 women, the prevalence of pre-cancerous cervical lesions was 3.33% (Nkfusai, Mubah, Yankam, Tambe, & Cumber 2019:1-12).

Whilst, a cross-sectional study, entitled prevalence of precancerous cervical lesions and high-risk HPV types in Yaounde, Cameroon, targeting HPV-positive women aged 20 and over, conducted between March and June 2020 reveals that pre-cancerous cervical lesions were found in 69.34% of participants. The study was performed on 616 women (Simo, Nono, Dongmo, Etet, Fonyuy, Kamdje, Yanou & Telefo 2021:1-7). The study also shows a higher prevalence of pre-cancerous cervical lesions than the above-mentioned study in the same country in different areas, which was 3.33% (Nkfusai et al 2019:1-12). This huge difference might be because of the sample size difference, the study area, the time of the study done, and the screening method used. The former used visual inspection methods but the later used the cytologic test, which was a Pap smear test.

2.3.2.2 Risk Factors Associated with Pre-cancerous Cervical Lesions

A cross-sectional study with 925 participants was conducted to determine the prevalence and risk factors associated with pre-cancerous cervical lesions among women in two cities in Cameron from June to November 2018. Factors associated with pre-cancerous cervical lesions were: age 1.85 [1.42-2.41; p= 0.001] and parity [OR= 1.46; 95% CI: 1.30-1.89; P= 0.004] (Bernard Wabo et al 2022:276).

Another cross-sectional study conducted on visual inspection with acetic acid positivity among female sex workers, between June 2014 and July 2015 in Kampala, Uganda, reveals that VIA positivity was associated with women who reported having more than one life-time sexual partners (AOR = 3.34, 95 %CI: 1.38–8.12), and HIV-positive women (AOR = 4.55; 95 %CI: 2.12–9.84) (Namale, Mayanja, Kamacooko, Bagiire, Ssli, Seeley, Newton & Kamali 2021:1-11).

Asseffa (2017:1-5) found that high parity, early marriage, having multiple sexual partners, poverty that forces a woman to engage in sex work for a living and co-infection with HIV that reduces immunity status are risk factors that contribute to the acquisition of HPV infection and its progression to CC. Lack of awareness regarding HPV infection and its effect in causing CC, and inadequacy of CC screening and treatment services are other contributing factors for pre-cancerous cervical lesions and CC development.

2.3.2.3 Treatment of Pre-cancerous Cervical Lesions

Cervical intraepithelial neoplasia (CIN) is a pre-malignant lesion that may exist at any one of three stages: CIN1, CIN2, or CIN3. If left untreated, CIN2 or CIN3 (collectively referred to as CIN2+) can progress to CC (WHO 2013 Guidelines). It is estimated that approximately 1–2% of women have CIN2+ each year. This rate is reported to be higher in women of HIV-positive status, at 10%. There is a clear consensus that high-grade cervical intraepithelial neoplasia (CIN II–III) lesions should be treated because they are more likely than low-grade lesions

(CIN I) to progress to cancer (FMOHE 2015). For the treatment of pre-cancerous lesions, the treatment options are cryotherapy, thermocoagulation, cold knife conization and loop electrosurgical excision procedure (LEEP).

Large-loop excision of the transformation zone (LLETZ): An excisional method for the treatment of CIN. A wire loop electrode powered by an electrosurgical unit (ESU) is used to resect the transformation zone along with the lesion. It removes the entire transformation zone (not just the lesion) along with an adequate extent of normal adjacent epithelium, to ensure there is a disease-free margin of at least 2–3 mm and the full depths of the crypts in the transformation zone have been removed. LLETZ is used for both diagnostic and therapeutic interventions.

Loop electrosurgical excision procedure (LEEP): This terminology has commonly been replaced by the more specific and original term LLETZ for therapeutic interventions.

Small-loop electrosurgical biopsy: A small loop (3–5 mm diameter) excision as a directed diagnostic biopsy, as an alternative to punch biopsy, especially where cancer, microinvasive cancer or glandular disease is suspected.

Thermal ablation: Refers to the destruction of abnormal cervical tissue by extreme temperature, commonly used for hyperthermia (elevated tissue temperatures of at least 100 °C).

Cryotherapy: The application of extreme hypothermia to the cervix by applying a highly cooled metal disc (cryoprobe) to the cervix and freezing the abnormal areas (along with normal areas) covered by it. This is another form of ablative treatment.

Cold knife conization (CKC): The surgical removal of the central cervix, including portions of the outer (ectocervix) and inner cervix (endocervix) using a scalpel. It is usually performed with anaesthesia in a hospital. The amount of tissue removed will depend on the size and site of the transformation zone and the

likelihood of finding invasive cancer. Excision treatments have been sub-divided by type.

There are factors affecting the choice of treatment options such as method effectiveness, safety and potential side effects, availability of qualified personnel to provide it, the size, extent, severity and site of the lesion, acceptability of treatment offered by the women, and availability of the method.

In low-resource settings, recent WHO guidelines recommend cryotherapy as a good alternative treatment for eligible VIA-positive lesions. Cryotherapy is a procedure that eliminates pre-cancerous lesions on the cervix by freezing them. It is a simple and inexpensive procedure, that can be completed in less than 30 minutes. It uses carbon dioxide gas or nitrous oxide gas as the coolant. It works by applying a highly cooled metal disc (cryotip or cryoprobe) to the cervix and freezing its surface using the “double-freeze” technique and it does not require anaesthesia. The cooled surface of the cervix becomes fragile, abnormal cells fall off the cervix and new healthy cells grow back.

Cryotherapy as a method of treatment for pre-cancerous lesions is effective and easier to implement than other treatment modalities. Furthermore, it has additional advantages, including the fact that it is affordable; there is no need for complicated equipment (although a supply of electricity is needed); and it can be done by less specialised personnel and thus can be implemented in a primary health care (PHC) setting. Evidence showed up to 90% cure rate in those women who received cryotherapy (FMOHE 2015).

A cross-sectional study was conducted among 356 VIA-positive women, aged 30-50 years old, registered at Temanggung District Health Office, Central Java, Indonesia between March 29 and April 31, 2018. Of the study participants, 217 women (60.7%) received cryotherapy (Napitupulu, Puspitaningtyas, Mualim, Kusumanto, Lazuardi, & Hutajulu 2020:1423-1429).

Another cross-sectional study conducted on 653 women on the Impact of visual inspection with acetic acid plus cryotherapy “see and treat” approach on the

reduction of the population burden of cervical pre-invasive lesions in Southeast Nigeria revealed that from the total number of women who tested VIA positive, (91%) of them were eligible for cryotherapy (Chigbu, Onyebuchi, Nnakenyi, & Egbuji 2017:239-243).

2.4 DESCRIPTION OF THE THEORETICAL FRAMEWORK

A theory is an integrated set of defined concepts, existence statements, and relational statements that are defined and interrelated to present a systematic view of a phenomenon (Gray et al 2017:1094). According to Creswell and Creswell (2018:336), theories in mixed methods research provide an orienting lens that shapes the types of questions asked, who participates in the study, how data are collected, and the implications made from the study (typically for change and advocacy). They present an overarching perspective used with research designs. Creswell and Creswell (2018:336) added that theory use in mixed methods studies may include theory deductively in quantitative theory testing and verification or inductively, as in an emerging qualitative theory or pattern. It also has distinctive features of providing a framework within which researchers collect, analyse, and integrate both quantitative and qualitative data. This framework takes two forms: (a) The use of a social science framework, and (b) The use of a transformative framework.

A framework is a combination of concepts and the connections between them, used to explain relationships (Gray, Grove & Sutherland 2017:1060). A theoretical framework is the ‘blueprint’ or guide for research (Grant & Osanloo 2016:12).

Different theories are best suited to different situations. According to (Glanz, Rimer & Viswanath 2008:26-35) the adequacy of theory is most often assessed in terms of three criteria:

- Its logic or internal consistency in not yielding mutually contradicting derivations.

- The extent to which it is parsimonious or broadly relevant while using a manageable number of concepts.
- Its plausibility for fitting in with prevailing theories in the field

Considering these facts, an appropriate theoretical framework, namely the HBM, was chosen for this study.

2.4.1 Health Belief Model

The HBM was developed in the 1950s, and continues to be one of the most accredited and widely used theories to investigate people's perceptions about the benefits of prevention, and at the same time, obstacles associated with adhering to preventive practices, thus allowing the model to predict the behaviour adopted, such as the decision to get vaccinated (Fallucca, Immordino, Riggio, Casuccio, Vitale & Restivo 2022:998). HBM is one of the first theories of health behaviour and remains one of the most widely recognised in the field. It was developed by a group of US Public Health Service social psychologists to explain why many people did not participate in public health programmes (Abraham & Sheeran, 2015:97-102).

In this perspective, health behaviours are influenced by a person's desire to avoid illness or to get well, and their confidence that the recommended action will achieve this. According to the HBM, individuals will act to protect or promote their health based on the following circumstances. If they are susceptible to a condition or problem, if the consequences of the condition are severe, if the recommended actions to deal with the problem are beneficial and if the benefits of action outweigh the costs or barriers (Luquis & Kensinger 2018:37–47).

The HBM suggests that behaviour change is the result of scrutinising information and weighing up potential consequences of actions or inactions before a decision is made. Individual behaviour is guided by the rationality of protecting one's health. The application of the HBM suggests that health risks

should be personalised to encourage an awareness of a threat to a person's health and thus his/her beliefs of susceptibility (Wills & Earle 2012:133-134).

The HBM comprises several primary concepts that explain why people will take action to prevent, to be screened for, or to control illness conditions: (1) Perceived susceptibility: refers to people's beliefs about the possibility of having a disease or condition; (2) Perceived Severity: people's feelings about the seriousness of having an illness or leaving it untreated, which includes the assessment of possible clinical (like death, disability, and pain), and social complications (such as effects of the conditions on work, family life, etc.); (3) Perceived benefits: refer to beliefs that the preventive behaviours are useful and effective in reducing the risk or seriousness of the impact of a threat; (4) Perceived barriers: refer to beliefs about the tangible and psychological costs of the advised action that may act as impediments for undertaking recommended behaviours; (5) Self-efficacy: self- efficacy is defined as "the conviction that one can successfully executes the behaviour required to produce the outcomes"; (6) Cues to action: contribute to the person's perception of the threat. Cues to action can be internal (e.g., bodily state or symptom) or external (e.g., a reminder about a doctor's appointment) (Babazadeh, Ghaffari-Fam, Oliaei, Sarbazi, Shirdel, Mostafa-Gharabaghi & Azizi 2019:1-9).

According to the HBM, readiness to take action is based on the following beliefs or conditions:

- I am susceptible to this health risk or problem.
- The threat to my health is serious.
- I perceive that the benefits of the recommended action outweigh the barriers or costs.
- I am confident I can carry out the action successfully.
- Cues to action are present to remind me to take action.

In the context of this particular study, perceived susceptibility refers to beliefs about the likelihood of contracting HPV infection and developing CC. Perceived

severity is the assessment of the seriousness of developing pre-cancerous cervical lesions and CC. Perceived benefits are assessments of the usefulness of getting screened for CC and the effectiveness of the HPV vaccine and associated positive consequences of avoiding the development of CC. Perceived barriers to the CC screening and the HPV vaccine include discomfort during the procedure, fear of results, safety concerns and any perceptions that inhibit someone from getting the vaccine (e.g., fear of needles, cost). Perceived self-efficacy is individuals' assessments of their ability to get screened for CC, and the HPV vaccine. Lastly, cues to action are external triggers prompting women to get screened for CC, and the HPV vaccine for themselves or their children (Guidry, Vraga, Laestadius, Miller, Occa, Nan, Ming, Qin, Fuemmeler & Carlyle 2020:305–311).

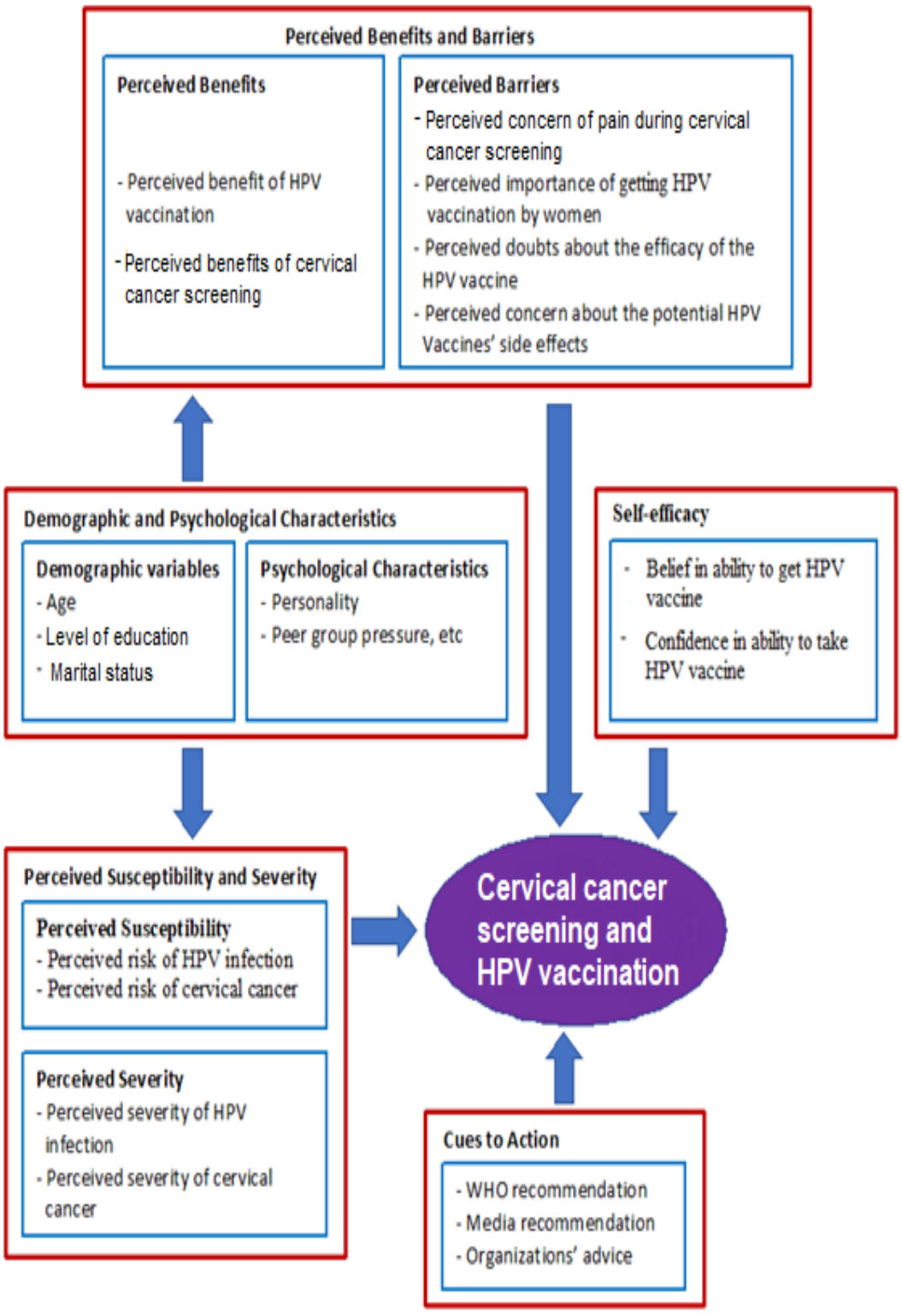

Figure 1.1: Conceptual framework adapted and modified from Health Belief Model

A study conducted by Donadiki, Jimenez-Garcia, Hernandez-Barrera, Sourtzi, Carrasco-Garrido, de Andres & Velonakis (2014:26) on HBM applied to non-compliance with the HPV vaccine among female university students, to determine why female university students refuse the HPV vaccine, highlighted that common barriers with regard to the acceptance of the vaccine included lack of information and knowledge levels concerning the vaccine, low perception of risk of acquiring the infection, misconceptions about safety, and the cost of the HPV vaccine were among the others.

An online cross-sectional survey was undertaken between June and August 2019 on 3,586 women in China, Fujian Province on Chinese mothers' intention to vaccinate daughters against human papillomavirus, and their vaccine preferences using HBM. The vast majority perceived HPV infection as severely harmful (91.4%). Most mothers also perceived HPV vaccination as beneficial, viewing it as effective in preventing HPV infection (84.6%). On the whole, the majority of mothers perceived few barriers to HPV vaccination. Of all the perceived barrier items, the highest proportion was reported on the perception that it was not worth spending money to have a daughter vaccinated against HPV (29.5%) followed by the perception that HPV vaccination leads to increased juvenile sexual acts (25.2%). For the cues-to-action item, only 29.8% reported having been often exposed to HPV vaccination promotion for adolescents on mass media. Among the six constructs of HBM, mothers' perceived benefits were the most influential predictors of intention to vaccinate daughters against HPV (OR = 2.02, 95% CI: 1.50–2.98). Another significant factor was having no barriers in taking time off for daughter vaccination (OR = 1.37, 95% CI: 1.01 − 1.72) (Lin, Su, Chen, Zhao, Zimet, Alias, He, Hu & Wong 2021:304-315).

Another cross-sectional study was conducted among 141 young adult women in Palermo, Italy, through the administration of a telephone questionnaire by a trained healthcare professional from May to September 2017. The questionnaire, consisted of 23 items on HPV infection and vaccination knowledge based on the HBM framework. Among the respondents, 84.4% were unvaccinated, and 15.6% had at least one dose of the HPV vaccine. Factors

associated with the refusal of the HPV vaccination were bachelors as the education level (OR = 10.2, p = 0.041), lower participation at school seminars on HPV (OR = 0.2, p = 0.047) and lower perception of HPV vaccine benefits (OR = 0.4, p = 0.048) (Restivo, Costantino, Fazio, Casuccio, D'Angelo, Vitale & Casuccio 2018:770).

Similarly, an analytic observational study with a case-control design, entitled HBM on the Determinants of Human Papillomavirus Vaccination in Women of Reproductive Age in Surakarta, Central Java, was conducted at Permata Harapan Oncology Clinic from January to February 2018 on 200 study participants. HPV vaccination increased with perceived severity (OR=22.81; 95% CI= 6.06 to 85.86; p=0.000), perceived susceptibility (OR=4.03; 95% CI= 1.25 to 13.09; p=0.020), perceived benefit (OR=6.57; 95% CI= 1.88 to 22.98; p=0.003), and HPV vaccination decreased with perceived barrier (OR=0.14; 95% CI= 0.04 to 0.51; p=0.003). In conclusion, HPV vaccination increases with perceived severity, perceived susceptibility, and perceived benefit, but decreases with the perceived barrier (Fitriani, Mudigdo & Andriani 2018:16-26).

2.4.2 Justification of Using the Chosen Theoretical Framework

Health belief model has been widely applied as a theoretical framework to explain health-promoting behaviours and guide researchers in their health behaviour interventions (Babazadeh et al 2019:1-9). Its reliability and validity have been previously approved to identify the beliefs in the field of CC prevention. A large body of research demonstrates the utility of the HBM in predicting vaccination and other preventive behaviours such as health screenings (Gruidry et al 2020:305-311), making it an appropriate framework for this study. These theoretical frameworks best fit this study's variables of interest. The HBM deals with the health-seeking behaviour component of the study. It is concerned with why people take actions to screen or control illnesses. The barriers or enabling factors of vaccination for HPV and CC screening service utilisation are best explained within the construct of this model. The model aided the researcher in maintaining the focus of the study. It also assisted in organising

the literature review, developing the data collection instrument, presenting and discussing the findings, and making recommendations. As discussed above, the HBM posits motivation for adopting healthy behaviours determined by perceptions of susceptibility, severity, benefits, barriers, self-efficacy, and cues to action (Guidry et al 2020:305-311). The first two constructs of the HBM helped the researcher to identify the risk perception of study subjects regarding HPV infection: perceived susceptibility and perceived severity. The rest of the model's constructs (Perceived benefits, perceived barriers, self-efficacy and cues to action) helped answer the research questions related to the study participants' perception regarding CC screening and vaccination for HPV infection.

2.5 PERCEPTION OF THE STUDY PARTICIPANTS

2.5.1 Risk Perception towards HPV Infection and Cervical Cancer

Risk perception of HPV infection and CC in this research was regarded as the beliefs, attitudes, or understanding of women towards the potential to be infected with HPV and develop CC. It was the risk posed by the women in contracting HPV infection and CC. Risk perception was considered as the women's subjective judgments about the likelihood of acquiring HPV infection and CC, or the subjective judgment that women made about the characteristics and severity of persistent HPV infection and CC. It incorporated the two HBM constructs: the perceived susceptibility and the perceived severity which frequently combined and labelled as perceived threats since both constructs concern threats.

2.5.1.1 Perceived Susceptibility

Perceived susceptibility refers to people's beliefs about the possibility of having a disease or condition (Babazadeh et al 2019:1-9). For people to take action, they must believe they are at risk of developing a disease, illness or negative health outcomes. When people believe they are at risk of developing a disease, they are more likely to do something to prevent it from happening. The individual perception that she has no risk is a factor that causes a woman of reproductive

age not to get CC screening and HPV vaccination. In this study, perceived susceptibility refers to the beliefs of study the participants about the likelihood of contracting HPV infection and CC.

A longitudinal study was conducted to examine why HPV vaccination rates are low even though there is a high efficacy of the HPV vaccine. The women in the study who did not intend to get the vaccine did not believe they were at risk of being infected with HPV. Most women not considering vaccination, did not believe they were susceptible to HPV infection and CC (55%) (Manhart, Burgess-Hull, Fleming, Bailey, Haggerty & Catalano 2011:5238–5244).

A study conducted among Iranian women shows that the vast majority of women reported low perceived risk and susceptibility regarding HPV infection and CC (Taghizadeh Asl, Van Osch, De Vries, Zendehdel, Shams, Zarei & De Vries 2020:1–12).

Also, a study conducted in the USA reveals a similar finding that the majority of the participants felt as they were at low risk for contracting HPV infection and CC (Goldfarb & Comber 2022:1-9).

Yet a similar finding was obtained in a study conducted in Durban, South Africa that participants reported feeling that they were at lower risk of acquiring HPV infection and developing CC (Russell, Ogilvie, Beksinska, Ogilvie, Beksinska, Nyirenda, Mitchell-Foster, Lavoie, Harder, Wood, Smith, Dietrich, Smit, Brockman, Gray & Kaida 2020:887–893).

In contrast, a study conducted in Turkey reveals different findings, suggesting that half of the participants were worried about getting HPV infection and CC (Yurtçu, Doğan, Karaaslan & Mutlu 2022:349–355).

According to a study conducted on Determinants of HPV vaccination in women of reproductive age in Surakarta, Central Java from January to February 2018 on 200 study participants, there was a relationship between perceived susceptibility and HPV vaccination which is statistically significant (OR=4.03;

95% CI= 1.25 to 13.09; p=0.020). High perceived susceptibility to HPV infection increased the HPV vaccination acceptance by 4.03 times than low perceived susceptibility to the infection (Fitriani et al 2018:16-26).

2.5.1.2 Perceived Severity

Perceived severity refers to people's feelings about the seriousness of having an illness or leaving it untreated, which includes the assessment of possible clinical (like death, disability, and pain), and social complications (such as effects of the conditions on work, family life, etc.) (Babazadeh et al 2019:1-9). HBM theory states that the perceived seriousness or severity of a disease can cause a person to perform a treatment effort. Severity can be based on medical consequences, like death or disability, or personal beliefs about how the condition or disease would affect their life. In this study, perceived severity was considered as the study participant's belief about the seriousness or severity of contracting HPV infection that possibly complicated to CC development.

A study done in the Philippines shows that participants believed HPV infection and CC to be a serious infection and they were at risk of getting it (Imoto, Honda & Llamas-Clark, 2020:3145–3151).

On the other hand, a study conducted in Argentina shows that most participants did not perceive having HPV infection as a serious condition (Victoria, Racquel, Lucila, Melisa, Viswanath & Silvina 2020:1-11).

The study conducted in Surakarta, Central Java from January to February 2018 on 200 study participants shows that there was a relationship between perceived seriousness and HPV vaccination which was statistically significant (OR=22.81; 95% CI= 6.06 to 85.86; p=0.000). High perceived severity of HPV infection consequence increased the HPV vaccination acceptance by 22.81 times than low perceived severity of the infection (Fitriani et al 2018:16-26).

2.5.2 Perception Regarding Cervical Cancer Screening and HPV Vaccination

Perception of cervical cancer screening and HPV vaccination in this research was regarded as the attitude or understanding of women towards the importance of getting HPV vaccination and CC screening. It incorporated four constructs of HBM: Perceived benefits, Perceived barriers, Self-efficacy and Cues to action those triggers women to get the HPV vaccination and CC screening.

2.5.2.1 Perceived Benefits

Perceived benefits refer to beliefs that preventive behaviours are useful and effective in reducing the risk or seriousness of the impact of a threat (Babazadeh et al 2019:1-9). In this study, perceived benefits were regarded as the study participants' opinions about the value or usefulness of getting the CC screening and HPV vaccination and the associated positive consequences in avoiding HPV-related diseases most importantly CC.

According to the cross-sectional study conducted in Palermo, Italy, from May to September 2017, among 141 young adult women of the local health unit through the administration of a telephone questionnaire by a trained health care professional based on the HBM framework, lower perception of HPV vaccine benefits (OR=0.4, p=0.048) was one of the factors associated with the refusal of the HPV vaccination (Restivo et al 2018:770).

Also, a study done in Tanzania indicates that perceived benefits for attending CC screening include treatment of symptoms and disease prevention (Linde, Rasch, Mwaiselage & Gammeltoft 2019:1-8).

Another study conducted in Riyadh, Saudi Arabia reveals that the participants believed undergoing regular cervical screening would help to find changes to

the cervix before cancer develops, and that CC treatment would be tolerable (Aldohaian, Alshammari, & Arafah 2019:6).

Donaldiki et al (2014:268-273), in a study looking at female college students' refusal of the HPV vaccine, determined that participants who scored high "no general benefits" which were general perceptions about the HPV vaccination, and "no specific benefits" which was the safety and efficacy of the vaccination, were less likely to be vaccinated.

An online cross-sectional survey undertaken between June and August 2019 on a total of 3,586 women in China, Fujian Province, on Chinese mothers' intention to vaccinate their daughters against HPV, and their vaccine preferences using the HBM, found that mothers' perceived benefits were the most influential predictors of intention to vaccinate their daughters against HPV (Lin et al 2021:304-315).

The study conducted in Surakarta, Central Java from January to February 2018 on a total of 200 study subjects, shows that there was a relationship between perceived benefit and HPV vaccination which was statistically significant (OR=6.57; 95% CI= 1.88 to 22.98; p=0.003). High perceived benefit increased the HPV vaccination by 6.57 times more than low perceived benefit (Fitriani et al 2018:16-26).

2.5.2.2 Perceived Barriers

Perceived barriers refer to beliefs about the tangible and psychological costs of the advised action that may act as impediments to undertaking recommended behaviours (Babazadeh et al 2019:1-9). Perceived barriers in this study were regarded as beliefs which had potentially negative consequences about the CC screening and HPV vaccination: includes lack of awareness towards the importance of CC screening and HPV vaccination, anxiety about the side effects of HPV vaccination, fear of needles, fear of the procedure of screening, and fear of the results, inhibit women from getting the vaccine and CC screening.

The cross-sectional survey undertaken between June and August 2019 on a total of 3,586 women in China, Fujian Province on Chinese mothers' intention to vaccinate daughters against HPV, and their vaccine preferences using HBM, shows that no perceived barriers were significant factors associated with intention to vaccinate daughters against HPV (OR = 1.37, 95% CI: 1.01 − 1.72) (Lin et al 2021:304-315).

A study conducted in Australia reveals that the most commonly stated barriers included lack of time, embarrassment, fear of results, irrelevance and male health professionals (Nagendiram, Bougher, Banks, Hall & Heal 2019:343–353).

Black, Hyslop and Richmond (2019:108), in a study done in Uganda, found that the most frequently reported barriers included embarrassment, fear of the screening procedure or outcome, residing in a remote or rural area, and limited resources/health infrastructure.

A study done in Ghana reveals that the majority of the participants believed that screening was not important because there was no cure for cancer (Plange, Abebrese & Adaobi 2023:1450-1462).

Yet another study conducted in Nepal indicated that the participants perceptions of barriers to their attendance at clinics for screening for CC were sociocultural, including mistrust and gossip, negative experiences in previous meetings with service providers, the challenging geography of the country, and financial limitations (Darj, Chalise & Shakya 2019:20-26).

The study conducted in Surakarta, Central Java from January to February 2018 on 200 participants shows that there was a relationship between the perceived barrier and HPV vaccination, which was statistically significant (OR=0.14; 95% CI= 0.04 to 0.51; p=0.003). High perceived barriers decreased the HPV vaccination by 0.14 times than low perceived barriers (Fitriani et al 2018:16-26).

2.5.2.3 Self-efficacy

Self-efficacy is defined as the conviction that one can successfully executes the behaviour required to produce the outcomes (Babazadeh et al 2019:1-9). Self-efficacy in this study was considered as the study participants' confidence and belief in ability to get CC screening and HPV vaccination.

A study was conducted in Alabama, USA between 2013 and 2016 on HPV Vaccination Hesitancy among 317 Latina immigrant mothers despite physician recommendation. The framework of the study was based on previous use of the PEN3 and the HBM. In the study, mothers who indicated lower self-efficacy scores in completing the vaccination series were more hesitant to vaccinate their daughters than mothers who displayed higher self-efficacy scores (OR .55; 95% CI .45-.67; P<.001) (Khodadadi, Redden & Scarinci 2020:661-670).

A study done in Suratthani Province; Thailand shows that village health volunteers with high perceived self-efficacy correlated with their confidence screening for CC (Bunkarn & Kusol 2021:179-183).

Similarly, a study done in Khuzestan Province, Iran reveals that there is a positive relationship between knowledge, attitude, self-efficacy, and women's practice with regard to undergoing CC screening test (Ghalavandi, Heidarnia & Zarei 2021:1-10).

2.5.2.4 Cues to Action

Cues to action are events, people, or things that trigger people to change behaviour. Advice from others, the illness of a family member or social media can provide cues. (Babazadeh et al 2019:1-9). In this study, cues to action were regarded as triggers like advice from health professionals, illness of a family member or relatives, and recommendations (from organisations such as the Ethiopian Ministry of Health, or the media) that prompt women to get the CC screening and HPV vaccination.

According to a study done by Richards (2016:342-355) on the intention of college students to receive the HPV vaccine, the influence of norms had a positive direct effect on student's intention to receive the HPV vaccine. If the participants felt support from their friends to get the vaccine, they were more likely to get it. Richards (2016:342-355) also discovered that the more the participants had contact with health information, the more likely they would be to receive the HPV vaccine. Lastly, not only does fear and vulnerability affect decisions to get the HPV vaccine but also contact with health information and communication with others will ultimately influence decisions to get the HPV vaccine.

A study conducted in Uganda indicates that the most frequent cue to action was having a recommendation by health care providers to attend a screening for CC (Black et al 2019:108).

Similarly, a Southeast Asian study reveals that the most common cues to action were related to receiving advice from health care workers, and educational status (Chua, Ma, Asjes, Lim, Mohseni & Wee 2021:4586).

Donaldiki et al (2014:268-273) determined that a common influence on the decision to get the HPV vaccine is the health care provider. If the health care provider provides a strong recommendation, this can change women's' intentions to receive the vaccine.

2.6 SUMMARY

In this chapter the researcher reviewed relevant literature on HPV infection and HPV vaccination internationally, in Africa and the Ethiopian context. The discovery of HPV as a cause of CC was discussed in the introduction section. Genotypes, prevalence and risk factors of HPV infection, and pre-cancerous cervical lesions, risk factors and their treatments were also discussed in detail. Prevention of HPV infection, history of HPV vaccine development and strategies for the provision of HPV vaccination were also reviewed and discussed in detail.

The study's theoretical framework and the HBM constructs were substantially described. The researcher also reviewed the literature regarding the risk perception of HPV infection and the perception of HPV vaccination in relation to HBM.

In the next chapter, Chapter 3, the research design and methodology adopted for this study will be addressed.

CHAPTER 3

RESEARCH DESIGN AND METHOD

3.1 INTRODUCTION

The previous chapter discussed the literature review on HPV infection published by different authors in various journals across the globe.

This chapter aims to provide a description and justification of the research design and the methods that the researcher followed to achieve greater control of the study's findings (Grove et al 2015:22). The decision regarding the research method was based on the appropriateness and practicality of the research design to address and meet the study purpose and objectives. The study population, sampling, research instruments, data collection procedures and analysis, and the ethical considerations followed while conducting the study are sufficiently described in this chapter. The procedures implemented to ensure the research findings' validity and reliability are also outlined. Separate procedures for quantitative and qualitative study approaches have been used as both encompass distinct purposes to serve.

The researcher also presents information regarding the use of mixed method research and explains why the explanatory sequential mixed methods research design was considered appropriate for this study. Meta inference, an overall conclusion made through integrating the inferences obtained from the qualitative and quantitative strands of a mixed method study, and the e-Delphi technique that enabled the researcher to achieve a common viewpoint of issues discussed by experts using questionnaires are also discussed in detail.

3.2 RESEARCH DESIGN

A research design is a general plan for implementation of a study, selected to answer a specific research question (Burns & Grove 2017:106. A research

design is a scheme, an outline or a plan a researcher uses to generate answers to research questions (Creswell & Plano Clark: 2017:100). Kasonde-Ng'andu (2013:16) defines research design as procedures for collecting, analysing, interpreting, and reporting data in research studies. Therefore, one can conclude in agreement with these scholar's opinions that a research design is a researcher's choice of the best way in which to answer a research question, with respect to several considerations, including number of subject groups, timing of data collection, and researcher intervention, if any.

Research designs are types of inquiry within qualitative, quantitative, and mixed methods approaches that provide specific direction for procedures in a research study (Creswell & Creswell 2018:49). Mixed methods research is widely used to answer complex questions in health and social sciences (Draucker, Rawl, Vode, & Carter-Harris 2021:1137–1147). This study adopted a mixed sequential design method.

3.2.1 Mixed Method Design

A mixed method design is a procedure for collecting, analysing, and mixing both quantitative and qualitative research methods in a single study to understand a research problem (Creswell 2012:22). The intention is to combine the perspectives, approaches, data forms, and analyses associated with quantitative and qualitative research to develop nuanced and comprehensive findings (Plano Clark 2019:107). Mixed method study involves the collection or analysis of both quantitative and/or qualitative data in a single study in which the data are collected concurrently or sequentially, are given a priority, and involve the integration of the data at one or more stages in the research process (Gutmann & Hanson 2002:25). Mixed methods research is the type of research in which a researcher or team of researchers combine elements of qualitative and quantitative research approaches (e.g., use of quantitative and qualitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration (Johnson, Burke, Onwuegbuzie & Lisa 2007:123).

Tashakkori and Teddlie (2003:1-8) identified three different approaches to mixed methodology, which are concurrent, sequential and conversion. According to the sequential approach (findings from one approach inform the other), the quantitative phase (numbers) is followed by the qualitative phase (personal experience) (Creswell 2013:14). The qualitative findings are used to contextualise the quantitative data (Creswell, Plano-Clark, Gutmann & Hanson 2003:5).

Thus, Creswell and Plano Clark (2011:33) outline the core characteristics of a mixed method in a single research study, both qualitative and quantitative strands of data are collected and analysed separately, and integrated – either concurrently or sequentially – to address the research question. Onwuegbuzie and Combs (2010:414) concur, writing “mixed analyses involve the use of at least one quantitative analysis and at least one qualitative analysis – meaning that both analysis types are needed to conduct a mixed analysis”. The authors emphasise the intent of the designs rather than the timing of the strands or the weight given to either strand. (a) The explanatory sequential design in which the collection and analysis of quantitative data precedes the collection and analysis of qualitative data. The design is used primarily to explain or expand quantitative results. (b) The exploratory sequential design in which the collection and analysis of qualitative data precedes the collection and analysis of quantitative data. This design is often used to develop an instrument, identify a new variable in a conceptual model, or inform intervention development. (c) The convergent design in which qualitative and quantitative data are compared or combined. This design provides a comprehensive understanding of a phenomenon or a validation of one of the sets of findings.

An explanatory sequential mixed method is one of the most common designs used in mixed methods research that involves a two-phase project in which the researcher collects quantitative data in the first phase, analyses the results, and then uses the follow-up qualitative phase to help explain the quantitative results (Creswell & Creswell 2018:329).

The researcher employed mixed method research because the overall goal of mixed methods research, of combining qualitative and quantitative research components, is to expand and strengthen a study's conclusions (Schoonenboom & Johnson 2017:110) and provide a better understanding of research problems than either approach alone (Creswell & Plano Clark 2007:5). The researcher wanted to understand the research objectives through multiple research phases. One data source alone may be insufficient. There was also a need to explain initial results, and be enhanced with a second method. The qualitative data enhanced and enriched the quantitative findings and, helped generate new knowledge (Mason 2006:6; Stange 2006:12; and Taylor & Trumbull 2005:126).

The researcher in this study specifically employed the explanatory sequential mixed methods research design (Quantitative → qualitative = explanation), which included an initial quantitative study and a follow-up qualitative interview with the priority on the quantitative phase. The qualitative results help to explain the initial study results and build better understanding of the significant and non-significant quantitative findings.

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Explanatory sequential design procedures: The study commenced with the collection and analysis of quantitative data. The second, qualitative phase of the study was designed so that it followed from (or connected to) the results of the first quantitative phase. Since this design began quantitatively, the researcher typically placed greater emphasis on the quantitative method than the qualitative method. Therefore, in this study, a quantitative approach was applied using a cross-sectional descriptive study design in order to describe the prevalence, genotypes and risk factors of HPV infection, and in addition, the prevalence of pre-cancerous cervical lesions, risk factors and treatments offered among women in the study area. The findings of the quantitative research were supplemented by a qualitative approach that was employed using exploratory, descriptive and contextual research design to explore and describe the perceptions of women regarding HPV vaccination, and CC screening which included HPV DNA testing and VIA testing among women, which finally aimed to drive an in-depth explanation on the quantitative result. Figure 3.1

Summarises how the explanatory sequential mixed method was conducted in this study.

Table 3.1: Summary of the research methods of the study

Approach	Population and Sampling	Data Collection	Data Analyses
PHASE 1: DESIGN AND IMPLMENT THE QUANTITATIVE STRAND			
Objective 1: Assess the prevalence of HPV infection			
Descriptive cross-sectional	All women attended cervical cancer screening at the selected health institutions in Adama (n = 383)	Interviews using structured close-ended questionnaire, and referring client's medical record	Descriptive summary statistics
Objective 2: Assess the HPV genotypes			
Descriptive cross-sectional	All women identified as having HPV infection	Refer client's medical record	Descriptive summary statistics
Objective 3: Assess the risk factors of HPV infection			
Descriptive cross-sectional	All women attended cervical cancer screening at the selected health institutions in Adama (n = 383)	Interview using structured close-ended questionnaire	Descriptive summary statistics
Objective 4: Assess the prevalence of precancerous cervical lesions			
Descriptive cross-sectional	All women identified as having HPV infection	Refer client's medical record	Descriptive summary statistics
Objective 5: Assess the risk factors of precancerous cervical lesions			
Descriptive cross-sectional	All women identified as having HPV infection	Refer client's medical record	Descriptive summary statistics
Objective 6: Identify the treatment offered			
Descriptive cross-sectional	All women identified as having precancerous cervical lesion through VIA test	Refer client's medical record	Descriptive summary statistics
PHASE 2: DESIGN AND IMPLMENT THE QUALITATIVE STRAND			
Objective 1: Explore and describe risk perceptions towards HPV infection and cervical cancer			
Exploratory descriptive contextual	Selected women participating in the study Purposive sampling (n = 10)	Focus group discussion using unstructured open-ended questions	Descriptive thematic analysis
Objective 2: Explore and describe perceptions towards cervical cancer screening			

Exploratory descriptive contextual	Selected women participating in the study Purposive sampling (n = 10)	Focus group discussion using unstructured open-ended questions	Descriptive thematic analysis
Objective 2: Explore and describe perceptions regarding HPV vaccination			
Exploratory descriptive contextual	Selected women participating in the study Purposive sampling (n = 10)	Focus group discussion using unstructured open-ended questions	Descriptive thematic analysis
PHASE 3: META INFERENCES			
Objective 1: Integrate findings from quantitative and qualitative strand of the study			
Explanatory sequential mixed method	Summary and interpretation of quantitative strand first and the follow-up qualitative strand summary and interpretation to help explain the quantitative results	Integration of summarised qualitative and quantitative results	Interpretation based on Quan – qual results
Objective 2: Develop an overall conclusion, explanation or understanding			
Explanatory sequential mixed method	Triangulate the quantitative and qualitative findings and draw an overall conclusion	Explanation of the findings based on the already set objectives	Develop understanding of the findings
PHASE 4: e-DELPHI			
Objective 1: To achieve a common viewpoint from experts			
Explanatory sequential mixed method	Selected health professional experts participating in the group communication Purposive sampling (N = 10)	Apply the three-stage e-Delphi method, solicit the experts' opinions, and reach consensus	Develop strategies based on quantitative and qualitative study findings, relevant literature review and e-Delphi expert viewpoints

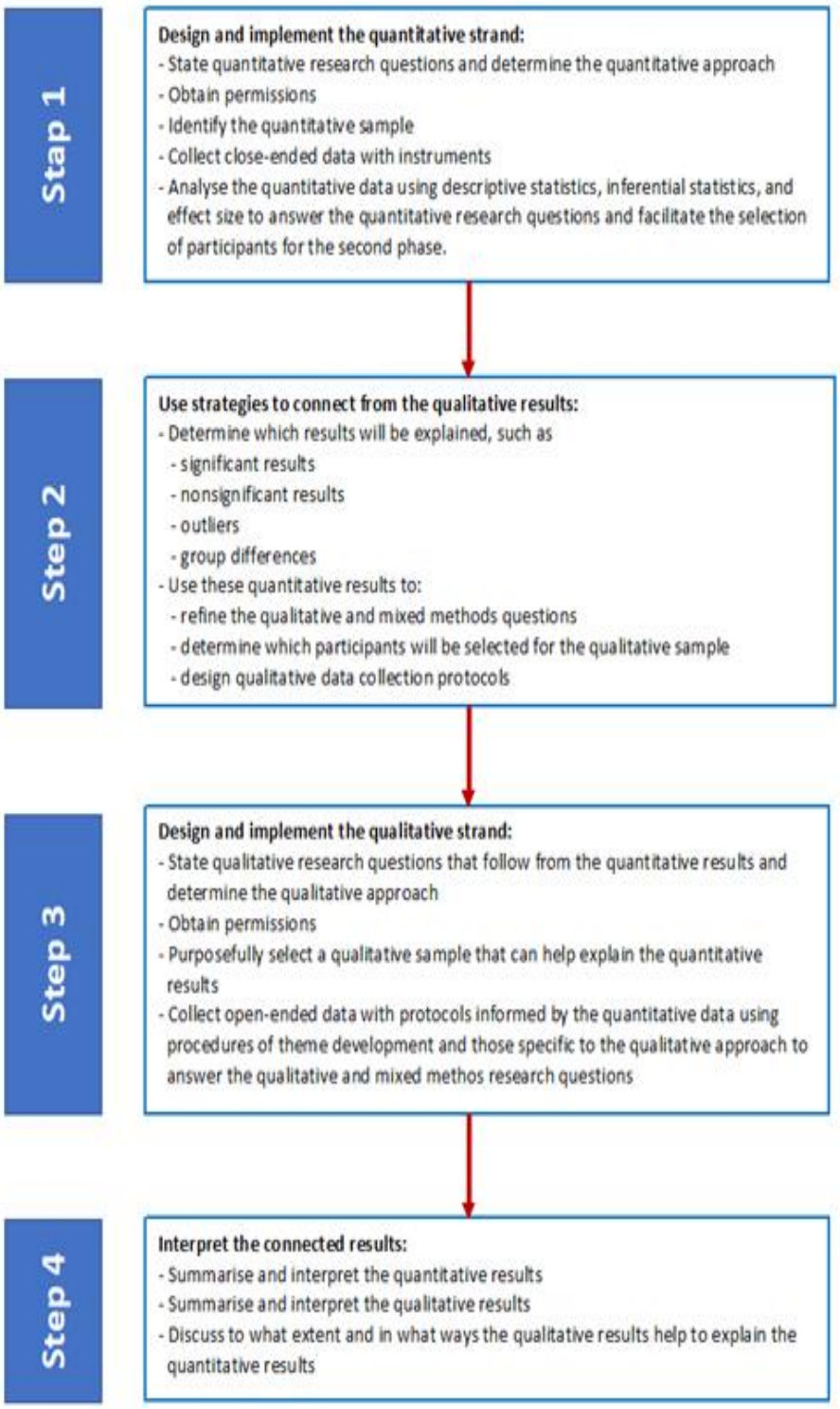

Figure 3.1: Explanatory sequential mixed methods design: adapted from Creswell and Plano Clark (2011)

3.2.1.1 Phase I: Quantitative Cross-sectional Research Design

Burns and Grove (2005:23) state that quantitative research is a formal, objective, systematic process in which numerical data are used to obtain information about the world. A quantitative approach deals with variables and might explore the association or cause-and-effect relationships between them. Creswell and Creswell (2018:41) define quantitative research as a means for testing objective theories by examining the relationship among variables. These variables in turn, can be measured typically on instruments, so that numbered data can be analysed using statistical procedures.

Quantitative research involves the collection of data so that information can be quantified and subjected to statistical treatment in order to support or refute alternative knowledge claims (Williams 2011:26). Furthermore, Williams, (2011:26) remarks that quantitative research starts with a statement of a problem, generating of hypothesis or research question, reviewing related literature, and quantitative analysis of data. Similarly, (Creswell 2003:4; Williams 2011:18) state that quantitative research employs strategies of inquiry such as experiments and surveys, and collects data on pre-determined instruments that yield statistical data.

A descriptive cross-sectional study is a study in which the disease or condition and potentially related factors are measured at a specific point in time for a defined population (National Emergency Medical Services for Children Data Analysis Resource Centre [NEDARC] 2010:1). Cross-sectional studies can be thought of as a "snapshot" of the frequency and characteristics of a condition in a population at a particular point in time (NEDARC 2010:1).

According to Burns and Grove (2017:207), as long as the purpose is to describe the variables, and the statistics are predominantly descriptive, the research is considered descriptive cross-sectional. This suggests that, if the information collected is purely of a descriptive nature, not involving the comparison of groups formed on the basis of exposure or outcome status, then this is a descriptive cross-sectional study.

A descriptive cross-sectional study inspects the prevalence of a disease or condition in a defined population at a specific point or period in time without attempting to draw any inferences or offer any causes for the prevalence.

In Phase I, a cross-sectional descriptive study design was employed to assess the prevalence, genotypes, and risk factors of HPV infection, and the prevalence of pre-cancerous cervical lesions, risk factors, and treatments offered among women who participated in the study.

3.2.1.2 Phase II: Qualitative Exploratory, Descriptive Research Design

Qualitative research is an approach to exploring and understanding the meaning individuals or groups ascribe to a social or human problem (Creswell & Creswell 2018:41). The process of research involves emerging questions and procedures, data typically collected in the participant's setting, data analysis inductively building from particulars to general themes, and the researcher making interpretations of the meaning of the data (Creswell & Creswell 2018:41).

In Phase II, the researcher employed qualitative exploratory, descriptive and contextual research design to explore and describe the risk perceptions of women regarding HPV infection and CC, as well as their perceptions concerning CC screenings and HPV vaccination.

Qualitative research refers to inductive, holistic, emic, subjective and process-oriented methods used to understand, interpret, describe and develop a theory on a phenomenon or setting (Burns & Grove 2003:356). It is a systematic, subjective approach used to describe life experiences and give them meaning (Burns & Grove 2003:356). Qualitative research is mostly associated with words, language and experiences rather than measurements, statistics and numerical figures.

Exploratory-descriptive qualitative research is qualitative research that lacks a clearly identified qualitative methodology (neither phenomenology, grounded theory, ethnography, nor historical research) (Gray et al 2017:1058). It is a study that the researchers have identified as being qualitative without indicating a specific approach or underlying philosophical basis (Gray et al 2017:1058).

3.2.1.3 Phase III: Meta Inferences

Tashakkori and Teddlie (2008:101) describe a "meta inference as an overall conclusion, explanation or understanding developed through an integration of the inferences obtained from the quantitative and qualitative strands of a mixed method study." Integration is a process in mixed method research in which the quantitative and qualitative strands of a study "come into conversation with each other" (Plano Clark 2019:108). Tashakkori and Teddlie (2008:105) describe the importance of an "integrative framework" for making validity claims for mixed method research. The integrative framework seeks to distinguish between inference quality (an attribute of the process of meaning-making and/or its outcomes) and data quality (an attribute of the inputs to the process of meaning-making).

The term meta-inference describes "the theoretical statements, narratives, or a study inferred from an integration of findings from quantitative and qualitative strands of mixed methods research" (Venkatesh, Brown & Bala 2013:29). It involves a two-phase project in which the researcher collects quantitative data in the first phase, analyses the results, and then uses a qualitative phase to help explain the quantitative results (Creswell & Creswell 2018:329).

In Phase III, the researcher collected and analysed quantitative data first, and then the qualitative data collection and analysis followed. The primary focus was to explain quantitative results by using qualitative data to explore certain results in more detail or help explain unexpected results (e.g., using follow-up interviews to better understand the results of a quantitative study). Greater emphasis was given to the quantitative strand. The researcher developed an

overall conclusion, explanation or understanding through an integration of the inferences obtained from the quantitative and qualitative strands of a mixed method study. Figure 3.2 explains the data mix that was used for phase 3.

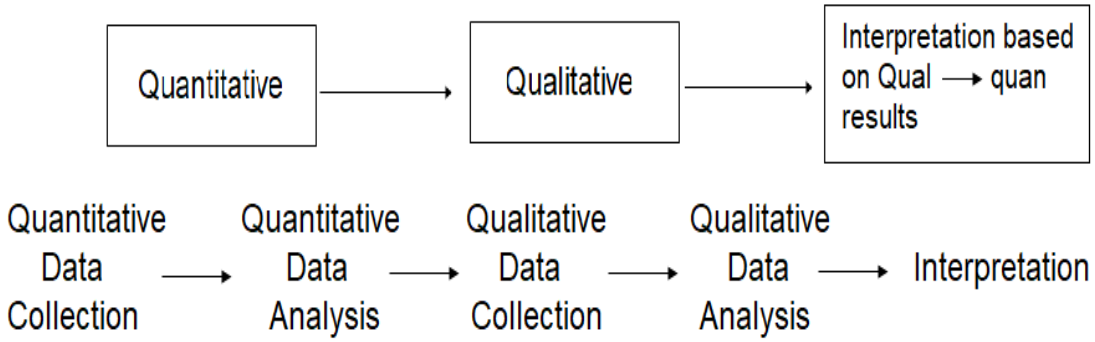

Figure 3.2: Sequence of data mix

3.2.1.4 Phase IV: e-Delphi

In Phase IV, the researcher further solicited expert opinion using of the e-Delphi technique. Delphi is a technique used to achieve a common viewpoint from experts using questionnaires to gather information of interest (Lindell & Demi 2018:164-165). This technique has been extensively used within health and social research to strengthen decision-making processes and reach consensus. It is based on the assumption that group judgments are more credible than individual judgments and can be applied in a wide variety of sectors, such as public health, society, transport, education, etc. (Giannarou & Zervas 2014:65-82).

According to Green (2014:1), e-Delphi is defined as a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with multiple challenges. The e-Delphi method allows experts to communicate and engage with each other online in their own time in their vicinities to solve problems until a consensus is reached. According to Bardhan, Ngeru and Pitts (2012:24), the e-Delphi technique in this era is important in evidence-based research as it enables participants to post their opinions and accrue their ideas online. With the use of the e-Delphi technique,

experts participate in different periods of time, at their own pace (Meshkat, Cowman, Gethin, Ryan, Wiley & Brick 2014:1-8). In the e-Delphi process, reaching a consensus by experts cannot be resolved in a once-off discussion. As an iterative process, e-Delphi involves a chance for initial feedback, collation of feedback, and distribution of collated feedback to participants for further review. Depending on the number of research questions and available time to reach a consensus, the e-Delphi process includes three rounds, to prevent exhaustion and attenuation (Green 2014:1).

In Phase IV, the researcher conducted a three rounds e-Delphi technique that enabled him to gather a common viewpoint from experts using questionnaires which finally helped the researcher to develop strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

3.3 RESEARCH METHOD

3.3.1 Study Setting

The study was conducted in Adama City, central Oromia region, Ethiopia which was founded in 1924. Adama forms a special zone of Oromia and is surrounded by East Shewa Zone. It is located at 8.54^{o}N 39.27^{o}E at an elevation of 1712 meters, 99km Southeast of the capital city of Addis Ababa. The city sits between the base of an escarpment to the west, and the Great Rift Valley to the east. Based on the 2007 census conducted by the central statistical agency of Ethiopia, this city had a total population of 220, 212, of whom 108,872 were men and 111,340 women. Currently, the total population size of the city estimated to be more than 324,000. According to the information from the Adama City Health Office, there are 1 governmental hospital, 5 private hospitals, 8 governmental health centres, 2 private health centres, 110 private clinics, 79 drug stores, 310 pharmacies and 10 non-governmental organisation clinics serving the people in the city. Among the public health facilities located in the city, namely: Adama Hospital, Adama Health Centre, Geda Health Centre, Biftu Health Centre, Boku

Shenen Health Centre, Hawas Health Centre, Anole Health Centre, Dembela Health Centre and Angatu Health Centre, at the time of this study, only two Health Centres (Adama and Geda) and one Hospital (Adama Hospital) were providing cervical screening tests. For this reason, the three health facilities were purposefully chosen for this study.

3.3.2 Population and Sampling

Often research focuses on a large population that, for practical reasons, it is only possible to include some of its members in the investigation. The population is too large to consider collecting information from all its members. Instead, a researcher selects a sample of individuals hoping that the sample is representative of the population. In sampling, this includes defining the "population" from which the sample is drawn. In other words, the population under study has to be first clearly defined. Otherwise, sampling cannot be conducted. Then, it becomes possible to draw a sample from the total population.

A population can be defined as including all people or items with the characteristics one wishes to understand. Given that there is rarely enough time or money to gather information from everyone or everything in a population, the goal becomes finding a representative sample (or subset) of that population. A representative sample has all the important characteristics of the population from which it is drawn.

3.3.2.1 Population

According to Burns and Grove (2017:1077), a population is a particular group of elements (individuals, objects, events, or substances) that is the focus of a study. It is a complete set of elements (persons or objects) that possess some common characteristic defined by the sampling criteria established by the researcher. Population is the set of all members of a defined group (Plichta & Kelvin 2013:56). It contains the elements (humans, animals, plants, events, venues, substances) that share at least one characteristic.

Target Population

A target population is the entire set of individuals or elements meeting the sampling criteria (Burns & Grove 2017:516). The target population (reference population) is the population an investigator wishes to draw a conclusion about.

3.3.2.1.1 Target Population for Phase I

In Phase I, the target population was all women aged 25 - 49 years residing in Adama City administration. The reason behind targeting this age group in this study was that, cervical screening was recommended for every woman 30–49 years of age, and earlier than this age range (starting from 25 years) for HIV-positive women (WHO 2021).

Inclusion criteria

Randomly selected women aged 25 - 49 years who have resided in Adama City for at least six months and have attended the selected health facilities during the study period

Exclusion criteria

Women beyond the 25 - 49 years age range, confirmed CC cases; women at advanced stage of disease and too ill to participate, mentally unstable to consent for participation, and unable to communicate properly were excluded from the study.

3.3.2.1.2 Target Population for Phase II

In Phase II, the target population was purposefully selected women residing in the Adama City administration.

Inclusion criteria

Purposefully selected women residing in Adama City for at least the past six months and who have attended the selected health facilities during the study period. The selection was based on participants importance to the subject under study, i.e. information-rich women believed to have some awareness about the topics to be discussed, and could have the ability to clearly articulate their experience during the FGD.

Exclusion criteria

Women beyond the 25 - 49 years age range, seriously sick, mentally ill, unable to communicate properly and lacking the necessary qualities mentioned above in the inclusion criteria were excluded from the study.

3.3.2.2 Sampling

Sampling is the process of selecting a group of people, events, behaviours, or other elements with which to conduct a study (Gray et al 2017:1087). Sampling is the process of selecting the number of study units from the defined target population. The study unit is the unit on which the information will be collected.

There are two divisions of sampling, namely, probability and non-probability sampling. The probability sampling Involves random selection procedures to ensure that each unit of the sample is chosen on the basis of chance, meaning, all units of the study population will have an equal non-zero chance of being included in the sample. Random sampling is a procedure in quantitative research for selecting participants. It means that each individual has an equal probability of being selected from the population, ensuring that the sample will be representative of the population (Creswell & Creswell 2018:334).

The probability samples are more likely to be representative of the population as compared to the non-probability samples. Most commonly probability

sampling techniques are used in quantitative researches. There are five kinds of probability sampling techniques: simple random sampling, systematic sampling, stratified sampling, cluster sampling, and multi-stage sampling.

On the other hand, in the non-probability sampling, every item has an unknown chance of being selected. There is an assumption that an even distribution of a characteristic of interest within the population exists. Elements are chosen arbitrarily, and there is no way to estimate the probability of any one element being included in the sample. Most commonly non-probability sampling techniques are used in qualitative researches. This sampling technique includes: convenience sampling, quota sampling, purposeful sampling and snowball sampling.

Sample size

A sample size is the number of study subjects or participants who actually participate in at least the first phase of a study (Gray et al 2017:1087).

3.3.2.2.1 Sample Size for Phase I

The sample size for Phase I was calculated using Raosoft calculator on the internet by considering the following assumptions: -

- Margin of error 5%
- Confidence level 95%
- Population size 96,432 (Women 15 years and above of age residing in Adama)
- Response distribution 50%

Accordingly, the sample size for Phase I was **383**.

3.3.2.2.2 Sample Size for Phase II

Qualitative research experts argue that there is no straightforward answer to the question of 'how many' and that sample size is contingent on a number of factors relating to epistemological, methodological and practical issues (Baker & Edwards 2012:1-8). In quantitative research, the sample size must be large enough to describe variables, identify relationships among variables, or determine differences between groups (Marshall & Rossman 2016:26). However, in qualitative research, the focus is on the quality of information obtained from the person, situation, event, or documents sampled versus the size of the sample. Generally, the sample sizes used in qualitative research are not justified (Marshall, Cardon, Poddar & Fontenot 2013:11-22) even though researchers are concerned about using the right sample size (Dworkin 2012:1319–1320).

In the qualitative study, there is a need to ensure enough data, but not too much, which is greater than 30 (Boddy 2016:426-432). Samples of 20 and 30 (and multiples of 10) are the most common (Mason 2010), with 25-30 being a typical recommendation (Dworkin 2012:1319-1320). Undoubtedly, the most widely used principle for determining sample size and evaluating its sufficiency is that of saturation. Concept saturation is a critical concept in qualitative research (Guest, Bunce & Johnson 2006:59-82).

The number of participants in a qualitative study is adequate when saturation of information is achieved in the study area, which occurs when additional sampling provides no new information, only redundancy of previously collected data (Gray et al 2017:550).

Data saturation: Saturation of data, also referred to as informational redundancy, occurs when additional sampling provides no new information, only redundancy of previously collected data (Charmaz 2014:45; Marshall & Rossman, 2016:56). It means that a researcher can be reasonably assured that further data collection would yield similar results and serve to confirm emerging themes and conclusions. According to Creswell and Creswell (2018:335),

saturation is when, in qualitative data collection, the researcher stops collecting data because fresh data no longer sparks new insights or reveals new properties. Alvesson and Skoldberg (2010) define saturation during interviews as the point when no new data is revealed by further collection of data since all the questions asked have been exhausted by the initial qualitative interviews. Important factors that must be considered in determining sample size to achieve saturation of data are (1) The scope of the study, (2) The nature of the topic, (3) The quality of the data, and (4) The study design (Charmaz 2014:45; Marshall & Rossman 2016:56; Morse 2012:18; Munhall 2012:12).

Focus group discussion is the other type of interview that involves carefully selected individuals who usually do not know each other. Homogeneous samples are preferred. These individuals are selected as they hold particular characteristics that the researcher believes are necessary for the topic of focus. The group discussion is held in a permissive environment in order to extract opinions and share ideas and perceptions through group interaction, and it is not necessary to reach a consensus.

FGD is conducted by a trained moderator in a non-structured and natural manner with a small group of respondents (8-10 individuals). The moderator leads the discussion, and it last 1-2 hours. The main purpose of FGD is to gain insights by listening to a group of people from the appropriate target market talk about specific issues. The FGD takes place in a private, quiet setting so that audio will be recorded; the helper takes notes.

In this phase of the study, the researcher formed focus groups each consisting of 10 members, and saturation or redundancy of information was achieved when three rounds of FGDs were held. A total of 30 participants took part in the study.

3.3.2.2.3 Sample Size for Phase IV

A group of experts participating in the Delphi method is called a “panel” (McMillan, King & Tully 2016:655). e-Delphi employs ‘experts’ as panel members (Taylor, Feltbower, Aslam, Raine, Whelan & Gibson 2016:2). In the

panel selection, the tips for the panel consist of size, panel member features, and the response rate (Giannarou & Zervas 2014:65-82). There is a complete agreement on how to choose the participants. They are not randomly but purposively selected to enter the research to apply their knowledge and experience with respect to the problem (Giannarou & Zervas 2014:65-82). Although it is sufficient to reach an acceptable size of 10 experts, there is no agreed standard for number of the participants (Avella 2016:305-321; Akins, Tolson & Cole 2005:37; Hsu & Sandford 2007:1-8). It has been pointed out that the purpose of the study and the resources available to participate influence on the selection of the participants, but there is no standard method to calculate the number of specialists needed to achieve stable data.

In Phase IV of sample size determination, the researcher purposefully recruited 10 health professional expert panellists (consisting of Doctors, Radiologists, Nurses working in oncology clinics, university lectures and health experts) from different parts of the country, who had knowledge of the topic under study, and agreed to participate in the study. The researcher was communicated with them through e-mail.

3.3.2.3 Sampling Technique

3.3.2.3.1 Sampling Technique for Phase I

In Phase I, the researcher used a systematic sampling technique which is defined as a sampling technique conducted when an ordered list of all members of the population is available and involves selecting every K^{th} individual on the list, starting from a point that is selected randomly (Gray et al 2017:1093). This means that it is a technique where the starting point of the sample is chosen randomly, and all the other elements are chosen using a fixed interval. This interval is calculated by dividing the population size by the target sample size.

Sampling fraction (K) = $\frac{N}{n}$

Where

K is the interval of sampling

N is the population size

n is the sample size

- N = 1,034 women based on the sum of a quarterly CC screening plan of the three chosen health facilities (Adama Hospital 420, Geda Health Center 328, and Adama Health Center 286).
- n = 383 (The minimum sample size calculated).
- An interval of K = 1,034/383 = 2.69 ≈ 3.
- The first woman to be included in the study was chosen randomly, by blindly picking one out of 3 pieces of papers numbered 1-3.
- Then every 3rd woman was taken until the samples reached 383

Proportional Allocation of the Sample Size

To ensure proportionate allocation of the sample size among selected health facilities, the sample size was distributed between the facilities based on the following formula, according to their annual plan for cervical screening.

$$nj = \frac{n}{N} Nj$$

Where

- j = 1, 2, ..., k. k is the number of health facilities.
- nj is the sample size of the j^{th} health facility.
- Nj is the population size of the j^{th} health facility = (Annual plan of CC screening of each facility: Adama Hospital 1,800, Geda Health Centre 1,193, and Adama Health Centre 1,144).
- n = n1 + n2 + ...+ nk is the total sample size = (383).
- N = N1 + N2 + ...+ Nk is the total population size = (4,137, total annual plan of the three facilities)

Schematic Representation of the Sample Size Allocation

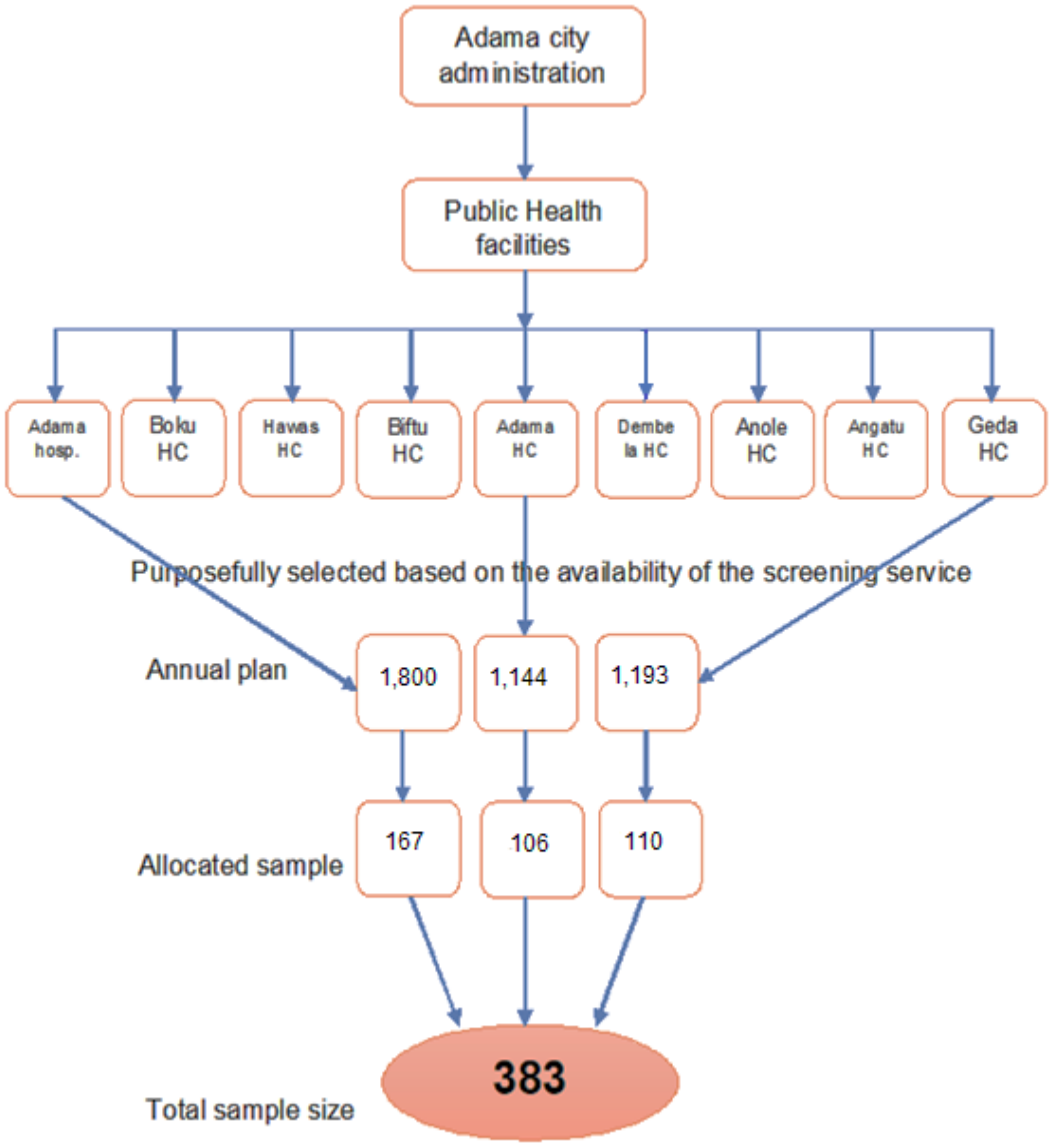

Figure 3.3: Schematic representation of sample size allocation among selected health facilities

3.3.2.3.2 Sampling Technique for Phase II

In Phase II, the researcher used the purposive sampling technique, which is defined as judgmental or selective sampling method that involves conscious selection by the researcher of certain subjects or elements to include in a study (Gray et al 2017:1081). It means that the inquirer selects individuals and sites for study because they can purposefully inform an understanding of the research

problem and central phenomenon in the study (Creswell 2013:156). The purposive sampling technique was used to explore and describe the perceptions of women regarding HPV infection and CC. The researcher, with the help of clinicians working at the selected CC screening centres, purposefully identified and recruited potentially eligible women who were readily accessible and already visited the selected screening centres. In order to enhance the credibility of the study, the selection focused on information-rich women believed to have some awareness about the topics to be discussed, and could have the ability to articulate their experience clearly during the discussion.

3.3.2.3.3 Sampling Technique for Phase IV

In Phase IV of the sampling technique, the researcher purposefully selected 10 expert panellists from different parts of the country. The recruited experts were health professionals who agreed to participate in the study and had expert knowledge of the topic under study. The researcher communicated with them by e-mail.

3.3.3 Ethical Issues Related to Sampling

All scientific procedures were followed appropriately to ensure that fair treatment of participants was practised while carrying out sampling activities. With regard to conducting the quantitative part of the study, the probability sampling technique was applied to ensure that every respondent was selected by chance, not by choice. Accordingly, the sample was representative of the target population who reside in the study area. Concerning the qualitative aspect of the study, the researcher purposefully selected some participants among women who had already took part in the quantitative section of the study, because they held particular characteristics that the researcher believed were necessary to the topic of focus for the FGD section. In the e-Delphi part, the researcher purposefully selected expert health professional panellists from different parts of the country, who had expert knowledge of the topic under study, and agreed to participate in the study.

3.3.4 Data Collection

Data collection is the precise, systematic gathering of information relevant to the research purpose and the specific objectives, questions, or hypotheses of a study (Gray et al 2017:1052).

3.3.4.1 Data Collection Approach and Method

3.3.4.1.1 Data Collection for Phase I

In Phase I, data collection was accomplished using a questionnaire, which is a common type of data collection tool for this type of study design. A questionnaire is a self-report form designed to elicit information that can be obtained through the subject's selection from a list of predetermined options or through textual responses of the subject (Gray et al 2017:1082). The questionnaire for this phase of the study was adapted and modified from different previous literature related to the topic of study, and from cervical cancer screening and treatment client intake form (FMOHE 2015) after permissions were obtained from each author through e-mail communication. The questionnaire considered all the following principles across this phase of the research.

- It was prepared in English language and translated into Amharic and Affan Oromo local languages by language experts in each language (who have MSc and above) and back to English to see its consistency and to avoid misinterpretation and misunderstanding. (Annexures F1, F2 and F3).

- It consisted of sociodemographic characteristics of study participants, reproductive history, risky sexual behaviour, and CC screening and treatment.

- It is pre-tested on 5% of study participants prior to conducting the actual data collection to assess the reliability and validity of the instrument in this population.

3.3.4.1.2 Data Collection for Phase II

In this phase of the study, the researcher employed a FGD to collect data from the study participants. The focus group strategy is designed to obtain the perspective of the normative group, not individual perspectives (Gray et al 2017:413). According to Gray et al (2017), an FGD constitutes with the purpose of collecting data on a specific topic from more than one research participant at the same time. One of the assumptions underlying the use of focus groups is that interactions among people can help them express and clarify their views in ways that are less likely to occur in a one-on-one interview. An FGD is designed to obtain the participants' perceptions of a focused topic in a setting that is permissive and non-threatening. Homogeneity of the group is a characteristic of focus groups (Krueger & Casey 2015:158).

In this phase of the study, three FGDs, incorporating 10 discussants in each group who were homogenous and did not know each other, were conducted to study women's perceptions concerning CC screening and HPV vaccination.

3.3.4.1.3 Data Collection for Phase IV

In this phase of the study, data were collected using a questionnaire through the e-Delphi method. As a part of the process, the responses from each questionnaire were fed back the experts in summarised form. In this phase an iterative multistage process designed to combine opinion into group consensus, the initial questionnaire collected qualitative comments, which were fed back to the participants in a quantitative form through a second questionnaire. After statistical analysis regarding group collective opinion, the results from the second questionnaire helped formulate the third quantitative questionnaire. This process was ongoing until consensus was obtained or the law of diminishing returns set in or took effect. That is, responses were summarised between rounds and communicated back to the experts through a process of controlled feedback. This process was repeated until a consensus was reached or until the number of returns for each round decreased.

In this study, collectively 3 rounds were conducted to seek to aggregate opinions from a diverse set of experts. The central constructs of an e-Delphi technique are building consensus. Consensus represents the collective opinion of an expert panel in solving problems when limited evidence exists (Douglas & Bonner 2011:13-23; Humphrey-Murto, Varpio, Gonsalves & Wood 2017:14–19). If no consensus is achieved, a majority ruling (Burns & Grove 2009:154) will be considered. The majority ruling is based on the idea of the participants' consent during the final round when at least 80% agreement is achieved on the investigated issue (O'Conner 2008:231-240).

The definition of consensus may vary from 51 to 80% (Humphrey-Murto et al 2017:14-19). Tack, Boardman, Layer, Schiefke, Jayne, Scarpignato and Emmanuel (2017:434–442) ranged the consensus from 75% to 80% agreement. Humphrey-Murto et al. (2017:14-19) also considered consensus when an item achieved 70% "agree" or "strongly agree" responses. This study considered an 80% agreement between panellists as a consensus.

3.3.4.2 Development and Testing of the Data Collection Instruments

Interviewer administered structured questionnaire, and FGDs were used as data collection instruments in this study for Phase I and Phase II respectively. For Phase I of the quantitative study, the questionnaire comprising close-ended questions was adapted and modified from previous related literature. An extensive literature review and consultation with the advisors and experts in the field of data collection were made while making the tool fit for use. Pre-testing of the instrument was done on 19 women (5% of the sample size) at randomly selected health facilities prior to the actual data collection period. The information obtained from the pre-test was not included in the actual data. During the pre-test, ambiguous or unclear words and sentences were rephrased and corrected to make the tool more understandable and suitable for use for both the data collectors and the respondents, and more importantly, to enhance its validity and reliability. For Phase II of the qualitative study, an unstructured tool comprised of initial open-ended questions for group discussion was

prepared to study the participants' risk perceptions concerning HPV infection and CC, and their perceptions regarding cervical cancer screening and HPV vaccination, which was addressed through FGD. The researcher conducted a pre-test on a group of 8 women in another health facility which was not part of the current study, to enhance the validity of the open-ended questions.

3.3.4.3 Characteristics of the Data Collection Instruments

1. The interviewer administered; close-ended structured questionnaire had the following three parts: -

- **Part I:** Addresses sociodemographic characteristics of participants, which included age, place of residence, educational status, and monthly income.

- **Part II:** Asks questions about the reproductive history of the respondents, which included marital status, parity, contraceptive use, condom use, family history of CC, pattern of menstrual bleeding, and history of post-coital bleeding.

- **Part III:** Assesses risky sexual behaviour that may put participants at risk of acquiring HPV infection, like age at first sexual intercourse, number of lifetime sexual partners, history of STIs, HIV sero-status and ART usage for HIV-positive participants, history of previous abnormal Pap smear test, cigarette smoking, and long-time usage of corticosteroids.

- **Part IV:** Questions pertaining to CC screening and treatments, which consisted of the type of screening visit, HPV DNA test and genotypes identified if positive for the test, VIA test for those tested positive for HPV, the treatment offered for VIA positive results, and reasons for referral if indicated.

2. The unstructured open-ended qualitative tool had one part: **-**

- **Part I:** Initial questions for the FGD, to study the participants' risk perception about HPV infection and CC, perception towards CC screening and HPV vaccination.

3.3.4.4 Data Collection Process

One MSc degree-qualified female nurse supervisor and three BSc-qualified female nurse data collectors, with previous extensive data collection experiences were recruited to collect the data in the quantitative phase of the study. The researcher trained them for two days prior to the commencement of data collection in order to standardise the data collection process. The topics covered during the training included the principles of conducting quality interviews, and the issue of obeying the basic ethical principles. The data collectors were trained adequately on assuring all aspects of the rights of respondents and stressing the obtaining of informed consent from each interviewee before data collection commences.

The data collection activities were undertaken at three public health facilities of Adama City (Adama Hospital, Geda and Adama Health Centres), where the CC screenings and treatments of pre-cancerous cervical lesion services are provided. The researcher supervised the data collection processes and helped the data collectors when his assistance was necessary. The actual data collection activities took place from March to July 2022.

In the qualitative phase of the study, to maintain integrity and credibility, the researcher conducted all qualitative data-gathering sessions through FGDs as a facilitator together with a moderator who had previous experiences in this regard. The details of data collection activities in the qualitative phase of the study are mentioned in Chapter 5.

3.3.4.5 Data Quality Control

The quality of the data was maintained before, during, and after the data collection activities. Before the data collection, adapting and modifying a structured questionnaire to suit quality data collection, training of data collectors and supervisor about the objective, the questionnaire, the methods and ethical issues of the study, and pre-testing of the questionnaire on 5% of the sample size were all conducted. During the data collection period, the data were checked for completeness and consistency by the supervisor and the investigator through close follow-up. After the data collection, the data were rechecked for completeness and consistency by the supervisor and principal investigator.

3.3.4.6 Ethical Considerations Related to Data Collection

Ethics refers to principles of conduct that distinguish between right and wrong actions (Shamoo & Khin-Maung-Gyi 2021:24). These principles may be embodied in a particular code, creed, or law, or they may exist as social conventions or norms (or morals). According to Pring (2000:142), ethics is defined as the search for rules of conduct that enable us to operate defensibly in the political contexts in which we have to conduct educational research. Ethics refers to an “ethos”, “way of life” or “social norms” for conduct that distinguishes between acceptable and unacceptable behaviour (Shah 2011:205; Akaranga & Ongong’a, 2013:8).

In studies, when the study subjects are human beings, care must be taken to ensure that their rights are protected. The main role of human participants in research is to serve as sources of data. Therefore, researchers have a duty to ‘protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research subjects’ (Yip, Han & Sng 2016:684-688).

A code of ethics is the ethical rules and principles drafted by professional associations that govern scholarly research in the disciplines (Creswell & Creswell 2018:327). The codes of conduct to protect the researched include ensuring anonymity of the researched and confidentiality of the responses.

3.3.4.6.1The Participants/Respondents

Participation in this study was in a voluntary basis by obtaining informed consent from each participant. Moreover, ethical principles and rules such as autonomy, and adhered to the basic ethical principles of anonymity, confidentiality and privacy, beneficence and non-maleficence, and justice were respected.

3.3.4.6.2 Basic Ethical Principles

According to the BELMONT REPORT on ethical principles and guidelines for the protection of human subjects of research (2021:1-15), the expression "Basic ethical principles" refer to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Varkey (2021:17-28) states the fundamental principles of ethics constitute four principles: autonomy, beneficence, nonmaleficence, and justice.

Autonomy

The right to self-determination is based on the ethical principle of respect for persons (Gray et al 2017:273). This principle holds that because humans are capable of self- determination, or making their own decisions, they should be treated as autonomous agents who have the freedom to conduct their lives as they choose without external controls. According to Shamoo and Khin-Maung-Gyi (2021:24), respect for the person requires that prospective research subjects should be given sufficient information regarding risks and benefits in order to weigh properly the prospect of enrolment in the research project. Furthermore, respect for the person requires that the enrolment of an individual into a research study should be voluntary, in other words, free from any duress, coercion, and undue influence. In this study, the researcher ensured

participants' right to self-determination by explaining the purpose and significance of the study to them; obtaining their informed consent; emphasising that participation is free and voluntary, and that they have the right to withdraw from the study at any time without the risk of penalty or prejudicial treatment.

Anonymity, Confidentiality and Privacy

Anonymity refers to keeping secret by not identifying the ethnic or cultural background of participants, refrain from referring to them by their names or divulging any other sensitive information about a participant (Mugenda 2003:55). The participants in this study were assured of privacy, confidentiality, and anonymity. Anonymity was assured as no names were neither written on the questionnaire nor asked and recorded during the individual interview and the FGD sessions. Rather, all details taken from the participants were kept anonymous by giving numerical code to each as it represented each participant. Accordingly, all the information collected was treated in strictest confidence. The documents and the data were kept in a safe place under lock and key so no one could access them. Privacy was assured by conducting the interviews in private rooms where no information could be overheard, and the information was used only for this research purpose.

Beneficence and non–maleficence

Beneficence is intertwined with that of non-maleficence and at times the two are lumped together (Shamoo & Khin-Maung-Gyi 2021:25). The right to protection from discomfort and harm is based on the ethical principles of beneficence, which holds that one should do good and, above all, do no harm (non-maleficence) (Gray et al 2017:1044). Beneficence imposes an obligation on researchers to minimise harm and maximise benefits. In this study, the participants were assured that their participation or the information they might provide would not be used against them in any way. The physical and psychological discomfort that the participants might face during the examination was kept minimised by all means possible, for instance, by making the screening procedure women-friendly.

Justice

The right to fair treatment is based on the ethical principle of justice. This principle holds that each person should be treated fairly and should receive what he or she is due or owed (Gray et al 2017:289). In research, the selection of subjects and their assignment to experimental or control group should be made impartially. In addition, their treatment during the course of a study should be fair (Gray et al 2017:289). It is the ethical principle of equity and fairness in the distribution of benefits and opportunities. According to Shamoo and Khin-Maung-Gyi (2021:26), in research with human subjects, justice requires that their selection should be fair to all individuals in that class. Therefore, those selected for research should reflect a fair sharing of burdens and benefits as to their social, sexual, and ethnic characteristics. Social justice requires that subjects should not be selected because of race, decisional incapacity, or condition (for example, being institutionalised). In this study, the participants were selected fairly for reasons directly related to the problem studied.

3.3.4.6.3 The Institutions

Permission of institutions participating in the study must be obtained in advance before any data collection activities are commenced. In this study, the researcher obtained ethical approval from the College of Human Sciences Research Ethics Review Committee at the University of South Africa (Annexure A). Additionally, a letter of cooperation was obtained from UNISA-Ethiopia centre and submitted to Oromia Health Bureau (Annexure B). Permission was granted from Ethical Review Committee of Oromia Health Bureau, and submitted to Adama City Health Office and Adama Hospital (Annexures B2 and B3). Moreover, a letter of cooperation was obtained from the Adama city Health Office, and submitted to Adama Health Centre and Geda Health Centre (Annexures B4 and B5). Finally, all the three health facilities granted permission for the study to be conducted.

3.3.4.6.4 Scientific Integrity of the Research

The origin of information, whether cited directly or indirectly, must always be acknowledged in all scientific writings (UNISA 2021:25). In other words, works of other authors used in any part of a thesis should be acknowledged. Accordingly, the researcher has fully acknowledged the works of other authors referred to in any part of this thesis using the Harvard referencing system, according to UNISA Department of Health Studies bibliographic style and reference techniques.

3.3.5 Data Analysis

Burns and Grove (2017:1052) state that data analysis in quantitative studies refers to a statistical testing of prevalence, relationship, and cause. In qualitative research, data analysis refers to a mechanism for reducing and organising data, and revealing meaning.

3.3.5.1 Data analysis for Phase I

In Phase I, the researcher employed quantitative data analysis to obtain the prevalence, genotypes and risk factors of HPV infection, and the prevalence of pre-cancerous cervical lesions and treatments offered among women residing in the study area.

All data generated were revised, checked for completeness, and coded for computerised data entry using the Epi Info 7 software programme. The data were checked and cleaned up by running frequencies, sorting and listing variables for consistency, and finally recoded and analysed using SPSS version 26.

Descriptive and summary statistics with frequency, proportion and odds ratio were used to describe the study population in relation to relevant variables and to assess the presence and degree of association between dependent and

independent variables. Discrete variables were presented with the use of tables and percentages. Fisher's exact and chi-square tests were used to test the comparison of proportions and logistic regression for bivariate and multivariate analysis with AOR, and 95% CI were used to see the effect of independent variables on the outcome variables. P-values less than 0.05 were used to decide whether observed differences in proportions were statistically significant. During analysis, the Omnibus tests model of coefficient was checked for significant that was considered as ($P < 0.05$) indicates the identified predictor in multivariate logistic regression would be better off. Furthermore, the Hosmer and Lemeshow test were checked for the fitness of model's assumption and it would not be significant (p: >0.05), indicates the model fit test would be doing well.

3.3.5.2 Data analysis for Phase II

Thematic analysis as an independent qualitative descriptive approach is mainly described as "a method for identifying, analysing and reporting patterns (themes) within data" (Braun & Clarke, 2006:79). It is a method of analysing qualitative data. Vaismoradi, Turunen and Bondas (2013:398-405) describe thematic analysis as a descriptive method that reduces the data in a flexible way that dovetails with other data analysis methods. It is used commonly because of the wide variety of research questions and topics that can be addressed with this method of data analysis.

In Phase II, the researcher employed a six-step process, which is the most common form of thematic analysis, to analyse women's risk perception of HPV infection and CC, their perception regarding CC screening and HPV vaccination among women residing in the study area.

The thematic analysis involves familiarization, coding, generating themes, reviewing themes, defining and naming themes, and finally the writing up (Braun & Clarke 2006:87).

- **Familiarisation**: Getting to know the data. The researcher has had a thorough overview of all the data collected, generally looked through the data to get familiar with it.

- **Coding**: Highlighting the sections of the data. The researcher has drawn attention to interesting features of the data systematically across the entire data set, and came up with shorthand labels or codes, collated data relevant to each code.

- **Generating themes**: Collating codes into potential themes, gathering all data relevant to each potential theme. The researcher has looked over codes created, identify patterns among them, and came up with themes by combining the codes.

- **Reviewing themes**: Checking if the themes work in relation to the coded extracts and the entire data set, generating a thematic map. The researcher has tried to make sure the themes generated were a useful and accurate representation of the data. Moreover, the researcher has returned to the data set and compared the themes against it.

- **Defining and naming themes:** Ongoing analysis for refining the specifics of each theme and the overall story that the analysis tells, generating clear definitions and names for each theme. The researcher has tried to formulate exactly what he meant by each theme and figured out how it helped him understood the data, and came up with a succinct and easily understandable name for each theme.

- **Writing up:** Producing the report. The researcher has written up the analysis of the data which included an introduction, aim, approach and the methodology that describes how the researcher collected the data and, explanation how the researcher conducted the thematic analysis itself.

3.3.5.3 Data Analysis for Phase IV

In this phase, the data analysis involved the analysis and careful management of qualitative and quantitative data. The qualitative data from the first round of the e-Delphi were analysed using content analysis techniques. To help structured debate, this technique can be used in conjunction with informal literature reviews and/or meta-analysis. Data collected from this initial stage were analysed by grouping similar items together. In subsequent rounds, participants were asked to rank/respond to the analysed options from the previous round. The Likert scaling technique was applied. Between rounds, the group's responses were analysed, summarised, and communicated back to the experts, a process called controlled feedback. This was repeated for three rounds. Subsequent rounds were analysed to identify convergence of expert responses, and to provide controlled feedback. Central tendencies (mean, median, and mode) and levels of dispersion (standard deviation and the inter-quartile range) were used. These results were fed back to participants in the next round.

3.4 RIGOUR OF THE STUDY: VALIDITY AND RELIABILITY/ TRUSTWORTHINESS

When applied to the quantitative research process, rigour implies a high degree of accuracy, consistency, and attention to all measurable aspects of the research (Gray et al 2017:91). In rigorous quantitative research, deductions are flawlessly reasoned, and decisions are based on the scientific method.

According to Gray et al (2017:93) rigour implies the following:

- The sample is chosen in accordance with pre-determined inclusion criteria.
- The site is chosen so as to eliminate the intrusion of happenings that might affect results.
- Any research intervention is enacted the same way every time it is implemented.

- Measurements are made accurately with well-calibrated equipment.
- Data are recorded precisely.
- Statistical analyses are appropriately made with consideration of their assumptions.
- Interpretations are accurate and fair.
- Recommendations are made in accordance with guidelines for generalisation.

The quality of scientific research and the instruments used are determined by their validity and reliability (Creswell & Plano Clark 2018:306). Good researches utilise procedures to ensure the validity of the data and results, and of their interpretation. Validity differs in quantitative and qualitative research, but in both approaches it serves the purpose of checking on the quality of the data, the results, and the author's interpretation of the data results.

Validity in mixed methods research is defined as employing strategies that address potential threats to drawing correct inferences and accurate assessments from the integrated data (Creswell & Plano Clark 2018:345). In quantitative research, the researcher is concerned about issues of validity and reliability. In qualitative research, there is more of a focus on validity than reliability (Creswell & Plano Clark 2018:306). In this research, the researcher strictly followed the principles of both validity and reliability.

3.4.1 Validity and Reliability of Phase I

3.4.1.1 Validity

Validity is the truthfulness of a research study. The validity of an interventional study represents the extent to which the study tests its underlying hypothesis, allowing support for the conceptual level of the study, and its theoretical framework (Gray et al 2017:362). The validity of an instrument indicates the extent to which it actually reflects or is able to measure the construct being examined (Gray et al 2017:585). In other words, an instrument is said to be valid

when it measures what it is supposed to measure. Quantitative validity, also called construct validity, means that the scores received from participants are meaningful indicators of the construct being measured (Creswell & Plano Clark 2018:306).

3.4.1.1.1 Internal Validity

Internal validity is the extent to which the researcher controls for the effects of extraneous variables in the study's design (Gray et al 2017:94). Internal validity reflects design-embedded decisions about how dependent variables and research variables are measured and how those values might be influenced by extraneous variables (Gray et al 2017:332). Internal validity is an assessment of the degree to which the measured relationships among variables are truly due to their interaction, and the degree to which other intrusive variables might have accounted for the measured value (Campbell 1957:159). In other words, the outcomes of a study result remain from the variables that were manipulated, measured, or selected rather than from other variables not systematically treated.

If the research is dome on the sample which is believed to be valid, the results are also representative of the population from which it is drawn. To maintain internal validity, the researcher in this study used probability sampling techniques to control extraneous variables. It would be given for consistency of instrument understanding, data collection and measurement in order to control instrument and testing biases. Inclusion and exclusion criteria were clearly defined.

3.4.1.1.2 External Validity

External validity is the extent to which study results are generalisable to the target population (Gray et al 2017:913). In other words, the findings of a study can be generalised to people or situations other than those observed in the study. External validity refers to the extent to which the findings of a particular study can be generalised across populations, contexts and time (Dellinger &

Leech 2007:15). External validity is strongest for studies with large, randomly selected samples, and it is still stronger when that sample is drawn from many different sites (Gray et al 2017:913).

To generalise validly the findings from a sample to some defined population require that the sample has been drawn from that population according to one of several probability sampling plans. To increase the generalisability of the findings of this study the researcher used probability sampling techniques. More importantly, the study was a piece of mixed methods research in which the combination of qualitative and quantitative studies has the potential to achieve triangulation, which is one of the important ways to enhance external validity (Bryman 1988:155).

3.4.1.1.3 Content/Construct Validity

Content validity examines the extent to which the measurement method includes all the major elements relevant to the construct being measured (Gray 2017:376-380). Evidence for this type of validity is obtained from the literature, representatives of the relevant populations, and relevant experts.

Construct validity focuses on determining whether the instrument actually measures the theoretical construct that it purports to measure, which involves examining the fit between the conceptual and operational definitions of a variable (Gray 2017:376-380). Construct validity represents the extent to which a study's operational definitions reflect its conceptual definitions and constructs, and how well the research process adheres to the operational definitions, consistently and predictably for the duration of the study (Campbell 1957:118).

Construct validity threat arises when investigators use inadequate definitions and measure variables based on those inadequate definitions (Modell 2005). In this study, the threats to construct validity were limited as it forwards explicit definitions for each variable via setting a conceptual framework and before running the model. Moreover, the use of multiple methods is likely to reduce the threats to the construct validity. The indicators used in the quantitative analysis

were further examined in the qualitative interviews to check the accuracy of the definition of indicators.

3.4.1.2 Reliability

Reliability is the degree of consistency with which the instrument measures the attribute it is designed to measure (Fletcher 2014:34). A reliable study instrument or tool produces the same value each time when it used repeatedly (Fletcher 2014:34). The reliability of an instrument denotes the consistency of the measures obtained of an attribute, concept, or situation in a study or in clinical practice (Gray 2017:370-375). Reliability is concerned with the precision, reproducibility, and comparability of a measurement method (Bartlett & Frost 2008:218). An instrument with strong reliability demonstrates consistency in the participant scores obtained, resulting in less measurement error (Bannigan & Watson, 2009:116).

Quantitative reliability means that scores received from participants are consistent and stable over time (Creswell & Plano Clark 2018:306). Researchers establish the reliability and construct validity of scores by selecting quality instruments and by analysing their data. They also use procedures throughout the study to reduce threats to internal validity (i.e., the extent to which cause-and-effect claims can be made) and to external validity (i.e., the extent to which the results can be generalised to other persons, settings, or times) (Creswell & Plano Clark 2018:306).

To ensure reliability, the researcher adopted and modified research tools and instruments used by other researchers with similar titles in consultation with the supervisor. Instruments were pretested for clarity, flow, cultural and moral fitness, and time requirement on 5% (19) of the sample size in Adama City at health institutions before the actual data collection is commenced. The findings were not included in the actual study. Feedbacks from the pre-teste, the reviewer and the research assistants were used to refine the instrument.

3.4.2 Trustworthiness for Phase II

In qualitative research, there is more of a focus on validity than reliability. Validity is one of the strengths of qualitative research and is based on determining whether the findings are accurate from the standpoint of the researcher, the participant, or the readers of an account (Creswell & Miller, 2000:135).

Trustworthiness means assessing whether the information obtained through the qualitative data collection is accurate, such as examining the extent to which the information is credible, transferable, dependable, and confirmable (Lincoln & Guba 1985:122). Qualitative validity comes from standards based on researchers, participants, and reviewers (Creswell & Miller 2000:113).

The researcher in this study considered the following strategies to determine trustworthiness: The first strategy was “Member-checking” which is a frequently used strategy in which the investigator took summaries of the findings back to key participants in the study and asked them whether the findings were an accurate reflection of their experiences. The second validity strategy was the triangulation of data drawn from several individuals such that the inquirer has built evidence for a code or theme from these sources or individuals during data analysis. A third strategy consisted of reporting disconfirming evidence. Disconfirming evidence is information that presents a perspective that is contrary to the one indicated by the established evidence. A report of disconfirming evidence in fact confirms the accuracy of the data analysis because, in real life, we expect the evidence for themes to diverge and include more than just positive information. A final strategy was asking others to examine the data. These others were peers who were familiar with qualitative research as well as the content area of the specific research.

3.4.3 Validity and Reliability for Phase IV

With the e-Delphi technique, reliability and generalisability of outcomes are ensured through the iteration of rounds during data collection and related

analyses that are guided by the principles of democratic participation and anonymity (Day & Bobeva 2005:50). Lincoln and Guba's (1985) criteria for qualitative studies could be applied to help ensure that credible interpretations of the findings are produced.

The criteria are based on four major issues, namely credibility (truthfulness), fittingness (applicability), auditability (consistency), and confirmability.

The researcher ensured credibility through the ongoing iteration and feedback from and to the experts, which according to Engles and Kennedy (2007) was viewed as member checks.

Fittingness was established using verification 443 of the applicability of e-Delphi findings.

Auditability was improved by utilising a clear audit trail of decisions of all the theoretical, methodological, and analytical decisions throughout the research process.

Confirmability was assessed by maintaining a detailed description of the e-Delphi collection and analysis processes.

To ensure validity the researcher used participants who had knowledge and an interest in the topic, and the use of successive rounds of the questionnaire helped to increase the concurrent validity.

3.5 SUMMARY

This chapter discussed the research design and method. The explanatory sequential mixed method research design, and why it was chosen for this study were discussed in detail. The selection of cross-sectional descriptive study design for the first phase of the study (the quantitative study part), and exploratory descriptive and contextual qualitative research design for the

second phase of the study (the qualitative study part), and finally, meta inference as an overall conclusion, explanation or understanding developed through an integration of the inferences obtained from the quantitative and qualitative strands of a mixed method study were clearly justified. The use of the e-Delphi technique to obtain a common viewpoint from experts using questionnaires was also explained. The application of systematic sampling technique for Phase I and purposive sampling technique for Phase II were discussed. The characteristics of the data collection tools and their application for each phase of the study were explained. This was augmented by data analysis applications and explanations of the underlying rationale for adopting specific data analyses. The ethical procedures that were followed to protect the rights of respondents were properly explained. Finally, the validity and reliability of the instruments and sampling procedure were also discussed.

Chapter 4 covers data analysis, presentation, and description of the quantitative research findings.

CHAPTER 4

ANALYSIS, PRESENTATION AND DESCRIPTION OF QUANTITATIVE RESEARCH FINDINGS

4.1 INTRODUCTION

The previous chapter discussed the research design and methods which guided the study. Further, the researcher discussed the explanatory sequential mixed method research design, and why it was chosen for this study. The selection of cross-sectional descriptive study design for Phase I of the study, and exploratory descriptive and contextual qualitative research design for Phase II of the study, and finally, meta inference as an integration of the inferences obtained from the quantitative and qualitative strands of a study were clearly justified. The use of the e-Delphi technique to obtain a common viewpoint from experts using questionnaires is also explained.

This chapter discusses the research findings based on the quantitative data analysis. Before statistical tests were applied, each variable was analysed using descriptive statistics in the case of continuous variables, and summary statistics in the case of categorical variables.

The findings address the objectives of the study, namely:

- To assess the prevalence of HPV infection among women who participated in the study.
- To assess the genotypes of HPV among women identified as having HPV infection.
- To identify the risk factors of HPV infection among women who participated in the study.
- To assess the prevalence of pre-cancerous cervical lesions among women identified as having HPV infection.

- To identify the risk factors of pre-cancerous cervical lesions among women who participated in the study.
- To identify the treatment offered for women identified as having pre-cancerous cervical lesions through VIA test.

4.2 SPECIMEN COLLECTION PROCEDURES AND LABORATORY TESTING

Prior to the collection of the specimens, the participants who agreed and consented to take part in the study were counselled and instructed not to use vaginal lubricants, vaginal medications, vaginal contraceptives, and douches within 48 hours before specimen collection. They were also instructed not to engage in sexual activity within 24 hours before specimen collection. Equipment and supplies required for specimen collection, such as a refrigerator, pelvic examination table, sterile vaginal speculums, gloves, cervical brush/broom, swabs, collection vials with specific collection media, specimen labels and biohazard discard bag/box were supplied for the collection of the specimen.

A private room was arranged to maintain privacy for the participants during data collection. After all the necessary preparations, the cervical specimens were collected from the participants by trained health professionals using the Abbott Cervi-Collect Specimen Collection Kit (4N73-06). Abbott Real-time High-Risk HPV (HR-HPV) is a qualitative in-vitro test for the detection of DNA from high-risk HPV genotypes in clinical specimens. In each package of the Abbott Cervi-Collect Specimen Collection Kit for HPV testing, one cervical brush and one transport tube with 2.4 mL specimen transport buffer (guanidine thiocyanate in a Tris buffer) to stabilise DNA till sample preparation were included. The collected specimens were labelled with the participants information and transported to the central laboratory for HR-HPV detection.

The participants were reminded to return to the setting two weeks following the specimen collection. Subsequently, the findings of their HPV tests were communicated to them; in particular, individuals who had tested positive for HPV

were given further VIA screenings to determine whether or not they had developed pre-cancerous cervical lesions. In order to get in touch with the participants when needed, their phone numbers were recorded.

4.2.1 HR-HPV Detection Procedure Using the Abbott Real-time PCR Method

The collected samples were transferred to the central laboratory. Qualified laboratory personnel used the Abbott m2000rt/SP polymerase chain reaction (PCR) technique to conduct laboratory testing. Polymerase chain reaction is a technique for rapidly producing millions of copies of specific segments of DNA in order to study them in detail. The following procedure was used to identify the major oncogenic HR-HPV genotypes determined as “HPV-16”, “HPV-18” and “Other HR-HPV” genotypes. The molecular testing principles are as follows: to amplify HPV targets, a primer mix of three forward primers and two reverse primers targeting a conserved late protein (L1 region) was utilised. Fluorescently labelled probes were used to create a signal for high-risk (HR) HPV genotypes.

Internal Control (IC) amplicons were produced using a primer set that targeted an endogenous human beta-globin sequence and identified using an IC specific probe. As a sample validity control for cell adequacy, sample extraction, and amplification efficiency, the Abbott Real-time HR HPV assay identifies the endogenous human beta-globin sequence. Different fluorophores were used to mark probes for HPV-16, HPV-18, non-HPV 16/18 genotypes (Other HR-HPV), and IC, allowing their signals to be distinguished in a single reaction.

4.2.2 Quality Control

Health professionals assigned to data collecting and laboratory testing activities received training from the researcher and an Abbott technical specialist prior to the start of data collection and sample testing. The researcher closely monitored the progress of the activities as they were being conducted. The laboratory testing was conducted in a laboratory accredited by the Ethiopian National

Accreditation Office (ENAO) (M0030). The external quality control in each run was included to monitor the quality of the test parameter. The IC which was an endogenous human beta-globin sequence monitored the entire PCR process from the extraction to amplification and detection steps. Meaning, IC was used as a sample validity control for cell adequacy, sample extraction, and amplification efficiency. In addition to site-based supervisions, the facilities were contacted via phone to address any problems during reporting and testing.

4.3 DATA MANAGEMENT AND ANALYSIS

4.3.1 Data management

Data management describes the organisation, storage, preservation, and sharing of data collected and used in a research project. It involves the everyday management of research data during the lifetime of a research project (for example, using consistent file naming conventions). It also involves decisions about how data will be preserved and shared after the project is completed (for example, depositing the data in a repository for long-term archiving and access).

Protecting the confidentiality of the data is a primary concern for the researcher (Gray et al 2017:795). The researcher kept a master list of participants and their code numbers, with participants' consent forms stored in a location separate from other data, locked in a file drawer to ensure participants' privacy. The raw data captured in SPSS and transcription were stored in password-protected computer. The supervisor and the researcher were the only people who were allowed access to the raw data. The researcher will keep data for five years after publishing the study results. These procedures are done to safeguard private information because it is protected under the Protection of Personal Information Act 4 of 2013 (POPIA). POPIA (Sections 11 and 14) emphasises consent, justification, and objection as well as record preservation and limitation during research.

4.3.2 Data Analysis

Data analysis refers to a mechanism for reducing and organising data to produce findings that require interpretation by the researcher (Burns & Grove 2003:479). Data analysis is a challenging and a creative process characterised by an intimate relationship of the researcher with the participants and the data generated (De Vos 2002:339). Burns and Grove (2011:535) describe data analysis as the technique used to reduce, organise and give meaning to data. It is the process of gathering, modelling, and analysing data in order to extract insights that can be used to make decisions. According to Kudyba (2014:227-246), data analysis is the process of inspecting, cleansing, transforming, and modelling data with the goal of discovering useful information, informing conclusions, and supporting decision-making.

4.3.2.1 Data Analysis for Phase I

Data analysis in quantitative research is a statistical testing of prevalence, relationship, and cause (Gray et al 2017:1052). Data analysis in quantitative research is the reduction, organisation, and statistical testing of information obtained in the data collection phase (Gray et al 2017:111). Quantitative data analysis is the statistical manipulation of numerical data for the purpose of describing phenomena or making inferences about how phenomena are related (Polit & Beck 2010:565).

In Phase I, the researcher conducted quantitative data analysis to obtain the prevalence, genotype and risk factors of HPV infection among women who participated in the study. Prevalence of pre-cancerous cervical lesions, risk factors and the treatment offered for women identified as having pre-cancerous cervical lesions through VIA test were also analysed in this phase of the study.

4.3.3 Data Processing and Analysis

Sociodemographic characteristics, reproductive history, risky sexual behaviours and CC screening and treatment variables responses were gathered using a structured questionnaire. All data generated were revised, checked for completeness, coded and entered into a computer using the Epi Info 7 software programme, then exported to SPSS version 26. Before analysis was done, data processing activities such as recoding, computing and counting were performed.

The arithmetic Mean for the average age of the participants, Median and Standard deviation were determined. Then, the characteristics of study participants across all categorical variables were explored using frequency distribution, and summary statistics to describe the characteristics of study participants across all numerical variables. Logistic regression for bivariate and multivariate analysis with AOR and 95% CI were used to identify the effect of independent variables on the outcome variable.

Cross-tabulations were performed to explore and display relationships between two categorical variables. During analysis, first bivariate regression was done to identify whether independent variables had association with dependent variable. Variables with a p-value of less than 0.25 were selected as candidates for multivariable analysis. Then, the selected variables were subjected to a multivariable regression model to identify variables that have association with HPV infection after adjusting for confounding effects.

The Omnibus tests model of coefficient was checked for significance that was considered as ($P < 0.05$); it indicates the identified predictor in multivariate logistic regression will be better off. The omnibus test is a likelihood-ratio chi-square test of the current model versus the null model. The significance value of less than 0.05 indicates that the current model outperforms the null model.

The final fitted regression model was developed using a standard model-building strategy, in which variables were entered and excluded based on a p-value of 0.05. A p-value of less than 0.05 was considered to declare the

significance of association. Crude and adjusted odds ratios along with 95% confidence intervals were calculated to estimate the strength of association. A histogram was used to check the normality of the data. The variance inflation factor was used to check the multi-collinearity between independent factors. Multicollinearity is a statistical phenomenon in which two or more predictor variables in a regression model are highly correlated (r), with r values ranging from -1 to 1.

Furthermore, the final fitted model was assessed for goodness-of-fit using the Hosmer and Lemeshow (HL) test, and it should not be significant; (p: >0.05) indicates the model fit test is doing well. The HL test is a goodness of fit test for logistic regression, especially for risk prediction models. A goodness of fit test tells us how well the data fits the model. Specifically, the HL test calculates if the observed event rates match the expected event rates in population subgroups.

4.4 RESEARCH RESULTS

4.4.1 Socio-demographic Characteristics of the Study Participants

A total of 383 respondents aged 25 - 49 years were participated in the study, with a response rate of 100%. The mean age of the study participants was 36.7 (median 37 years) with a standard deviation of 6.6 years. One hundred and one (26.4%) of the participants were in the age group of 30 - 34 years, followed by 87 (22.7%) aged 35 - 39 years. All of the study participants, 383 (100%) reside in Adama City. Concerning their educational status, about 176 (46%) of the respondents were at the Elementary/Junior (1-8) education level. With regard to their occupation, unemployed participants comprised the largest proportion of the study participants, 169 (44.1%), followed by self-employed, 123 (32.1%). Slightly more than half of the participants, 200 (52.2%) had a monthly income of 3000 – 5000 ETB. (Table 4.1).

Table 4.1: Socio-demographic characteristics of study participants, Adama, Ethiopia, 2022.

Variables	Frequency	Percentage (%)
Age		
25-29	52	13.6
30-34	101	26.4
35-39	87	22.7
40-44	81	21.1
45-49	62	16.2
Residence		
In Adama	383	100
Educational status		
Unable to read and write	70	18.3
Elementary/Junior (1-8)	176	46.0
High school (9-12)	69	18.0
Diploma/Degree and above	68	17.8
Occupation		
Self-employed	123	32.1
Employed (Govt, private, NGO)	91	23.8
Unemployed	169	44.1
Family Income per month		
< 3000 ETB	129	33.7
3000 – 5000 ETB	200	52.2
> 5000 ETB	54	14.1

4.4.2 Reproductive History of Study Participants

Table 4.2 shows that slightly more than half of the study participants, 208 (54.3%) were married. With regard to their parity, 305 (79.6%) of the participants gave birth 1-5 times. Slightly greater than half, 210 (54.8%) of the study participants were not using any contraceptive method during the study period. Concerning condom use, 216 (56.4%) of the participants had not used a condom during sexual intercourse, followed by 143 (37.3%) of those who always used a condom during sexual intercourse. The entire participants, 383 (100%) did not have a family history of CC. With regard to menstrual bleeding, slightly

more than half, 198 (51.7%) of the participants had regular (21 - 35 intervals) menstrual bleeding patterns. The vast majority, 365 (95.3%) of the study participants did not have a history of post-coital bleeding.

Table 4.2: Reproductive history of study participants, Adama, Ethiopia, 2022

Variables	Frequency	Percentage (%)
Marital status		
Single	43	11.2
Married	208	54.3
Divorced	88	23
Widowed	44	11.5
Number of births (Parity)		
0	69	18.0
1-5	305	79.6
>5	9	2.3
Method of contraception		
Oral contraceptive Pills	53	13.8
Depo Provera (Injectable)	99	25.8
Implant	21	5.5
I do not use	210	54.8
Do you use condom		
Yes, always	143	37.3
Yes, sometimes	24	6.3
No, I do not use	216	56.4
Family history of cervical Cancer		
No	383	100.0
Pattern of menstrual bleeding		
Regular (21 - 35 intervals)	198	51.7
Irregular	185	48.3
History of post-coital bleeding		
Yes	18	4.7
No	365	95.3

4.4.3 Risky Sexual Behaviour and Other Health Risk Factors of the Participants

Two hundred and seventy (70.5%) of study participants' sexual debut was before age 20. The majority of the participants, 305 (79.6%) had more than one life-time sexual partners. Three hundred eighteen (83%) of the participants' sexual partners had another sexual partner/s. With regard to history of any STI other than HIV, more than half, 259 (67.6%) had no history of STI, and the same number, 259 (67.6%) of the participants' sexual partners had no history of STI. Two hundred and seventy-two (71.0%) of the study participants were HIV-positive, and all of them were on antiretroviral therapy (ART). Almost all of the study participants, 381 (99.5%) did not have a history of abnormal Pap smear tesst. Almost all of the study participants, 378 (98.7%) had no history of cigarette smoking. Similarly, 377 (98.4%) of the participants had no history of corticosteroid usage for longer periods (Table 4.3).

Table 4.3: Risky sexual behaviour and other health risk factors of study participants, Adama, Ethiopia, 2022

Variables	Frequency	Percentage (%)
Age at first sexual intercourse?		
< 20	270	70.5
≥ 20	113	29.5
Life time sexual partner?		
One	78	20.4
More than one	305	79.6
Your sexual partner had another partner?		
Yes	318	83.0
No	65	17.0
History of any STI?		
Yes	124	32.4
No	259	67.6
Partner history of STI?		
Yes	124	32.4
No	259	67.6
HIV sero-status?		
Negative	111	29.0
Positive	272	71.0
Currently on ART?		
Yes	272	71.0
No	111	29.0
History of abnormal Pap smear?		
Yes	2	0.5
No	381	99.5
Do you smoke cigarettes?		
Yes	5	1.3
No	378	98.7
Long time corticosteroids use?		
Yes	6	1.6
No	377	98.4

4.4.4 Cervical Cancer Screening and Treatment

4.4.4.1 Prevalence of Human Papillomavirus Infection

Of the overall study participants who took part in the study, 102 (26.6%) tested positive for HPV, and the rest, 281 (73.4%), tested negative for HPV (Figure 4.1).

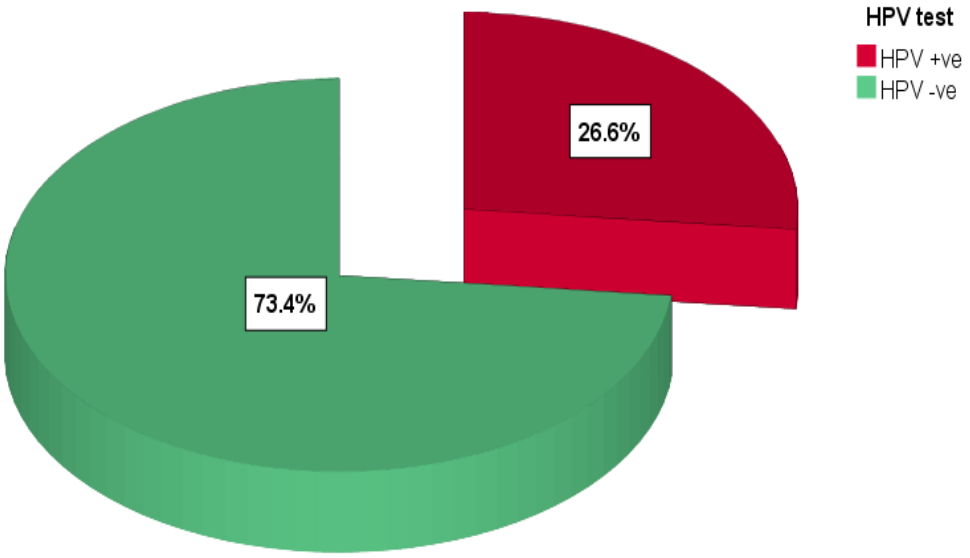

Figure 4.1: Prevalence of HPV infection among study participants, Adama, Ethiopia, 2022

4.4.4.2 Human Papillomavirus Genotypes Distribution

Figure 4.2 shows that the majority of the HPV genotypes identified from the total of 102 HPV-positive cases were other high-risk (Other HR) HPV genotypes 65 (63.7%), followed by HPV-16 which was 23 (22.5%). Human papillomavirus 18 (HPV-18) was detected in 6 (5.9%) of study participants who tested positive for HPV. On the other hand, multiple infections with HPV-16 and other HR-HPV were found in 4 (3.9%) of the study participants, and the same number 4 (3.9%) multiple infections with HPV-18 and other HR-HPV infections were also identified among study participants who tested positive for HPV.

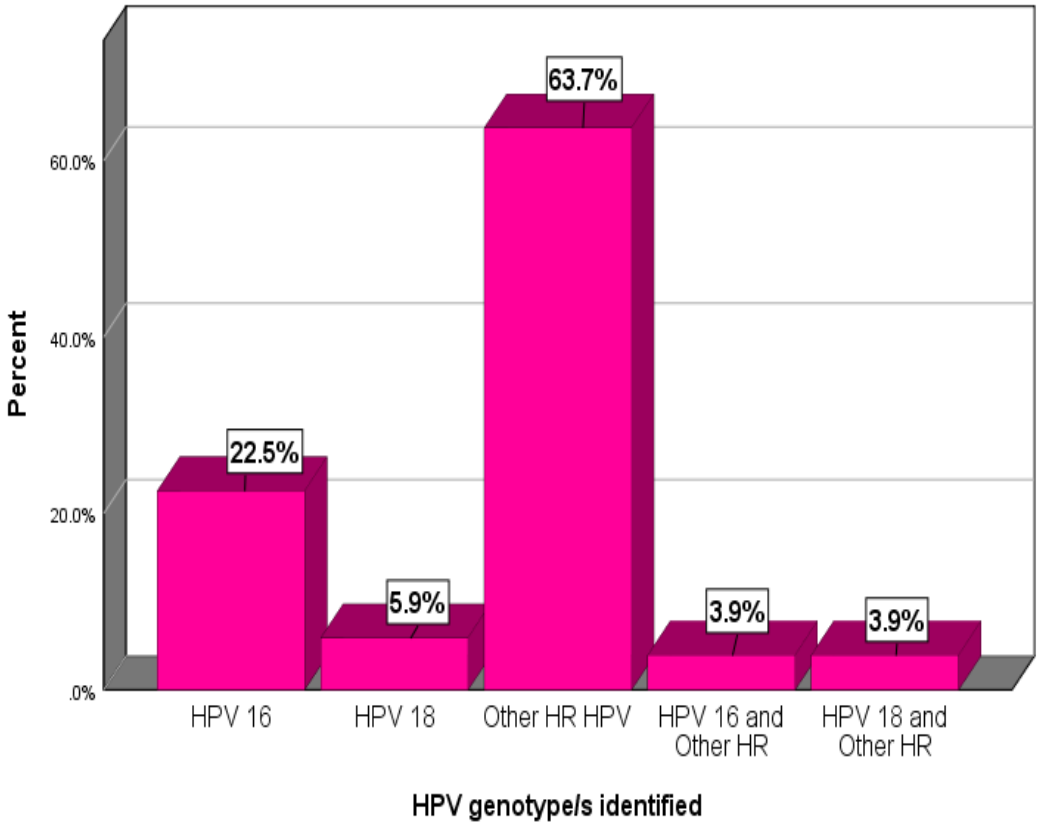

Figure 4.2: HPV genotypes distribution among HPV-positive study participants, Adama, Ethiopia, 2022

Figure 4.3 shows that HPV infection was not detected in most study participants, 281(73.4%). With regard to the overall distribution of HR-HPV genotypes among the entire study population, other HR-HPV genotypes, HPV-16, HPV-18, HPV-16 and other HR-HPV, and HPV-18 and other HR-HPV were detected on 65(17%), 23(6%), 6(1.6%), 4(1%), and 4(1%) of the study participants, respectively.

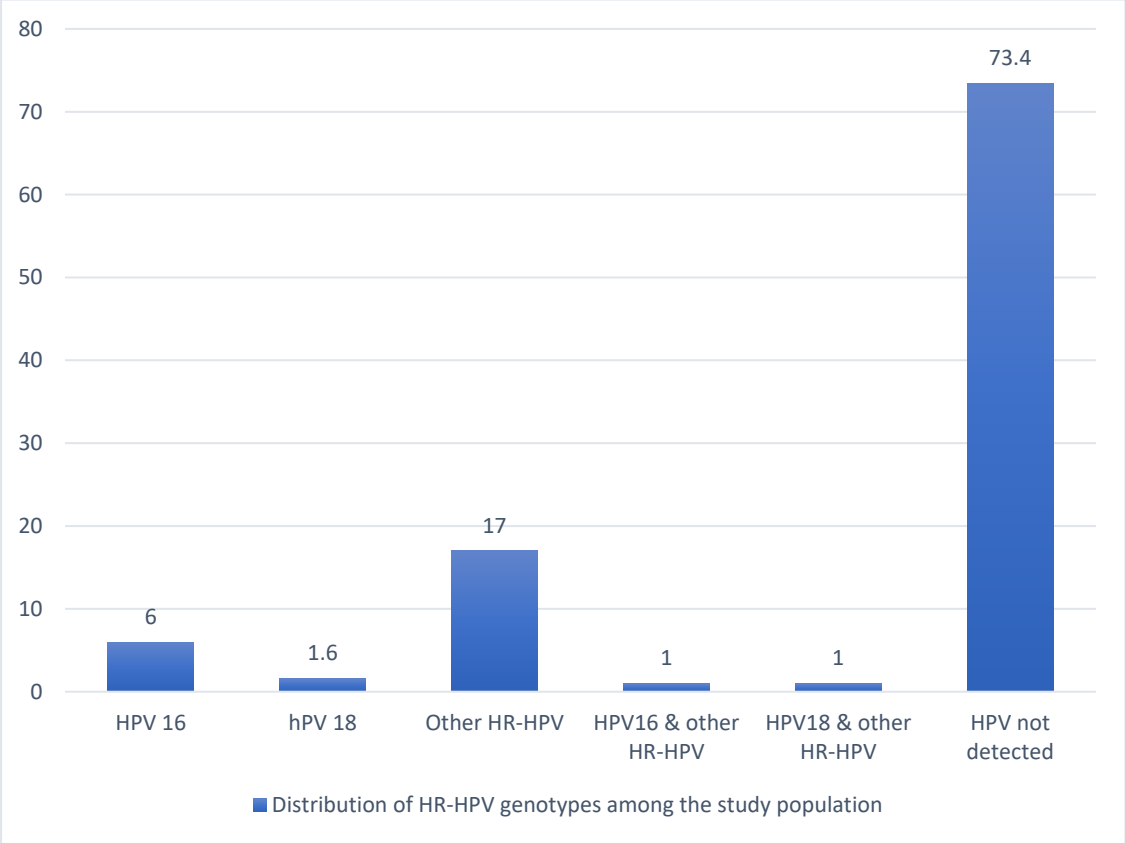

Figure 4.3: HPV genotype distribution among the entire study participants, Adama, Ethiopia, 2022

4.4.4.3 Prevalence of Pre-cancerous Cervical Lesions

Following HPV screening, positive study participants for HPV underwent VIA test to determine whether they had already developed pre-cancerous cervical lesions or not. The prevalence of pre-cancerous cervical lesions among 102 HPV-positive cases identified was 48 (47.1%). (Figure 4.4).

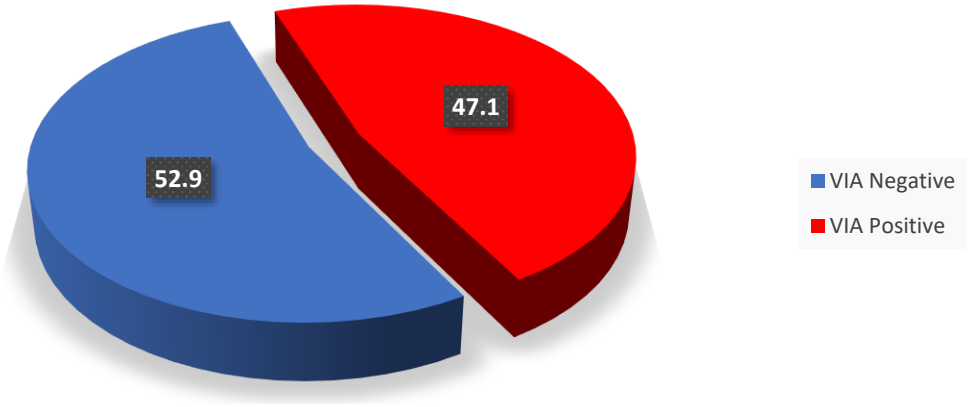

Figure 4.4: Prevalence of VIA-positive cases among HPV-positive study participants, Adama Ethiopia, 2022

The overall prevalence of pre-cancerous cervical lesions among the entire women who took part in the study was 48 (12.5%) (Figure 4.5)

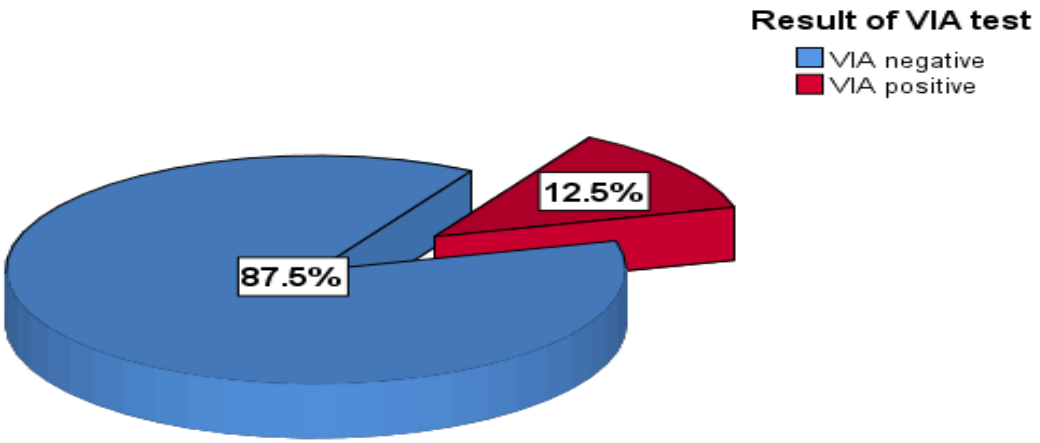

Figure 4.5: The overall prevalence of VIA-positive cases among all study participants, Adama, Ethiopia, 2022

4.4.4.4 Treatment Offered for Pre-cancerous Cervical Lesions

The treatment offered for the majority of women identified as having pre-cancerous cervical lesions was cryotherapy, 39 (81.3%), followed by thermocoagulation, 5 (10.4%) and no treatment/not eligible 4 (8.3%) (Figure 4.6).

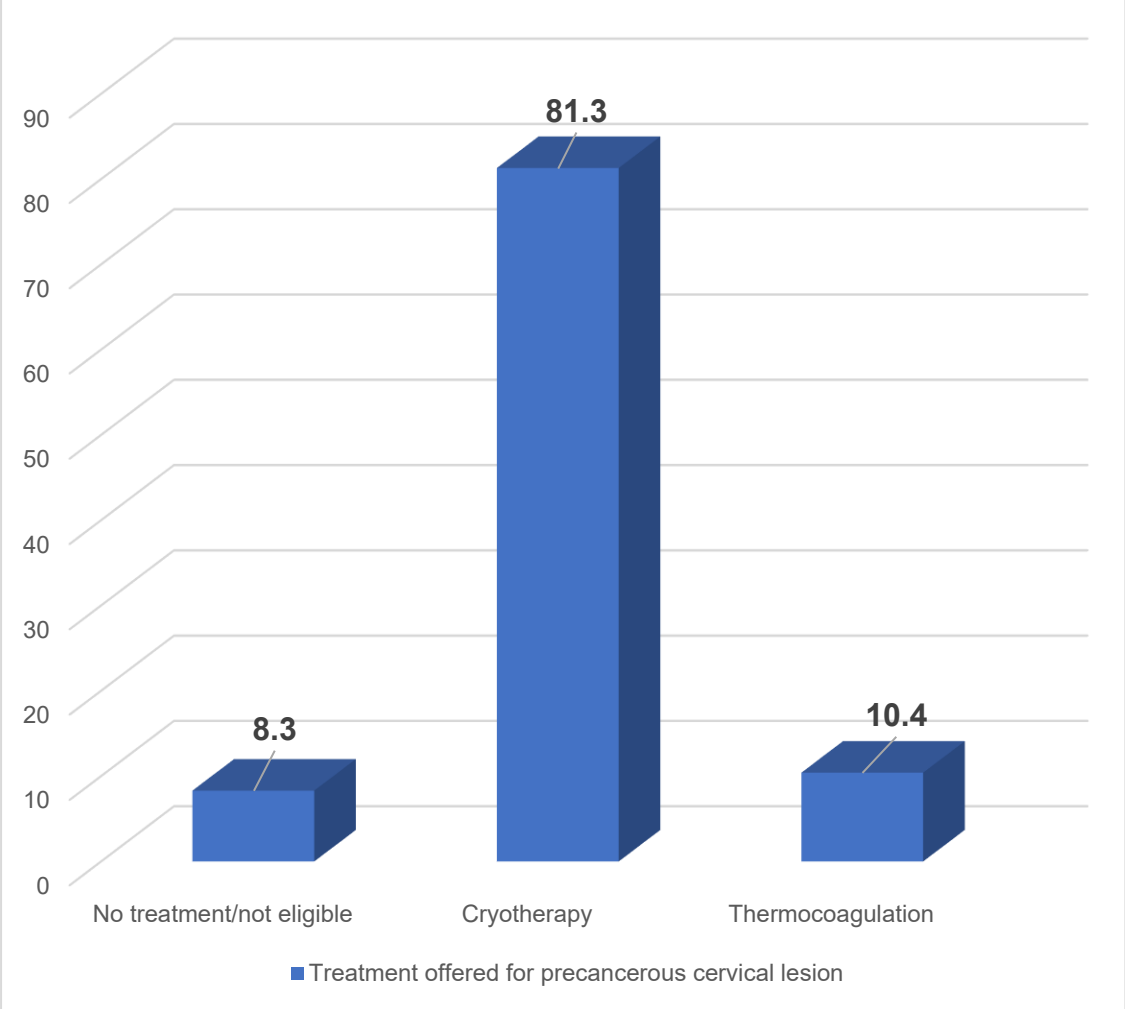

Figure 4.6: Treatment offered for women with pre-cancerous cervical lesions, Adama, Ethiopia, 2022

4.4.5 Risk Factors Associated with High-risk Human Papillomavirus Infection

Binary logistic regression analysis was done to identify the critical variables independently associated with HR-HPV infection. In bivariate analysis: age group, family income, marital status, contraceptive use, condom use, post-coital bleeding, age at first sex, lifetime sexual partner, history of any STI and HIV sero-status were the candidate variables identified for multivariate analysis with a p-value of ≤ 0.25. In the multivariate analysis, after controlling for the effect of other confounding factors, six variables: marital status (being divorced), post-coital bleeding, age at first sex, lifetime sexual partner, history of STI and HIV sero-status were identified as independent factors significantly associated with HR-HPV infection with a p-value of < 0.05. The odds of having risk factors of HR-HPV infection among women who were divorced were almost 3 times more likely to have risk of acquiring HR-HPV infection than their counterparts (AOR = 2.96: 95% CI: 1.18, 7.40). Women who had a history of post-coital bleeding were almost 8 times more likely to have a risk of acquiring HR-HPV infection compared to those women who had no history of post-coital bleeding (AOR = 7.97: 95% CI: 2.17, 29.24). Participants who had a history of early sexual debut before age 20 were 3.6 times more likely to have a high risk of acquiring HR-HPV infection compared to those who had a history of their first sexual intercourse at age 20 or later (AOR = 3.59: 95% CI: 1.69, 7.65). Women who had a history of more than one lifetime sexual partner were 5 times more likely to have a risk of acquiring HR-HPV infection compared to their counterparts (AOR = 5.25: 95% CI: 1.73, 15.96). Study participants with a history of STI were 2 times more likely to have a risk of acquiring HR-HPV infection compared to their counterparts (AOR = 2.36: 95% CI: 1.32,4.20). HIV-positive participants were 12 times more likely to have a risk of acquiring HR-HPV infection than their counterparts (AOR = 12.37: 95% CI: 4.57, 33.48). (Table 4.4).

Table 4.4: Risk factors associated with HR-HPV infection among study participants, Adama, Ethiopia, 2022

Variables	HPV Negative (# 281)		HPV Positive (# 102)		COR (95%CI)	AOR (95% CI)
	No	%	No	%		
Age Group						
25-29	34	12.1	18	17.6	3.12(1.26,7.74)*	2.45(0.77,7.81)
30-34	70	24.9	31	30.4	2.61(1.15,5.94)*	2.65(0.94,7.46)
35-39	72	25.6	15	14.7	1.23(0.50,3.02)	0.96(0.32,2.90)
40-44	52	18.5	29	28.4	3.28(1.42,7.61)*	2.46(0.88,6.88)
45-49	53	18.9	9	8.8	1	1
Educational Status						
Unable to read and write	49	17.4	21	20.6	1.19(0.57,2.50)	
Elementary/Junior (1 - 8)	133	47.3	43	42.2	0.90(0.47,1.70)	
High school (9 – 12)	49	17.4	20	19.6	1.13(0.54,2.40)	
Diploma/Degree & above	50	17.8	18	17.6	1	
Occupational Status						
Self-employed	86	30.6	37	36.3	1.22(0.73,2.05)	
Employed (Govt, NGO)	70	24.9	21	20.6	0.85(0.47,1.55)	
Unemployed	125	44.5	44	43.1	1	
Family Income						
< 3000 ETB	91	32.4	38	37.3	2.09(0.93,4.69)*	1.65(0.61,4.42)
3000 – 5000 ETB	145	51.6	55	53.9	1.90(0.87,4.14)*	2.18(0.85,5.60)
> 5000 ETB	45	16	9	8.8	1	1
Marital Status						
Single	29	10.3	14	13.7	1.15(0.46,2.86)	1.19(0.40,3.53)
Married	169	60.1	39	38.2	0.55(0.26,1.15)*	2.52(0.36,17.85)
Divorced	52	18.5	36	35.3	1.65(0.76,3.58)*	2.96(1.18,7.40)*
Widowed	31	11	13	12.7	1	1
Parity						
0	48	17.1	21	20.6	1.53(0.29,8.00)	
1 – 5	226	80.4	79	77.5	1.22(0.25,6.01)	
> 5	7	2.5	2	2	1	
Contraceptive Use						
Oral **contraceptive** pills	42	14.9	11	10.8	0.54(0.26,1.10)*	1.29(0.37,4.45)
Depo Provera (Injectable)	81	28.8	18	17.6	0.45(0.25,0.82)*	1.18(0.40,3.49)
Implant	17	6	4	3.9	0.49(0.16,1.48)*	1.53(0.31,7.45)
I do not use any	141	50.2	69	67.6	1	1
Do You Use Condom?						
Yes, always	88	31.3	55	53.9	2.84(1.75,4.60)*	2.52(0.38,16.55)
Yes, sometimes	16	5.7	8	7.8	2.27(0.91,5.68)*	1.64(0.21,12.41)
No, I do not use	177	63	39	38.2	1	1
Menstrual Bleeding						
Regular (21-35 days)	143	50.9	55	53.9	1.13(0.72,1.78)	
Irregular	138	49.1	47	46.1	1	
Post-coital Bleeding						
Yes	5	1.8	13	12.7	8.06(2.80,23.24)**	7.97(2.17,29.24)*
No	276	98.2	89	87.3	1	1
Age at First Sex						
< 20 years	179	63.7	91	89.2	4.71(2.41,9.22)**	3.59(1.69,7.65)*
≥ 20 years	102	36.3	11	10.8	1	1
Lifetime Sexual Partner/s						
One	74	26.3	4	3.9	1	1
More than one	207	73.7	98	96.1	8.76(3.11,24.64)**	5.25(1.73,15.96)*

Sexual Partner/s' Partner/s						
Yes	233	82.9	85	83.3	1.03(0.56,1.89)	
No	48	17.1	17	16.7	1	
History of STI						
Yes	76	27.0	48	47.1	2.40(1.50,3.83)**	2.36(1.32,4.20)*
No	205	73.0	54	52.9	1	1
HIV sero-status						
Negative	106	37.7	5	4.9	1	
Positive	175	62.3	97	95.1	11.75(4.63,29.80)**	12.37(4.57,33.48)**

Note: 1 = Reference category, * Significantly associated, ** Highly significantly associated

4.4.6 Risk Factors Associated with Pre-cancerous Cervical Lesion

To identify the important variables which were independently associated with pre-cancerous cervical lesions, binary logistic regression analysis was done, and in bivariate analysis: age group, marital status, contraceptive use, condom use, post-coital bleeding, age at first sex, lifetime sexual partner, and HIV sero-status were the candidate variables selected for multivariable logistic regression analysis with a p-value of ≤ 0.25.

In the multivariable analysis, after controlling for the effect of other confounding factors, 4 variables: post-coital bleeding, age at first sex, lifetime sexual partner, and HIV status were identified as independent factors significantly associated with pre-cancerous cervical lesion with a p-value of < 0.05. (Table 4.5).

The odds of having the risk of pre-cancerous cervical lesion development among women who had a history of post-coital bleeding were 25 times more likely to have risk of developing pre-cancerous cervical lesions compared to those women who had no history of post-coital bleeding (AOR = 25.34: 95% CI: 6.22, 103.20). Women who had a history of early sexual debut before age 20 were almost 4 times more likely to have risk of developing pre-cancerous cervical lesion compared to those who had history of their first sexual intercourse at age 20 or later (AOR = 3.96: 95% CI: 1.24, 12.69). Study participants who had a history of more than one lifetime sexual partner were 8 times more likely to have a risk of acquiring pre-cancerous cervical lesion compared to their counterparts (AOR = 8.37: 95% CI: 1.00, 70.14). HIV-positive participants were almost 11 times more likely to have a risk of developing pre-cancerous cervical

lesions compared to their counterparts (AOR = 10.96: 95% CI: 2.25, 53.37). (Table 4.5).

Table 4.5: Risk factors associated with precancerous cervical lesions among study participants, Adama, Ethiopia, 2022

Variables	VIA Negative (# 335)		VIA Positive (# 48)		COR (95% CI)	AOR (95% CI)
	No	%	No	%		
Age Group						
25-29	47	14.0	5	10.4	1	1
30-34	86	25.7	15	31.3	1.64(0.56,4.79)	2.31(0.65,8.18)
35-39	83	24.8	4	8.3	0.45(0.12,1.77)	0.71(0.16,3.13)
40-44	63	18.8	18	37.5	2.69(0.93,7.76)*	3.31(0.91,12.03)
45-49	56	16.7	6	12.5	1.01(0.29,3.51)	1.44(0.31,6.73)
Educational Status						
Unable to read and write	58	17.3	12	25	1.55(0.59,4.07)	
Elementary/Junior (1 - 8)	160	47.8	16	33.3	0.75(0.31,1.84)	
High school (9 – 12)	57	17	12	25	1.58(0.60,4.15)	
Diploma/Degree & above	60	17.9	8	16.7	1	
Occupational Status						
Self-employed	105	31.3	18	37.5	1.21(0.61,2.38)	
Employed (Govt, NGO)	82	24.5	9	18.8	0.77(0.34,1.77)	
Unemployed	148	44.2	21	43.8	1	
Family Income Per Month						
< 3000 ETB	113	33.7	16	33.3	1.39(0.48,4.00)	
3000 – 5000 ETB	173	51.6	27	56.3	1.53(0.56,4.18)	
> 5000 ETB	49	14.6	5	10,4	1	
Marital Status						
Single	32	9.6	11	22.9	2.18(0.72,6.54)*	3.16(0.82,12.15)
Married	193	57.6	15	31.3	0.49(0.18,1.35)*	1.63(0.16,16.75)
Divorced	72	21.5	16	33.3	1.41(0.51,3.89)	1.82(0.55,6.05)
Widowed	38	11.3	6	12.5	1	1
Parity						
0	59	17.6	10	20.8	1	
1 – 5	269	80.3	36	75	0.79(0.37,1.68)	
> 5	7	2.1	2	4.2	1.69(0.31,9.31)	
Contraceptive Use						
Oral contraceptive pills	49	14.6	4	8.3	0.40(0.13,1.16)*	0.73(0.13,4.21)
Depo Provera/Injectable	92	27.5	7	14.6	0.37(0.16,0.86)*	1.07(0.25,4.67)
Implant	20	6	1	2.1	0.24(0.03,1.86)*	0.74(0.07,8.26)
I do not use any	174	51.9	36	75	1	1
Do You Use Condom?						
Yes, always	115	34.3	28	58.3	3.26(1.67,6.36)*	1.85(0.19,18.53)
Yes, sometimes	19	5.7	5	10.4	3.53(1.16,10.77)*	1.27(0.11,15.19)
No, I do not use	201	60	15	31.3	1	1
Menstrual Bleeding						
Regular (21-35 **days**)	174	51.9	24	50	1	
Irregular	161	48.1	24	50	1.08(0.59,1.98)	
Post-coital Bleeding						
Yes	5	1.5	13	27.1	24.51(8.25,72.82)**	25.34(6.22,103.20)**
No	330	98.5	35	72.9	1	1
Age at First Sex						
< 20 years	226	67.5	44	91.7	5.31(1.86,15.14)*	3.96(1.24,12.69)*

≥ 20 years	109	32.5	4	8.3	1	1
Lifetime Sexual Partner/s						
One	77	23	1	2.1	1	1
More than one	258	77	47	97.9	14.03(1.90,103.34)*	8.37(1.00,70.14)*
Sexual Partner/s' Partner/s						
Yes	277	82.7	41	85.4	1.23(0.52,2.87)	
No	58	17.3	7	14.6	1	
History of any STI						
Yes	108	32.2	16	33.3	1.05(0.55,2.00)	
No	227	67.8	32	66.7	1	
HIV sero-status						
Negative	109	32.5	2	4.2	1	1
Positive	226	67.5	46	95.8	11.09(2.64,46.54)*	10.96(2.25,53.37)*

Note: 1 = Reference category, * Significantly associated,

4.5 DISCUSSION

The aim of this quantitative phase of this study was to assess the prevalence, genotype distribution and risk factors of HPV infection among women who participated in the study at selected public health institutions in Adama, Ethiopia. It was also aimed at assessing the prevalence, risk factors, and treatment offered for women identified as having pre-cancerous cervical lesions in the study area. The understanding that persistent infection with high-risk HPV is crucial for the pathogenesis of CC, that led to new approaches for primary and secondary prevention.

In Ethiopia, it was already started vaccinating school girls aged 14 years since 2018 using Gardasil-4™ targeting HPV-16 and HPV-18, the two most common oncogenic types; however, alongside vaccinating young girls, early screening of women, not the target group of the vaccination, remains the most significant method to decrease deaths attributable to CC. In the present study, the researcher determined the general and genotype-specific prevalence of HPV in a facility-based screening of asymptomatic women in Adama, Ethiopia. This epidemiological information and potential predictors of infection are crucial to evaluate vaccination and achieve the aim of CC control in the country.

The prevalence of HPV infection in the present study was estimated to be 26,6%. This finding was comparable with the findings reported from Western

Kazakhstan, with the overall prevalence of HPV infection 25% (Balmagambetova et al 2019:1089-1096), and from Kinshasa, the Democratic Republic of the Congo with a pooled prevalence of 27.8% (Mutombo et al 2019:4-5). Comparatively, the finding in the present study was much lower than the study reported from Eastern Cape Province in South Africa 76% (Mbulawa et al 2021:5), and lower than the study reported in Istanbul, Turkey with a prevalence of 35% (Bakir et al 2021:45-46), and North Tongu District, Ghana (32.3%) (Krings et al 2019:1-20).

On the other hand, the present finding was much higher than the prevalence of HR-HPV infection reported from Maccabi HealthCare HMO, Israel 9% (Feinberg et al 2021:494-500), and Anbar Province, Iraq 12.9% (Obaid et al 2021:1-6). It was also higher than the finding reported from Mainland China, which was 19% (Li et al 2019:1030-1037), Peru 19% (del Valle-Mendoza et al., 2021:2-3), Canarian Islands 13.6% (Andujar et al 2020:1-12), North-Western Zimbabwe 17% (Fitzpatrick et al 2019:24-25), and Kilimanjaro and Dar es Salaam, Tanzania 18.9% (Mchome et al 2021:56-62). The discrepancy might be due to differences in socio-demographic characteristics of the study participants, study setting, and study period differences. In addition, more than half of the participants in this study were HIV-positive women, which might also have contributed to the higher rate of HR-HPV infection in the study area.

It is well-identified that HPV-16 and HPV-18 genotypes together are responsible globally for about 70% - 80% of CCs and pre-cancerous cervical lesions. Moreover, both genotypes are more prevalent types worldwide (WHO 2017:241-268). Three vaccines against HPV are being administered to encounter HPV-16 and HPV-18 infection which are responsible for approximately 70% of global CC cases (Kumar, Sahu, Kumari, Dixit & Khare 2022:1-16). Accordingly, all the three currently licenced and available HPV vaccines, Bivalent (Cervarix®), Quadrivalent (Gardasil4®) and Nine-valent (Gardasil9®), provide protection mainly against the two major high-risk oncogenic genotypes, and especially in the case of Gardasil9, it provides additional protection against other HR-HPV genotypes.

In the present study, identification of the major oncogenic HR-HPV genotypes was determined as “HPV-16”, “HPV-18” and ‘’Other HR-HPV’’ (The rest of high-risk HPV genotypes other than HPV-16 and HPV-18 were considered as Other HR-HPV). The proportions of HPV-16 and HPV-18 were 22.5% and 5.9%, respectively. Other HR-HPV genotypes altogether accounted for 63.7% of all the HPV-positive cases. On the other hand, despite a low proportion, multiple infections with HPV-16 and Other HR-HPV were found in 3.9% of HPV-positive cases, and the same proportion 3.9% were also identified in multiple infections with HPV-18 and Other HR-HPV.

In terms of detecting the two most prevalent and highly oncogenic HR-HPV genotypes, the present study’s finding was significantly higher than a study done in Changsha, Hunan, China, with HPV-16 (9.3%) and HPV-18 (3.5%). Other HR-HPVs detected include HPV-52 (28.01%), HPV-58 (14.83%), HPV-53 (10.84%), and HPV-39 (9.64%) (Gao et al 2021:1-10). Meanwhile, the finding of the present study was significantly higher in terms of the most oncogenic HR-HPVs, specifically HPV-16 proportion than the study done in the Eastern Cape Province, South Africa with HPV-16 and HPV-18 accounted for only 8.5% and 8%, respectively. Other HR-HPVs accounted for, HPV-59 (13.6%), HPV-51 (-10.8%. In the aforementioned study, infection with multiple HPV types was more common than single HPV type infection. For example, the proportion of infection with two different HPV types was 15.5% (Mbulawa et al 2021:5). On the other hand, the finding of this study was significantly lower than the study done in Kilimanjaro and Dar es Salaam, Tanzania that among HPV-positive women with high-grade squamous intraepithelial lesions (HSILs), the most common genotypes were HPV-16 (32.5%), HPV-18 (16.7%) and Other HR-HPVs include HPV-58 (19.3%), and HPV-52 (16.7%) (Mchome et al 2021:56-62). This difference in genotype frequency in various studies might be due to geographic variations and host immunogenetic factors. The discrepancy might also be due to differences in socio-demographic characteristics of the study participants and study setting differences.

In the present study, the odds of being divorced (AOR = 2.96: 95% CI: 1.18, 7.40), having a history of post-coital bleeding (AOR = 7.97: 95% CI: 2.17, 29.24),

having early sexual debut before age 20 (AOR = 3.59: 95% CI: 1.69, 7.65), having a history of more than one lifetime sexual partner (AOR = 5.25: 95% CI: 1.73, 15.96), history of STI (AOR = 2.36: 95% CI: 1.32,4.20), and being HIV-positive (AOR = 12.37: 95% CI: 4.57, 33.48) were risk factors identified as having statistically significant association with the acquisition of HR-HPV infection. This finding was almost consistent with a finding by Asseffa (2017:1-5) that high parity, early marriage, having multiple sexual partners, poverty that forces a woman to engage in sex work for a living and co-infection with HIV that reduces immunity status are risk factors that contribute to the acquisition of HPV infection and its progression to CC. Meanwhile, the finding of the present study was almost consistent with a study conducted in rural Eastern Cape, South Africa, that HIV-positive status (OR 2.52, 95% CI 1.63–3.90), having ≥3 lifetime sexual partners (OR 2.12, 95% CI 1.16–3.89) and having a vaginal discharge currently/in the previous week (OR 2.13, 95% CI 1.18–3.85) increased the risk of acquiring HR-HPV infection.

In contrast, the current study's finding was not consistent with a study done in Changsha, Hunan, China, that risk factors of HPV infection identified in the study were Age (OR 1.01; 95% CI 1–1.01; P < 0.05) and alcohol consumption (OR 1.30; 95% CI 1.09–1.56; P < 0.01) (Gao et al 2021:1–10). Meanwhile, the current study's finding was not consistent with a study done in North Tongu District, Ghana, that being single (AOR: 2.6; 95%CI: 1.8–3.8; p- value: <0.001), having a steady partner but not living together (AOR: 2.2; 95%CI: 1.6–2.9; p-value: <0.001), living with someone but not being married (AOR: 1.3; 95%CI: 1.0–1.7; p-value: 0.047), and first sexual partner (AOR: 3.3; 95%CI: 1.1–9.3; p-value: 0.027) were factors associated with HPV infection. On the other hand, two associated factors with high-risk HPV positivity: being divorced (AOR: 1.9; 95%CI: 1.2–3.0; p-value: 0.011) and having more sexual partners (AOR: 5.0; 95%CI: 1.7–14.6; p-value: 0.004) were consistent with the current finding (Krings et al 2019:1-20). The discrepancy might be due to difference in socio-demographic characteristics of the study participants, study setting and study period differences.

In the current study, the prevalence of pre-cancerous cervical lesion among the total respondents who took part in the study was 12.5%. This finding was almost in line with a study conducted in a Tertiary Care Hospital in Bangalore, India, that a total of 516 women were screened by a single round of VIA testing with a positive rate of 11.2% (Jagruthi & Hemavathi 2019:2758). The current study's finding was relatively higher than the finding obtained in Bamenda, Cameroon, 3.3% (Nkfusai et al 2019:1-12). In contrast, the finding of this study was much lower than a study conducted in Maccabi HealthCare HMO, Israel, with a prevalence of abnormal PAP LBC results 37% (Feinberg et al 2021:494-500). The difference might be because of the sample size difference, the study setting, the time of the study done, and the screening method used.

In the present study, the odds of risk of pre-cancerous cervical lesion development among studied women show that participants who had a history of post-coital bleeding (AOR = 25.34: 95% CI: 6.22, 103.20), history of early sexual debut before age 20 (AOR = 3.96: 95% CI: 1.24, 12.69), history of having more than one lifetime sexual partner (AOR = 8.37: 95% CI: 1.00, 70.14), and being HIV-positive (AOR = 10.96: 95% CI: 2.25, 53.37) were risk factors identified as having statistically significant association with the development of pre-cancerous cervical lesions. The finding of the present study was somewhat in line with a study conducted in Kampala, Uganda, that reveals VIA positivity was associated with women who reported having more than one life-time sexual partners (AOR = 3.34, 95 %CI: 1.38–8.12), and being HIV-positive (AOR = 4.55; 95 %CI: 2.12–9.84) (Namale et al 2021:1-11). In contrast, the current study's finding was not consistent with a study conducted in Cameron, that revealed factors associated with pre-cancerous cervical lesions were: age 1.85 (1.42-2.41; p= 0.001), and parity (OR= 1.46; 95% CI: 1.30-1.89; P= 0.004) (Bernard Wabo et al 2022:276). The discrepancy might be due to difference in socio-demographic characteristics of the study participants, study settings and study period differences.

In the current study, the treatment offered for the majority of women identified as having pre-cancerous cervical lesions was cryotherapy 81.3%, followed by thermocoagulation 10.4%, and no treatment/not eligible for cryotherapy or

thermocoagulation 8.3%. This study finding was inconsistent with a study conducted in Central Java, Indonesia, in which the study participants who tested positive for the VIA test, only 60.7% of them received cryotherapy (Napitupulu et al 2020:1423-1429). The present study's finding was almost comparable with a study conducted in Southeast Nigeria, that from the total women who tested VIA positive, 91% of them were eligible for cryotherapy (Chigbu et al 2017:239-243). The discrepancy might be due to differences in socio-demographic characteristics of the study participants, study settings and study period differences.

4.6 OVERVIEW OF THE RESEARCH FINDINGS

First and foremost, the researcher could highlight the significant prevalence (26.6%) that was found in the present study, which was more than two-fold higher than the global pooled prevalence of HPV (11.7%). Nonetheless, the figure found was almost consistent with the prevalence in sub-Saharan Africa that estimated to be (24%) (WHO 2017). With regard to the distribution of HPV genotypes, the most oncogenic HR-HPV genotypes; HPV-16 and HPV-18 were found at a large significant proportion 22.5%, and 5.9%, respectively. Comparatively, Other HR-HPV genotypes altogether accounted for the highest proportion of HPV infection 63.7%. Moreover, the overall prevalence of pre-cancerous cervical lesion could not be underestimated (12.5%).

In this study, risk factors identified altogether for the occurrence of HPV infection and for the development of pre-cancerous cervical lesions in those who have already acquired HPV infection were not basically different from the commonly recognised risk factors for the occurrence of both conditions including, early sexual debut, having multiple sexual partners, HIV infection, and contracting other STIs, etc.

4.7 SUMMARY

In this chapter, data from 383 study participants were analysed, presented, and discussed. At the start, the socio-demographic characteristics of the participants

were analysed, followed by the reproductive history, and then the risky sexual behaviour and other health risk factors of the study participants, particularly focused on the frequency distribution and percentage of each variable under each category were analysed substantially.

Next, considering the specific objectives of the current study, the prevalence of HPV infection, the genotype distribution of HPV, specifically at HPV-positive respondents' level in particular and at entire study populations' level in general were crucially determined. Meanwhile, the prevalence of pre-cancerous cervical lesions at the HPV positive cases' levels as well as at the entire study population's level were also discussed. Treatments offered for pre-cancerous cervical lesions cases were discussed as well. In addition, logistic regression analysis concerning risk factors associated with HPV infection acquisition and the risk factors associated with pre-cancerous cervical lesion development in those already HPV-acquired cases were analysed and interpreted in detail.

More importantly, a substantial discussion of the present study findings compared to others on similar research topics worldwide was presented in detail. Accordingly, possible justifications for the variations identified between the current and previous study findings were also explained. Finally, an overview of the study findings was presented.

The next chapter, Chapter 5 will focus on the analysis, presentation and description of the qualitative phase of the research findings.

CHAPTER 5

ANALYSIS, PRESENTATION AND DISCUSSION OF QUALITATIVE DATA

5.1 INTRODUCTION

The previous chapter discussed the analysis, presentations and description of the research findings of the quantitative phase.

This chapter presents the research findings of the qualitative phase of the study. In this phase of the study, the researcher employed exploratory, descriptive, and contextual research design to explore and describe the risk perceptions of women regarding HPV infection and CC, their perceptions regarding CC screenings and HPV vaccination. Three FGDs, one at each selected health facility of the study, consisting of 10 participants in each group, were conducted till redundancy of ideas was obtained. The FGDs involved women who underwent CC screening at the selected health facilities.

5.2 DATA COLLECTION AND MANAGEMENT OF THE QUALITATIVE PHASE

Qualitative research is a scholarly and rigorous approach used to describe life experiences, cultures, and social processes from the perspectives of the persons involved (Gray et al 2017:1081). Qualitative research involves collecting and analysing non-numerical data (e.g., text, video, or audio) to understand the concepts, opinions, or experiences of the study participants. It can be used to gather in-depth insights into a problem or generate new ideas for research. Qualitative data are data representing information and concepts that are not represented by numbers. Data are often gathered from interviews and focus groups, personal diaries and lab notebooks, maps, photographs, and other printed materials or observations. Qualitative data are sometimes referred to as categorical data, which are data that can be arranged into categories

based on physical traits, gender, colours or anything that does not have a number associated with it.

Qualitative data collection is vital in qualitative research. It is the gathering of non-numerical information, such as words, images, and observations, to understand individuals' attitudes, behaviours, beliefs, and motivations in a specific context. It seeks to understand social phenomena through in-depth exploration and analysis of people's perspectives, experiences, and narratives. Qualitative data is collected through methods of observations, one-to-one interviews, conducting focus groups, and similar methods.

Gray et al (2017:413) explain that interviews are focused conversations between the participant and the qualitative researcher that produce data as words. As an interviewer, the researcher seeks information from a number of individuals, whereas the focus group strategy is designed to obtain the perspective of the normative group, not individual perspectives (Gray et al 2017:413). Qualitative interviews means that the researcher conducts face-to-face interviews with participants, interviews participants by telephone, on the Internet, or engages in focus group interviews with six to twelve interviewees in each group. These interviews involve unstructured and generally open-ended questions that are few in number and intended to elicit views and opinions from the participants (Creswell & Creswell 2018:333).

Data were collected once permission was sought hierarchically from concerned bodies as it is already mentioned in Chapter 3 under ethical considerations related to data collection. Permission was received including consent for participation and recording of information from participants who took part in the study (Annexure E). The researcher was supported by departmental supervisors at the respective health facilities departments to select women who met the inclusion criteria (see the inclusion criteria for the qualitative phase).

5.2.1 Focus Group Discussion

Focus group discussion is one of the methods of data collection commonly used in qualitative research. Focus group discussion is designed to obtain the participants' perceptions in a focused topic in a setting that is permissive and non-threatening, and homogeneity of the group is a characteristic of focus groups (Krueger & Casey 2015:158). According to Gray et al (2017), FGDs constitute with the purpose of collecting data on a specific topic from more than one research participant at the same time. It is a research method that brings together a small group of people to answer questions in a moderated setting. The questions are designed to shed light on a topic of interest. According to Creswell and Plano Clark (2017:89), in the focus group, the attempt is to elicit multiple meanings from the participants, to build a deeper understanding than the survey yields, and to possibly generate a theory or pattern of responses that explain the survey results. One of the assumptions underlying the use of focus groups is that interactions among people can help them express and clarify their views in ways that are less likely to occur in a one-on-one interview.

Focus groups are more useful and less expensive than individual interviews for revealing a wide range of participants' beliefs and experiences through a moderated interaction (Mbous, Mohamed & Rudisill 2022:2). As a rule of thumb, research topics related to thoughts, beliefs, and feelings work well in focus groups.

In the current study, the focus group strategy was used because it is designed to obtain the perspective of the normative group, not individual perspectives (Gray et al 2017:413). Moreover, because the researcher sought direction, explanation, or in-depth dialogue, a focus group was a good fit for this study. The researcher conducted all qualitative data-gathering sessions from the study participants to maintain integrity and credibility.

5.2.2 Advantages and Disadvantages of Focus Group Discussion

5.2.2.1 Advantages

They are fairly straightforward to organise and results have strong face validity. They are usually inexpensive, even if the researcher compensates participants. A focus group is much less time-consuming than a survey or experiment, and the researcher gets immediate results. Focus group results are often more comprehensible and intuitive than raw data.

5.2.2.2 Disadvantages

It can be difficult to assemble a truly representative sample. Focus groups are generally not considered externally valid due to their small sample sizes. Due to the small sample size, the researcher cannot ensure the anonymity of respondents, which may influence their desire to speak freely. Depth of analysis can be a concern, as it can be challenging to get honest opinions on controversial topics. There is much room for error in the data analysis and a high potential for the observer's dependency in drawing conclusions.

5.2.3 Steps of Focus Group Discussion

The following steps were followed while carrying out FGDs (George 2023:1-3).

5.2.3.1 Step 1: Choose a Topic of Interest

The first and fore most step that the researcher should take for an FGD is choosing topics of discussion based on the goal of the study. Hence, the researcher chose objective-based discussion topics aimed at identifying women's risk perception of HPV infection and CC, and feelings or perceptions concerning CC screening and HPV vaccination.

5.2.3.2 Step 2: Define the Research Scope

It was already determined that a focus group was the right choice for the data collection process of the qualitative phase. The researcher then thought about what he expected the group discussion to yield. The scope of the research was set, which helped the researcher formulate clear questions and recruit the right study participants in order to obtain what was expected from the group discussion. Women, aged 25 – 49 years, who were residing in the study area, and had already visited the CC screening facilities were chosen to discuss the research questions listed under the next step.

5.2.3.3 Step 3: Determine the Focus Group Questions

Open-ended flexible research questions, critically important for the analysis were formulated. This study referred to the constructs of the HBM in order to formulate the qualitative research questions. The model aided the researcher in maintaining the focus of the study in this particular phase. During the construction of the questions, special attention was given to the research objectives of the study. Moreover, to check the validity of the open-ended qualitative questions, the researcher conducted a pre-test on a group of 8 women in other health facility not part of the current study but located in a similar environment.

The questions were discussed in a group setting and lasted for 63 minutes. The process helped the researcher to determine the target group's reaction to and understanding of the initial qualitative questions: whether the questions were understandable, culturally appropriate, acceptable to the audience, and appropriate for FGD. Accordingly, some amendments like making the questions more understandable to the participants, were made. The collected information from the pre-test were not included in the actual data.

The following qualitative research questions were formulated by the researcher with guidance from similar previous studies. The questions were developed based on the objectives of the study, and used as a starting point for the FGDs.

- What do you know about HPV infection? how it transmits? what are the preventive aspects?
- Could you please tell me your perception with regard to the risk of acquiring HPV infection?
- Could you please tell me your perception regarding CC screening?
- Could you please tell me your perception regarding HPV vaccination?

5.2.3.4 Step 4: Select a Facilitator and a Moderator

The researcher was a facilitator and selected a moderator who was well-experienced in this regard; to coordinate the technology, take notes, and observe the behaviour of the participants during the discussion.

5.2.3.5 Step 5: Recruiting Participants

Potentially eligible women who were readily accessible and had visited the CC screening centres/clinics were purposefully identified with the support of their treating clinicians and recruited by the researcher. After informing them of the purpose of the study, eligible consenting target women, who were consented to participate were selected. During the selection, in order to enhance the credibility of the study, much attention was given to information-rich women who were believed to have some awareness about the topics to be discussed, and could have the ability to clearly articulate their experiences during the discussion. Meanwhile, the time and place for FGD were arranged at the participants' convenience. To reduce social desirability biases, homogenous participants who did not know the facilitator, the moderator, or each other were recruited. Moreover, anonymity, not identifying participants by name were considered, and video recordings were also avoided.

5.2.3.6 Step 6: Set up the Focus Group

At this step of the research, focus groups each consisting of 10 participants per clinic were formulated based on the eligibility criteria mentioned above in the study participants recruitment step. Meanwhile, the time, date, places, and when and where the discussions would be hold also set in advance. By obtaining permission of the respective facilities, each FGDs were arranged to be conducted at each study facilities' meeting rooms. The sites were convenient for all, and possible noise destructors and other interfering situations that could cause interruptions to the discussions were minimised a head of time to make it more conducive for the discussion. The sessions time was set in advance, according to the participants' time of convenience from 10 Am to 11:30 Am in the morning.

5.2.3.7 Step 7: Host the Focus Group

Before each discussion session is commenced, the researcher considered conducting a tech check prior to the arrival of the participants, and noted any environmental or external factors that could affect the mood of the group. The researcher made sure that he was organised and ready.

The researcher welcomed participants to the FGD, introduced himself and the moderator, and the topic of discussion, and stated ground rules or suggestions for the FGD. Participants were requested permission to audio-record and transcribe the interview. They were assured that all data would be de-identified and thus remain confidential. Before the discussion commenced, the researcher made the participants feel at ease and forthcoming with their responses.

The researcher began with an opening welcoming statement: "We are here today to discuss some CC issues with you. We would like to have your perceptions on it". Then, let participants know their ideas would be valuable to the study. To allow participants relaxed and settled into the space a bit, the discussion started out with icebreaker. As a facilitator, the researcher strived to

remain neutral, refrained from reacting to responses and body language not appropriate for these sessions (e.g., nodding, raising eyebrows).

Discussion topics were forwarded by the researcher to the study participants step by step. Probing questions, not leading questions were used as a follow-up after an open-ended question to help the researcher understand why a participant responded in a certain way. Active listening, such as parroting back answers or asking for clarification was applied to encourage participation and signal that the researcher was listening.

Less talkative members were questioned directly to encourage them to participate in the discussion actively. Participants were also asked to elaborate on their answers or to give examples. The researcher tried to keep the discussion focused but remained flexible. Totally, three focus group discussions, each involved 10 members, altogether consisted 30 study participants were held till saturation point was reached, meaning, until information redundancy occurred.

At the end of each session, the researcher helped each group reach some final conclusions together. Each FGD lasted 62 to 69 minutes. The group discussions were audio-recorded, and each session accomplished smoothly. Besides, the moderator took notes on important points. Finally, the researcher thanked the participants, and appreciated them for their time and commitment. Monetary incentive, i.e., reimbursing the transportation/taxi cost that the participants spent was done by the researcher. After concluding the FGDs, the facilitator and the moderator debriefed each other based on the recording of initial impressions of the discussion and any highlights, issues, or immediate conclusions they had drawn.

5.2.3.8 Step 8: Analyse the Data and Report the Results

At this step, transcribing and cleaning the data was done. Initially, numbers were assigned to each participant for organisational purposes. All the audio recordings were transcribed verbatim by the researcher and the moderator who

have appreciable experience with it. Transcripts were double-checked for accuracy by the researcher. Data were then analysed using qualitative thematic content analysis and framework analysis. The thematic content analysis was used in exploring and describing the risk perceptions of women regarding HPV infection and CC, their perceptions with regard to CC screenings and HPV vaccination. The framework analysis helped in classifying and summarising data within a thematic framework.

First, familiarisation was done with the data in their entirety by listening to audio-recording and reading field notes and the transcripts repeatedly. Then, thematic analysis was done to develop a coding scheme. Categories followed the six constructs of the HBM (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy and cues to action) (Babazadeh et al 2019:1-9) as themes to classify the codes. These coding categories were all-inclusive and mutually exclusive. Therefore, themes were used as a unit of analysis for the qualitative data. Then, the researcher summarised and classified the data within a thematic framework. Detailed information on the steps was explained under the data analysis of the qualitative study part.

In this phase of the study, the researcher used the consolidated criteria for reporting qualitative research (COREQ) to improve the quality of reporting the aspects of this research. For improving the quality of reporting qualitative research COREQ - a 32-item checklist is recommended (Tong, Sainsbury & Craig 2007:352-356). COREQ is a 32-item checklist that the criteria included in it can help researchers to report important aspects of the research team, study methods, context of the study, findings, analysis and interpretations. It enhances the standard of qualitative research reporting.

5.3 DATA ANALYSIS OF THE QUALITATIVE STUDY

Qualitative data analysis allows researchers to dig deep into research findings and reveal the complex meanings of qualitative data. Thematic analysis is a method of analysing qualitative data. Themes from qualitative analysis are

supported by quotes from the participants. Thematic analysis as an independent qualitative descriptive approach is mainly described as “a method for identifying, analysing and reporting patterns (themes) within data” (Braun & Clarke, 2006:79). Vaismoradi, Turunen and Bondas (2013:398-405) describe thematic analysis as a descriptive method that reduces the data in a flexible way that dovetails with other data analysis methods. It is used commonly because of the wide variety of research questions and topics that can be addressed with this method of data analysis. It is usually applied to a set of texts, such as an interview or transcripts.

The researcher closely examined the data to identify common themes - topics, ideas and patterns of meaning that came up repeatedly. Thematic analysis is a good approach to research in which a researcher tries to discover something about people’s views, opinions, knowledge, experiences or values from qualitative data, for example, interview transcripts, social media profiles, or survey responses. To achieve the goal of describing and understanding participant perspectives, qualitative methods of sampling, data-gathering, and analysis allow for more flexibility than the methods of the quantitative paradigm (Creswell, 2013:402).

However, a limitation of using thematic analysis is that it does not necessarily produce a theory and may conclude by identifying the obvious (Coolican, 2014). Since data analysis in most qualitative designs begins as data are gathered, insights from early data may suggest additional questions that might be asked or other modifications to the study methods.

Once the researcher decided to use thematic analysis, there are different approaches to consider. For example, the distinction between inductive and deductive approaches: an inductive approach involves allowing the data to determine the researcher’s own themes. On the other hand, a deductive approach involves coming to the data with some preconceived themes the researcher expects to find reflected there, based on theory or existing knowledge.

The thematic analysis involves familiarization, coding, generating themes, reviewing themes, defining and naming themes, and finally writing up (Braun & Clarke 2006:87).

- **Familiarisation**: Getting to know the data. The researcher will have a thorough overview of all the data collected, generally looked through the data to get familiar with it.

- **Coding**: Highlighting the sections of the data. The researcher will draw attention to interesting features of the data systematically across the entire data set, and came up with shorthand labels or codes, collated data relevant to each code.

- **Generating themes**: Collating codes into potential themes, gathering all data relevant to each potential theme. The researcher will look over codes created, identify patterns among them, and come up with themes by combining the codes.

- **Reviewing themes**: Checking if the themes work in relation to the coded extracts and the entire data set, generating a thematic map. The researcher will try to make sure the themes generated are useful and accurate representation of the data. Moreover, the researcher will return to the data set and compare the themes against it.

- **Defining and naming themes:** Ongoing analysis for refining the specifics of each theme and the overall story that the analysis tells, generating clear definitions and names for each theme. The researcher will try to formulate exactly what he meant by each theme and figure out how it helps him understand the data, and come up with a succinct and easily understandable name for each theme.

- **Writing up:** Producing the report. The researcher writes up the analysis of the data which include an introduction, aim, approach and the methodology

that describes how the researcher collected the data and, explanation how the researcher conducted the thematic analysis itself.

The already aforementioned two main approaches of qualitative data analysis: the deductive approach involves analysing qualitative data based on a structure that the researcher predetermines. A researcher can use the questions as a guide for analysing the data. This approach is quick and easy and can be used when a researcher has a fair idea about the likely responses that he is going to receive from the sample population. On the contrary, the inductive approach is not based on a pre-determined structure or set ground rules/framework. It is a more time-consuming and thorough approach to the qualitative analysis process. An inductive approach is often used when a researcher has very little or no idea of the research phenomenon.

In Phase II of the study, the researcher employed the deductive approach of thematic analysis which involves coming to the data with some preconceived themes the researcher expects to find reflected there, based on theory or existing knowledge. In this regard, the reason why the researcher preferred the deductive approach to the inductive one here was, because the present phase of the study is the follow-up qualitative study with the priority given to the quantitative phase already conducted in Chapter 4. Hence, the researcher has already gained some idea of the research phenomenon. Moreover, the results found from this qualitative phase help explain the initial study results and build a better understanding of the quantitative findings.

The present phase of the study used a theory-driven thematic analysis approach to analyse the qualitative data with the key constructs of the HBM. The model comprises several primary concepts that explain why people will take action to prevent, to be screened for, or to control illness conditions. The six constructs of HBM are: Perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy and cues to action (Babazadeh et al 2019:1-9). These key constructs of the HBM were used as themes in the present study.

Meanwhile, the researcher used the aforementioned six-step guide of thematic analysis provided by Braun and Clarke (2006:87): familiarisation, coding, generating themes, reviewing themes, defining and naming themes, and writing up the analysis for the qualitative data in the current.

First, the researcher read the participants' responses several times and became familiar with the data by compiling the participants' open-ended responses to the unstructured questions. Preliminary notes were made about possible relations to the constructs of the HBM. Second, initial codes were generated throughout the data. Third, the codes were reviewed for potential themes under each of the constructs of the HBM. Fourth, the researcher reviewed the themes to ensure that the codes fit within the themes and that the themes fit within the structure of the HBM. Fifth, the themes were named, defined, and refined. Finally, the researcher related the themes and codes to the study aims. The shorthand labels or codes in the process of this thematic analysis grouped around the domains of the HBM and sub-themes were developed from the participants' responses. (Table 5.1)

Table 5.1: Themes adapted from the six constructs of HBM and sub-themes developed from the participants responses

Themes	Sub-themes
Risk perception of HPV infection	
1. Perceived susceptibility	1.1 Lack of information about HPV 1.2 Unaware of risk factors
2. Perceived severity	2.1 Scare of the name cervical cancer itself 2.2 Feel stress and nervous
Perception about cervical cancer screening	
3. Perceived benefits	3.1 Remove worry 3.2 Early detection of symptoms 3.3 Get treated 3.4 Prevent cancer development
4. Perceived barriers	4.1 Fear of the result 4.2 Negative influence from peers
5. Self-efficacy	5.1 Enhance belief 5.2 Feel confident
6. Cues to action	6.1 Recommendation from others 6.2 Perceived bad experiences happened to others
Perception about HPV vaccination	
7. Perceived benefits	7.1 Prevention of cancer
8. Perceived barriers	8.1 Lack of awareness 8.2 Feel distracted

5.3.1 Risk Perception of Women towards Human Papillomavirus Infection and Cervical Cancer

According to the Concise Oxford Dictionary (Tenth Edition), perception is the ability to see, hear, or become aware of something through the senses. It is the state of being or process of becoming aware of something in such away. Perceived risk of contracting a disease refers to individuals' subjective perception of their susceptibility to the disease. For example, women must believe that there is a possibility of getting CC before they will be interested in uptake of CC screening. Risk perception of women towards HPV infection and CC in this research was regarded as the beliefs, attitudes, or understanding of

women towards the potential to be infected with HPV infection and develop CC. It was the risk posed by the women in contracting HPV infection and CC.

Risk perception was considered as the women's subjective judgments about the likelihood of acquiring HPV infection and CC, or the subjective judgment that women made about the characteristics and severity of HPV infection and CC. The risk perception incorporated here the two HBM constructs: the perceived susceptibility and the perceived severity, which are frequently combined and labelled as perceived threats since both constructs concern threat.

5.3.1.1 Theme 1: Perceived Susceptibility

Perceived susceptibility refers to people's beliefs about the possibility of having a disease or condition (Babazadeh et al 2019:1-9). For people to take action, they must believe that they are at risk of having a disease, illness or negative health outcomes. When people believe that they are at risk of a disease, they will be more likely to do something to prevent it from happening. The individual perception that she is not susceptible to any risk is a factor that causes a woman of reproductive age not to get CC screening and HPV vaccination. The HBM predicts that women will be more likely to adhere to the CC screening recommendation if they feel that they are susceptible to CC (Sadat 2012).

In this part of the study, perceived susceptibility referred to as beliefs of study participants about the likelihood of contracting HPV infection that possibly led to CC development.

5.3.1.1.1 Sub-theme 1.1: Lack of information about HPV

With the exception of one person, every study participant knew very little or nothing at all about HPV infection. They alluded to having heard about CC in the media and when people talk about it, but they did not have information about what causes CC. Only a few women knew that CC is caused by a virus, and among these women, only one mentioned HPV as a cause for CC.

"I do not know what causes cervical cancer, except that it is fatal. I was told by the health workers that the infection occurs when having sex with many people." (FGD 3: Participant 1).

"From what I understand, sometimes when it itches in the genital area or if there is something that feels hardened in the area, I think it is because of not being treated for this condition in time, it takes root, and I think this will be changed to cancer. Apart from this, I do not have information about what causes cervical cancer." (FGD 1: Participant 4).

5.3.1.1.2 Sub-theme 1.2: Unaware of risk factors

Almost all participants in this study had little information about the risk factors that predispose individuals to contract HPV infection and CC. The main risk factors associated with the acquisition and persistence of HPV infection include early sexual debut, a high number of sexual partners, infection with other STIs, including HIV, and host susceptibility, which were not well known by the study participants. Only a few women were aware of one of the risk factors of HPV infection which was having many sexual partners, as they had heard this from health workers. Hence, the study participants perceived that they were less susceptible to HPV infection and the following risks, such as CC development. This implies that a lack of information about the problem led participants to an improper impression that they were not susceptible to the problem.

"I have heard about cervical cancer in the media, I have also heard when people were talking about it. But I did not have the information about how a person is exposed to this infection. I never thought that I was susceptible to the infection." (FGD1: Participant 1).

"I do not know much about cervical cancer; I have heard health workers say that it can be caused by having sex with many men, and I had no such kind of relationship, so, I did not think I was susceptible to cervical cancer." (FGD1: Participant 10).

5.3.1.2 Theme 2: Perceived Severity

Perceived severity refers to people's feelings about the seriousness of having an illness or leaving it untreated, which includes the assessment of possible clinical (like death, disability, and pain), and social complications (such as effects of the conditions on work, family life, etc.) (Babazadeh et al 2019:1-9). HBM theory states that the perceived seriousness or severity of a disease can cause a person to perform a treatment effort. Severity can be based on medical consequences, like death or disability, or personal beliefs about how the condition or disease would affect their life. If women think that CC is a severe disease and believe that getting CC would have serious medical, social and economic consequences for them, it is more likely to obtain a CC screening test (Sadat 2012).

In this part of the study, perceived severity was considered as the study participants' belief about the seriousness or severity of contracting HPV infection that would possibly complicate to CC development if the problem persisted.

5.3.1.2.1 Sub-theme 2.1: Scare of the name cervical cancer itself

Most of the study participants mentioned that they feel fear and anxiety even when they hear the name of CC itself. Participants' perceived severity of CC was very high. This concern about the disease caused participants to be screened.

> "I fear the name cervical cancer itself; I feel scared even when people talk about It. I have heard of people dying from cervical cancer. I got tested because I was afraid that this would happen to me." (FGD 2: Participant 3).

> "Cervical cancer, the name itself used to shock and scare me. I got tested, because I was afraid that the disease would happen to me. The health workers explained to me that if the infection is diagnosed and treated in time, it can be cured. I calmed down a bit" (FGD 3: Participant 5).

5.3.1.2.2 Sub-theme 2.2: Feel stress and nervous

All the study participants mentioned that CC is serious and fatal, and they also understood that it is treatable if it is identified and managed at its earliest stage of development according to the information the respondents got from health professionals. Study participants' perceived severity of HPV infection and CC was very high.

> "I always worry and feel nervous about what would happen if I got the cancer, because I hear so often that people have died from it." (FGD 2: Participant 2).

> "I understand cervical cancer is deadly because I have heard and seen people die from cervical cancer up close. I feel stressed because I recently found out that an acquaintance of mine died of cervical cancer, a very serious and deadly disease." (FGD 1: Participant 10).

5.3.2 Perception about Cervical Cancer Screening

Perception of CC screening in this research was regarded as the attitude or understanding of women towards the importance of getting screened for HPV infection and CC. Two types of CC screening methods were considered in the current study: VIA and Molecular (Nucleic Acid tests (NAT) includes HPV DNA (e.g., Abbott). Perception of CC screening in this part of the research incorporated four constructs of HBM: Perceived benefits of getting screened for HPV infection and CC, Perceived barriers to being screened for HPV infection and CC, Self-efficacy to get screening for HPV infection and CC, and Cues to action that trigger women to get screened for HPV and CC.

5.3.2.1 Theme 3: Perceived Benefits

Perceived benefits refer to beliefs that preventive behaviours are useful and effective in reducing the risk or seriousness of the impact of a threat (Babazadeh et al 2019:1-9).

In this part of the study, perceived benefits were regarded as the participants' opinion of the value or usefulness of getting the CC screening and associated positive consequences in avoiding HPV-related diseases, most importantly CC.

5.3.2.1.1 Sub-theme 3.1: Remove (eliminate) worry

Most participants mentioned that they were freed from worrying about whether they had CC. They recommended others get tested and get rid of the worry of being diagnosed with CC like they did. They added that if symptoms are detected, early treatment can help them prevent the problem from being turned into cancer.

> "By getting screened, I have removed the worry of whether I have the problem or not. For the time being, I have confirmed that I am free of the infection, and I will protect myself from it in the future. As recommended by the health workers, I will come for checkups every two years." (FGD 2: Participant 8).

> "My screening took away my worry, because I have been diagnosed and treated, and I am doing well now. As advised by health workers, I am coming every time they gave me an appointment to monitor my health." (FGD 2: Participant 5).

5.3.2.1.2 Sub-theme 3.2: Early detection of symptoms

The most important part of being screened for CC is early detection of pre-cervical cancer lesions if present. Study participants mentioned that they

benefited from being screened for CC because it helped them to detect the problem before it got complicated.

> “I benefited from the examination because it helped me to know the presence of the disease before it took root. If I had not been screened, I would not have known known until the disease worsened and I fell into bed.” (FGD 2: Participant 4).

> “Getting screened is for own health; I am glad of being screened for cervical cancer. It helped me to know about the presence of the disease before it gets complicated.” (FGD 3: Participant 9).

5.3.2.1.3 Sub-theme 3.3: Get treated (Receive treatment)

The most important part of being screened for CC is early detection of pre-cervical cancer lesions if present and being treated in time. This benefits women to be treated early before the lesions turn to cancerous form.

> “The examination helped me to be aware of my health condition and get treated in time. If I had not been examined and treated in time, I would have developed uterine cancer over time.” (FGD 1: Participant 1).

> “I benefited from being screened because I got treatment in time; now I feel good health” (FGD 1: Participant 3).

5.3.2.1.4 Sub-theme 3.4: Prevent developing cancer

All women who participated in the study were aware of the benefit of being screened for CC. They already understood that if a woman is diagnosed with a pre-cancerous cervical lesion, it is possible for her to prevent cancer development by getting treated early for the symptom before it worsens and turns into cancer form.

> “As health workers told me, a woman diagnosed with pre-cancer symptoms can develop cancer within ten to fifteen years if not treated in time. I felt benefited because I have got treated in time before the symptoms developed into cancer.” (FGD 2: Participant 3).

> “I have learned that cervical cancer can be prevented if diagnosed and treated early, and that is what I did. I was treated in time before it turned to cancer.” (FGD 3: participant 1).

5.3.2.2 Theme 4: Perceived Barriers

Perceived barriers refer to beliefs about the tangible and psychological costs of the advised action that may act as impediments to undertaking recommended behaviours (Babazadeh et al 2019:1-9).

Perceived barriers in this part of the study were regarded as beliefs that had potentially negative consequences about the CC screening, including a lack of awareness towards the importance of having screened for CC.

5.3.2.2.1 Sub-theme 4.1: Fear of the result

All the study participants had come to the health facilities for other health services, but accepted the invitation to participate in the study. Some of the participants expressed that they were afraid of what the results of the examination would be.

> “When they asked me if I wanted to be screened for cervical cancer, I was scared because I had no previous experience. It was scary for me to get screened because I had worried about what if I should have it (cervical cancer), but I got tested and I am glad I got an answer.” (FGD 3: Participant 7).

> “Of course, I was afraid to be screened, afraid of being positive for the infection, but it is also necessary to be examined because it is for one’s own benefit.” (FGD 1: Participant 4).

5.3.2.2.2 Sub-theme 4.2: Negative influence from peers

The participants of the study did not experience serious barriers to getting screened. In fact, some of them expressed that some people discouraged them from getting tested because of fear of positive results.

> “I had come to the health facility to get rid of the contraceptive I was using, but when workers advised me to have cervical cancer screening, I immediately accepted the advice and decided to get screened. In fact, some people around me tried to scare me about the result, but I did not want to think twice, should not we pay for treatments when we get sick?” (FGD1: Participant 9).

> “My friend tried to pull me back from getting screened, saying that there are so many other things to worry about and why you put yourself in trouble, but I got screened.” (FGD 2: Participant 10).

5.3.2.3 Theme 5: Self-efficacy

Self-efficacy is defined as the conviction that one can successfully executes the behaviour required to produce the outcomes (Babazadeh et al 2019:1-9). Self-efficacy in this part of the study was considered to be the participants’ confidence and belief in their ability to get the CC screening.

5.3.2.3.1 Sub-theme 5.1: Enhance belief

All the participants in the study believed that it is possible to prevent cancer development in a woman who already diagnosed as having a pre-cancerous cervical lesion by receiving timely treatment before the lesion turns into cancer. This condition enhanced the women’s motivation to be tested for CC.

"I was told that if women are diagnosed with the symptoms of cervical cancer and follow the treatment in time before it gets serious, they will be cured, and my heart believes that I will be cured, so I will do what I am told. For this reason, I have a plan for this. I have hope and I will implement it." (FGD 3: Participant 7).

"The health workers told me that a woman can be cured of the infection if early symptoms are detected on examination and treated timely. This increased my interest to be examined." (FGD 1: Participant 8).

5.3.2.3.2 Sub-theme 5.2: Feel confident

Most of the study participants felt confident they would not develop CC because they had already screened for CC. Those who were diagnosed as having pre-cancerous cervical lesions received timely treatment. This helped women develop confidence in being screened for CC.

"I am normally very afraid of cancer, but they told me here that this is a sign, not a cancer. They explained to me that it can be cured and will disappear. I was treated, now I am calm and have full confidence that I will be cured." (FGD 1: Participant 1).

"The health workers examined me and told me that there was a sign on the edge of my uterus. They explained to me that after ten to fifteen years it can be turned into cancer. They advised me to be treated and then I received the treatment. They told me that it would disappear. I have confidence, I will be cured." (FGD 1: Participant 3).

5.3.2.4 Theme 6: Cues to Action

Cues to action are events, people, or things that trigger people to change behaviour. Advice from others, the illness of a family member or social media can provide cues. (Babazadeh et al 2019:1-9). In this phase of the study, cues to action were regarded as triggers like advice from health professionals, illness

of a family member or relatives, recommendations from organisations such as the Ethiopian Ministry of Health, or media that prompt women to have CC screening.

5.3.2.4.1 Sub-theme 6.1: Recommendation (Motivation) from others

Some of the participants stated that they had heard about people who died of CC. Others mentioned that they knew women who died of the same cancer, and this condition motivated them to get tested. Most participants explained that when they came to the health facilities for other services, health workers advised them to undergo pre-cancer screening, and they did so. Some others explained that they had heard about CC screening in the media, and with this in mind, they were motivated to get screened.

> “I had information about cervical cancer screening before. Additionally, the health workers told me about it when I came to this health centre for other services, these motivated me to get tested.” (FGD 1: Participant 6).

> “I did not have the idea to get screened before, because I did not have the Information about cervical cancer screening, but my friend knew about it and motivated me to get tested.” (FGD 2: Participant 7).

5.3.2.4.2 Sub-theme 6.2: Perceived bad experiences happened to others

The reason why some of the participants decided to get screened was that they knew women suffering from CC or heard about women who died of CC.

> “I recently knew that an acquaintance of mine died of cervical cancer, I was afraid that this would happen to me, so I was decided to be screened.” (FGD 1: Participant 10).

> “I have heard that there were women who have died of cervical cancer, so I came here and got tested because I was afraid that this would happen to me.” (FGD 2: Participant 6).

5.3.3 Perception about Human Papillomavirus Vaccination

The HPV vaccination prevents invasive CC by preventing infection with major oncogenic types of HPV (Lei et al 2020:1340-1348).

In this research, perception about HPV vaccination was regarded as the attitude or women's understanding of the importance of getting HPV vaccination. It incorporated two constructs of HBM: Perceived benefits of getting HPV vaccination and perceived barriers to getting HPV vaccination.

5.3.3.1 Theme 7: Perceived Benefits

Perceived benefits in this part of the study were regarded as the participants' opinions of the value or usefulness of getting the HPV vaccine and associated positive consequences in avoiding HPV-related diseases, most importantly CC.

5.3.3.1.1 Sub-theme 7.1: Prevention of cancer

Participants who were aware of the existence of the HPV vaccine believed that being vaccinated for HPV can prevent the development of CC.

> "I have heard about a vaccine given for cervical cancer prevention, and if get it, I believe I can prevent myself from getting cervical cancer." (FGD 1: Participant 7).

> "I knew there is a vaccine for cervical cancer; if everyone gets vaccinated, it would be possible to prevent the cancer." (FGD 3: Participant 9).

5.3.3.2 Theme 8: Perceived Barriers

Perceived barriers in this part of the study were regarded as beliefs which had potentially negative consequences about HPV vaccination: including a lack of

awareness towards the importance of the vaccine and eligibility to receive the vaccine.

5.3.3.2.1 Sub-theme 8.1: Lack of awareness

Most of the participants were unaware of the HPV vaccine, and even those who were aware of its existence did not have adequate information about who was eligible to be vaccinated according to the country's health policy. They believed the vaccine could be given to females in their age groups.

> "Of course, I have heard about the existence of the vaccine, but I have no idea who will be given, when and where it will be given." (FGD 3: Participant 5).

> "I want to be vaccinated, but I do not know why it is not given to us." (FGD 2: Participant 3).

5.3.3.2.2 Sub-theme 8.2: Feel distracted

Some of the study participants stated that they had heard in the media about HPV vaccine that was given only to females aged 14 years. These participants felt distracted as if they were ignored because they perceived that the vaccine could be given to females of all age groups.

> "I heard in the media that there is a vaccine that protects females against cervical cancer-causing infections, but it is given only to 14-year-old girls. How do I know the benefit of it if it is not given to us too?" (FGD 2: Participant 6).

> "As I heard in the media, the vaccine is given only to fourteen-year-old girls, and I already passed this age" (FGD 3: Participant 6).

5.4 DISCUSSION

The HBM suggests that people will take action to prevent, screen for, or control conditions of ill health if they regard themselves as susceptible to the condition, if they believe it could have potentially serious consequences, if they believe that a course of action available to them would be beneficial in reducing either their susceptibility to or the severity of the condition, and if they believe that the anticipated barriers to taking action are outweighed by its benefits (Luquis & Kensinger 2018:37–47).

The present study identified participants' risk perception towards HPV infection and CC, which incorporated the two HBM constructs: the perceived susceptibility and the perceived severity, which are frequently combined and labelled as perceived threats. The study found that almost all of the participants had poor information pertaining to HPV infection. Most of them reported that they had heard about CC, but they did not have information about what causes the cancer. Similarly, the study found that almost all of the participants were unaware of the main risk factors associated with the acquisition and persistence of HPV infection, such as early sexual debut, a high number of sexual partners, infection with other STIs, including HIV, and host susceptibility.

This lack of information caused most of the study participants to perceive themselves as less susceptible to HPV infection and CC. This finding is consistent with a study conducted among Iranian women which indicates that the vast majority of women reported low perceived risk and susceptibility regarding HPV infection and CC (Taghizadeh Asl et al 2020:1–12). The finding further supports what Goldfarb and Comber (2022:1-9) reported in a study conducted in the USA, which revealed that the most participants felt as if they were at low risk for contracting HPV infection and CC. A similar finding was obtained in a study conducted in Durban, South Africa, in which participants reported feeling that they were at lower risk of acquiring HPV infection and developing CC (Russell et al 2020:887–893). In contrast, a study conducted in Turkey revealed different findings, indicating that half of the participants were

worried about getting HPV infection and CC (Yurtçu et al 2022:349–355). The discrepancy might be because of the sample size difference, the study setting, the time of the study done, and the screening methods used.

However, the present study shows that women's perceived severity of CC was very high. Most of the participants mentioned that they feel fear and anxiety even when they hear the name CC itself. This finding was consistent with a study conducted in the Philippines in which participants believed HPV infection and CC to be serious infections and they were at risk of getting it (Imoto et al 2020:3145–3151). In contrast, a study conducted in Argentina shows that most participants did not perceive that having an HPV infection was a serious condition (Victoria et al 2020:1-11). The discrepancy might be because of differences in the study setting, culture and people's perception of the severity of a particular disease.

In general, referring to the two constructs of HBM: perceived susceptibility and perceived severity; in combination know as risk perception or perceived threat, the current study revealed low perceived susceptibility and high perceived severity among participants regarding HPV infection and CC. This is in line with the study done in Iran, in which participants had an overall low perceived susceptibility and high perceived severity regarding HPV infection and CC (Taghizadeh Asl et al 2020:1–12).

In conclusion, participants' perceived susceptibility to HPV infection and CC was low. Whereas, the perceived severity of CC was high, which caused them to get screened for CC. This finding aligns with a study conducted in Johannesburg, South Africa, which indicates that women who perceived CC to be a severe disease were more likely to have had CC screening (Chisale Mabotja, Levin & Kawonga 2021:1-13). The HBM theory suggests that the perceived seriousness or severity of a disease can cause a person to perform a treatment effort.

The study participants' major perceived benefits of being screened for CC were removing worry, early detection of pre-cervical cancer lesions, being treated in time if symptoms present, and preventing CC development. This finding was

consistent with a study conducted in Tanzania, which indicated that perceived benefits for attending CC screening include treatment of symptoms and disease prevention (Linde et al 2019:1-8). The result of this study was also similar to the study done in Riyadh, Saudi Arabia, in which the participants believed undergoing regular cervical screening would help to find changes to the cervix before cancer develops, and that CC treatment would be tolerable (Aldohaian et al 2019:6).

Concerning perceived barriers, this study reveals that fear of the result and negative peer influence were barriers that pulled participants back from getting screened for CC. The findings of this study, except for fear of results, were different from the study conducted in Australia in that the most commonly stated barriers included lack of time, embarrassment, fear of results, irrelevance and male health professionals (Nagendiram et al 2019:343–353). Similarly, the participants' perceived barriers identified in this study were different from those in a study conducted in Uganda, except for fear of the outcome. The most frequently reported barriers to the Ugandan study include embarrassment, fear of the screening procedure or outcome, residing in a remote or rural area, and limited resources/health infrastructure (Black, Hyslop & Richmond 2019:108). Again, the result of the current study was different from the study conducted in Ghana, in which most participants believed that screening was not important because there was no cure for cancer (Plange et al 2023:1450-1462). Yet the finding of this study was not in agreement with a study conducted in Nepal, in which the participants' perceptions of barriers to their attendance at clinics for CC screening were sociocultural, including mistrust and gossip, negative experiences in previous meetings with service providers, the challenging geography of the country, and financial limitations (Darj et al 2019:20-26). These discrepancies might be because of the differences in the study setting, the time of the study done, the culture, and the screening methods used.

Perceived self-efficacy in this study revealed that all the participants had full confidence in being screened for CC. They believed that it is possible to prevent the development of CC by undergoing CC screening tests and getting treated in time before it turns into cancer form if pre-cancerous lesions were diagnosed

early. In this regard, the finding of this study was consistent with a study conducted in Suratthani Province, Thailand, in which village health volunteers with high perceived self-efficacy correlated with their confidence screening for CC (Bunkarn & Kusol 2021:179-183). Similarly, the finding of this study was in agreement with a study done in Khuzestan Province, Iran, in which it was found there was a positive relationship between knowledge, attitude, self-efficacy, and women's practice with regard to undergoing CC screening (Ghalavandi et al 2021:1-10).

Participants' cues to action include recommendations from health workers and perceived bad experiences that previously happened to others. All these motivated them to get screened for CC. This finding was similar to the study done in Uganda, which indicates that the most frequent cue to action was having a recommendation by health care providers to attend the screening (Black et al 2019:108). The finding of this of study was also almost similar with the study done in Southeast Asia, which indicates that the most common cues to action were receiving advice from health care workers, and the educational status of the participants (Chua et al 2021:4586).

5.5 SUMMARY

The study's qualitative phase data were collected from the study participants through FGDs. The following qualitative research questions were formulated by the researcher based on the objectives of the study, and used as a starting point for the FGDs: What do you know about HPV infection? How it transmits? What are the preventive aspects? Could you please tell me your perception with regard to the risk of acquiring HPV infection? Could you please tell me your perception regarding cervical cancer screening? Could you please tell me your perception regarding HPV vaccination?

The collected data were analysed based on the six-step guides of thematic analysis provided by Braun and Clarke (2006:87): namely, familiarisation,

coding, generating themes, reviewing themes, defining and naming themes, and writing up.

The codes in the process of this thematic analysis were grouped around the six domains of the HBM: namely, perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and cues to action which were used as themes in this qualitative section of the study. Sub-themes were developed based on the study participants' responses under each construct of the HBM. Finally, a discussion of the findings in relation to the findings of other researchers was presented.

Chapter 6 presents meta inference, integration of both the quantitative and qualitative studies, by triangulating the results.

CHAPTER 6

INTEGRATION OF QUANTITATIVE AND QUALITATIVE FINDINGS

6.1 INTRODUCTION

The previous chapters, dealt with the analysis, presentation and discussion of quantitative data in Chapter 4 and qualitative data in Chapter 5.

This chapter presents the integration of quantitative and qualitative results. In this explanatory sequential mixed research methods design, the quantitative and the qualitative databases are analysed separately. Then, the third phase of this study namely the meta inference, integration of the two databases called connecting the quantitative results to the qualitative strand was made by the researcher. This is the point of integration in an explanatory sequential design (Creswell & Creswell 2018:304).

6.2 META INFERENCES

The term meta-inference describes “the theoretical statements, narratives, or a study inferred from an integration of findings from quantitative and qualitative strands of mixed methods research” (Venkatesh, Brown & Bala 2013:29). Tashakkori and Teddlie (2008:101) describe a “meta inference as an overall conclusion, explanation or understanding developed through an integration of the inferences obtained from the quantitative and qualitative strands of a mixed method study.” Integration is a process in mixed method research in which the quantitative and qualitative strands of a study “come into conversation with each other” (Plano Clark, 2019:108).

Tashakkori and Teddlie (2008:105) describe the importance of an “integrative framework” for making validity claims for mixed method research. The integrative framework seeks to distinguish between inference quality (an

attribute of the process of meaning-making and/or its outcomes) and data quality (an attribute of the inputs to the process of meaning-making). Meta inference involves a two-phase project in which the researcher collects quantitative data in the first phase, analyses the results, and then uses a qualitative phase to help explain the quantitative results (Creswell & Creswell 2018:329). Meta inference refers to the integration of inferences obtained through qualitative and quantitative studies in a mixed methods design. In mixed methods, meta-inferences integrate the understandings gleaned from the qualitative and quantitative strands of the study. They go beyond what the quantitative and qualitative strands can explain alone. Meta-Inferences, the whole being greater than the sum of the parts.

Integration is an intentional process by which the researcher brings quantitative and qualitative approaches together in a study. Quantitative and qualitative data then become interdependent in addressing common research questions and hypotheses (Guetterman, Fetters & Creswell 2015:2). Meaningful integration allows researchers to realise the true benefits of mixed methods to “produce a whole through integration that is greater than the sum of the individual qualitative and quantitative parts (Fetters & Freshwater 2015:115–117).

There are four main mechanisms of data integration in mixed-method research studies: connection, construction, fusion, and incorporation (Creswell & Clark 2017). From these, connection concerns the use of a set of analysed data to lead the collection of other data, and it is very common in sequential explanatory research studies that start with the quantitative stage and use (connect) the statistical information to define even the subjects/participants of the subsequent qualitative stage.

Purpose of combining data:

- Enriching: - This is achieved by using qualitative work to identify issues or obtain information on variables not obtained by quantitative surveys.

- Examining: - Refers to generating hypotheses from qualitative work to be tested through the quantitative approach.

- Explaining: - Involves using qualitative work to understand unanticipated results from quantitative data.

- Triangulation: - Facilitates validation of data through cross-verification from more than two sources.

To ensure that the information derived from research data accurately reflects the truth about phenomena under investigation, different research methods are used. There are different ways to combine qualitative and quantitative data, such as triangulation, complementarity, development, expansion, or embeddedness. Each design has its own strengths and limitations, and requires different methods of data collection, analysis, and interpretation. For example, triangulation involves comparing and contrasting data from different sources or methods to validate or challenge a finding, while complementarity involves using data from one source or method to enhance or explain data from another.

Triangulation is one method that helps increase the validity, reliability, and legitimation, which encompasses the credibility, dependability, confirmability and transferability of research findings (Michael 2019:103-105). Triangulation is employed to increase the validity of inference in quantitative and qualitative research.

Triangulation in research means using multiple datasets, methods, theories, and/or investigators to address a research question. It is a research strategy that can help enhance the validity and credibility of the findings and mitigate the presence of any research biases in the work.

Triangulation is mainly used in qualitative research, but it is also commonly applied in quantitative research. If researchers decide on mixed methods research, they will always use methodological triangulation (Bhandari 2023).

There are four main types of triangulations in research: -

- Data triangulation: Using data from different times, spaces, and people.
- Investigator triangulation: Involving multiple researchers in collecting or analysing data.
- Theory triangulation: Using varying theoretical perspectives in the research.
- Methodological triangulation: Using different methodologies to approach the same topic (Bhandari 2023).

Besides to the four main types of triangulations in research, there is also Time triangulation: which involves collecting data at multiple time points to explore changes in the phenomenon over time. For example, a study on the impact of a policy change may collect data before and after the policy change to explore its effects.

Triangulation can help researchers identify inconsistencies, biases, or gaps in the data, and can help to build a more robust and nuanced understanding of the phenomenon being studied.

A triangulated study should provide insight and a multi-dimensional perspective into the research question. According to Tashakkori and Teddlie (2003: 671-702) triangulation is often used to describe research where two or more methods are used, known as mixed methods. Combining both quantitative and qualitative methods to answer a specific research question may result in one of the following three outcomes: (1) The results may converge and lead to the same conclusions; (2) The results may relate to different objects or phenomena but may be complementary to each other and used to supplement the individual results, and (3) The results may be divergent or contradictory. Converging results aim to increase the validity through verification; complementary results highlight different aspects of the phenomenon or illustrate different phenomenon

and divergent findings can lead to new and better explanations for the phenomenon under investigation.

On the other hand, triangulation is time-consuming and labour-intensive, often involving an interdisciplinary team. The results may be inconsistent or even contradictory. Morse (2010) distinguishes two types of methodological triangulations: simultaneous and sequential. In the former, two methods are used at the same time; in the latter the inference gained from one method informs the use of a second method.

In the current study which used sequential explanatory mixed methods, the quantitative data was collected and analysed first, and then followed by the collection and analysis of qualitative data. The primary focus was to explain quantitative results by using qualitative data to explore certain results in more detail or help explain unexpected results (e.g., using follow-up focus FGDs to better understand the results of a quantitative study). Greater emphasis was given to the quantitative strand. Hence, sequential methodological triangulation was the method of choice in this regard.

6.3 TRIANGULATION OF QUANTITATIVE AND QUALITATIVE FINDINGS

According to Noble and Heale (2019), research triangulation refers to the process that helps to increase the credibility and validity of research. In other words, research triangulation basically aims at validating the results of a study. Triangulation makes use of mixed methods to achieve the aim of validating research findings. In using methodological triangulation, researchers use different methods to approach the same research question. Methodological triangulation is the most common type of triangulation, and researchers often combine quantitative and qualitative research methods in a single study. Methodological triangulation is useful because it avoids the flaws and research bias that come with reliance on a single research technique.

In Phase III of the study, methodological triangulation was used which was sequential in type that the researcher incorporated both sets of data into the interpretation of the overall results. The quantitative data was first statistically analysed to establish clear predictors, and then triangulated with the thematically analysed qualitative data to be used in the development of strategies.

In the present study, the prevalence of HPV infection was estimated to be 26,6% which was higher than the worldwide prevalence of 11.7%. The major oncogenic HR-HPV genotypes were determined in this study as “HPV-16”, “HPV-18” and “Other HR-HPV”. The proportions of HPV-16 and HPV-18 were 22.5% and 5.9%, respectively. ‘’Other HR-HPV’’ genotypes altogether accounted for 63.7% of all the HPV positive cases. Similarly, the qualitative finding of the present study shows that almost all the participants had poor or insufficient information about HPV infection. This caused the participants to perceive themselves as not susceptible to HPV infection. According to HBM, when people believe they are at risk for a disease, they will be more likely to do something to prevent it from happening. However, participants in this study believed themselves not at risk, which contributed to high prevalence of HPV infection in the study area.

In the present study, being divorced, having a history of post-coital bleeding, having an early sexual debut before age 20, having a history of more than one lifetime sexual partner, having a history of STIs, and being HIV positive were risk factors identified as having statistically significant association with the acquisition of HR-HPV infection. According to the qualitative findings, almost all participants in this study had little information about these risk factors that predispose individuals to contract HPV infection.

The prevalence of pre-cancerous cervical lesion among the total respondents who took part in the study was 12.5%. Participants’ perceived severity of CC was very high. The perceived benefits of screened for CC were early detection of symptoms, getting treated in time if symptoms present, and prevention of CC development. Most of the study participants explained that they feel fear and anxiety even when they hear the name of cervical cancer itself. Moreover, they

mentioned that cervical cancer is serious and fatal according to the qualitative study finding.

One of the constructs of HBM stated that perceived seriousness or severity of a disease can cause a person to perform a treatment effort. Meanwhile, all study participants stated their happiness in getting screened for CC because it helped them become more aware of their health status. Most participants mentioned that they freed from worry of whether they have CC or not. Moreover, screening for CC benefited those women diagnosed as having pre-cancerous cervical lesion to be treated early before the lesions turned into cancerous form. The HBM theory suggests that if an individual believes that a particular action will reduce susceptibility to a health problem or decrease its seriousness, then he or she is likely to engage in that behaviour regardless of objective facts regarding the effectiveness of the action.

The present study recognised the risk of pre-cancerous cervical lesion development among studied women, therefore, respondents who had a history of post-coital bleeding, early sexual debut before age 20, history of having more than one lifetime sexual partner, and being HIV positive were risk factors identified as having statistically significant association with the development of pre-cancerous cervical lesion.

According to the qualitative findings, almost all participants who took part in this study had little information about these risk factors that would predispose HR-HPV-positive individuals to the development of pre-cancerous cervical lesions. Perceived barriers that prevented participants from getting screened for CC were fear of the screening result and negative influence from others not to be screened. According to HBM, even if an individual perceives a health condition as threatening and believes that a particular action will effectively reduce the threat, barriers may prevent engagement in the health-promoting behaviour. In other words, the perceived benefits must outweigh the perceived barriers in order for behaviour change to occur.

In the current study, the treatment offered for the majority of women identified as having pre-cancerous cervical lesions was cryotherapy 81.3%, followed by thermocoagulation 10.4%, and no treatment/not eligible for cryotherapy or thermocoagulation 8.3%. Concerning the qualitative finding of the study, participants perceived self-efficacy revealed that all of them had full confidence to be screened and treated for CC. They believed it is possible to prevent the development of CC by getting treated for the lesion before it turns into a cancer form.

The developers of the HBM recognised that confidence in one's ability to effect change in outcomes (i.e., self-efficacy) was a key component of health behaviour change. Meanwhile, participants' cues to action identified in the qualitative study were recommendations from health workers, and perceived bad experiences happened on others motivated them to get screened for CC.

According to the constructs of HBM, individuals who believe they are at high risk for HPV infection and CC development and who have an established relationship with health care workers may be easily persuaded to get screened for CC after seeing a public service announcement, whereas individuals who believe they are at low risk for HPV infection and CC development and also do not have reliable access to health care workers may require more intense external cues in order to get screened. Hence, all these beliefs and perceptions of participants identified in the study might cause them to be screened for CC, and might contributed to the recognition of the aforementioned percentage of pre-cancerous cervical lesions.

In conclusion, triangulation of both quantitative and qualitative findings to answer a specific research question may result in one of the following three outcomes: the results may be convergent, complementary, or divergent (contradictory) (Tashakkori & Teddlie 2003:671-702). This study reveals convergent outcome of quantitative and qualitative findings that supported each other and led to the same conclusions. Converging results aim to increase the validity through verification.

6.4 SUMMARY

In this phase of the study, meta inference, sequential methodological triangulation of both quantitative and qualitative findings, was presented. The results revealed convergent outcome of quantitative and qualitative findings that led to the same conclusions.

The next chapter, Chapter 7 presents the strategies development and validation process or activities.

CHAPTER 7

STRATEGIES DEVELOPMENT AND VALIDATION

7. 1 INTRODUCTION

The previous chapter dealt with the meta inference, methodological triangulation of the quantitative and qualitative study findings. The results reveal that convergent outcome of quantitative and qualitative findings that led to the same conclusions.

This chapter presents the strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women. The strategies were developed based on the quantitative and qualitative study findings and relevant literature review. The chapter incorporated the guiding principles, strategies development, validation of the strategies developed, and a summary. The methods, steps, and processes used in the development of the strategies were discussed in detail.

7.1.1 Guiding Principles of the Strategies

The following key principles guide the HPV infection and CC prevention and control strategies:

- Awareness creation
- Community involvement
- Inter-sectorial collaboration
- Equity and accessibility of services
- Systematic and integrated approach
- Sustainability of services
- Evidence-based approach focusing on best practice
- Improving metrics, monitoring, evaluation and innovation.

7.2 STRATEGIES DEVELOPMENT

This is the fourth phase of the study. The basic aim of this phase was to develop strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

Strategy: This is the skill of making or carrying out plans to achieve a goal". It is the art of devising or employing plans or stratagems toward a goal. *(Merriam-Webster Dictionary 2021, sv "strategy").* A strategy is a careful plan or method for achieving a particular goal usually over a long period of time. It is the plan for deploying resources to establish a favourable position.

Strategy development: This is the process of creating a plan of action for achieving specific goals and objectives. It involves analysing the current situation, identifying opportunities and threats, and determining the resources needed to execute the plan. It is a continuous process that is essential for the success of a plan.

7.2.1 Framework of the Strategies

The strategy development used in this phase of the study has five steps which the researcher applied to design and develop a strategic plan to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women. (Figure 7.1 Steps of strategy development).

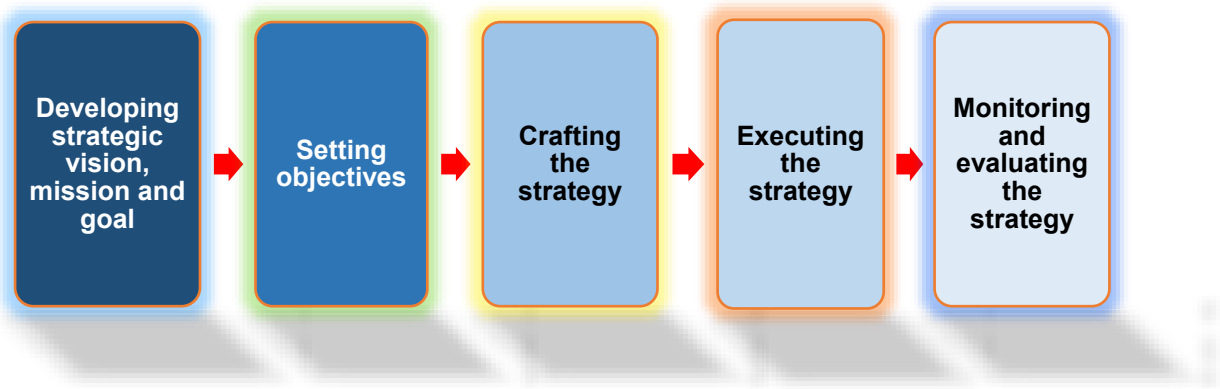

Figure 7.1: Steps of strategy development. Source Thompson, Strickland and Gamble (2009)

7.2.2 Developing Strategic Vision, Mission and Goal

7.2.2.1 Vision

The strategies document envisions effective and efficient national HPV prevention and treatment strategies to achieve the long-term goal of reducing CC incidence, morbidity, and mortality in Ethiopia by adopting an integrated approach of HPV vaccination, CC screening, and effective treatment.

7.2.2.2 Mission

To curtail mortality and morbidity from CC among women in Ethiopia by the provision of integrated services that deliver a full range of HPV prevention, screening, diagnostic, treatment, and care options to CC patients.

7.2.2.3 Goal

To reduce CC incidence and mortality in Ethiopia to less than 4 women per 100,000 women-years by 2030.

7.2.3 Setting Objectives

7.2.3.1 General objective

To develop strategies to promote the prevention and control of HPV infection and its sequela CC among women in Ethiopia based on the findings from quantitative and qualitative data of the study and relevant literature review.

7.2.3.2 Specific objectives

- Incorporate expertise input through e-Delphi in developing the strategies.
- Develop strategies to promote the prevention and control of HPV infection and its sequela CC.

7.2.4 Scope of the Strategies

These strategies will assist policy-makers, health services planners, health programme managers and other professionals in the health sector responsible for choosing strategies for the preventing and controlling of CC at the country, regional and district levels of the health system. The strategies are intended primarily to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

7.2.5 Strategies and Recommended Interventions/Activities

The strategies presented below were developed based on current study's findings, relevant aspects of reviewed literature, the study's theoretical framework, and the researcher's insights. Moreover, experts in the field enriched these strategies through their feedback in three rounds. (Figure 7.2 Process of the strategies development).

Twelve strategies and their recommended interventions/activities are presented under three components of prevention and control: primary prevention, secondary prevention, and tertiary care. The primary prevention includes prevention of HPV infection either through behaviour change mechanisms, such as avoiding early sexual debut or avoiding multiple sexual partners, and through biological mechanisms, such as the HPV vaccine. The secondary prevention includes screening and treating pre-cancerous lesions with effective outpatient methods. The tertiary care includes managing invasive CC (i.e., surgery, radiation therapy, and chemotherapy), as well as palliative care. (Table 7.1 Summary of findings of the study and identified strategies).

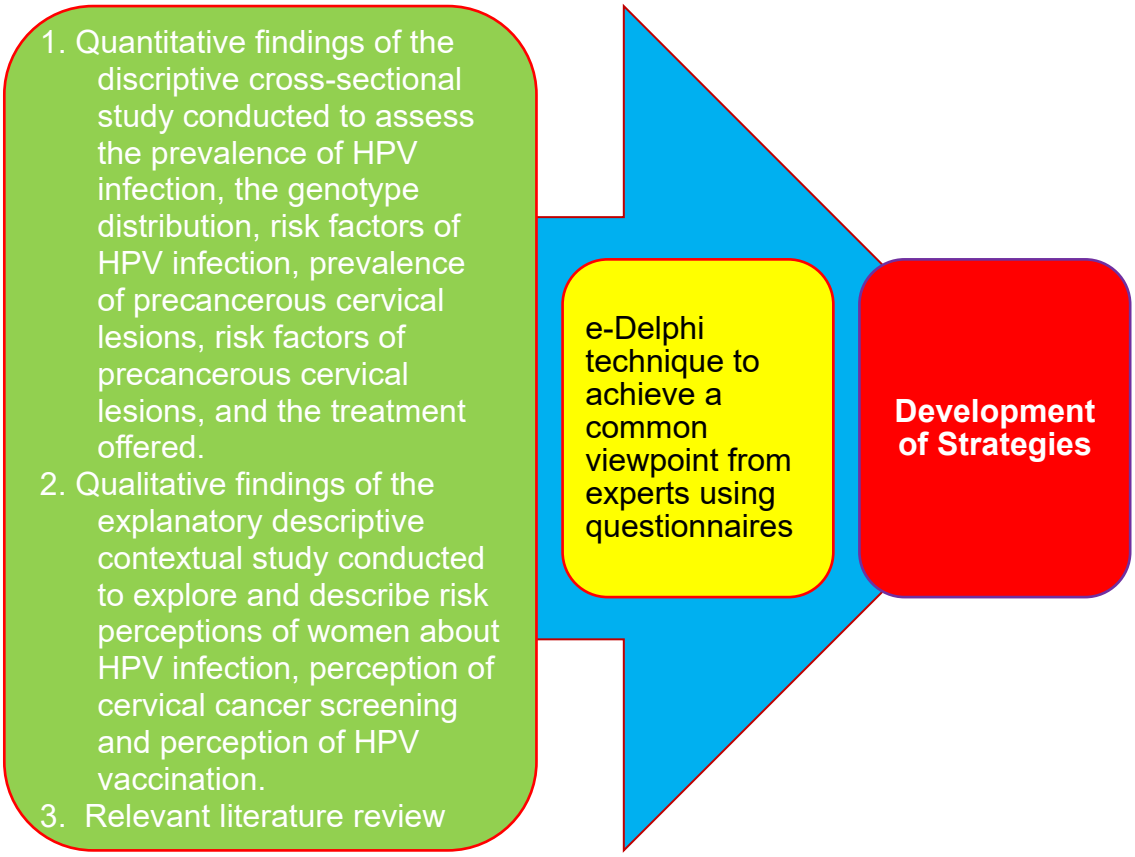

Figure 7.2: Process of the strategies development

7.2.5.1 Summary Findings of the Study in Phase 1 and 2

The findings of the study through quantitative and qualitative phases are summarised in a table, in a way to help the researcher develop strategies based on these groundworks. (Table 7.1 Summary of findings of the study and identified strategies).

Table 7.1: Summary findings from quantitative and qualitative data and identified strategies

Summary findings	Identified strategies
• High prevalence of HPV infection • High proportion of "Other HR-HPV" infection other than HPV 16 and 18 • Poor or no sufficient information about HPV infection • Little information about risk factors of HPV infection • No perceived susceptibility of HPV infection • Low risk perception of HPV infection • High prevalence of precancerous cervical lesion • High perceived severity of cervical cancer • Good perceived benefits of cervical cancer screening • Little information about risk factors that predispose to precancerous cervical lesion • Fear of the result of cervical cancer screening (Perceived barrier) • Negative pear influence about cervical cancer screening (Perceived barrier) • Full confidence to be screened for cervical cancer (Good self-efficacy) • Recommendation from health workers to be screened for cervical cancer (Cues to action) • Perceived bad experience happened on others (Cues to action) • Lack of awareness about HPV vaccine	1. Develop public awareness of HPV infection. 2. Promote community awareness of the risk factors of cervical cancer 3. Introduce HPV vaccination into national immunisation programmes. 4. Switch to Nonavalent (Gardasil 9) HPV vaccination 5. Population-based HPV vaccination for all girls and females aged 9-26 years 6. Population-based cervical cancer screening for all women aged 25/30-49 years using VIA. 7. Strengthen facilities providing early detection and treatment of pre-cancerous cervical lesions. 8. Improve and increase access to facilities providing effective management of invasive cervical cancer and palliative care 9. Combine strategies of HPV vaccination and cervical cancer screening 10. Networking, partnership and collaboration with all stakeholders 11. Reinforce research capacity and establish collaboration 12. Monitoring and evaluation of cervical cancer prevention and control activities

7.2.5.2 Methodology

At this phase of the study, the e-Delphi method was used to develop strategies. The e-Delphi method is a forecasting process framework based on the results of multiple rounds of questionnaires sent to a panel of experts. After each round of questionnaires, the experts were presented with an aggregated summary of the previous round, allowing each expert to adjust their answers according to the group responses. This process combines the benefits of expert analysis with elements of the wisdom of crowds. This is based on the assumption that group judgments are more credible than individual judgments (Giannarou & Zervas 2014:65-82). The e-Delphi method allows experts to communicate and engage with each other online in their own time and vicinities to solve problems until a consensus is reached. Since the responses of the participants are anonymous, individual panellists do not have to worry about the repercussions of their opinions. Consensus can be reached over time as opinions are swayed, making the method very effective.

7.2.6 Levels of Prevention and Control of HPV and Cervical Cancer

7.2.6.1 Primary Prevention

Primary prevention deals with keeping the disease process from becoming established by eliminating causes of disease or increasing resistance to disease through health promotion, prevention of exposure, and prevention of disease. The primary prevention approach is the most cost-effective long-term method of CC control, especially when integrated with other programmes, such as the Expanded Programme on Immunisation, Reproductive Health, and HIV/AIDs Control. The approach is primarily helpful in reducing exposures to modifiable risk factors at individual and community levels. Primary prevention involves ways of preventing HPV infection which include: HPV vaccination for girls aged 9-14 years, health information and warnings about tobacco use, and sexuality education tailored to age and culture (i.e., delaying sexual debut and avoidance

of having multiple sexual partners). HPV vaccination is the major approach for primary prevention.

7.2.6.1.1 Strategy 1: Develop public awareness of HPV infection

There was a huge knowledge deficit on HPV infection among study participants identified while conducting FGD. Moreover, the prevalence of HR-HPV infection among the studied population was very high. Community education and awareness creation activities are crucial to fill this gap.

Objective 1: To establish public awareness of HPV infection

Objective 2: To raise knowledge in the community on the prevention of HPV

Table 7.2: Public awareness development of HPV infection

Strategy	Objectives	Interventions/Activities
Strategy 1: Develop public awareness of HPV infection	**Objective 1:** To establish public awareness of HPV infection	Develop TV and radio programs regarding HPV
		Brochures to enhance public awareness on HPV infection and its consequences
		Transmit message through clubs and other existing community level structures about HPV infection and its consequences
		Organise community mobilisation events including workshops with key community and religious leaders
		Organise and deliver community-based health education, using health extension workers on HPV infection
	Objective 2: To raise knowledge in the community on the prevention of HPV infection	Train health workers and media on HPV infection prevention and advocacy
		Provide health education to the community on prevention of HPV infection
		Produce HPV prevention awareness messages and channel them through health extension workers (HEW)

7.2.6.1.2 Strategy 2: Promote community awareness of the risk factors of cervical cancer

There are a number of risk factors that play a significant role in the development of CC. The factors include: sexual activity before age 20, multiple sexual partners, exposure to STIs, smoking, immunosuppression: HIV/AIDS, chronic corticosteroid use, etc. Educating the public about these risk factors plays a substantial role in preventing and controlling of CC development.

Objective 1: To raise awareness of the community on risk factors of cervical cancer

Objective 2: To notify the community of the preventive measures to be taken to prevent cervical cancer development

Table 7.3: Promoting community awareness of the risk factors of cervical cancer

Strategy	Objectives	Interventions/Activities
Strategy 2: Promote community awareness of the risk factors of cervical cancer	**Objective 1:** To raise awareness of the community on risk factors of cervical cancer	Utilise mass media to disseminate information on risk factors for cervical cancer development
		Organise community awareness campaigns and education programmes on risk factors of cervical cancer
		Engage partners, neighbours, religious leaders, community leaders and significant others to improve knowledge on risk factors of cervical cancer
		Conduct community-based health education, using health extension workers to improve community awareness and knowledge of cervical cancer risk factors
	Objective 2: To notify the community of the preventive measures to be taken to prevent cervical cancer development	Conduct community-based health education, using health extension workers on avoidance of identified cervical cancer risk factors like exposure to sexual transmitted infections
		Utilise mass media to disseminate information on avoidance of risk factors of cervical cancer
		Transmit message through clubs and other existing community level structures about risk factors of cervical cancer
		Encourage young girls to delay early sexual debut before age 20
		Develop and utilise health message targeting the cultural and traditional practices being conducted in the community that may intensify risk factors of cervical cancer like having multiple sexual partners

7.2.6.1.3 Strategy 3: Introduce HPV vaccination into national immunisation programmes.

Vaccines are critical in the prevention and control of many communicable diseases like HPV infection and, therefore, underpin global health security. Immunisation is the foundation of a healthy, productive population. Preventing infections reduces the burden on health systems, and a healthier population is a more productive one. It is crucial to introduce HPV vaccination into the national immunisation programmes to maximise its accessibility, besides delivering it through campaigns. As of 2020, HPV vaccines have been introduced into national immunisation programmes in more than 100 countries (Markowitz & Schiller 2021:367-378). Many European countries have already introduced vaccination into their national immunisation programmes recommending vaccination for preadolescent females (Fallucca et al 2022:998).

The World Health Organization recommends that routine HPV vaccination be included in national immunisation programmes based on the following key considerations: (WHO 2009:118-131).

- Prevention of cervical cancer or other HPV-related diseases, or both, constitutes a public health priority
- Vaccine introduction is programmatically feasible
- Sustainable financing can be secured
- The cost-effectiveness of vaccination strategies in the country or region is considered
- HPV vaccination is targeted at adolescent girls prior to their sexual debut

Objective 1: To incorporate HPV vaccination into routine immunisation programmes

Table 7.4: Introducing HPV vaccination into national immunisation programmes

Strategy	Objectives	Interventions/Activities
Strategy 3: Introduce HPV vaccination into national immunisation programmes	**Objective 1:** To incorporate HPV vaccination into routine immunisation programmes	Reinforce and sustain strong leadership, management and coordination of immunization programmes at all levels
		Build and sustain strong political and financial commitment for HPV immunization
		Incorporate HPV vaccination into routine immunisation programs
		Ensure the availability of an adequate, effective, sustainable health workforce
		Secure high-quality supply chains for HPV vaccines and related commodities and effective vaccine management
		Establish and maintain a well-functioning vaccine safety system involving all stakeholders
		Provide training to health care workers about HPV vaccination
		Strengthen supply chains to ensure that HPV vaccines are always available in the right quantity and form at the right time, in the right place and stored and distributed under the right conditions.
		Promote integration with other supply chains for more effective delivery of HPV vaccine
		Strengthen collaboration with Gavi alliance

7.2.6.1.4 Strategy 4: Switch to Nonavalent (9vHPV) HPV vaccination

The present study reveals that the majority of the HPV genotypes identified among the total of 102 HPV-positive cases were other high-risk (Other HR HPV) genotypes, accounted for 63.7%, followed by HPV-16 (22.5%) and HPV-18

(5.9%) of study participants tested positive for HPV. In Ethiopia, the currently available HPV vaccine is Gardasil®4 (4vHPV), which protects vaccinated girls against HPV-6, 11, 16, and 18 HPV genotypes. There is a Nonavalent vaccine, Gardasil 9, similar to Gardasil but containing L1 VLPs of five additional oncogenic types HPV-31, 33, 45, 52, and 58, and thus has the potential to provide type-specific protection against approximately 90% of CCs worldwide (de Martel et al 2017:664-670, Markowitz & Schiller 2021:367-378).

Objective 1: To shift from 4vHPV vaccination to 9vHPV in Ethiopia.

Table 7.5: Switching to Nonavalent (9vHPV) HPV vaccination

Strategy	Objectives	Interventions/Activities
Strategy 4: Switch to Nonavalent (9vHPV) HPV vaccination	**Objective 1:** To shift from 4vHPV vaccination to 9vHPV in Ethiopia	Provide training to health care workers about 9vHPV vaccine
		Secure high-quality supply chains for HPV vaccines and related commodities and effective vaccine management
		Establish and maintain a well-functioning vaccine safety system involving all stakeholders
		Strengthen collaboration with Gavi alliance
		Build and sustain strong political and financial commitment to switch to 9vHPV HPV vaccination
		Promote public awareness on the advantages of switching to 9vHPV HPV vaccination
		Switch to Nonavalent (9vHPV) HPV vaccination
		Conduct mentoring and supportive supervisions

7.2.6.1.5 Strategy 5: Population-based HPV vaccination for all girls and females aged 9-26 years

Vaccinating girls prior to their sexual debut will protect them from CC. In most developing countries, young adolescents do not routinely interact with health systems, as a result, ensuring access to vaccines poses a challenge. The WHO recommends that the primary target population for vaccination should be selected based on the age of initiation of sexual activity and the feasibility of reaching young adolescent girls through schools, health-care facilities or community-based settings (WHO 2021). In Ethiopia, the HPV vaccine is delivered primarily through a school-based approach. Where many young girls drop out of school early, community programmes might help fill the gap. Hence, population-based vaccination of girls aged 9-26 years maximises the chance to get many young eligible girls for HPV vaccination who are not able to join schools and/or drop out of school at an early age.

Objective 1: To organise and deliver population-based HPV vaccination for all girls aged 9-26 years

Table 7.6: Population-based HPV vaccination for all girls aged 9-26 years

Strategy	Objectives	Interventions/Activities
Strategy 5: Population-based HPV vaccination for all girls aged 9-26 years	**Objective 1:** To organise and deliver population-based HPV vaccination for all girls aged 9-26 years	Develop community awareness on the importance and availability HPV vaccination for girls and young women through different media
		Reinforce human-resource capacity
		Provide training to health care workers
		Secure high-quality supply chains for HPV vaccines and related commodities and effective vaccine management
		Establish and maintain a well-functioning vaccine safety system involving all stakeholders
		Provide population-based HPV vaccination for all girls aged 9-26 years
		Conduct mentoring and supportive supervisions of health care workers

7.2.6.2 Secondary Prevention

Secondary prevention deals with women who are already infected with HPV, and should be screened to determine whether they have early, easily treatable precancerous cervical lesions. This preventive approach involves screening and treatment of women for pre-cancerous cervical lesions if they have developed, and before the lesions progress to cancer. Early detection and treatment of pre-cancerous lesions are known to greatly reduce the burden of CC development. There are three different types of tests currently available for screening of pre-cancerous cervical lesions: Cytology-based screening or Conventional (Pap)

and liquid-based cytology (LBC), Visual inspection with Acetic Acid (VIA), and HPV testing for high-risk HPV types. Cervical cancer screening is recommended for all women aged 30–49 years every 5 years. Organised screening is a more cost-effective and acceptable approach than opportunistic (i.e., taking advantage of a woman's visit to the health facility for another purpose) screening, making better use of available resources and ensuring that the greatest number of women will benefit.

7.2.6.2.1 Strategy 1: Population-based cervical cancer screening for all women aged 25/30-49 using VIA

Early detection of pre-cancerous cervical lesions through screening is the most effective method of preventing CC development.

Objective 1: To increase the uptake of VIA test to detect pre-cancerous cervical lesions among women aged 30-49 years.

Table 7.7: Population-based cervical cancer screening for all women aged 25/30-49 years using VIA

Strategy	Objectives	Interventions/Activities
Strategy 6: Population-based cervical cancer screening for all women aged 25/30-49 using VIA	**Objective 1:** To increase the uptake of VIA test to detect pre-cancerous cervical lesions among women aged 30-49 years	Develop community awareness on the importance and availability of VIA
		Engage partners, neighbours, religious and community leaders, and significant others to improve knowledge and perceptions of cervical cancer screening.
		Reinforce human-resource capacity to conduct VIA
		Equip health facilities with VIA supplies
		Make VIA services available at all health facilities from health centre level
		Integrate health education on cervical cancer screening in the health facilities
		Provide cervical cancer screening using VIA
		Conduct mentoring and supportive supervisions
		Facilitate referral of women who need further investigation

7.2.6.2.2 Strategy 2: Strengthen facilities providing early detection and treatment of pre-cancerous cervical lesions

In order to detect and treat pre-cancerous cervical lesions at their earlier stage of development, appropriate CC screening services should be available and accessible to users.

Objective 1: To strengthen cervical cancer screening and treatment services.

Objective 2: To increase the accessibility of cervical cancer screening and treatment services to users

Table 7.8: Strengthen facilities providing early detection and treatment of pre-cancerous cervical lesions

Strategy	Objectives	Interventions/Activities
Strategy 7: Strengthen facilities providing early detection and treatment of pre-cancerous cervical lesions	**Objective 1:** To strengthen cervical cancer screening and treatment services	Ensure the availability of supplies, materials and technical support for cervical cancer screening programmes.
		Training of Midwives, Nurses and Doctors on cervical cancer screening and treatment
		Equip health facilities with VIA and cryotherapy machines, accessories and supplies
		Conduct community awareness on the availability and importance of VIA and cryotherapy
		Link cervical cancer screening to other reproductive health services such as family planning, HIV care and treatment and STIs treatment.
	Objective 2: To increase the accessibility of cervical cancer screening and treatment services to users	Increase the accessibility of cervical cancer screening and treatment centres
		Ensure the availability of supplies, materials, and technical support for cervical cancer screening services and treatment
		Ensure the availability of an adequate, effective, sustainable health workforce
		Develop referral system for LEEP and more-advanced treatment

7.2.6.3 Tertiary Care

The purpose of tertiary care is to cure or considerably prolong the life of patients who have already developed CC, and to ensure the best possible quality of life for cancer survivors. The components of tertiary care include surgery, radiotherapy, chemotherapy, and palliative care. Palliative care improves the quality of life of patients and families who face life-threatening illness, by providing pain- and symptom-management, spiritual and psychosocial support from diagnosis to the end of life and bereavement. Palliative care should be strategically linked to CC prevention, early detection, and treatment services.

7.2.6.3.1 Strategy 1: Improve and increase access to facilities providing effective management of invasive cervical cancer and palliative care

The most effective and efficient treatment of invasive CC is when it is linked to early detection programmes and follows evidence-based quality of care using a multidisciplinary approach. Effective palliative care services should be integrated into the existing health care system at all levels of care, including home-based care. These should be adapted to the specific cultural, social, and economic setting.

Objective 1: To achieve efficient and adequate treatment facilities for patients diagnosed as having invasive cervical cancer.

Objective 2: To establish palliative care service and integrate it into the existing health care system

Table 7.9: Improving and increasing access to facilities providing effective management of invasive cervical cancer and palliative care

Strategy	Objectives	Interventions/Activities
Strategy 8: Improve and increase access to facilities providing effective management of invasive cervical cancer as well as palliative care	**Objective 1:** To achieve efficient and adequate treatment facilities for patients diagnosed as having invasive cervical cancer	Open new sites/facilities for the treatment of cervical cancer patients
		Train different levels of health professionals for cervical cancer treatment
		Expand chemotherapy, hormonal therapy, radiotherapy and surgical treatment services to regional teaching hospitals
		Ensure availability of cervical cancer treatment equipment, medicine and supplies
		Strengthen inventory of required equipment, medicine and supplies with scientific quantifications and forecast
		Provide invasive cervical cancer care for patients diagnosed and on treatment
	Objective 2: To establish palliative care service and integrate it into existing health care system	Conduct awareness campaigns on palliative care that target policy-makers, the public, media, health care personnel and regulators
		Build both institutional and community capacity on palliative care
		Mobilize communities through awareness-raising, training and recognition
		Support health professionals to incorporate palliative care skills into their daily services
		Build capacity of the health care providers and care givers on palliative care
		Strengthen community and home-based palliative care services including establishment of nutritional support services for cancer patients
		Establish social support services for cervical cancer patients and provide palliative care
		Improve rehabilitation services

7.2.6.4 Combined Strategies

7.2.6.4.1 HPV-FASTER Approach

HPV vaccination and CC screening are complementary preventive options often implemented as separate and non-coordinated public health programmes. A combined strategy of these two preventive approaches aims to address this disconnect by combining both strategies to accelerate the reduction of CC incidence and mortality and make the programmes both cost-effective and sustainable.

In this regard, there is a concept called HPV-FASTER protocol which deals with offering HPV vaccination to women in a broad age range of 9 to 45 years irrespective of HPV infection status. Women of any age above 25/30 years would, in addition to the vaccination, be screened using a validated HPV test as part of their initial visit; women who test HPV-positive would be offered triage and follow-up diagnostic tests and treatment in accordance with recommended guidelines.

Results from two Phase III trials comparing HPV vaccination against placebo among adult women aged up to 45 years and 55 years for 4vHPV and 2vHPV vaccines, respectively, demonstrating high protection against HPV type specific infections and persistent infections. The excellent and consistent results of the HPV screening trials provide the basis for the HPV-FASTER proposal. The recognition of indications to vaccinate adult women in Europe and the US which do not include an upper age limit, favour the exploration of combined protocols of screening and vaccination and broadening the vaccine indications in developed and developing countries (Faster 2018:1-5).

The best data available from population studies in adult women that would resemble the HPV-FASTER proposal are the results of the vaccination programme in Australia that included women up to 26 years of age with an average vaccination coverage close to 65%, followed by a switching of the

screening programme to an HPV based primary screening alternative (Faster 2018:1-5).

The HPV-FASTER protocol is a one-visit approach for CC preventive campaigns. A major benefit of the HPV-FASTER protocols is that the predicted subsequent needs for screening may be dramatically reduced to one/two lifetime visits, thus increasing sustainability and compliance as well as alleviating of the burden and workload at the health centres (Faster 2018:1-5).

Even though HPV vaccines lack a therapeutic effect against the development of cervical lesions in women who are already HPV-positive, no safety concerns were reported in those who received three doses of HPV vaccines or in women inadvertently vaccinated in the first months of pregnancy (Faster 2018:1-5). Figure 7.3 provides a schematic representation of the HPV-FASTER concept.

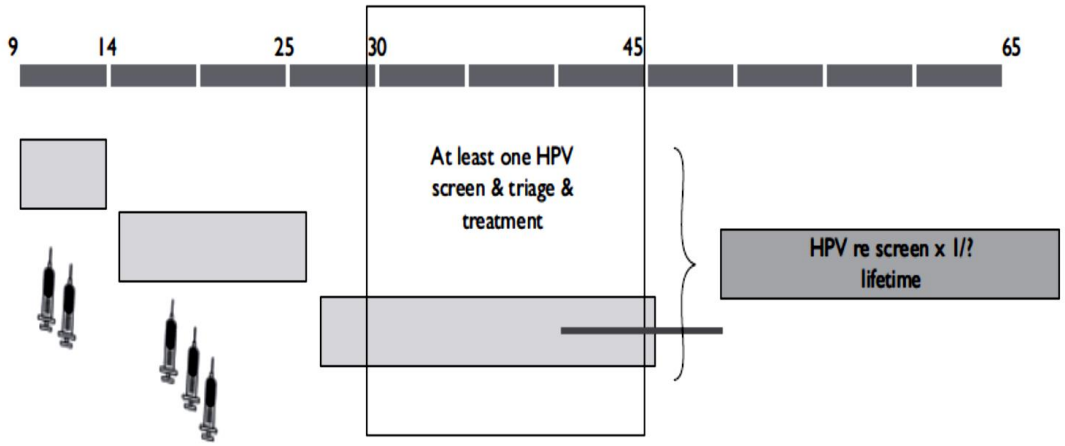

Figure 7.3: A schematic representation of the HPV-FASTER concept. Source HPV-FASTER 2018:2

7.2.6.4.2 Modified HPV-FASTER Approach

As stated in HPV vaccination (CDC 2021), HPV vaccines can be given starting at age 9 through 45 years who are not already vaccinated. Despite the vaccination trials in adult women confirmed the safety of the vaccination (Faster 2018:1-5), it is not recommended in age 27 through 45 years as it provides less

benefit, because more people in this age range have already been exposed to HPV infection (CDC 2021). CDC (2021) recommends HPV vaccination at age 11-12 years, and teens and young adults through age 26 years who did not already start or finish the vaccine.

As per the researcher's point of view, the HPV-FASTER protocol can be applied in Ethiopia with some modifications (Since it is not currently feasible to make use of it all in all) integrated with the national approach in the country that is 'Screen and treat'. This means that the already started HPV vaccination in the country for girls 14 years of age should be upgraded to 9 to 26 years of age irrespective of their HPV status rather than providing it for girls and women 9 to 45 years of age according to HPV-FASTER protocol. The reason here is that the HPV vaccine works more effectively with women up to 26 years, and provides less benefit to women above this age limit as it is already mentioned above. HPV vaccine is most effective when administered in adolescence, before exposure to the virus through sexual activity. There is, however, value in vaccinating older teenagers and young adults, at least up to the age of 26 because it can protect against a new infection or re-infection and block transmission to a new partner (Meites, Szilagyi & Chesson 2019:698–702).

In the USA, HPV vaccination is now recommended for all men and women up to the age of 26 (Baker et al 2020:1-34). There is also some evidence supporting the vaccination of all women up to the age of 30 (or older) at the same time as a cervical screen (Baker, Kelly & Medeiros 2020:1-34). On the other hand, women of any age above 25/30 years would be screened using VIA rather than HPV DNA test (since it is not currently affordable in the country), and women who test VIA-positive would be offered a treatment in the 'Single visit' approach like cryotherapy or thermocoagulation or LEEP service based on the requirement and availability of the service in the facility. Figure 7.4 a modified schematic representation of the HPV-FASTER concept.

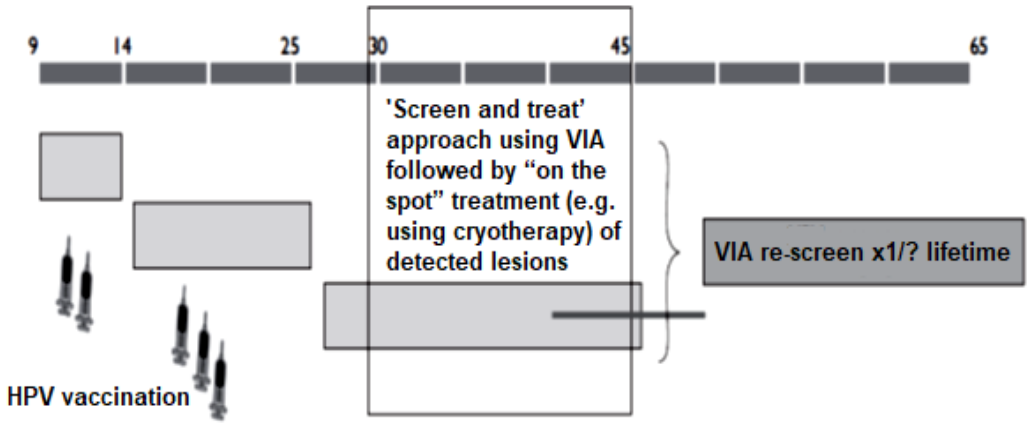

Figure 7.4: Modified schematic representation of the HPV-FASTER concept

7.2.6.4.3 Strategy 1: Combined strategy of HPV vaccination and cervical cancer screening

HPV vaccination and CC screening are often implemented as separate and non-coordinated public health programmes. A combined strategy of these two preventive approaches aims to address this disconnect by combining both strategies with the ultimate purpose of accelerating the reduction of CC incidence and mortality and making the programmes both cost-effective and sustainable. A comprehensive approach which uses vaccination in partnership with screening will maximise effectiveness. This combined strategy screening considers CC screening for women aged 30 and older once or twice in their lifetimes, in conjunction with vaccination of adolescent girls and women who are not yet sexually active.

Objective 1: To integrate HPV vaccination and cervical cancer screening services.

Table 7.10: Combined strategies of both HPV vaccination and cervical cancer screening

Strategy	Objectives	Interventions/Activities
Strategy 9: Combined strategies of HPV vaccination and cervical cancer screening	**Objective 1:** To integrate HPV vaccination and cervical cancer screening services	Develop community awareness on the importance of HPV vaccination and cervical cancer screening
		Ensure the availability of supplies, materials and technical support for both HPV vaccination and cervical cancer screening programmes.
		Increase the number and accessibility of both HPV vaccination and cervical cancer screening centres
		Training of Midwives, Nurses and Doctors on both HPV vaccination and cervical cancer screening
		Advocacy of integrated HPV vaccination and cervical cancer screening services
		Provide integrated services: HPV vaccination to teens and young adults through age 26 years irrespective of their HPV status, and cervical cancer screening to women aged 25/30 years once or twice in the lifetimes
		Conduct mentoring and supportive supervisions
		Develop referral system for more-advanced service

7.2.6.4.4 Strategy 2: Networking, partnership and collaboration with all stakeholders

Success will depend on building and strengthening partnerships and collaboration with community, national, regional and global stakeholders as part of a coordinated effort to improve access to high-quality and affordable HPV vaccination and CC screening services

Objective 1: To develop network, partnership and collaboration with local and international partners

Table 7.11: Establishing network, partnership and collaboration with local and international partners

Strategy	Objectives	Interventions/Activities
Strategy 10: Networking, partnership and collaboration with all stakeholders	**Objective 1:** To develop networks, partnerships and collaboration with local and international partners.	Establish networks with organizations working on HPV vaccination and cervical cancer screening
		Strengthen partnership and collaboration with local and international partners
		Strengthen community level partnership through engagement using existing structures
		Map all stakeholders working on palliative care and engage them
		Strengthen collaboration with Gavi alliance
		Improve intersectoral collaboration

7.2.6.4.5 Strategy 3: Reinforce research capacity and establish collaboration.

The application of any health-related interventions in the community must be made based on the research findings. Evidence-based best practices are crucial in the preventing and controlling of HPV infection and CC

Objective 1: To scale up research done on HPV and cervical cancer

Objective 2: To strengthen local capacity to conduct implementation research.

Table 7.12: Reinforcing research capacity and establishing collaboration

Strategy	Objectives	Interventions/Activities
Strategy 11: Reinforce research capacity and establish collaboration	**Objective 1:** To scale up research on HPV and cervical cancer	Develop partnerships and collaboration with local and international partners
		Encourage researchers to conduct more research on the prevention and control of HPV and cervical cancer
		Improve research capacity on this thematic area
		Conduct more research on screening and treatment of HPV and cervical cancers
		Provide incentives for those researchers who are conducting research on this thematic area
	Objective 2: To strengthen local capacity to conduct implementation research	Encourage researchers to conduct more research on implementation research
		Strengthen collaboration with local and international partners in executing research done
		Provide incentives for those researchers who are conducting research on this thematic area
		Reinforce all stakeholders to implement evidence-based research findings

7.2.6.4.6 Strategy 4: Monitoring and evaluation of cervical cancer prevention and control activities

Monitoring and evaluation of CC prevention and control activities is very important to look at the effectiveness of the strategy being undertaken. Facility-level data recording should be used to monitor and evaluate the specific services provided at the facility.

Objective 1: To establish monitoring and evaluation of cervical cancer prevention and control interventions.

Table 7.13: Monitoring and evaluation of cervical cancer prevention and control activities

Strategy	Objectives	Interventions/Activities
Strategy 12: Monitoring and evaluation of cervical cancer control activities	**Objective 1:** To establish monitoring and evaluation of cervical cancer prevention and control interventions	Carry out a baseline cervical cancer situational analysis
		Develop monitoring and evaluation guidelines and tools
		Develop a monitoring and evaluation framework for cervical cancer control
		Conduct a mid-cycle (year 2-3) assessment of plan implementation
		Evaluate the findings against the baseline assessment
		Evaluate the findings against the developed guidelines and tools
		Evaluate the findings against the developed framework

7.2.7 Implementation of the Strategies

Executing developed strategies is one of the steps of strategies development according to Thompson et al (2009). This will be accomplished by concerned bodies after it is approved.

Table 7.14: Implementation of the strategies

Strategies	Objectives	Interventions	Monitoring Indicators	Responsible Bodies	Time Frame in Years						
					1	2	3	4	5	6	7
Strategy 1 Develop public awareness of HPV infection	**Objective 1:** To establish public awareness of HPV infection	• Develop TV and radio programs about HPV infection • Brochures to enhance public awareness on HPV infection and its consequences • Transmit message through clubs and other existing community level structures about HPV infection and its consequences • Organize community mobilization events including workshops with key community and religious leaders • Organise and deliver community-based health education, using health extension workers on HPV infection	• Number of community mobilization sessions • Number of awareness creation sessions conducted per year • Number of health education sessions conducted • Number of messages developed and disseminated	Federal Ministry of Health (FMoH), Oromia Health Bureau (OHB), other stakeholders							
	Objective 2: To raise knowledge in the community on the prevention of HPV infection	• Train health workers and media on HPV infection prevention and advocacy • Provide health education to the community on prevention of HPV infection • Produce HPV prevention awareness messages and channel them through health extension workers (HEW)									
Strategy 2 Promote community awareness of the risk factors of cervical cancer	**Objective 1:** To raise awareness of the community on risk factors of cervical cancer	• Utilise mass media to disseminate information on risk factors cervical cancer development • Organise community awareness campaigns and education programmes • Engage partners, neighbours, religious leaders, community leaders and significant others to improve knowledge on risk factors of cervical cancer • Conduct community-based health education, using health extension workers to improve community awareness and knowledge of cervical cancer risk factors	• Number of awareness creation sessions conducted per year • Number of health education sessions conducted • Number of community awareness campaigns organised • Number of people educated on risk factors of cervical cancer • Number of people with the correct knowledge of risk factors of cervical cancer	FMoH, OHB, other stakeholders							
	Objective 2: To notify the community of the preventive measures to be taken to avoid cervical cancer development	• Conduct community-based health education, using health extension workers on avoidance of identified cervical cancer risk factors like exposure to sexual transmitted infections • Utilise mass media to disseminate information on avoidance of risk factors of cervical cancer • Transmit message through clubs and other existing community level structures about risk factors of cervical cancer • Encourage young girls to delay early sexual debut before age 20 • Develop and utilise health message targeting the cultural and traditional practices being conducted in the community that may intensify risk factors of cervical cancer like having multiple sexual partners									
Strategy 3 Introduce HPV vaccination into national immunisation programmes	**Objective 1:** To incorporate HPV vaccination into routine	• Reinforce and sustain strong leadership, management and coordination of immunization programmes at all levels • Build and sustain strong political and financial commitment for HPV immunization	• Number of health professionals trained • Percent of facilities with uninterrupted supply of HPV vaccination and equipment	FMoH, OHB, other stakeholders							

	immunisation programmes	• Incorporate HPV vaccination into routine immunisation programs • Ensure the availability of an adequate, effective, sustainable health workforce • Secure high-quality supply chains for HPV vaccines and related commodities and effective vaccine management • Establish and maintain a well-functioning vaccine safety system involving all stakeholders • Provide training to health care workers about HPV vaccination • Strengthen supply chains to ensure that HPV vaccines are always available in the right quantity and form at the right time, in the right place and stored and distributed under the right conditions • Promote integration with other supply chains for more effective delivery of HPV vaccine • Strengthen collaboration with Gavi alliance	• Number of girls get vaccinated for HPV								
Strategy 4 Switch to Nonavalent (Gardasil 9) HPV vaccination	**Objective 1:** To shift from 4vHPV vaccination to 9vHPV in Ethiopia	• Provide training to health care workers about 9vHPV vaccine • Secure high-quality supply chains for HPV vaccines and related commodities and effective vaccine management • Establish and maintain a well-functioning vaccine safety system involving all stakeholders • Strengthen collaboration with Gavi alliance • Build and sustain strong political and financial commitment to switch to 9vHPV HPV vaccination • Promote public awareness on the advantages of switching to 9vHPV HPV vaccination • Switch to Nonavalent (9vHPV) HPV vaccination • Conduct mentoring and supportive supervisions	• Number of health professionals trained • Percent of facilities with uninterrupted supply of 9vHPV vaccination and equipment • Number of girls get vaccinated for 9vHPV • Number of public awareness creation sessions conducted	FMoH, OHB, other stakeholders							
Strategy 5 Population-based HPV vaccination for all girls aged 9-26 years	**Objective 1:** To organise and deliver population-based HPV vaccination for all girls aged 9-26 years	• Develop community awareness on the importance and availability HPV vaccination for girls and young women through different media • Reinforce human-resource capacity • Provide training to health care workers • Secure high-quality supply chains for HPV vaccines and related commodities and effective vaccine management • Establish and maintain a well-functioning vaccine safety system involving all stakeholders • Provide population-based HPV vaccination for all girls aged 9-26 years • Conduct mentoring and supportive supervisions	• Number of awareness creation sessions conducted • Number of health professionals trained • Percent of facilities with uninterrupted supply of HPV vaccination and equipment • Number of girls get vaccinated for HPV	FMoH, OHB, other stakeholders							
Strategy 6 Population-based cervical cancer screening for all women aged 25/30-49 using VIA	**Objective 1:** To increase the uptake of VIA test to detect pre-cancerous cervical lesions among women aged 30-49 years	• Develop community awareness on the importance and availability of VIA • Engage partners, neighbours, religious and community leaders, and significant others to improve knowledge and perceptions of cervical cancer screening • Reinforce human-resource capacity to conduct VIA • Equip health facilities with VIA supplies • Make VIA services available at all health facilities from health centre level • Integrate health education on cervical cancer screening in the health facilities • Provide cervical cancer screening using VIA • Conduct mentoring and supportive supervisions	• Number of awareness creation sessions conducted • Number of health professionals trained on VIV • Percent of facilities with uninterrupted supply of medicine and equipment • Number of women underwent cervical cancer screening • Percent of referred cases for advanced investigation and care	FMoH, OHB, other stakeholders							

		• Facilitate referral of women who need further investigation										
Strategy 7 Strengthen facilities providing early detection and treatment of precancerous cervical lesions	**Objective 1:** To strengthen cervical cancer screening and treatment services	• Ensure the availability of supplies, materials and technical support for cervical cancer screening programmes • Training of Midwives, Nurses and Doctors on cervical cancer screening and treatment • Equip health facilities with VIA and cryotherapy machines, accessories and supplies • Conduct community awareness on the availability and importance of VIA and cryotherapy • Link cervical cancer screening to other reproductive health services such as family planning, HIV care and treatment and STIs treatment	• Number of facilities established • Number of trained professionals • Number of awareness creation sessions conducted per year • Percent of health facilities with uninterrupted supply of medicine and equipment • Percent of referred cases for advanced care and treatment	FMoH, OHB, other stakeholders								
	Objective 2: To increase the accessibility of cervical cancer screening and treatment service to users	• Increase the number and accessibility of cervical cancer screening and treatment centres • Ensure the availability of supplies, materials, and technical support for cervical cancer screening treatment services • Ensure the availability of an adequate, effective, sustainable health workforce • Develop referral system for LEEP and more-advanced treatment										
Strategy 8 Improve and increase access to facilities providing effective management of invasive cervical cancer and palliative care	**Objective 1:** To achieve efficient and adequate treatment facilities for patients diagnosed as having invasive cervical cancer	• Open new sites/facilities for the treatment of cervical cancer patients • Train different levels of health professionals for cervical cancer treatment • Expand chemotherapy, hormonal therapy, radiotherapy and surgical treatment services to regional teaching hospitals • Ensure availability of cervical cancer treatment equipment, medicine and supplies • Strengthen inventory of required equipment, medicine and supplies with scientific quantifications and forecast • Provide invasive cervical cancer care for patients diagnosed and on treatment	• Number of facilities established • Number of trained professionals • Number of active community and home-based palliative care centres • Number of community mobilization sessions • Number of palliative care centres supported • Number of awareness creation sessions conducted per year • Percent of health workers and care givers with the correct knowledge on basic principles of palliative care • Number of social support services provided • Number of cancer rehabilitation centres offering uninterrupted services • Percent of health facilities with uninterrupted supply of medicine and equipment	FMoH, OHB, other stakeholders								
	Objective 2: To establish palliative care service and integrate it into the existing health care system	• Conduct awareness campaigns on palliative care that target policy-makers, the public, media, health care personnel and regulators • Build both institutional and community capacity on palliative care • Mobilize communities through awareness-raising, training and recognition • Support health professionals to incorporate palliative care skills into their daily services • Build capacity of the health care providers and care givers on palliative care • Strengthen community- and home-based palliative care services including establishment of nutritional support services for cancer patients • Establish social support services for cervical cancer patients and provide palliative care services • Improve rehabilitation services										
Strategy 9 Combine strategies of HPV vaccination and cervical cancer screening	**Objective 1:** To integrate HPV vaccination and cervical cancer screening services	• Develop community awareness on the importance of HPV vaccination and cervical cancer screening • Ensure the availability of supplies, materials and technical support for both HPV vaccination and cervical cancer screening programmes • Increase the number and accessibility of both HPV vaccination and cervical cancer screening centres	• Number of community mobilization sessions • Number of health workers trained • Number of centres stablished • Number of awareness creation sessions conducted per year • Number of girls get vaccinated for HPV	FMoH, OHB, other stakeholders								

		• Training of Midwives, Nurses and Doctors on both HPV vaccination and cervical cancer screening • Advocacy of integrated HPV vaccination and cervical cancer screening services • Provide integrated services: HPV vaccination to teens and young adults through age 26 years irrespective of their HPV status, and cervical cancer screening to women aged 25/30 years once or twice in the lifetimes • Conduct mentoring and supportive supervisions • Develop referral system for more-advanced service	• Number of women underwent cervical cancer screening • Percent of health facilities with uninterrupted supply of medicine and equipment									
Strategy 10 Networking, partnership and collaboration with all stakeholders	**Objective 1:** To develop network, partnership and collaboration with local and international partners	• Establish networks with organizations working on HPV vaccination and cervical cancer screening • Strengthen partnership and collaboration with local and international partners • Strengthen community level partnership through engagement using existing structures • Map all stakeholders working on palliative care and engage them • Strengthen collaboration with Gavi alliance • Improve intersectoral collaboration	• Number of networks stablished • Number of functional networks • Number of intersectoral collaborations established	FMoH, OHB, other stakeholders								
Strategy 11 Reinforce research capacity and establish collaboration	**Objective 1:** To scale up research done on HPV and cervical cancer	• Develop partnerships and collaboration with local and international partners • Encourage researchers to conduct more researches on the prevention and control of HPV and cervical cancer • Improve research capacity on this thematic area • Conduct more researches on screening and treatment of HPV and cervical cancers • Provide incentives for those researchers who are conducting research on this thematic area	• Number of research papers published • Number of functional networks established	FMoH, OHB, other stakeholders								
	Objective 2: To strengthen local capacity to conduct implementation research	• Encourage researchers to conduct more researches on implementation research • Strengthen collaboration with local and international partners in executing research done • Provide incentives for those researchers who are conducting research on this thematic area • Reinforce all stakeholders to implement evidence-based research findings										
Strategy 12 Monitoring and evaluation of cervical cancer prevention and control activities	**Objective 1:** To establish monitoring and evaluation of cervical cancer prevention and control interventions	• Carry out a baseline cervical cancer situational analysis • Develop monitoring and evaluation guidelines and tools • Develop a monitoring and evaluation framework for cervical cancer control • Conduct a mid-cycle (year 2-3) assessment of plan implementation • Evaluate the findings against the baseline assessment • Evaluate the findings against the developed guidelines and tools • Evaluate the findings against the developed framework	• Baseline report • Results of baseline assessment used for planning • Monitoring and evaluation guidelines developed and used at all levels of health care system • Monitoring and Evaluation framework for cervical cancer developed and disseminated • Quarterly reports on cervical cancer available	FMoH, OHB, other stakeholders								

7.2.8 Monitoring and Evaluation

Monitoring is the continuous assessment of goods, services and performance of programmes through input, process, and outcome data collected regularly from supportive supervision, regular reports, routine record keeping and surveillance (Wroblewski & Lipinsky 2018:22-27). Monitoring is a continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing development intervention with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds (OECD 2002:10). Monitoring is a collection and analysis of measurements of the key elements of a programme or project performance over time to examine progress.

Evaluation is the periodic assessment of achievements of programmes through information generated from ongoing monitoring and performance indicators. It helps to identify the cause of under-achievement and make timely corrections (Engelhardt 2018:128-140). Evaluation is also the systematic and objective assessment of an on-going or completed project or programme, its design, implementation, and results. The aim is to determine the relevance and fulfilment of objectives, development efficiency, effectiveness, impact and sustainability (OECD 2002:10). Evaluation is a rigorous, scientifically based collection of information about programme activities, characteristics, and outcomes to determine the merit/worth of a specific programme.

Monitoring and evaluation are very important to look at how effective the strategy is being undertaken. Facility-level data recording should be used to monitor and evaluate the specific services provided at the facility. In the context of CC prevention and control programme it focuses on introducing the tools and formats that are important in follow up of the activities. The data recorded and reported using these tools is used for decision-making at different levels of Ministry of Health structure, which helps, for quality improvement of the activities in the prevention and control of HPV and CC. Information gathered from the registers will be used to calculate monthly statistics based on the indicators. The

health facility in-charge of using the trained service providers will be responsible for compiling data on a monthly basis. The data compiled and reported to the Woreda/district then to region and finally to Federal Ministry of health will help for further analysis that will be used in planning, monitoring, and evaluation at different level.

7.3 VALIDATION OF THE STRATEGIES

Strategy validation is the process through which the strategists know the extent to which a strategy is able to achieve its objectives. It helps researchers to compare and contrast objective realities (Higgins, Arnold, Weise, Pellicano & Trollor 2021:2356-2369).

7.3.1 Purpose of the Validation

The purpose of validating the strategies was to authenticate or ensure that the strategies were of good, acceptable, achievable and attainable quality and nature.

7.3.2 Evaluation Criterion

A criterion is a standard or principle used in evaluation as the basis for evaluative judgment. The purpose of evaluation criteria is to support consistent, high-quality evaluation within a common framework. Criteria for evaluating the interim strategies were distributed to the experts to evaluate the draft strategies. Accordingly, the criteria consist of Clarity and presentation, Specificity, Relevance, Effectiveness, Validity, Reliability and Sustainability (OECD 2021:36)

Table 7.15: Evaluation criteria, adapted from OECD (2021)

Criteria	Strongly disagree	Disagree	Agree	Strongly agree
Clarity and presentation Are the strategies precise, simple and easily understandable?				
Specificity Are the strategies specific enough and focused on the prevention and control of HPV and cervical cancer?				
Relevance Are the strategies appropriate for the prevention and control of HPV and cervical cancer				
Effectiveness Are the strategies developed in a way to achieve their objectives?				
Validity Are the strategies valid to measure what they are supposed to measure.				
Reliability Are the strategies consistent enough to measure the attribute they are designed to measure				
Sustainability Will the benefits of the strategies last?				

7.3.3 The Process of Validation

As already mentioned in section 7.2.6 (Methodology), the e-Delphi method was used in the process of the development of these strategies. A three-stage e-Delphi method consisting of: stage one - preparation, stage two - identification of convergence of experts' responses, and stage three - reaching consensus was applied in the validation process of the strategies. Figure 7.3 The flow of a three-stage e-Delphi approach).

In this an iterative multistage process designed to combine opinion into group consensus, the initial questionnaire collected qualitative comments, which were analysed and summarised and fed back to the participants in a quantitative form through a second questionnaire. After statistical analysis regarding group collective opinion, the results from the second questionnaire helped formulate the third quantitative questionnaire. This process was ongoing until a consensus was obtained or the law of diminishing returns set in. In other words, responses were summarised between rounds and communicated back to the experts through a process of controlled feedback. This process was repeated until a consensus was reached. The mean score of the panellists' aggregate score in each strategy was used as a final score or value for that particular strategy.

7.3.3.1 Preparation

Review of available evidences regarding the prevention of HPV infection and CC control were made prior to data collection tool development. Then open-ended qualitative questions were formulated to collect the general views of experts on this area.

7.3.3.2 Expert Panel Development

Ten health professional expert panellists (consisted of Doctors, Radiologists, Nurses working in oncology clinic, University lecturers and other Health experts) from different parts of the country, who had collective experience in developing national guidelines, strategies and training packages were purposefully recruited. After explaining the objective of the study, experts were invited by e-mail to join the panel.

7.3.3.3 e-Delphi Round One: Scoping

In the first round, the researcher dispatched the open-ended qualitative questions to the experts via their email. The data collected from this initial round were analysed using content analysis technique by grouping similar items

together. The researcher then formulated draft strategies based on findings from the quantitative and qualitative phases of the current study, incorporating a summary of the round one panel and relevant information from the literature review.

7.3.3.4 e-Delphi Round Two

In round two, the draft strategies were sent to the panellists with a separate checklist containing evaluation criteria. In this particular round, participants were asked to respond to the given options regarding the draft strategies. The evaluation checklist sought to identify the strengths, weaknesses and missing items in the draft strategies. Besides responding to the given options, the experts provided their comments, inputs and thoughts regarding the strategies on the space provided for this purpose on the attached checklist. Statistical analysis was done using the collected round two quantitative data to identify the convergence of experts' responses, and to provide controlled feedback. The summary of round two, which constituted the result of the statistical analysis and the constructive comments and inputs from panellists helped further strengthen the development of the draft strategies.

7.3.3.5 e-Delphi Round Three

In round three, the draft strategies, incorporated the inputs from round two were communicated back to the experts for the third-round panel. A four scale Likert scaling technique with scores (1 for Strongly disagree, 2 for disagree, 3 for agree and 4 for strongly agree) were applied to give scores to each strategy using the given criteria. Data collected from the third round were analysed by using frequency and percentage to identify the convergence of experts' responses. The e-Delphi was terminated after this round, the findings were summarised and the final report was prepared.

7.3.3.6 Analysis and Final Report

Communicating back the summary reports of the group's responses, a process called controlled feedback repeated for three rounds until consensus was reached for each strategy. The analysis of the results, finalising the e-Delphi summary report, and preparing a consensus statement were made. The consensus statement was distributed among panellists for final comments, and their responses were collected. Finally, a consensus judgement was applied. Table 7.14 Evaluation of each of the strategies.

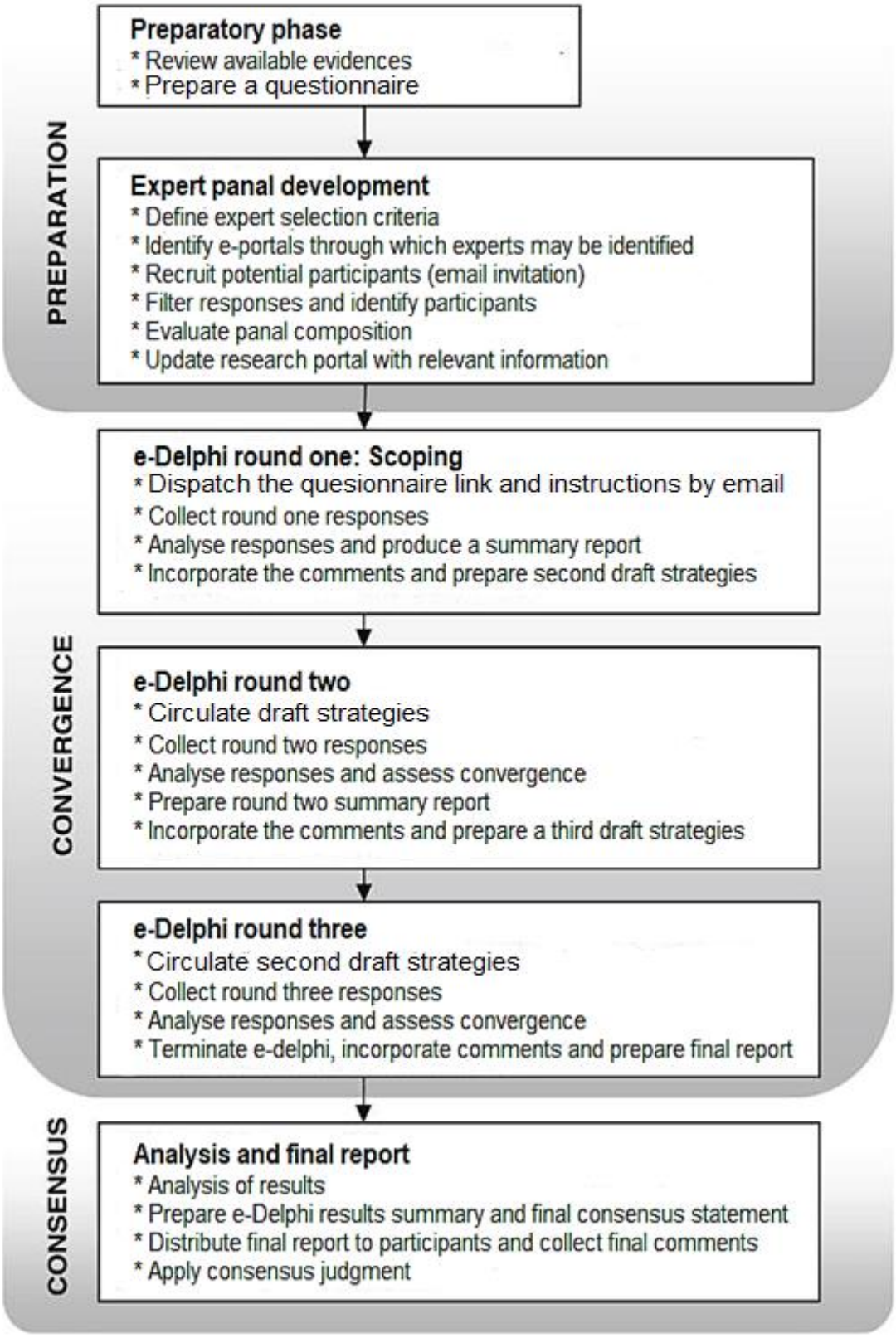

Figure 7.5: A three-stage e-Delphi approach. Adapted and modified from Day and Bobeva 2005

7.3.3.7 Description of the Final Results

The maximum total score for each strategy was 28, since there were 7 criteria each with a possible maximum score of 4. Likewise, because there were 10 evaluators, the possible maximum aggregate value of each strategy was 280. The researcher considered that a strategy that scored 22.4 points and more out of 28 was regarded as acceptable strategy in the prevention and control of HPV and CC, as it represented an 80% acceptance level. Tack et al. (2017:434–442) ranged the consensus from 75% to 80% agreement. None of the strategies evaluated scored less than 22.4 points.

Table 7.16: Evaluation of the strategies with their scores and the mean scores with percentile

Strategy	Evaluator/Expert panellist										Total	Mean Scores and Percentage
	1	2	3	4	5	6	7	8	9	10		
	Scores and Percentile											
1	27	28	26	26	28	27	27	26	28	28	271	27.1 (97%)
2	26	24	24	22	25	24	28	27	26	25	251	25.1 (90%)
3	28	28	27	26	26	28	28	26	27	27	271	27.1 (97%)
4	28	28	27	28	28	27	27	28	28	28	277	27.7 (99%)
5	28	28	28	28	28	28	28	28	28	28	280	28 (100%)
6	28	28	27	26	28	28	27	27	28	28	275	27.5 (98%)
7	26	27	25	28	26	24	26	28	24	26	260	26 (93%)
8	27	26	28	27	27	26	28	27	26	28	270	27 (96%)
9	26	28	28	27	27	26	28	28	27	27	272	27.2 (97%)
10	27	26	28	26	26	28	27	27	26	26	267	26.7 (95%)
11	25	23	26	25	24	26	28	26	26	28	257	25.7 (92%)
12	24	26	25	24	27	28	24	26	26	25	255	25.5 (91%)

7.4 SUMMARY

This chapter discussed and presented strategies to prevent and control HPV infection and its sequela CC. The approaches to developing the strategies and their components have been clearly described. The researcher in this phase of the study applied five steps to design and develop strategies according to the steps of strategy development (Thompson et al 2009).

The strategies have vision, mission and goal, and objectives have also been set. Crafting of strategies and development of implementation framework and, finally, the strategic plan of monitoring and evaluation activities of the strategies have been constructed. A three-stage e-Delphi method was applied in the development process and validation activities of the strategies. In total, 12 well-designed strategies have been formulated as a final strategy development. These strategies can be used by policy-makers, health service managers, health planners, professionals, and by researchers to strengthen the effort of CC prevention and control activities throughout the country.

The next chapter, Chapter 8 concludes the study, describes summary and interpretation of the research findings, and makes recommendations for practice and further research. Moreover, contributions and limitations and final concluding remarks of the study are provided.

CHAPTER 8

CONCLUSIONS AND RECOMMENDATIONS OF THE STUDY

8.1 INTRODUCTION

In the previous chapter, the development of strategies to prevent and control HPV infection and its sequela CC were discussed. The approaches to developing the strategies and their components have been clearly described. Five steps of strategy development were applied to design and develop strategies. A three-stage e-Delphi method was employed in the formulation process and validation activities of the strategies. A total of 12 well-designed strategies have been formulated as a final strategy development.

This final chapter of the current study presented the research design and method applied in the study, summary and interpretation of the research findings, conclusion and recommendations, contributions of the study, limitations and concluding remarks. In this last chapter, the researcher developed an overall conclusion, explanation or understanding through an integration of the inferences obtained from the qualitative and quantitative strands of a mixed method study. The chapter pinpoints the limitations of the study and the recommendations that emanate from the study.

8.2 RESEARCH DESIGN AND METHODS

The researcher in this study specifically employed the explanatory sequential mixed methods research design which included an initial quantitative study and a follow-up qualitative interview with a priority on the quantitative phase. The qualitative results help explain the initial study results and build a better understanding of the significant and non-significant quantitative findings. Cross-sectional descriptive study design for the quantitative study part and exploratory descriptive and contextual qualitative research design for the qualitative study part were used. Data from 383 study participants were collected using a pre-

tested structured questionnaire in the quantitative phase of the study. Three rounds of FGDs were conducted in the qualitative phase of the study to collect data from the participants. Systematic sampling technique for the quantitative phase and purposive sampling technique for the qualitative phase of the study were employed. Descriptive statistical analysis for quantitative and thematic analysis which was guided by HBM for qualitative data were conducted. Meta inference as an overall conclusion, explanation or understanding developed through an integration of the inferences obtained from the quantitative and qualitative strands of the mixed method study was applied. Finally, the three-round e-Delphi technique was conducted to obtain common viewpoints from experts in the development of strategies.

8.2.1 Purpose of the Study

The main purpose of this study was to develop strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

8.2.2 Objectives of the Study

In order to achieve the purpose/aim of the study, the objectives were:

Phase 1: Quantitative Phase

- To assess the prevalence of HPV infection among women who participated in the study.
- To assess the HPV genotypes among women identified as having HPV infection.
- To assess the risk factors of HPV infection among women who participated in the study.
- To assess the prevalence of pre-cancerous cervical lesions among women identified as having HPV infection.

- To assess the risk factors of pre-cancerous cervical lesions among women who tested positive for HPV.
- To identify the treatments offered for women identified as having pre-cancerous cervical lesions through VIA test.

Phase 2: Qualitative Phase

- To explore and describe the risk perceptions of women who participated in the study regarding HPV infection.
- To explore and describe the perceptions of women who participated in the study pertaining to CC screening.
- To explore and describe the perceptions of women who participated in the study about HPV vaccination

Phase 3: Meta Inferences

- To integrate findings from quantitative and qualitative strands of mixed methods research.
- To develop an overall conclusion, explanation or understanding through an integration of the inferences obtained from phase 1 and phase 2 studies.

Phase 4: e-Delphi

- To develop strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

8.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

Findings from the quantitative and qualitative phases of the study are summarized briefly in line with the study objectives of each phase and overall flow of the research in Chapter 4,5, and 6.

8.3.1 Prevalence of HPV Infection among the Study Participants

The prevalence of HPV infection among study participants was determined to see the extent to which the infection was distributed in the study area. In this particular study, the prevalence of HPV infection was estimated to be 26,6%, which was more than twice the worldwide prevalence of 11.7%. In comparison, the figure found was almost consistent with the prevalence in sub-Saharan Africa, estimated at 24%.

8.3.2 HPV Genotypes Identified in the Study Area

HPV infection was detected in 102 women who took part in the study. The distribution of the genotypes was studied to point out which HPV genotype is predominantly present in the study area. The most oncogenic HR-HPV genotypes; HPV-16 and HPV-18 were found at a large significant proportion 22.5%, and 5.9%, respectively. HPV-16 and HPV-18 are highly prevalent genotypes worldwide. This study also revealed the distribution of these two most oncogenic HPV genotypes in the study area with a significant proportion as indicated above. Predominantly, Other HR-HPV genotypes altogether accounted for the highest proportion of HPV infection among HPV-positive women, which was 63.7%.

8.3.3 Risk Factors of HPV Infection and Pre-cancerous Cervical Lesions

Variables independently associated with the acquisition of HR-HPV infection among study participants were clearly identified. Being divorced, having a history of post-coital bleeding, having an early sexual debut before age 20, having a history of more than one lifetime sexual partner, having a history of STI, and being HIV-positive were risk factors identified as having statistically significant association with the acquisition of HR-HPV infection. Meanwhile, women who had a history of post-coital bleeding, early sexual debut before age 20, history of having more than one lifetime sexual partner and being HIV-positive were risk factors identified as having statistically significant association

with the development of pre-cancerous cervical lesions. In this research, risk factors identified altogether for the occurrence of HPV infection and for the development of pre-cancerous cervical lesions in those who have already acquired HPV infection were not basically different from the commonly recognised risk factors for the occurrence of both conditions (i.e., early sexual debut, having multiple sexual partners, HIV infection and contracting other STIs and the like).

8.3.4 Prevalence of Pre-cancerous Cervical Lesions among Participants

In this study, all 102 participants identified as having HPV infection underwent a VIA test to check whether or not they had already developed pre-cancerous cervical lesions following the acquisition of the infection. The prevalence of pre-cancerous cervical lesions among HPV-positive cases was 47.1%. The overall prevalence of pre-cancerous cervical lesions among the entire women who took part in the study was 12.5 %. The result revealed that about half of HPV-positive women developed pre-cancerous cervical lesions, which indicated how common the problem was in HPV-positive cases. Meanwhile, the extent of pre-cancerous cervical lesions among the entire study participants revealed a significant figure which could not be underestimated.

8.3.5 Treatments Offered for Women with Pre-cancerous Cervical Lesions

In the study area, there was a ‘screen and treat’ approach using VIA that gives immediate results followed by ‘on the spot’ treatment (e.g., using cryotherapy) of detected lesions, without any further tests unless a suspected cancer is a preferred approach. Therefore, the treatment offered for the majority of HPV-positive women identified as having pre-cancerous cervical lesions was cryotherapy 81.3%, followed by thermocoagulation 10.4% and the rest 8.3% were not treated or not eligible for cryotherapy or thermocoagulation. The instant treatment offered for women with pre-cancerous cervical lesions helps not to miss cases because of delay in treatment and, most importantly, helps to prevent the development of CC through time.

8.3.6 Risk Perceptions of Women Regarding HPV Infection and Cervical Cancer

Risk perception incorporates the two HBM constructs: the perceived susceptibility and the perceived severity which are frequently combined and labelled as perceived threats since both constructs concern threat. Almost all study participants had poor or no sufficient information about HPV infection. Hence, they perceived that they were less susceptible to HPV infection. With regard to the perceived severity of CC, most of the study participants mentioned that they feel fear and anxiety even when they hear the name of CC itself. Their perceived severity of CC was very high and this caused the participants to be screened. Referring to these two constructs of HBM in combination known as risk perception or perceived threat, the current study revealed low perceived susceptibility and high perceived severity regarding HPV infection and CC among study participants. This implies that there was a knowledge gap on what causes CC despite having a high perceived severity of the particular cancer.

8.3.7 Perceptions of Women Pertaining to Cervical Cancer Screening

The study participants' major perceived benefits of being screened for CC were early detection of pre-cervical cancer lesions, being treated in time if present, and prevention of CC development. The HBM theory suggests if an individual believes that a particular action will reduce susceptibility to a health problem or decrease its seriousness, then he or she is likely to engage in that behaviour regardless of objective facts regarding the effectiveness of the action.

8.3.8 Perceptions of Women about HPV Vaccination

Most of the study participants were unaware of the existence of the HPV vaccine, and even those who were aware of its existence did not have adequate information about who is eligible to be vaccinated for HPV according to the country's current health policy. Some of the study participants stated that they had heard in the media about the HPV vaccine which was given only to females

aged 14 years. These participants felt distracted as if they were ignored because they perceived that the vaccine could be given to females of all age groups.

8.3.9 Integration of Quantitative and Qualitative Findings

In the current study which used sequential explanatory mixed methods, the quantitative data were collected and analysed first, and then the collection and analysis of qualitative data followed. The primary focus was to explain quantitative results by using qualitative data to explore certain results in more detail or help explain unexpected results (e.g., using follow-up FGDs to better understand the results of a quantitative study). Greater emphasis was given to the quantitative strand. Methodological triangulation was used which was sequential in type that the researcher incorporated both sets of data into the interpretation of the overall results. The quantitative data was first statistically analysed to establish clear predictors, and then triangulated with the thematically analysed qualitative data to be used in the development of strategies.

8.3.10 Application of e-Delphi

The e-Delphi method was used in the process of development and validation of strategies. A three-stage e-Delphi method consisting: Stage one - preparation, stage two - identification of convergence of experts' responses, and then stage three - reaching consensus was used.

8.4 CONCLUSIONS AND RECOMMENDATIONS

8.4.1 Conclusions

This study attempted to consolidate and present the factual and conceptual findings of the research. The main objective of this study was to develop evidence-based strategies to promote the prevention and control of HPV infection and its sequela CC among Ethiopian women.

Based on the findings of the study, the researcher reached the following conclusions:

- There was high prevalence of HPV infection among participants in the study area.
- Other HR-HPV genotypes were the major oncogenic HR-HPV genotypes identified in the study area followed by HPV-16 and HPV-18.
- Being divorced, having a history of post-coital bleeding, having an early sexual debut before age 20, having a history of more than one lifetime sexual partner, having a history of STI, and being HIV-positive were risk factors identified as having statistically significant association with the acquisition of HR-HPV infection.
- There was high a prevalence of pre-cancerous cervical lesions among HPV positive cases and among the entire women who took part in the study.
- Cryotherapy was the major treatment offered for HPV-positive women who were identified as having pre-cancerous cervical lesions.
- Almost all the study participants had poor/no information about HPV infection.
- Regarding risk perception, there was low perceived susceptibility but high perceived severity of HPV infection and CC.
- Early detection of symptoms, getting treated in time if present, and prevention of CC development were the major perceived benefits of participants recognised in the study.
- Lack of awareness of the existence of the HPV vaccine and the eligibility to get vaccinated.

8.4.2 Recommendation

On the basis of the study outcomes, the researcher makes the following recommendations for practice and further study.

8.4.2.1 Recommendation to Ministry of Health

The Ministry of Health should:

- Organise and deliver awareness creation campaigns and education programmes to the community about HPV infection, CC, the possible risk, screening for CC by stressing more emphasis on preventive measures of the infection and CC development.
- Incorporate HPV vaccination into routine immunisation programmes. As a result, eligible girls who, for various reasons, have not received the HPV vaccine administered as part of a campaign are welcome to visit any local health institution at any time to receive the vaccination.
- Switch to Nonavalent (9vHPV) HPV vaccination from 4vHPV. As the result of the study shows other high-risk types of HPV have been found in addition to HPV-16 and 18, and the switch from 4vHPV to 9vHPV allows to reach these additional high-risk types in Ethiopia.
- Organise and deliver population-based HPV vaccination for all girls aged 9-26 years.
- Organise and deliver population-based CC screening for all women aged 25/30-49 using VIA.
- Integrate HPV vaccination and CC screening services. Therefore, this allows to prevent and control HPV infection and CC in a coordinated and comprehensive manner by vaccinating those girls who are eligible for the HPV vaccine, and performing CC screening for those who are 25/30 – 49 years of age and already sexually active and ineligible for the vaccine.
- Link CC screening to other reproductive health services such as family planning, HIV care and treatment and STIs treatment.
- Strengthen and increase the accessibility of facilities providing services of both HPV vaccination and early detection and treatment of pre-cancerous cervical lesions.
- Secure high-quality supply chains and safety system for HPV vaccines and related commodities and effective vaccine management.

- Equip health facilities with VIA and cryotherapy machines, accessories and supplies.
- Ensure the availability of an adequate, effective, sustainable health workforce.
- Arrange seminars, workshops and ongoing on-the-job training for health service providers.
- Improve and increase access to facilities providing effective management of invasive CC and palliative care.
- Strengthen partnerships and collaboration with local and international partners such as the Gavi Alliance.
- Reinforce research capacity on the prevention and control of HPV and CC and facilitate their implementations.
- Develop a referral system for LEEP and more-advanced investigations and treatments.
- Make provision for and introduce strong performance evaluation, data management, monitoring, and supervision systems in health facilities.
- Test and approve strategies developed by the researcher

8.4.2.2 Recommendation to Oromia Health Bureau

The Oromia Health Bureau should:

- Develop community awareness on the importance and availability of HPV vaccination for girls and young women through different media.
- Develop community awareness on the importance and availability CC screening for women aged 25/30-49 years through different media.
- Training of midwives, nurses and doctors on CC screening and treatment.
- Ensure the availability of supplies, materials and technical support for both HPV vaccination and CC screening programmes in the region.
- Establish and maintain a well-functioning HPV vaccine safety system involving all stakeholders.
- Increase the number and accessibility of CC screening and treatment centres in the region.

- Develop a referral system for LEEP and more-advanced investigation and treatment.
- Establish monitoring and evaluation of HPV infection and CC prevention and control interventions

8.4.2.3 Recommendation to Adama City Health Office

The Adama City Health Office should:

- Organise community mobilisation events including workshops with key community and religious leaders.
- Provide advocacy and information dissemination on HPV vaccination and CC screening activities through different outlets.
- Conduct community-based health education using health extension workers on avoidance of identified CC risk factors.
- Reinforce human-resource capacity.
- Ensure the availability of supplies, materials and technical support for both HPV vaccination and CC screening programmes.
- Provide population-based HPV vaccination for all girls aged 9-26 years.
- Provide population-based CC screening for all women aged 25/30-49 using VIA.
- Conduct mentoring and supportive supervisions

8.4.2.4 Recommendation to Health Facilities

The health facilities should:

- Promote community awareness of the importance and availability of HPV vaccination for girls and young women.
- Provide health education on CC screening in the health facilities.
- Ensure the availability of supplies and materials for both HPV vaccination and CC screening activities.
- Establish and maintain a well-functioning HPV vaccine safety system.

- Link CC screening to other reproductive health services such as family planning, HIV care and treatment and STIs treatment.
- Provide HPV vaccination for all girls aged 9-26 years.
- Provide CC screening for all women aged 25/30-49 using VIA.

8.4.2.5 Recommendation to the Community

The community should:

- Ensure its participation at all levels of designing, implementing, monitoring, and evaluating of HPV infection and CC prevention and control activities.
- Ensure no discrimination and stigma towards CC patients.
- Participate in social support services for CC patients.
- Provide palliative care services for CC patients

8.4.2.6 Recommendation for Further Research

Further studies should be conducted on the following topics:

- Opportunities and challenges in the implementation of an integrated HPV vaccination and cervical cancer screening services.
- Community awareness on HPV vaccination and CC screening services.
- Service providers' perceptions on the implementation of an integrated HPV vaccination and CC screening services.
- Community-based HPV vaccination and associated factors for all girls aged 9-26 years.
- Community-based CC screening and associated factors for all women aged 25/30-49 using VIA.
- Assessment of sequela of HPV infection other than CC.
- Assessment towards the implementation and success of the strategic plan of an integrated HPV vaccination and CC screening services

8.5 CONTRIBUTION OF THE STUDY

The present research contributed immensely valuable information to the body of scientific knowledge. Deep insight and intuitive understanding were gained regarding HPV infection and CC in the study area from both quantitative and qualitative phases of the research. Policy makers, health service managers, health planners, professionals working on the prevention and control of CC in the country, and researchers will benefit a lot from the findings of this particular study. The proposed strategies that emanated from the study's findings will significantly contribution to the effort being undertaken to prevent and control the occurrence of CC in the country.

8.6 LIMITATIONS OF THE STUDY

Limitations are aspects of the study that decrease the generalisability of the findings Gray et al 2017:114). These may or may not be the results of problems or weaknesses of the study. This study attempted to base its generalisations on diverse scientific vantage points. However, it can be affected by the following limitations:

- The study was restricted to three public health facilities where CC screening services were provided in the study area. Therefore, the findings may not be full reflection of other health facilities.

- The quantitative phase of the study was a cross-sectional study that cross-sectional study by its nature has a weakness to detect casual or cause and effect relationships.

- The qualitative phase of the study applied FGDs to collect data from participants. Since FGD is sort of an interview, the data might be influenced by social-desirability bias. To reduce this, the researcher recruited homogenous participants who did not know the facilitator, the moderator, or each other. Anonymity, not identifying participants by their names was also

considered. Moreover, FGDs are generally not considered externally valid due to their small sample sizes.

- Additionally, the e-Delphi Method was employed to solicit opinions, comments and inputs from experts during the formulation and validation of strategies. Therefore, it reflects the shortcomings of the e-Delphi method like the issue of reliability (i.e., if two panels received the same question they may not come to the same consensus).

8.7 CONCLUDING REMARKS

This research was conducted on ‘Strategies to Promote the Prevention and Control of HPV Infection and its Sequela CC Among Ethiopian Women.’ Tremendous findings were obtained from both the quantitative and qualitative phases of the study. Accordingly, strategies are developed to tackle HPV infection and its long-term consequence CC. FMOH and other relevant stakeholders should test these strategies in the field for their cost and implementation feasibility before they are directly implemented throughout the country.

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ANNEXURES

Annexure A. Letter of Approval from UNISA

UNISA university of south africa

COLLEGE OF HUMAN SCIENCES RESEARCH ETHICS REVIEW COMMITTEE

14 December 2021

Dear Mr. Tadesse Fikre Lema

Decision:
Ethics Approval from 14 December 2021 to 14 December 2026

NHREC Registration # :
Rec-240816-052
CREC Reference # :
14113007_CREC_CHS_2021

Researcher(s): Name: Mr. Tadesse Fikre Lema
Contact details: 14113007@mylife.unisa.ac.za
Name: Dr. Nombulelo Veronica Sepeng
Contact details: sepennv@unisa.ac.za

TITLE: Strategies to Promote the Provision of Human Papillomavirus Vaccine among Ethiopian Women

Purpose: PHD

Thank you for the application for research ethics clearance by the Unisa College of Human Science Ethics Committee. Ethics approval is granted for five years.

The ***low risk application*** *was reviewed by* College of Human Sciences Research Ethics Committee, in compliance with the Unisa Policy on Research Ethics and the Standard Operating Procedure on Research Ethics Risk Assessment.

The proposed research may now commence with the provisions that:

1. The researcher(s) will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.
2. Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study should be communicated in writing to the College Ethics Review Committee.
3. The researcher(s) will conduct the study according to the methods and procedures set out in the approved application.
4. Any changes that can affect the study-related risks for the research participants, particularly in terms of assurances made with regards to the protection of participants' privacy and the

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

confidentiality of the data, should be reported to the Committee in writing, accompanied by a progress report.

5. The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study. Adherence to the following South African legislation is important, if applicable: Protection of Personal Information Act, no 4 of 2013; Children's act no 38 of 2005 and the National Health Act, no 61 of 2003.
6. Only de-identified research data may be used for secondary research purposes in future on condition that the research objectives are similar to those of the original research. Secondary use of identifiable human research data require additional ethics clearance.
7. No fieldwork activities may continue after the expiry date **(14 December 2026).** Submission of a completed research ethics progress report will constitute an application for renewal of Ethics Research Committee approval.

Note:

*The reference number **14113007_CREC_CHS_2021** should be clearly indicated on all forms of communication with the intended research participants, as well as with the Committee.*

Yours sincerely,

Signature: 

Prof. KB Khan
CHS Research Ethics Committee Chairperson
Email: khankb@unisa.ac.za
Tel: (012) 429 8210

Signature: PP 

Prof K. Masemola
Exécutive Dean: CHS
E-mail: masemk@unisa.ac.za
Tel: (012) 429 2298

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

Annexure B. Support Request Letters

Annexure B1: Support request letter to Oromia Reginal Health Bureau

25 October 2022
UNISA-ET/KA/ST/29/25-10-2022

OROMIA REGIONAL HEALTH BUREAU
ADDIS ABABA

Dear Madam/Sir,

The University of South Africa (UNISA) extends warm greetings to you and the staff members of your esteemed hospital. By this letter, we want to confirm that Mr. Tadesse Fikre Lemma (student number 14113007) is a PhD student in the Department of Health Studies at UNISA. Currently, he is at the stage of data collection on his doctoral research entitled "***Strategies to Promote the Provision of Human Papillomavirus Vaccine among Ethiopian Women.***"

This is therefore to kindly request your cooperation in assisting the student in any way that you can. We would like to thank you in advance for all the assistance that you would provide to the student. Attached, please find the ethical clearance that the student received from the Department of Health Studies.

Sincerelv.

UNISA-ETHIOPIA CENTER
P.O.BOX:13836
ADDIS ABABA
TEL+251912191483

Dr. Tsige GebreMeskel Aberra
Director

University of South Africa
P.O.Box: 13836, Addis Ababa, Ethiopia
Ethiopia - Regional Learning Centre
Telephone: +251 11 435 2244/ +251 11 435 0078
Facsimile: +251 11 435 1242/43/44
Mobile: +251 912 191483
www.unisa.ac.za

Annexure B2: Support request letter to Adama town health office

Biiroo Eegumsa Fayyaa Oromiyaa
Oromia Health Bureau
Saarbet (Calcalii) - Finfinnee

የኦሮሚያ ጤና ጥበቃ ቢሮ
ሳርቤት(ጨልጨሊ) - ፊንፊኔ

Lakk/Ref.NO

Guyyaa/Date

Waajjira Fayyaa Bul. Mag Adaamaatiif

Hospitaala Kom/Isp. Fi Kollejji Fayyaa Adaamaatiif

B/J

Dhimmi: Xalayaa Deggersa Kennuu Ilaala.

Akkuma beekamu Biiroon Keenya Ogeyyii, dhabbile akkasumas namoota qorannoo fi Gamaggama jalqabaa fi Xumuraa(baseline and Endline Assessment) geggessuuf propozaala dhiyeffatan propoozaala isaanii madaaluun akkasumas iddoo biratti ilaalchisani fudhatama argatan (approved) dhiyeffatan, propoozaala isaanii ilaaluudhaan waraqa deggersa ni kenna.

Haaluma kanaan qorannoo mata duree "Strategies to Promote the Provision of Human Papillomavirus Vaccine Among Ethiopian Women" jedhuu irrattii Magaalaa/Hospitaala keessan irratti qorannoo hojjechuudhaaf propoozaala isaani koree "**Health Research Ethical Review Committee**" Biiroo keenyatti dhiyeffatani jiru. Haaluma kanaan koreen "**Health Research Ethical Review Committee"** Biiroo keenya piropoozaali kana ilaaluun mirkanesse qorannoon kun akka geggeeffamuu murtesse jira. Kanaafuu, hojii qorannoo kana irratti deggersa barbaachisa **Obbo Taddesee Fiqree (PI)f** akka gootaniif isin Beeksifna.

Qorannoon kun qacceffamee eerga xumuramee booda firii isaa koppii tokko **BFO** tiif akka galii godhan galagalcha xalayaa kanaan isin beeksifna. Anis, **Obbo Taddesee Fiqree (PI)** wayitii qorannoon kun qaaceffame xumuramu firii isaa koppii tokko BFO tiif galii gochuuf mallattoo kootiin ni mirkanessa.

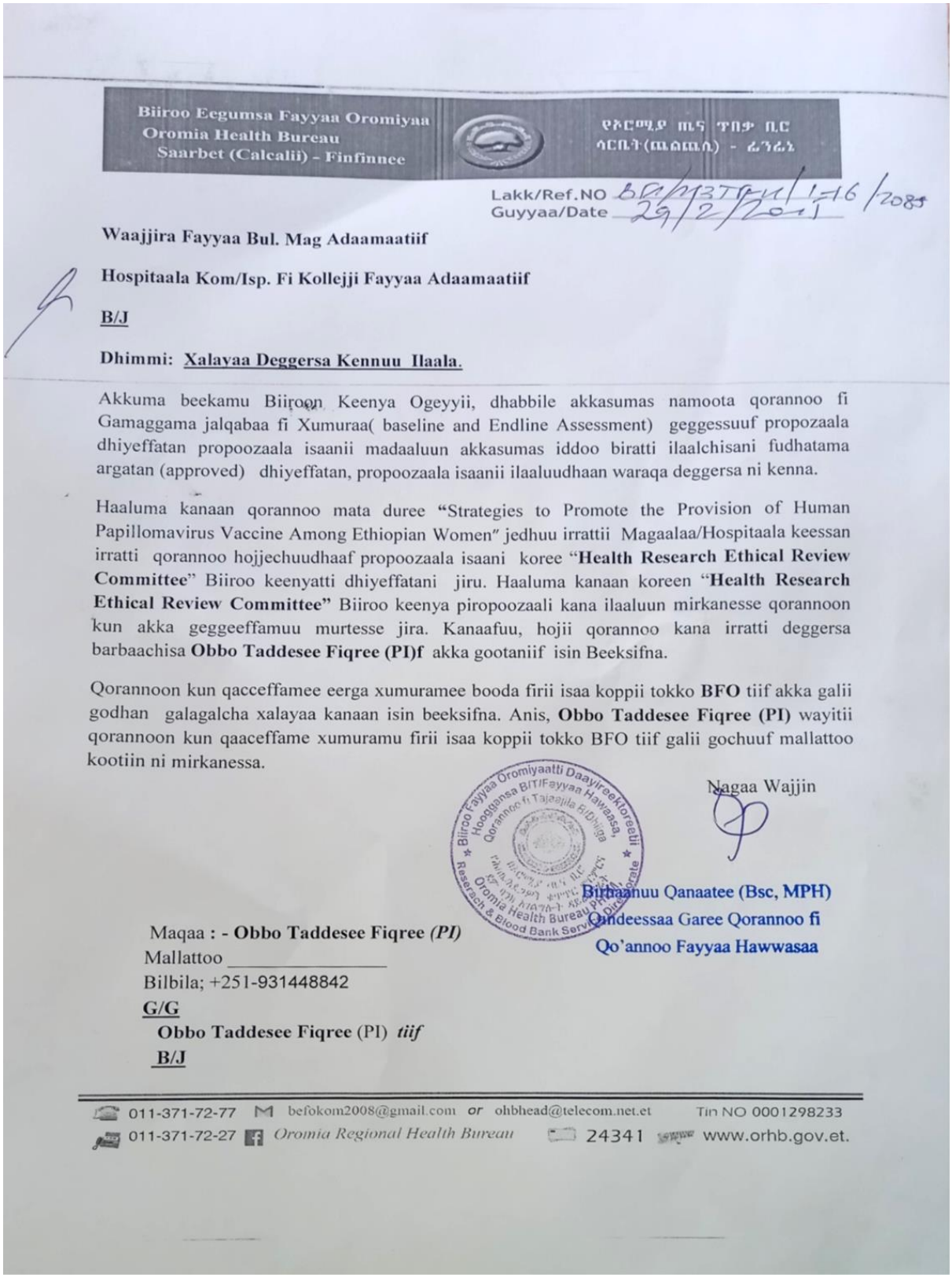
Nagaa Wajjin

Birhaanuu Qanaatee (Bsc. MPH)
Qindeessaa Garee Qorannoo fi Qo'annoo Fayyaa Hawwasaa

Maqaa : - **Obbo Taddesee Fiqree *(PI)***
Mallattoo _______________
Bilbila; +251-931448842
G/G
Obbo Taddesee Fiqree (PI) ***tiif***
B/J

011-371-72-77 befokom2008@gmail.com *or* ohbhead@telecom.net.et Tin NO 0001298233
011-371-72-27 *Oromia Regional Health Bureau* 24341 www.orhb.gov.et.

Annexure B3: Support request letter to Adama hospital



Biiroo Eegumsa Fayyaa Oromiyaa
Oromia Health Bureau
Saarbet (Calcalii) - Finfinnee

የኦሮሚያ ጤና ጥበቃ ቢሮ
ሳርቤት(ጠልጠለ) - ፊንፊኔ

Lakk/Ref.NO BQ/ማ3ፕ/1-16/2089
Guyyaa/Date 29/2/2014

Waajjira Fayyaa Bul. Mag Adaamaatiif

Hospitaala Kom/Isp. Fi Kollejji Fayyaa Adaamaatiif

B/J

Dhimmi: Xalayaa Deggersa Kennuu Ilaala.

Akkuma beekamu Biiroon Keenya Ogeyyii, dhabbile akkasumas namoota qorannoo fi Gamaggama jalqabaa fi Xumuraa(baseline and Endline Assessment) geggessuuf propozaala dhiyeffatan propoozaala isaanii madaaluun akkasumas iddoo biratti ilaalchisani fudhatama argatan (approved) dhiyeffatan, propoozaala isaanii ilaaluudhaan waraqa deggersa ni kenna.

Haaluma kanaan qorannoo mata duree "Strategies to Promote the Provision of Human Papillomavirus Vaccine Among Ethiopian Women" jedhuu irrattii Magaalaa/Hospitaala keessan irratti qorannoo hojjechuudhaaf propoozaala isaani koree "**Health Research Ethical Review Committee**" Biiroo keenyatti dhiyeffatani jiru. Haaluma kanaan koreen "**Health Research Ethical Review Committee"** Biiroo keenya piropoozaali kana ilaaluun mirkanesse qorannoon kun akka geggeeffamuu murtesse jira. Kanaafuu, hojii qorannoo kana irratti deggersa barbaachisa **Obbo Taddesee Fiqree (PI)f** akka gootaniif isin Beeksifna.

Qorannoon kun qacceffamee eerga xumuramee booda firii isaa koppii tokko **BFO** tiif akka galii godhan galagalcha xalayaa kanaan isin beeksifna. Anis, **Obbo Taddesee Fiqree (PI)** wayitii qorannoon kun qaaceffame xumuramu firii isaa koppii tokko BFO tiif galii gochuuf mallattoo kootiin ni mirkanessa.

Nagaa Wajjin

Biiroo Fayyaa Oromiyaatti Daayireektoreetii Hoggansa B/T/Fayyaa Hawwasaa, Qorannoo fi Tajaajila B/Dhiiga
Oromia Health Bureau Research & Blood Bank Service Directorate

Birhaanuu Qanaatee (Bsc, MPH)
Qindeessaa Garee Qorannoo fi
Qo'annoo Fayyaa Hawwasaa

Maqaa : - **Obbo Taddesee Fiqree** ***(PI)***
Mallattoo _____
Bilbila; +251-931448842
G/G
Obbo Taddesee Fiqree (PI) ***tiif***
B/J

011-371-72-77 befokom2008@gmail.com or ohbhead@telecom.net.et Tin NO 0001298233
011-371-72-27 *Oromia Regional Health Bureau* 24341 www.orhb.gov.et.

Annexure B4: Support request letter to Adama health centre

Waajjira Eegumsa Fayyaa
Magaalaa Adaamaa

Adama City Administration Bulchiinsa
Health offic e

Lakk /Ref.No ~~ABK/Baa~~/1315/15
Guyyaa /Date/ ቀን 30-7-15

Buufataa Fayyaa Gadaatiif
Buufataa Fayyaa Adaamaatiif
Adaamaa

Dhimmi: - Xalayaa Deeggersaa Ilaala.

Akkumaa mata dure irraatti ibsuu yaalametti Biiroon Eegumsaa Fayyaa Oromiyaa xalayaa lakk BEFO/HBTFH/1-16/2085 guyyaa 29/2/2015 nuf barreessanin **Obbo Taddesee Fiqree(PI)** qorannoo gagessuuf Piroppoozaala dhiyyefachuu isaan nu beeksisee jira. Haalumaa kanan mata duree **"Strategies to Promote the Provision of Human Papillomavirus Vacccine Among Ethiopian Women"** jedhurratti qorannoo gageessisuuf piroppoozaalii koree "Health Research Ethical rewiew Committee" BEFO waan eyyameef isinis kanumaa hubachuun degersaa barbachisaa ta'e akka gootanif isiin beeksifina.

Bulchiinsa Magaalaa Adaamaatii Waajjira Fayyaa Magaalaa Adaamaa

Nagaa wajjin
Maariswat La'aka(BSC,MPH)
ማርሸት ኣለቃ
Q/Balaa Tasaa Fayyaa Hawasaa
ድንገተኛ የሕሉሳ ጤና አስተባባሪ

G/G
Obbo Taddesee Fiqree(PI) tiif
B/jiraanitti

Wajjiraa Eegumsa Fayyaa B/M/Adaamaa
Adama City Administration Health Office
Bilbila +251221111524 /+ 251221115772 Telephone
L.S.P 561
P.O Box 561 Fax

Annexure B5: Support request letter to Geda health centre

Waajjira Eegumsa Fayyaa
Magaalaa Adaamaa

Adama City Administration Bulchiinsa
Health offic e

Lakk /Ref.No WEF/ama/1315/15
Guyyaa /Date/ ቀ 30-2-15

Buufataa Fayyaa Gadaatiif
Buufataa Fayyaa Adaamaatiif
Adaamaa

Dhimmi: - Xalayaa Deeggersaa Ilaala.

Akkumaa mata dure irraatti ibsuu yaalametti Biiroon Eegumsaa Fayyaa Oromiyaa xalayaa lakk BEFO/HBTFH/1-16/2085 guyyaa 29/2/2015 nuf barreessanin **Obbo Taddesee Fiqree(PI)** qorannoo gagessuuf Piroppoozaala dhiyyefachuu isaan nu beeksisee jira. Haalumaa kanan mata duree **"Strategies to Promote the Provision of Human Papillomavirus Vacccine Among Ethiopian Women"** jedhurratti qorannoo gageessisuuf piroppoozaalii koree "Health Research Ethical rewiew Committee" BEFO waan eyyameef isinis kanumaa hubachuun degersaa barbachisaa ta'e akka gootanif isiin beeksifina.

Bulchiinsa Magaalaa Adaamaatti Waajjira Fayyaa Magaalaa Adaamaa

Nagaa wajjin

Maariskat La'aka(BSC,MPH)
Q/Balaa Tasaa Fayyaa Hojiwasaa

G/G
Obbo Taddesee Fiqree(PI) tiif
B/jiraanitti

Wajjiraa Eegumsa Fayyaa B/M/Adaamaa
Adama City Administration Health Office

Bilbila +251221111524 /+ 251221115772
Telephone

L.S.P 561
P.O Box 561 Fax

Annexure C. Request for Permission to Conduct a Study

Request for permission to conduct research at Adama hospital and two health centres (Adama and Geda) in Adama city administration.

Strategies to Promote the Prevention and Control of HPV Infection and its Sequela Cervical Cancer among Ethiopian Women

Date_____

Health Facility _____

Adama

Dear_____,

I, Tadesse Fikre Lema doing research with Prof. MM Moleki and Dr. A Mosalo, senior lecturers in the Department of Health Studies at the University of South Africa. We are inviting you to participate in a study entitled “Strategies to Promote the Prevention and Control of HPV Infection and its Sequela Cervical Cancer among Ethiopian Women”

The aim of the study is to determine the prevalence, genotypes and risk factors of HPV infection, and perception of women towards HPV screening and vaccination in order to develop Strategies to Promote the Prevention and Control of HPV Infection and its Sequela Cervical Cancer.

Your institution has been selected because the HPV infection cases and death rate are reported to be high. Also, women are still found not utilising the HPV infections screening services as expected by the Federal Ministry of Health.

The study will entail: the population of the study will include women who utilise Adama hospital and two health centres (Geda and Adama) found in Adama city. Data will be collected from 383 sampled women in quantitative phase, and purposefully selected 30 women in qualitative phase until the point of data saturation. In phase 1: quantitative research design, the data will be collected using questionnaire as the data collection instrument and in phase 2: qualitative research design, focus group discussion will be used as a method of data collection. Open ended and probing questions will be used to all participants. The questionnaire will take about 20 - 30 minutes to be completed and Focus group discussion will take about 1 hour or less of participant’s time.

The benefits of this study are: prevalence, genotypes and risk factors of HPV infection in the study area will be determined. Participants (women) will become aware of HPV screening services available at their local health centres and be able to utilize them as expected by the Federal Ministry of Health.

Potential risks: Medium risk will be there since there is direct human participant involvement. The participants will face some sort of physical and psychological discomfort during the examination. This will be alleviated by making the screening procedure women-friendly.

Feedback procedure will entail: The results of the study will be sent to the UNISA library, so that other people can read and use it for referencing in their research studies. The Federal Ministry of Health of Ethiopian will also receive a copy of the results. Presentation of the results at the conferences and publication in accredited Journals will also be done. A copy of the results will also be sent to each health institution, where the study was done, so that the participants can access the feedback.

Yours sincerely,

Tadesse Fikre Lema

Registered professional Midwife

Annexure D. Information Sheet

Annexure D1. English version information sheet

The interview should be conducted after an individual is informed about the aim of the study and granted consent /agreement to be interviewed.

Introduction

My name is …… I am working as data collector for a study being conducted by PhD candidate Tadesse Fikre from UNISA intitled "Strategies to promote the prevention and control of HPV infection and its sequela cervical cancer among Ethiopian women". The aim of this study is to develop strategies to promote the prevention and control of HPV infection and its sequela cervical cancer among Ethiopian women.

You are invited to participate in this study, and during the interview you will be asked some short questions. Your participation in the study is upon purely voluntary basis. All the information you provide us will be kept completely confidential, your name will not be asked or be written on the questionnaire and will never be used in connection with any of the information you will provide. The interview will be conducted in private and will take approximately 20-30 minutes. You have a right to refuse to participate in the study, to interrupt the interview at any time and not to answer any question that you do not want to answer. Your refusal does not affect the service delivery that you deserve. However, your honest answers to these questions will help us to develop strategies to promote the prevention and control of HPV infection and its sequela cervical cancer. We would like to thank you in advance for your cooperation.

The questionnaire consists of the following parts: -

Part I - Socio-demographic Characteristics

Part II - Reproductive History

Part III - Risky Sexual Behaviour and Other health risk factors

Part IV – Cervical Cancer Screening and Treatment

Are you willing to participate in the study? Yes ☐ No ☐

If yes Continue, If no Stop

Interviewer's name _____ ____Date_____Signature_____

Supervisor's name _____ ___Date_____Signature_____

Annexure D2. Amharic version information sheet/የመረጃ ወረቀት የአማርኛ ትርጉም

ቃለ ምልልሱ መደረግ ያለበት ግለሰቡ ስለ ጥናቱ ዓላማ መረጃ ከተሰጠውና ቃለ ምልልሱን ለማድረግ ፍቃዱን ከሰጠ ወይም ከተስማማ ነዉ።

መግቢያ

ሥሜ _____ ይባላል። እየሰራሁ ያለሁት የፒኤች ዲ እጩ የሆኑት አቶ ታደሰ ፍቅሬ በደቡብ አፍሪካ ዩንቨርሲቲ ዩኒሳ "በኢትዮጵያውያን እናቶች መካከል የኤች ፒ ቪ ኢንፌክሽንን እና እሱን ተከትሎ የሚመጣውን የማህጸን በር ነቀርሳ/ካንሰር የመከላከልና የመቆጣጠር ስልቶችን ማስፋፋት" በሚል ርዕስ እያደረጉ ባለው ጥናት በመረጃ ሰብሳቢነት ነው።

የጥናቱ ዓላማ በኢትዮጵያውያን እናቶች መካከል የኤች ፒ ቪ ኢንፌክሽንን እና እሱን ተከትሎ የሚመጣውን የማህጸን በር ነቀርሳ ለመከላከልና ለመቆጣጠር ስልቶችን መንደፍ ነው።

እርስዎም በጥናቱ እንድትሳተፉ ተጋብዘዋል፤ እናም በቃለ ምልልሱ ወቅት አጫጭር ጥያቄዎችን ይጠየቃሉ። በጥናቱ ላይ ያለዎት ተሳትፎ በፍቃደኝነት ላይ የተመሰረተ ነው። የሚሰጡን ሁሉም መረጃዎች ሙሉ በሙሉ በሚስጥር ይጠበቃሉ፤ ሥምዎ በመጠይቁ ላይ አይጠየቅም ወይም አይጻፍም እና ከሚሰጡት ማንኛውም መረጃ ጋር በተያያዘ በጭራሽ ጥቅም ላይ አይውልም። ቃለ መጠይቁ የሚካሄደው በሚስጥር ሲሆን በግምት ከ20 እስከ 30 ደቂቃ ይወስዳል። በጥናቱ ላይ ላለመሳተፍ፤ በማንኛውም ጊዜ ቃለ መጠይቁን ለማቋረጥ እና ለመመለስ የመይፈልጉትን ማንኛውንም ጥያቄ ላለመመለስ መብት አለዎት። በጥናቱ አለመሳተፍዎ ሊያገኙት የሚገባዎት የአገልግሎት ላይ ተጽዕኖ አያመጣም፤ ሆኖም ለእነዚህ ጥያቄዎች የሚሰጡት ትክክለኛ መልስ የኤች ፒ ቪ ኢንፌክሽንን እና የማህጸን በር ነቀርሳን ለመከላከል እና ለመቆጣጠር የሚረዱ ስልቶችን ለማዘጋጀት ይረዳናል። እርስዎ ለሚያደርጉልንን ትብብር አስቀድመን ልናመሰግን እንወዳለን።

መጠይቁ የሚከተሉትን ክፍሎች ይዟል

ክፍል 1 - የስነ ማህበራዊ ባህሪያትክፍል

ክፍል 2 - የስነ ተዋልዶ ታሪክ

ክፍል 3 - አጋላጭ ወሲባዊ ባህሪያቶች እና ሌሎች አጋላጭ ሁኔታዎች

ክፍል 4 - የማህጸን በር ነቀርሳ ምርመራ እና ህክምና ክፍል

በጥናቱ ለመሳተፍ ፍቃደኛ ነዎት? አዎ ☐ አይደለሁም ☐

አዎ ከሆነ ቀጥል፤ ካልሆነ አቁም

የቃለ ምልልስ አድራጊው ሥም _____ቀን_____ፊረማ_____

የሱፐርቫይዘር ሥም _____ቀን_____ፊርማ_____

Annexure D3. Affan Oromoo version information sheet/Waraqaa odeeffannoo varziinnii Affan Oromoo

Seensa

Maqaan koo _____jadhamaa, ani kadhimama PhD obbo Taadasee Fiqiree, Yunivarsiitii Afrikaa Kibbaa, (UNISA) keessatti mata duree “Dubartoota Itoophiyaa biratti, tooftaalee ittisaa fi to’annoo infekshinii HPV fi hordofee kan dhufu kaanserii morma gadameessaa dubartootaa” qorannoo jedhu ilaalchisee odeeffanoo funanuudhaaf. Kaayyoon qorannoo kanaa tooftaalee ittisaa fi to’annoo infekshinii HPV fi kana hordofee kan dhufu kaanserii morma gadameessaa dubartootaa Itoophiyaa biratti guddisuuf gargaaran qopheessuudha. Isinis qo’annoo kana irratti akka hirmaattan kan affeeramtan yoo ta’u, yeroo af-gaaffii gaaffilee gaggabaaboo tokko tokko isin gaafana. Qo’annicha irratti hirmaachuun keessan fedhii keessan qofaan kan raawwatamudha. Odeeffannoon isin nuuf kennitan hundi guutummaatti iccitiin kan eegamu yoo ta’u, maqaan keessan gaaffilee irratti hin gaafatamu ykn hin barreeffamu akkasumas odeeffannoo isin kennitan kamiyyuu waliin walqabatee gonkumaa itti hin fayyadamnu. Af-gaaffiin kun dhuunfaan kan gaggeeffamu yoo ta’u, tilmaamaan daqiiqaa 20-30 kan fudhatu ta’a. Qo’annoo irratti hirmaachuu diduu, yeroo barbaaddetti gaaffii fi deebii addaan kutuu fi gaaffii deebii kennuu hin barbaanne kamiyyuu deebisuu dhiisuuf mirga guutuu qabda. Diduun kee kenniinsa tajaajilaa siif malu irratti dhiibbaa hin qabu. Haa ta’u malee, deebii amanamaa gaaffilee kanaaf kennitan tooftaalee ittisaa fi to’annoo infekshinii HPV fi hordofee kan dhufu kaansarii morma gadameessaa dubartootaa guddisuuf nu gargaara. Tumsa nuuf gootan hundumaaf dursinee isin galateeffanna.

Af-gaaffichi kutaalee afur qaba

Kutaa 1ffaa- Amala hawaasummaa fi ummataa

Kutaa 2ffaa - Qorannoo hala walhormaataa

Kutaa 3ffaa-Amala saalqunnamtii balaadhaaf saaxiluufi sababoota fayyaa biroo

Kutaa 4ffaa - Kaanserii morma gadameessaa sakata’uu fi yaaluu.

Qorannoo kana irratti hirmaachuuf eyyamamoo dha? Eyyee ☐ Mitii ☐

Yoo eyyee ta’e itti fufi, miti yoo ta’e dhaabi.

Maqaa af-gaaffii geeggeessu _____Guyyaa_____Mallattoo_____

Maqaa suppervyizerii _____Guyyaa_____Mallattoo_____

Annexure E. Consent to Participate in the Study

Annexure E1. English version consent to participate in the study

I, _____ (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without penalty.

I am aware that the findings of this study will be processed into a research report, journal publications and/or conference proceedings, but that my participation will be kept confidential unless otherwise specified.

I agree to the recording of the interview between myself and the researcher.

I have received a signed copy of the informed consent agreement.

Participant's Name & Surname……..

Participant's

Signature……..Date…….

Researcher's Name & Surname……..…

Researcher's

signature……..Date…….

Annexure E2. Amharic version consent to participate in the study/በጥናቱ ለመሳተፍ የስምምነት ቅጽ የአማርኛ ትርጉም

እኔ _____ (የተሳታፊ ሥም) በዚህ ጥናት ላይ እንድሳተፍ ፍቃደኝነቴን የጠየቀኝ ግለሰብ የጥናቱን ባህሪ፤ አካሄድ፤ ጥናቱ ሊያስገኘው የሚችለውን ጥቅምና እንዲሁም በጥናቱ ወቅት ሊኖር ያሚችለውን አለመመቸት (የጎንዮሽ ተጽዕኖ) አስቀድሞ እንደነገረኝ አረጋግጣለሁ።

በመረጃ መስጫው ቅጽ ላይ የተገለጸውን የጥናቱን ዓላማ አጉበቤ (ገለጻ ተደርጎልኝ) ተረድቻለሁ። ስለ ጥናቱ አላማ ገለጻ በተሰጠበት ወቅትም ጥያቄዎችን ለመጠየቅ በቂ እድል ነበረኝ፤ እናም በጥናቱ ለመሳተፍ ተዘጋጅቻለሁ። በጥናቱ መሳተፌ በፍቃደኝነት ላይ የተመሰረተ መሆኑን እና ያልተመቸኝ ነገር ካለ ያለምንም ቅጣት በማንኛዉም ሰዓት ማቋረጥ እንደምችል ተረድቻለሁ። የዚህ ጥናት ግኝት ለዘገባ፤ ለህትመት እና በስብሰባ ላይ ለማቅረብ እንደሚዘጋጅ፤ ነገር ግን የኔ በጥናቱ መሳተፌ አስፈላጊነቱ ተገልጾና ተስማምቼ ካልሆነ በስተቀር በምስጢር እንደሚያዝ ተገንዝቤአለሁ። በእኔ እና በጥናት አድራጊው መካከል የሚደረገውን የቃለ ምልልስ ድምጽ እንዲቀዳ ተስማምቻለሁ። የስምምነቱን ቅጽ ግልባጭም ወስጃለሁ።

የተሳታፊ ሙሉ ሥም _____

የተሳታፊ ፊርማ _____ ቀን _____

የጥናት አድራጊው ሙሉ ሥም _____

የጥናት አድራጊው ፊርማ _____ ቀን _____

Annexure E3. Affan Oromoo version consent to participate in the study/Qorannaa irratii hirmaachuudhaf unkka walii galtee varziinnii Affan Oromoo

Anii _____ (maqaa hirmaataa), namni qorannoo kana irrattii hirmaachuuf hayyama koo waa'ee maalummaa, hojimaata, faayidaa argachuu danda'uu fi rakkina miidhaa cinaa akka natti hime nan mirkaneessa.

Qorannicha akka waraqaa odeeffannoo irratti ibsametti dubbisee (naaf ibsamee) hubadheera.

Yeroo kaayyoo qorannichaa nuuf ibsanitti gaaffii gaafachuuf carraa gahaa argadheera, qorannicha irrattis hirmaachuuf qophaa'eera.

Hirmaannaan koo fedhii koo akka ta'ee fi yeroo kamiyyuu adabbii malee gaaffii natti hintolle yoo jiraate addaan kutuu akkan danda'u hubadheera.

Argannoon qorannoo kanaa gara gabaasa qorannoo, maxxansa joornaalii fi/ykn konfiraansiif akka qophaa'uu, (adeemsifamu), garuu qorqnnoo kan irratti hirmaannaan koo barbaachisummaan isaa ibsamee fi yoo ani irratti walii gale malee iccitiin akka eegamu hubadheera.

Af-gaaffii anaa fi qorataa gidduutti taasifamu sagaleen koo waraabamuu irratti walii galeera.

Koppii waliigaltee hayyama waraqaa qorannoo kana kan mallattaa'e fudhadheera.

Maqaa Hirmaataa_____

Mallatoo _____ Guyyaa _____

Maqaa qorannoo geggeesuu_____

Mallattoo_____ Guyyaa_____

Annexure F. Questionnaire

Annexe F1. English version questionnaire for quantitative phase of the study

QUESTIONNAIRE				
Name of Health Facility: _____				
Participant Code: _____		**Date: _____**		**Time: ____**
Please tick (make a √ mark) in the provided boxes.				
S.No	**Variables**	**Responses**		**Remark**
Part I - Socio-demographic Characteristics				
1	Age?	_____Years		
2	Place of residence	☐	In Adama	
		☐	Outside Adama	
3	What is your educational status?	☐	Unable to read and write	
		☐	Elementary/Junior (1-8)	
		☐	High School (9-12)	
		☐	Diploma/Degree and Above	
4	What do you do for a living? (Occupation)	☐	Self-employed	
		☐	Employed (Govt, private, NGO)	
		☐	Unemployed	
		☐	Others, specify_____	
5	Income per month	☐	< 3000 ETB	
		☐	3000 – 5000 ETB	
		☐	> 5000 ETB	
Part II - Reproductive History				
6	What is your marital status?	☐	Single	
		☐	Married	
		☐	Divorced	
		☐	Widowed	
7	How many times did you give birth? (Parity)	☐	0	

		☐	1 – 5	
		☐	> 5	
8	What contraceptive method do you use currently?	☐	Oral contraceptive Pills	
		☐	Depo Provera (Injectable)	
		☐	Implant	
		☐	IUCD	
		☐	Others, specify_____	
		☐	I do not use	
9	Do you use condom during sexual intercourse?	☐	Yes, always	
		☐	Yes, sometimes	
		☐	No, I do not use	
10	Do you have family history of cervical cancer?	☐	Yes	
		☐	No	
11	How is the pattern of your menstrual bleeding?	☐	Regular (21-35 intervals)	
		☐	Irregular	
12	History of post-coital bleeding	☐	Yes	
		☐	No	
Part III - Risky Sexual Behaviour and Other health risk factors				
13	At what age you had your first sexual intercourse?	☐	< 20	
		☐	≥ 20	
14	How many life-time sexual partner/s do you have?	☐	One	
		☐	More than one	
15	Does your sexual partner/s have another sexual partner/s	☐	Yes	
		☐	No	
16	History of any sexually transmitted infection (STI)?	☐	Yes	
		☐	No	
17		☐	Yes	

	History of any STI of your spouse/sexual partner/s?	☐	No	
18	What is your HIV Sero-status?	☐	Negative	From client's medical record
		☐	Positive	
		☐	Not tested for HIV recently	
19	Currently on Antiretroviral therapy? (ART)	☐	Yes	
		☐	No	
20	Do you have history of previous abnormal Pap smear test?	☐	Yes	
		☐	No	
		☐	Not tested	
21	Do you smoke cigarettes?	☐	Yes	
		☐	No	
22	Longer time corticosteroids usage?	☐	Yes	
		☐	No	
Part IV – Cervical Cancer Screening and Treatment				
23	Type of screening visit?	☐	First time	
		☐	Re-screening after previous negative result	
		☐	Post treatment follow-up	
24	Do you want to be tested for HPV now?	☐	Yes	
		☐	No	
25	What is the result of the HPV test?	☐	HPV negative	From client's medical record
		☐	HPV positive	
26	If HPV positive, what HPV genotype/s identified?	☐	HPV 16	From client's medical record
		☐	HPV 18	
		☐	Other HR-HPV	
		☐	HPV 16 and other HR-HPV	
		☐	HPV 18 and other HR-HPV	

		☐	HPV 16 and 18	
		☐	HPV not detected	
27	If HPV positive, VIA test done?	☐	Yes	
		☐	No	
28	What is the result of the VIA test?	☐	VIA negative	From client's medical record
		☐	VIA positive	
29	Treatment given for the precancerous cervical lesion?	☐	No treatment/not eligible	From client's medical record
		☐	Cryotherapy	
		☐	Thermocoagulation	
		☐	LEEP service	
30	Reasons for referral/linkage if any?	☐	Referred for LEEP service	From client's medical record
		☐	Referred for CC evaluation	
		☐	Linked for CC evaluation	
		☐	Others, specify_____	
		☐	Not referred	

Annexure F2. Amharic version questionnaire for quantitative phase of the study/ ለኳንቲቴቲቭ የጥናቱ ክፍል መጠይቅ የአማርኛ ትርጉም

መጠይቅ				
የጤና ተቋሙ ስም: _____				
የተሳታፊ ኮድ: _____		**ቀን:** _____		**ሰዓት:** _____
እባክዎ ለተሰጡት መልሶች ይችን ምልክት √ ፊት ለፊት ካለው ሳጥን ላይ ያስቀምጡ				
ተ.ቁ	**መጠይቆች**	**መልሶች**		**አስተያየት**
ክፍል 1 - የስነ ማህበራዊ ባህሪያት				
1	እድሜሽ ስንት ነው?	_____ዓመት		
2	የመኖሪያ አካባቢሽ?	☐	አዳማ ዉስጥ	
		☐	ከአዳማ ዉጭ	
3	የትምህርት ሁኔታሽ ምን ይመስላል?	☐	መጻፍና ማንበብ የማይችል	
		☐	የመጀመርያ ደረጃ (1-8)	
		☐	የሁለተኛ ደረጃ (9-12)	
		☐	ዲፕሎማ/ዲግሪ እና ከዛ በላይ	
4	የሥራ ሁኔታሽ?	☐	የግል ሥራ	
		☐	ተቀጣሪ (የመንግስት፣ መንግስታዊ ያልሆነ)	
		☐	ሥራ የሌላት	
		☐	ሌሎች ካሉ፡ ጥቀሽ_____	
5	ወርሃዊ ገቢሽ?	☐	< 3000 ኢትብ	
		☐	3000 – 5000 ኢትብ	
		☐	> 5000 ኢትብ	
ክፍል 2 - የስነ ተዋልዶ ታሪክ				
6	የትዳር ሁኔታ?	☐	ያላገባች	
		☐	ያገባች	
		☐	የተፋታች	
		☐	ባሏ የሞተባት	
7	ስንት ጊዜ ወልደሻል?	☐	0	
		☐	1 – 5	
		☐	> 5	
8	በአሁኑ ጊዜ ምን አይነት የእርግዝና መከላከያ እየተጠቀምሽ ነው?	☐	ክኒን	
		☐	መርፌ	
		☐	በክንድ ላይ የሚቀበር	
		☐	በማህጸን የሚቀመጥ	
		☐	ሌሎች ካሉ፡ ጥቀሺ_____	
		☐	አልጠቀምም	
9	በግብረ ሥጋ ግንኙነት ወቀት ኮንዶም ትጠቀሚያለሽ?	☐	አዎ፡ ሁል ጊዜ	
		☐	አዎ፡ አንዳንድ ጊዜ	
		☐	የለም፡ አልጠቀምም	
10	በቤተሰብ ውስጥ በመሃጸን በር ነቀርሳ የተያዘ ሰው ነበር?	☐	አዎ	
		☐	የለም	

11	የወር አበባሽ አመጣጡ እንዴት ነው?	☐	በመደበኛ (በየ 21-35 ቀኑ ምልልስ)	
		☐	ይዛባል	
12	ከግብረ ሥጋ ግንኙነት በኋላ መድማት ያጋጥምሻል?	☐	አዎ	
		☐	የለም	
ክፍል 3 - ኢጋላጭ ወሲባዊ ባህሪያቶች እና ሌሎች ኢጋላጭ ሁኔታዎች				
13	የመጀመርያ የግብረ ሥጋ ግንኙነት ያደረግሽው በስንት ዓመትሽ ነበር?	☐	< 20	
		☐	≥ 20	
14	ምን ያህል የሂዎት ጊዜ የግብረ ሥጋ ግንኙነት ጓደኛ/ኞች አለ/ሉሽ?	☐	አንድ	
		☐	ከአንድ በላይ	
15	የግብረ ሥጋ ግንኙነት ጓደኛሽ ሌላ የጉብረ ሥጋ ግንኙነት ጓደኛ አለዉ?	☐	አዎ	
		☐	የለዉም	
16	የአባላዘር በሽታ ይዞሽ ያውቃል?	☐	አዎ	
		☐	የለም	
17	የግብረ ሥጋ ግንኙነት ጓደኛ/ኞችሽ የአባላዘር በሽታ ይዞት/ዟቸው ያውቃል?	☐	አዎ	
		☐	የለም	
18	የኤች አይ ቪ በሽታ ሁኔታ?	☐	ኔጌቲቭ	ከደምበኛው የህክምና መዝገብ
		☐	ፖዘቲቭ	
		☐	በቅርብ አልተመረመርኩም	
19	አሁን የኤች አይ ቪ መድሃኒት እየወሰድሽ ነው?	☐	አዎ	
		☐	አይደለም	
20	ከዚህ በፊት በማህጸን በር ላይ ችግር እንዳለ የሚያሳይ የፓፕ ስሚር ምርመራ ነበረሽ?	☐	አዎ	
		☐	የለኝም	
		☐	አልተመረመርኩም	
21	ሲጋራ ታጨሻለሽ?	☐	አዎ	
		☐	አላጨስም	
22	ለረጅም ጊዜ የኮርቲኮስቴሮይድ (አለርጂ መከላከያ) ተጠቃሚ ነሽ?	☐	አዎ	
		☐	አይደለሁም	
ክፍል 4 – የማህጸን በር ካንሰር ምርመራ እና ህክምና				
23	ለምርመራ የመጣሽበት አይነት?	☐	ለመጀመርያ ጊዜ	
		☐	ከኔጌቲቭ ውጤት በኋላ ለድግመ ምርመራ	
		☐	ከህክምና በኋላ ለክትትል	
24	አሁን ኤች ፒ ቪ መመርመር ትፈልጊለሽ?	☐	አዎ	
		☐	አልፈልግም	
25	የኤች ፒ ቪ ምርመራ ውጤቱ ምን ነበር?	☐	ኤች ፒ ቪ ነጌቲቭ	ከደምበኛው የህክምና መዝገብ
		☐	ኤች ፒ ቪ ፖዘቲቭ	
26	ኤች ፒ ቪ ከተገኘብሽ, ምን አይነት ኤች ፒ ቪ ነዉ የተገኘዉ?	☐	ኤች ፒ ቪ 16	ከደምበኛው የህክምና መዝገብ
		☐	ኤች ፒ ቪ 18	
		☐	ሌላ አደገኛ-ኤች ፒ ቪ	
		☐	ኤች ፒ ቪ 16 እና ሌላ አደገኛ-ኤች ፒ ቪ	
		☐	ኤች ፒ ቪ 18 እና ሌላ አደገኛ-ኤች ፒ ቪ	
		☐	ኤች ፒ ቪ 16 እና 18	

		☐	ኤች ፒ ቪ አልተገኘም	
27	ኤች ፒ ቪ ከተገኘብሽ, የቪ አይ ኤ ምርመራ ተደርጓል?	☐	አዎ	
		☐	አልተደረገም	
28	የቪ አይ ኤ ምርመራ ዉጤት ምን ነበር?	☐	ቪ አይ ኤ ኔጌቲቭ	ከደምበኛው የህክምና መዝገብ
		☐	ቪ አይ ኤ ፖዘቲቭ	
29	ለማህጸን በር ቅድመካንሰር ቁስለት የተሰጠዉ ህክምና?	☐	አልታከመም/ለህክምናዉ ብቁ አይደለም	ከደምበኛው የህክምና መዝገብ
		☐	ክራዮቴራፒ	
		☐	ተርማልኮአጉሌሽን	
		☐	የሊፕ አገልግሎት	
30	ለበለጠ ህክምና ተልካ ከሆነ የተላከችበት/ሊንክ የተደረገችበት ምክንያት?	☐	ለሊፕ አገልግሎት	ከደምበኛው የህክምና መዝገብ
		☐	ለማህጸን በር ካንሰር ግምገማ	
		☐	ሊንክ ለማህጸን በር ካንሰር ግምገማ	
		☐	ሌላ ካለ፡ ይጠቀስ_____	
		☐	ለበለጠ ህክምና አልተላከችም	

Annexure F3. Affan Oromo version questionnaire for quantitative phase of the study/Gaafannoo Affan Oromo

Gaafannoo				
Maqaa dhaabbata fayyaa:_____				
Koodii hirmaataa: _____		**Guyyaa: _____**		**Sa'aa: ___**
Maaloo saanduqa qophaa'e keessatti mallattoo √ kaa'aa.				
T.L.	**Gaaffii**	**Deebii**		**Yaada**
Kutaa 1ffaa – Amalaa hawaasummaa fi ummataa				
1	Umurii?	_____waggaa		
2	Eessa jiraatta? (Iddoo jireenya kee)	☐	Adaamaa kassaa	
		☐	Adaamaa alaa	
3	Sadarkaan barumsa kee meeqa?	☐	Barressuu fi dubbisu hin danda'u	
		☐	Giddu-galeessa (1-8)	
		☐	Ol-aanaa (9-12)	
		☐	Dippiloomaa/digree fi isaa ol	
4	Hojiin kee maali?	☐	Haadha manaa	
		☐	Hojjataa dhuunfaa	
		☐	Hojjataa mootummaa	
		☐	Hojjataa mit-mootummaa	
		☐	Hojii hin qabu	
5	Galiin keetii kan ji'aa	☐	< 3000 qarshii	
		☐	3000 – 5000 qarshii	
		☐	> 5000 qarshii	
Kutaa 2ffaa - Odeeffannoo haala hormaataan kan walqabate				
6	Haala gaa'ilaa? (Bultii)	☐	Kan hin eerumne	
		☐	Eerumte	
		☐	Abaan manaa kan irraa dhu'ee	
		☐	Kan hiikatte	
7	Yeroo meeqa dima deessee?	☐	0	
		☐	1 – 5	
		☐	> 5	
8	Maloota da'umsa ittisan isa kam fayyadamta?	☐	Kinini liqifamu	
		☐	Lilme/marfee	
		☐	Kan gogaa jala awwaalamu	
		☐	Kan gadameessa keessa galchan	
		☐	Undaa hin fayyadamuu	
9		☐	Eeyyan yaroo hundaa	

	Yaroo walqunnamtii saalaa, koondomii fayyadamtall?	☐	Eeyyan gaaf tokko tokko	
		☐	Lakki hin fayyadamuu	
10	Kanaan dura maatii kee keesaa Kaanserii morma gadameessa kan qabamee jiraa?	☐	Eeyyan	
		☐	Lakki	
11	Marsaan laguu kee akkamiin sitti dhufa?	☐	Ji'a ji'an	
		☐	Deddebi'een	
		☐	Dhaabbatera /menopause	
		☐	Wal-qunamtii saalaan booda dhiiguu	
12	Walqunamtii saalaan booda dhiigaa sii iraa dhufaa?	☐	Eeyyan	
		☐	Lakki	
Kutaa 3ffaa – Amaloota rakkoo walqunamtti saalaa				
13	Walqunnamtii saalaa si'a duraaf ummurii meeqatti jalqabdee?	☐	< 20	
		☐	≥ 20	
14	Amma ammatti hiriyyaa meeqa qabda	☐	Tokkoo	
		☐	Tokkoo o'l	
15	Hiriyyaa kee hiriyyaa kaan biraa qabaa?	☐	Eeyyan	
		☐	Hin qabuu	
16	Dhibee walqunnamtii saala qabamtee beektaa?	☐	Eeyyan	
		☐	Lakki	
17	Hiriyyaa kee dhibee walqunnamtii saalaa qabamee beekaa?	☐	Eeyaan	
		☐	Lakki	
18	Qorannoon HIV kee maal fakkaata?	☐	Nageetiivii	Galmee qorannoo dhukbsata a irraa
		☐	Posatiivii	
		☐	Hin qoramnee	
19	Yoo qorannoon HIV kee posatiivaa ta'ee, dawaa HIV fudhachaa jirtaa?	☐	Eeyyan	
		☐	Lakki	
20	Kannan duraa morma gadameessa kee irra rakkoo kan haagarssisuu qooranoo Paap Smiirii qabdaa turtee?	☐	Eeyyan	
		☐	Lakki	
		☐	Hin qooramnee	
21	Sijaaraa ni xuuxxaa?	☐	Eeyyan	
		☐	Lakki	
22	Dawaa alaarjii (Kortikosteroyidii)	☐	Eeyyan	
		☐	Lakki	

	yaroo dheeraaf fudhechaa jirtaa?			
Kutaa 4ffaa – Qorannoo fi yaala Kaanserii morma gadameessaa				
23	Qorannoo kamiif dhufte?	☐	Yaroo jalqabaaf	
		☐	Qorannoo marsaa lammataf, bu'aan qoranoo duraa nageetiivii ta'ee bodaa	
		☐	Hordoffii yaalan booda	
24	HPV dhaaf qoratamuu ni barbaadda?	☐	Eeyyan	
		☐	Lakki	
25	Bu'aan qoranoo HPV keetii maali?	☐	HPV +ve	Galmee qorannoo dhukbsata a irraa
		☐	HPV -ve	
		☐	Hin beekamnee	
26	Yoo HPV posatiivii tate'e, gossa kami dha?	☐	HPV 16	Galmee qorannoo dhukbsata a irraa
		☐	HPV 18	
		☐	Kan biraa hiyii riskii (HR) Huumaan paappiloomaa vaayirasii	
27	Yoo HPV posatiivii, VIA dhaaf qoratamtee	☐	Eeyyan	
		☐	Lakki	
28	Bu'aan qorannoo VIA kee? Maali	☐	VIA posatiivii	Galmee qorannoo dhukbsata a irraa
		☐	VIA nageetiivii	
		☐	Kaanserii morma gadameessaaf kan shakkisiisu	
		☐	Hin beekamnee	
29	Yoo VIA posatiivii ta'e, gosaa kami tajaajilaa yaala kaansarii duraa sii keeneemee?	☐	Hin yaalamne	Galmee qorannoo dhukbsata a irraa
		☐	Kaariyooteeraappii (Cryotherapy)	
		☐	Termocoaguleshen(Thermo coagulation)	
		☐	Tajaajila Loop electrosurgical excision procedure (LEEP)	
30	Yoo ol-ergamtaniittu ta'e sababasaa/linkaajii yoo jiraate?	☐	Kutaa deddebi'anii Yaala Gadameessaa LEEP	Galmee qorannoo dhukbsata a irraa
		☐	Kutaa deddebi'anii Yaala Gadameessaa kan shakkame itt ilaalamu	
		☐	Gara tajajila LEEP dabarsuu	
		☐	Gara Yaala Gadameessaa kan shakkame itt ilaalamu titi ol-erguu	

Annexure G. Confidentiality Agreement with Research Third Party

Hereby, I_____, ID number_____, in my personal capacity as a Data collector/Supervisor/Statistician collaborating with Mr. Tadesse Fikre Lema on research titled “Strategies to promote the prevention and control of HPV infection and its sequela cervical cancer among Ethiopian women” acknowledge that I am aware of and familiar with the stipulations and contents of the conditions of ethical clearance specific to this study. I shall conform to and abide by these conditions. Furthermore, I am aware of the sensitivity of the information collected and the need for strict controls to ensure confidentiality obligations associated with the study.

I agree to the privacy and confidentiality of the information that I am granted access to in my duties as a Data collector/Supervisor/Statistician. I will not disclose nor sell the information that I have been granted permission to gain access to in good faith, to anyone.

I also confirm that I have been briefed by the research team on the protocols and expectations of my behaviour and involvement in the research as a Data Collector.

Signed: _____

Date: _____

Annexure H. Interview Guide (FGD)

Annexure H1. English version FGD guide for qualitative phase of the study

Introduction

The researcher purposefully selected focus group discussants from women who already took part in the quantitative study. Moreover, the researcher developed unstructured and generally open-ended questions as a starting point for the focus group discussion based on the objectives of the study. The questions are few in number and are intended to elicit views and opinions from the participants regarding the issues to be discussed. The FGDs conducted in Amharic.

Place of interview _____ Group code _____

Name of facilitator _____ Signature _____

Name of moderator _____ Signature _____

Number of discussants _____ Date _____

The following question are raised to initiate the discussion:

- What do you know about HPV infection? how it transmits? what are the preventive aspects?
- Could you please tell me your perception about risk of acquiring HPV infection?
- Could you please tell me your perception regarding cervical cancer screening?
- Could you please tell me your perception regarding HPV vaccination?

Follow-up questions

1. What is cervical cancer?
2. What do you think about the causes of cervical cancer?
3. How do you explain the severity of cervical cancer?
4. To what extent do you think that you are at risk of acquiring cervical cancer
5. Who recommended you to get screened for cervical cancer?
6. What do you think about the benefits of getting vaccinated for HPV?
7. What is your perception about the benefits of having cervical screening?

Probing questions for clarity will be used during the interview such as:

‘Tell me more about…?

‘What, where, when should cervical cancer screening be done?’

‘For whom it should be done?’. ‘You said …, please explain? Etc…

Annexure H2. Amharic version FGD guide for qualitative phase of the study/ ለኳሊቴቲቭ የጥናቱ ክፍል የትኩረት ቡድን ውይይት መመርያ የአማርኛ ትርጉም

መግቢያ

የጥናቱ አድራጊ ቀደም ብሎ በኳንቲቴቲቭ የጥናቱ ክፍል ከተሳተፉ ሴቶች መካከል የትኩረት ቡድን ተዎያይዎችን ሆን ብሎ መርጧል። በተጨማሪም የጥናቱ አድራጊ በጥናቱ አላማዎች ላይ በመመስረት ለትኩረት ቡድን ውይይት መነሻ የሚሆኑ ያልተዋቀሩ እና በአጠቃላይ ክፍት የሆኑ ጥያቄዎችን አዘጋጂቷል። ጥያቄዎቹ በቁጥር ጥቂቶች ሲሆኑ ተሳታፊዎች ዉይይት በሚደረግበት ጉዳይ ላይ ያላቸዉን ምልከታ እና አስተያየት ለማስገኘት የታሰቡ ናቸዉ። የትኩረት ቡድን ውይይቶቹ የተካሄዱት በአማርኛ ቋንቋ ነዉ።

ዉይይቱ የሚካሄድበት ቦታ _____ የቡድን መለያ ኮድ _____

የአዎያይ ሥም _____ ፊርማ _____

የተባባሪ አዎያይ ሥም _____ ፊርማ _____

የተዎያዮች ብዛት _____ ቀን _____

ዉይይቱን ለማስጀመር የሚከተሉት ጥያቄዎች ተነስተዋል:

- ስለ ኤች ፒ ቪ በሽታ ሰምተዉ ያዉቃሉ? እንዴት ይተላለፋል? ስለ አማጭ ተዋህሲያኑስ ያዉቃሉ?
- በኤች ፒ ቪ በሽታ የመያዝ ዕድልዎ ምን ያክል ነዉ?
- ስለ የማህጸን በር ነቀርሳ ምርመራ ያለዎት አመለካከት ምንድን ነዉ?
- ስለ ማህጸን በር ነቀርሳ መከላከያ ክትባት ያለዎት አመለካከት ምንድን ነዉ?

የክትትል ጥያቄዎች

1. የማህጸን በር ነቀርሳ ምንድን ነዉ?
2. ስለ ማህጸን በር ነቀርሳ መንስኤዎች ምን ያስባሉ?
3. የማህጸን በር ነቀርሳን ክብደት እንዴት ይገልጹታል?
4. እርስዎ በምን ያክል መጠን በማህጸን በር ነቀርሳ የመያዝ አደጋ ላይ ነኝ ብለዉ ያስባሉ?
5. የማህጸን በር ነቀርሳ ምርመራ እንዲያደርጉ ማን መከረዎት?
6. የኤ ች ፒ ቪ ክትባትን መከተብ ስላለዉ ጥቅም ምን ያስባሉ?
7. የማህጸን በር ነቀርሳ ምርመራ ማድረግ ስለሚያስገኛቸዉ ጥቅሞች ያለዎት ግንዛቤ ምንድን ነዉ?

በቃለ መጠይቁ ወቅት የበለጠ ገለጻን የሚጠይቁ ጥያቄዎች ጥቅም ላይ ይዉላሉ፤ እነሱም እንደ፡-

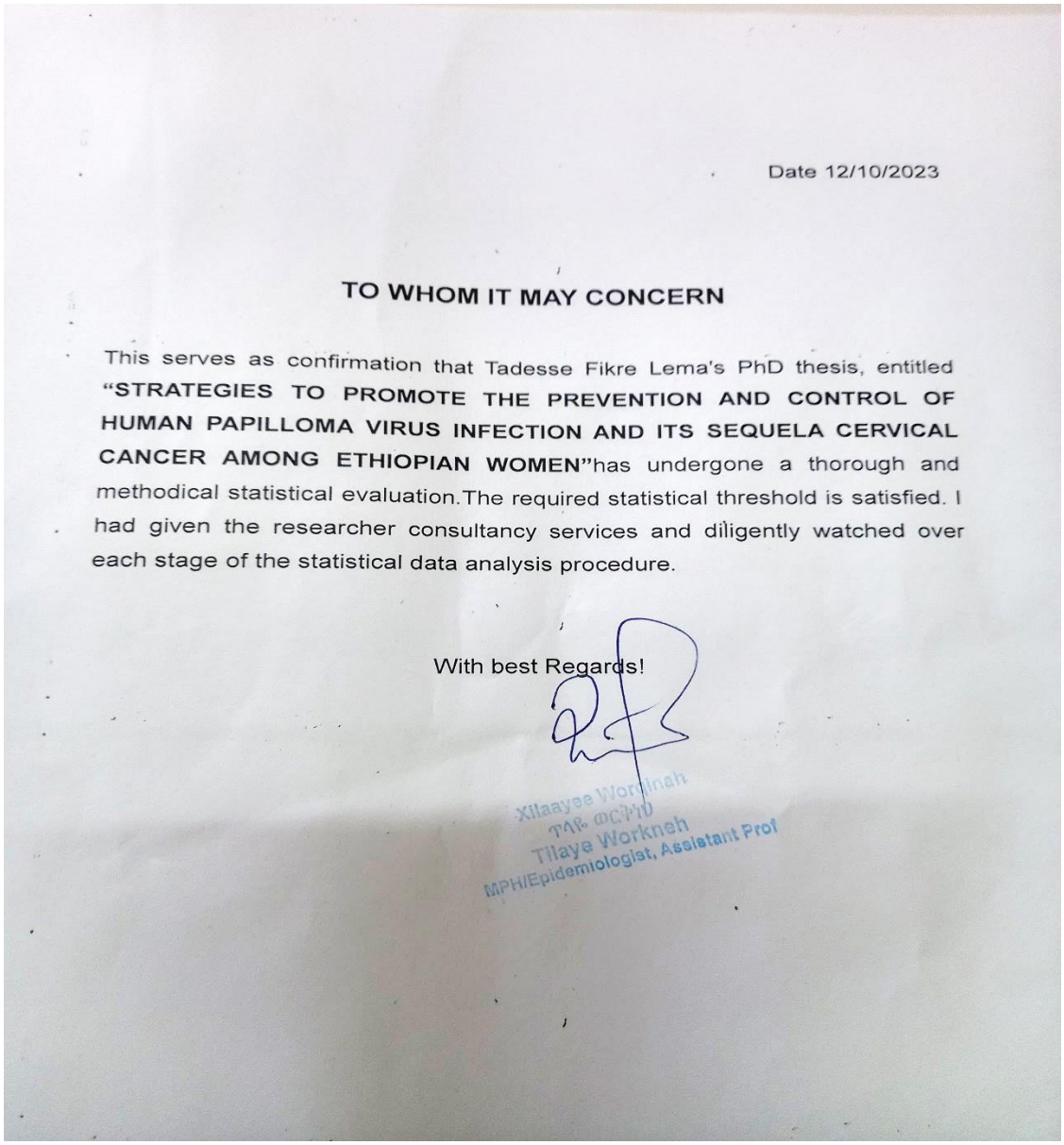
‘ስለ.....የበለጠ ይንገሩኝ?’

‘ምን፤ የት፤ መቼ ነዉ የማህጸን በር ነቀርሳ ምርመራ መደረግ ያለበት?’

‘ለማን ነዉ ይሄ መደረግ ያለበት’

‘..... ብለዋል፤ እባክዎ ያብራሩት? ወዘተ...

Annexure I. Confirmation paper from a statistician



Date 12/10/2023

TO WHOM IT MAY CONCERN

This serves as confirmation that Tadesse Fikre Lema's PhD thesis, entitled **"STRATEGIES TO PROMOTE THE PREVENTION AND CONTROL OF HUMAN PAPILLOMA VIRUS INFECTION AND ITS SEQUELA CERVICAL CANCER AMONG ETHIOPIAN WOMEN"**has undergone a thorough and methodical statistical evaluation.The required statistical threshold is satisfied. I had given the researcher consultancy services and diligently watched over each stage of the statistical data analysis procedure.

With best Regards!

Xilaayee Worknah
ታላ ወርቅነህ
Tilaye Workneh
MPH/Epidemiologist, Assistant Prof

Annexure J. Certificate from Language Editor

NIM Editorial
Bryanston, Gauteng, 2074
Cell: +27 82 587 4489
Email: info@nimeditorial.co.za
www.nimeditorial.co.za

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Editorial Certificate

To Whom It May Concern,

This certificate confirms that the thesis entitled; **STRATEGIES TO PROMOTE THE PREVENTION AND CONTROL OF HUMAN PAPILLOMAVIRUS INFECTION AND ITS SEQUELA CERVICAL CANCER AMONG ETHIOPIAN WOMEN** by **TADESSE FIKRE LEMA** was edited by an expert English editor with a PhD. The following issues were corrected: grammar, spelling, punctuation, sentence structure, phrasing, and formatting.

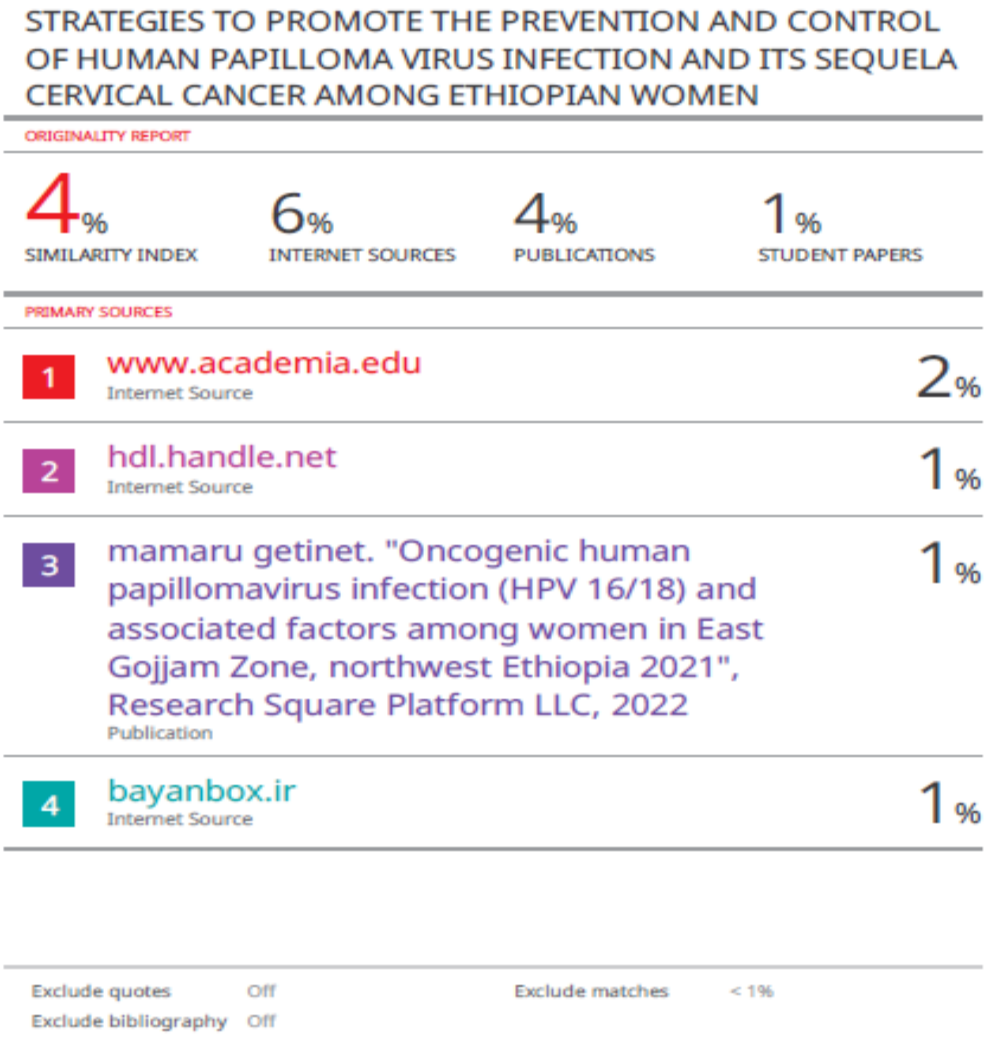
Signed on behalf of NIM Editorial by:

.....

Dr N.I. Mabidi

Founder & Chief Editor

Annexure K. Turnitin Originality Report



STRATEGIES TO PROMOTE THE PREVENTION AND CONTROL OF HUMAN PAPILLOMA VIRUS INFECTION AND ITS SEQUELA CERVICAL CANCER AMONG ETHIOPIAN WOMEN

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