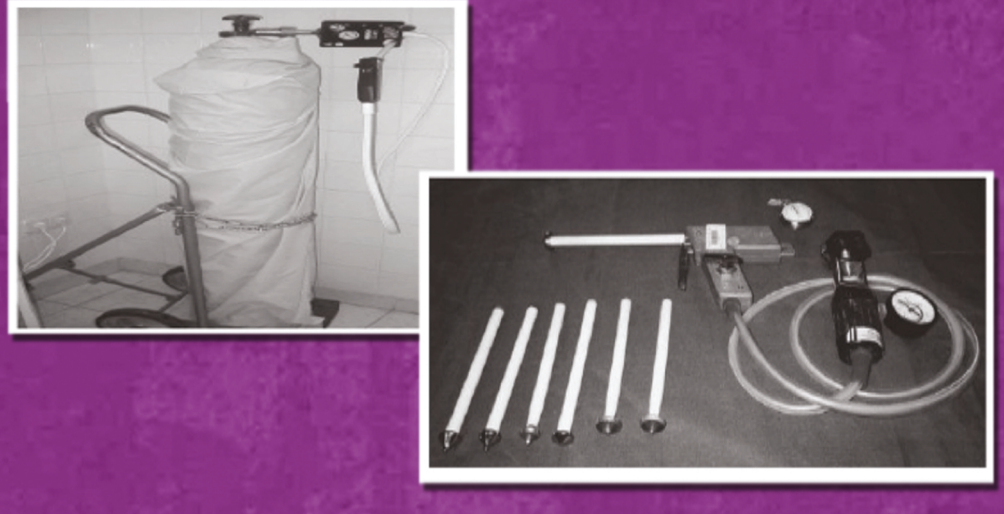
Federal Democratic Republic of Ethiopia
Ministry of Health

Guideline for Cervical Cancer Prevention and Control in Ethiopia



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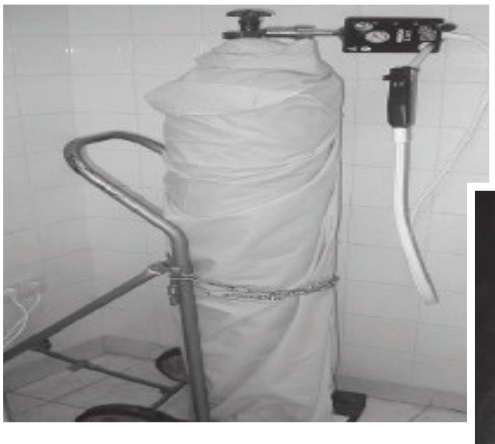

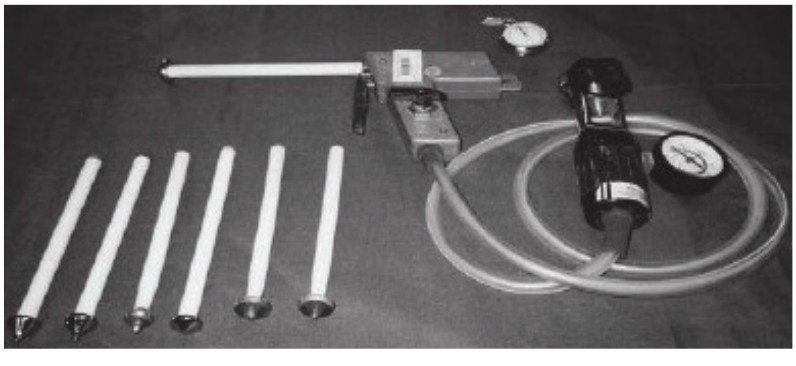

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ABBREVIATIONS

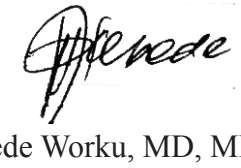
ACCP	Alliance for Cervical Cancer Prevention
AIDS	Acquired Immune Deficiency Syndrome
ASR	Age-standardized Rate
CTC	Care and Treatment Centre
EPI	Expanded Programmed for Immunization
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HLD	High-level Disinfectant
HPV	Human Papilloma Virus
HR-HPV	High risk HPV
HMIS	Health Management Information System
HO	Health Officer
IEC	Information, Education, Communication
LEEP	Loop Electrosurgical Excision Procedure
Ob/Gyn	Obstetrician and Gynecologist
PLHIV	People Living with HIV
RCH	Reproductive and Child Health
RHMT	Regional Health Management Team
RRCHCO	Regional Reproductive and Child Health Coordinator
SCJ	Squamo-columnar Junction
SDG	Service Delivery Guidelines
STI	Sexually Transmitted Infection
STA	See-and-Treat Approach
SVA	Single Visit Approach
USAID	United States Agency for International Aid
VIA	Visual Inspection with Acetic Acid
WHIS	Woreda Health Information System
WHO	World Health Organization
WRCHCO	Woreda Reproductive and Child Health Coordinator

FOREWORD

Comprehensive reproductive health refers to "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity in all matters relating to the reproductive health system, its functions and processes", as defined during the 1994 International Conference on Population and Development in Cairo and subsequently endorsed and implemented in Ethiopia since 1997 by the Federal Ministry of Health (FMOH) and its partners. Reproductive health includes: meeting the needs of individuals and couples for a variety of safe, effective and affordable methods of fertility regulation from which they can make an informed choice; reduction of pregnancy-related morbidity and mortality as well as reduction of newborn deaths and disabilities; prevention and management of reproductive tract infections, including HIV/AIDS and other sexually transmitted diseases; and the provision of services for the early detection and management of cancers and other conditions of the reproductive tract. Although reproductive health in general has been an important area of focus for the country, efforts to address the specific area of reproductive tract cancers have been minimal to date. In response to this gap and to the ever-increasing rates of cervical cancer, and informed by the success of small pilot projects in generating demand for such services, the FMOH decided in 2013 to embark on development and implementation of a national cervical cancer prevention and control program.

The FMOH National Guidelines for Cervical Cancer Prevention and Control provide the most current up-to-date knowledge and direction on cervical cancer screening, treatment and management. These guidelines provide a solid foundation from which service providers in all health facilities, in the public and private sectors as well as non-governmental organizations, can provide quality and standardized cervical cancer prevention and treatment services. The FMOH also encourages the use of this guideline by managers, policymakers and training institutions. This Guideline will be reviewed periodically based on stakeholder and provider observations and feedback, national and international experience and guidance, scientific developments, and the preferences and values of patients and communities regarding intervention and delivery approaches. The Government of Ethiopia believes that individuals and couples have the right to have access to comprehensive, high quality reproductive healthcare and services, including cervical cancer prevention, and that the use of these services is a critical factor in the socioeconomic development and well-being of every Ethiopian citizen, especially for women.

Screening for cervical cancer can save a woman's life if the signs are discovered early and treated in a timely fashion. I urge all health workers to promote this service so as to save lives and reduce the suffering of many women from cervical cancer.



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In particular, the ministry would like to express gratitude to the following health professionals and experts for their unreserved commitment and professional contributions:

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CHAPTER 1
INTRODUCTION

1.1 Background

The population of Ethiopia is estimated to be nearly 86 million people, of whom 83.8% live in rural areas and 16.2% are urban dwellers (CSA, 2007). Women and men constitute 49.5% and 50.5% of the total population, respectively. Almost one quarter (23.4%) of the total population is made up of women of reproductive age (between 15 and 49 years of age) (FMOH, 2014). The median age of marriage for women is 16 years (EDHS, 2011). The total fertility rate (TFR) in Ethiopia is 4.1 lifetime births per woman (CSA & FMOH, 2014). Over the years, the TFR has declined, as observed in the last three Demographic and Health Surveys (DHS) and the recent mini DHS: 5.5 children in 2000, 5.4 children in 2005, 4.8 children in 2011 and 4.1 in 2014 (CSA & FMOH, 2014). The adult HIV prevalence in 2010/2011 was estimated to be 1.5%, with a higher prevalence among women (1.9%) than among men (1.0%), (EDHS, 2011).

The potential primary health service coverage reached 92% of the population, yet the per capita health service utilization per year, as measured by out-patient attendance, remains low at 0.29 (FMOH, 2012). Health service delivery in Ethiopia follows a three-tier system: the Primary Health Care Unit (PHCU), which consists of five satellite health posts, one Health Centre, and a Primary Hospital to serve 5,000, 25,000 and 100,000 population, respectively; a General Hospital, which serves a population of one million people; and a Specialized Hospital, which serves area population of five million. The cadres of health care providers range from Health Extension Workers (HEWs), who carry out their duties at the community and health-post levels, to medical specialists.

It is well-known that the education of girl's delays marriage and first birth, increases health access, improves partner communication and advances women's status in the community. In the past two decades, girls' enrollment in school has significantly increased in Ethiopia. In addition there has been a narrowing of the gender gap although there still is a difference in favor of boys. Gross enrolment rate (GER) for girls at primary level in 2008/09 was 90.7% and increased to 92.4% in 2012/14, while GER for boys increased from 97.6% to 98.2% during the same period. This showed a narrowing of the gender gap from 6.9 percentage points in 2008/09 to 5.8 percentage points in 2012/13. However, it is worth mentioning that there is a significant variation among regions. Whereas gender disparities are small in Addis Ababa, Amhara, Somali and Tigray regions, the gap is higher in Benshangul Gumuz, Harari, SNNP, Oromia and the Gambella regions (MoE, 2013).

1.2 Global and National Burden of cervical cancer

Cancer of the cervix is the second most common cancer among women worldwide, with about 500,000 new cases diagnosed and over 250,000 deaths every year. In low- and middle-income countries (LMICs), including Ethiopia, cervical cancer is the commonest cancer affecting reproductive

organs and also the leading cause of death from cancer among women. In 2010, it was estimated that 20.9 million women were at risk of developing cervical cancer in Ethiopia with an estimated 4,648 and 3,235 annual numbers of new cases and deaths, respectively.

The majority of cancers (over 80%) in sub-Saharan Africa are detected at a late stage, predominantly due to lack of information about cervical cancer and a dearth of prevention services. Late-stage disease is associated with low survival rates after surgery or radiotherapy. In addition, these treatment modalities may be lacking/limited, or too expensive and inaccessible, for many women in low-resource countries, including Ethiopia.

Cervical cancer is potentially preventable, unlike other reproductive organ cancers. Effective screening programs can lead to a significant reduction in the morbidity and mortality associated with this cancer. In high-income countries, regular screening with a Pap smear has been shown to lower the risk for developing invasive cervical cancer, through detecting precancerous changes.

However, in LMICs, only approximately 5% of eligible women undergo cytology-based screening in a five-year period. In virtually all LMICs, cytology-based services are confined to teaching hospitals or private laboratories in urban areas. The barriers to scale-up of cervical cytology-based screening programs in Ethiopia include the lack of trained and skilled professionals, supplies, laboratory infrastructure and equipment. Furthermore, the absence of a well-organized surveillance and recall system is a major obstacle to effective implementation: women with abnormal findings may not receive their results, let alone treatment or follow-up. These are some of the barriers that prevent cytology-based screening programs from being effective in LMICs.

Visual Inspection with Acetic Acid (VIA) is an evidence-based and affordable alternative approach for cervical cancer screening in low-resource settings. Studies have reported VIA sensitivity for detecting precancerous lesions comparable to or greater than cervical cytology, while requiring fewer resources and feasible to carry out in low level health facilities (ACCP, 2009). In addition, VIA provides immediate results, thus promoting linkage of screening with treatment. This “see and treat” method ensures adherence to treatment soon after diagnosis, and reduces the risk that women will get lost in the referral system. VIA combined with cryotherapy (freezing of precancerous lesions of the cervix), ideally in a single visit approach (SVA), is an effective and efficient strategy for secondary prevention of cervical cancer in low-resource settings, and can be conducted by competent clinicians and nurses (ACCP, 2007).

Linking screening to treatment in a SVA is programmatically critical, as the SVA strategy minimizes the number of patients with abnormal screening results being lost to follow-up and not receiving appropriate treatment—a major cause for low program performance and impacting LMICs. This linkage is not only clinically important; it is cost-effective (Goldie 2005, Mandelblatt, 2002). Once-in-a-lifetime VIA testing combined with cryotherapy in a SVA strategy for eligible lesions was the most cost-effective approach; defined as the least amount of money spent per life-year saved or cancers avoided. VIA-based program using the SVA strategy have been shown to significantly reduce precancerous lesions of the cervix, cervical cancer incidence and mortality (ACCP 2009). When SVA

is not feasible, an alternative strategy is the screen-and-treat approach (STA), whereby screening is conducted with immediate results provided, and treatment, if needed, is performed later that day or at a designated time shortly after screening. If the STA strategy is utilized, it is essential that good counseling occurs at the time of screening to minimize loss to follow-up of women requiring treatment. Given the difficulty of sustaining a high-quality cervical cytology-based screening program, and the proven effectiveness of the VIA approach, Ethiopia has looked to VIA combined with cryotherapy for cervical cancer prevention.

Cryotherapy as a method of treatment for precancerous lesions is effective and easier to implement than other treatment modalities such as loop electrosurgical excision procedure (LEEP), loop excision of the transformation zone (LETZ) and cone biopsy. Cryotherapy is affordable; there is no need for complicated equipment and it can be done by midlevel health personnel and thus can be implemented in a primary health-care (PHC) setting. Secondary prevention of cervical cancer through screening and treatment of precancerous lesions of the cervix is associated with an overall reduction of morbidity and mortality due to cancer of cervix.

1.3 Ethiopia's Experience in Cervical Cancer screening using VIA

Health facility data compiled by Tikur Anbesa specialized referral hospital from 1996 – 2008 showed 30.3% of all cancers diagnosed in the hospital were cervical cancer. The estimated coverage of cytology-based cervical cancer screening in Ethiopia is 1.6% in urban settings and 0.4% in rural areas (WHO, 2003).

VIA screening combined with access to cryotherapy was piloted in Ethiopia by the FMOH in collaboration with Pathfinder[1]. The service was introduced in 2009as a single-visit approach to cervical cancer prevention integrated into a comprehensive care package for people living with HIV at 14 Hospitals The service was subsequently initiated in eleven additional health facilities (clinics of the Family Guidance Association of Ethiopia (FGAE), military hospitals, and some other facilities) making the service available in a total of 25 health institutions.

Based on the lessons learned from the pilot (obtained through careful documentation and efforts to

examine and understand the success and challenges faced), the Federal Ministry of Health has decided to scale up the service further into public healthcare facilities. Accordingly, the Ministry has developed this comprehensive cervical cancer prevention and control guideline along with preparation of VIA and cryotherapy training materials. Over the past 20 years, the Government of Ethiopia has honored its national and international commitments by adopting and implementing a series of policies and national strategies aimed at creating the necessary conditions for all Ethiopians to have access to

1 Pathfinder International Ethiopia has implemented a SVA of VIA screening and cryotherapy of cervical cancer for HIV positive women under the project name of "Addis Tesfa" Cervical Cancer prevention (CCP) project from October, 2009 – September, 2014

basic health and social services, as well as in ensuring women's economic, political and human rights and their full participation in the development process.

The Federal Democratic Republic of Ethiopia has declared its commitment to gender equality, equity, and empowerment of women by stipulating the rights of women in its Constitution, by issuing the Women's Policy of Ethiopia and revising Family Law and Criminal Law. It established the machinery for facilitating and monitoring the mainstreaming of gender issues in the development process. The Government has also incorporated gender issues into various national policies including those relating to social, health, education and training, HIV/AIDS, population and other sector policies.

Considering the existing socio-cultural realities in Ethiopia; it is essential to change women's status in the community. Thus, the Government of Ethiopia has established constitutional rights, laws, directives, and strategies to empower women. However, realizing these rights calls for collective action from all stakeholders.

The Health Policy of Ethiopia boldly states that the health needs of women and children deserve particular attention. The policy recommends decentralizing services and "enriching the concept and intensifying the prevention of reproductive organ cancer (ROC)". The central pillar of the health sector of the government is "improving the health of the population" through promotive, preventive, curative and rehabilitative health services (MoFED, 2010).The FMOH gives due emphasis to a comprehensive approach to reproductive health, meeting the reproductive needs of women and men at all stages of their lives. One important need, often overshadowed by the more traditional aspects of reproductive health, is the detection and treatment of reproductive organ cancers (ROCs) which tend to affect both women and men) later in life. This is also true in Ethiopia, where ROCs are widespread, but are rarely acknowledged health problems.

Effective prevention and control of ROCs requires a holistic response from all stakeholders including the community. Thus, national and sub-national level cervical cancer prevention and screening requires policy interventions and multi-sectoral collaboration. Appropriate policies and legislation should be created and implemented to tackle the main risk factors (early marriage, multiple sexual partnerships, use of condoms). Advocacy and awareness raising activities should target policy makers, individuals and the population at large.

Communities should participate in developing their own health. Primarily the service shall be provided integrated within the existing health service delivery. Primary health care, particularly the Health Extension Program (HEP) and health centers, will play a central role in promoting the health of the community via health promotion and disease prevention to address risk factors for cervical cancer. Thus, it is mandatory to create awareness regarding ROCs at the community level. Socially and culturally appropriate and acceptable health promotion and awareness raising strategies should be designed and implemented. Standardized print and audiovisual materials on the prevention, detection and treatment of ROCs, particularly on cancers affecting women, e.g. materials on self-breast examination, early signs and symptoms of cervical/endometrial cancer, and cervical cancer screening, should be developed and distributed to raise awareness among health workers and the community in

large.

Quality health services should be provided for those in need. Essential cervical cancer prevention, screening, treatment and care should be provided within the PHC (HCs and primary hospitals) and services need to be linked to the higher level through a functional referral network. Resources need to be given due priority; and this includes the need for a skilled health workforce (both in number and training needs), infrastructure and essential medicines, diagnostic, palliative and therapeutic technologies must be availed as appropriate.

It is also important to conduct periodical assessment in order to determine the effectiveness of programs and frequency and type of ROCs. The Ministry will establish appropriate surveillance strategies, particularly cancer registries. Accordingly the Ministry is planning the expansion of cancer registries, from the one existing registry to an additional five. The information obtained from the registries will provide better understanding and evidence of the national cancer situation. In addition, the Ministry encourages individuals and institutions to conduct epidemiological and operational studies in order to expand the local evidence for action.

In summary, a clear strategy and action plan is required in order to achieve the stated goals. Thus, this document outlines the framework for the prevention and control of cervical cancer and for the reduction of morbidity and mortality attributable to cervical cancer. This guideline has been developed in order to enable the translation of this plan and to help define or redefine operational tools to implement.

1.5 Goal and Objectives of the Guideline

Goal: The main goal of this guideline is to provide healthcare providers, implementing partners and other stakeholders involved in the prevention and control of cervical cancer in Ethiopia with a standardized Cervical Cancer Prevention and control health service delivery directive.

Objectives:

- To lay out a standardized strategy for the implementation of cervical cancer screening and treatment
- To prevent avoidable mortality due to cervical cancer in Ethiopia
- To provide guidance and coordination for the prevention and control of cervical cancer in Ethiopia among different stakeholders

1.6 About the Current Guideline

The Ethiopia Guidelines for Cervical Cancer Prevention and Control include the three components of prevention and control: 1) primary prevention, 2) secondary Prevention, and 3) tertiary care.

Primary prevention includes prevention of infection with Human Papilloma Virus (HPV) either through behavior change mechanisms, such as abstinence or condom use, or through biological

mechanisms, such as the HPV vaccine. Secondary prevention, which is the main focus of the guideline, includes screening and treating precancerous lesions with effective outpatient methods. Tertiary care includes management of invasive cervical cancer (i.e. surgery, radiation therapy and chemotherapy), as well as palliative care. The guideline recommends an integrated, phased approach for introducing cervical cancer prevention services in the country, with coordination of the national strategy according to national, regional and district-level priorities. The guideline will be reviewed periodically to include updated information and inform public policy.

The guideline is intended for use by healthcare providers, trainers, managers, supervisors and policymakers:

As a reference guide for cervical cancer prevention and control in the context of a national program; To provide guidance to support effective planning, organization, implementation and monitoring of comprehensive cervical cancer prevention and control services.

1.7 Leadership and Coordination

For a cervical cancer prevention program to succeed, the health sector needs a genuine partnership whereby ownership of the program is shared with other stakeholders. Collaboration with relevant stakeholders is recommended to increase the utilization, coverage and sustainability of a cervical cancer prevention program in Ethiopia.

Governmental organizations, the nongovernmental sector, community groups, faith-based organizations, civil society organizations—including medical professional associations and others - should be engaged for advocacy, social mobilization and dissemination of cervical cancer prevention program activities.

The Federal Ministry of Health at National level and the Regional Health bureaus at Regional level will lead efforts regarding the cervical cancer prevention and control program. The National cancer committee, under the auspices of the First Lady, will play a coordination role as well as being actively involved in resource mobilization and mainstreaming of cervical cancer prevention and control in Ethiopia.

Who are the Main Actors?

1.7.1 National Cancer Committee

The goal of the National cancer committee is to coordinate and raise funds for the prevention, early detection, treatment and control of cancers in Ethiopia in general and cervical cancer in particular. Thus, under the auspices of the First Lady, the national cancer committee will play a central role in

resource mobilization, coordination, high level advocacy and actively engaging in the mainstreaming of cervical cancer prevention and control efforts in the country.

The Federal Ministry of Health will play a leading role in cervical cancer prevention, control, treatment and care. The Ministry is primarily tasked to develop and provide guidelines, training materials and implementation strategies, as well as to guide the prevention and control of cervical cancer efforts in the country. In addition, the Ministry should guide and assist regional health bureaus and implementing partners in performing their duties and responsibilities according to the national strategy and priorities. It will be in the Ministry's interest to produce local evidence through research and surveillance, adopt international scientific recommendations and disseminate to national stakeholders through various methodologies for action.

1.7.3 Regional Health Bureaus

Regional Health Bureaus (RHBs) will have the responsibility to ensure availability, accessibility and utilization of health services. The RHBs will play a major role in planning, implementing, coordinating monitoring and evaluation of cervical cancer prevention and control programs in their regions. According to their context, RHBs may adopt/adapt a regional cervical cancer prevention and control guideline and implementation plan.

1.7.4 Health Facilities

Health facilities are responsible for the provision of standardized and quality healthcare (promotive, preventive and curative) as per the national standard. Health facilities should design and implement appropriate communication and advocacy strategies to increase the utilization of cervical cancer promotive, preventive and curative health services by their community. Active participation of communities and individuals in health service delivery and utilization must be coordinated within the health facilities themselves.

1.7.5 Partners

In this document, "partners" is defined broadly and includes, but is not limited to: UN agencies, donors, NGOs, private sector, professional associations, patient associations, NCD consortium. Unless and otherwise stated, partners involved in the prevention and control of cervical cancer in Ethiopia shall abide within the framework of this guideline. All services provided in the field of cervical cancer by all stakeholders should be made in reference to this guideline.

CHAPTER 2

Advocacy, Communication and Social Mobilization

Community mobilization is an important component of a comprehensive cervical cancer prevention and control program. This section outlines the role of advocacy, communication and social mobilization in promoting cervical cancer prevention.

Advocacy, communication and social mobilization are three distinct sets of activities, all of which have the shared goal of bringing about behavioral change. These activities complement health system improvements and help achieve cervical cancer prevention and control goals by empowering communities and maintaining political and financial support.

Advocacy primarily aims to secure needed financial resources and change policies and guidelines by influencing stakeholders such as politicians, decision-makers and journalists.

Behavior Change Communication (BCC) seeks to increase awareness of cervical cancer prevention, influence social norms and facilitate behavior change amongst selected individuals or sub-populations to prevent cervical cancer.

Social mobilization is a broad-scale movement to engage people's participation in achieving a specific development goal of cervical cancer prevention and control by embracing the principle of community involvement.

Accurate information is essential to improving understanding of both HPV and cervical cancer amongst health care workers, educators, policy makers, parents and patients. Many do not know the cause and burden of cervical cancer and may not be able to understand the value of cervical cancer prevention activities. Without such understanding and strong advocacy, individuals are less likely to access services. Women and community members must be aware of the problem of cervical cancer, their potential risk of developing the disease and facilities in which they can access cervical cancer prevention services.

To improve knowledge, it is important to first decide how best to frame the information by considering socio-cultural realities. Effective framing can help to avoid social resistance. Community readiness and acceptance will help to ensure access of women to cervical cancer screening and treatment services, which is essential to ensure the success of a cervical cancer prevention program.

To increase use of cervical cancer prevention services, an information and education plan that considers a combination of community-, facility- and media-based strategies should be implemented to inform women and their partners about the benefits and availability of cervical cancer prevention

services. Direct contact with health care providers and peer educators, is also an alternative strategy for increasing use of services.

The FMOH recommends that information and education strategies should be directed towards women who have never been screened before, and towards their partners and family members who can encourage them to solicit screening and comply with follow-up instructions. Healthcare providers should pass on clear and consistent messages in a language that is understood by the audience. The following three basic types of informational and educational strategies are recommended:

Facility-based: One-on-one and/or group education to inform patients who are attending health facilities

Community-based (outreach): One-on-one and/or group education to inform people in the home and community settings

Media based: Using radio, television and print media to convey messages to a larger and more dispersed audience

mHealth and eHealth: with the advancement of technologies it may also be possible to conduct health education and awareness creation via mobile and electronic media.

To increase awareness of cervical cancer prevention the following advocacy strategies are recommended:

Conduct advocacy meetings: at different levels, such as women groups, policymakers, politicians, development partners, religious leaders and community champions.

Promote advocacy campaigns: at national, regional, district, village and community levels.

An outcome of interest for advocacy, BCC and social mobilization activities is that women actually access the cervical cancer prevention services available. The communication strategies and messages should be monitored and evaluated to assess their effectiveness and to guide future efforts. The following section describes the roles that various stakeholders can play in community education and mobilization.

2.1 Health Facilities

Health facilities are responsible for the implementation and design of appropriate communication and advocacy strategies to increase the utilization of cervical cancer prevention services. A good communication strategy at this level requires well-trained staff to provide education and counseling to clients.

Health care workers may not have a clear understanding of HPV infection and its relationship to cervical cancer development and prevention. This situation is exacerbated by the “nature” of cervical cancer—the fact that clear symptoms are not present until the cancer is at an advanced stage.

Health care workers need to be educated about how to help patients understand the enormous advantages offered by the various cervical cancer prevention services, as well as their limitations.

Identification of settings for information delivery: The FMOH recommends integration of cervical cancer prevention services in the following settings: reproductive and child health clinics, gynecology clinics, outpatient clinics, as well as care and treatment clinics (CTCs). Mobile/outreach clinics are also encouraged to increase uptake of the program.

2.2 Health Extension Workers and Health Development Army

FMOH have deployed 39,000 Health Extension Worker and three million more members of the health development army to mobilize and disseminate health messages. In Ethiopia, health development armies and HEWs are an essential part of the community, and could play a key role in promoting the acceptability of cervical cancer prevention services. It is important to provide HEWs and the HDA with the correct information about cervical cancer prevention program. The roles of HEWs and HDA will include:

- Advocating for and providing information about cervical cancer prevention services.
- Identifying the eligible groups and assisting women in making decisions to attend the health facilities for cervical cancer prevention services.
- Engaging cervical cancer survivors (persons who have successfully been treated for cervical cancer) in education and advocacy for cervical cancer prevention. People with first-hand knowledge of the importance of early detection can provide powerful messages based on their experience.

2.3 Communication Channels

It is recommended that a combination of communication channels be used to advocate for cervical cancer prevention. The messages used during the communication must be: consistent, culturally specific and appropriate to local communities.

Communication channels include:

- Electronic: televisions, radio, mobile phones, social media, internet
- Printed materials: newspapers, posters, brochures
- Cultural and festival activities

The following audiences can be used effectively to deliver appropriate messages:

- Government leaders
- Political leaders
- Religious leaders (groups)
- Cultural groups (local artists)

- Community leaders such as counselors and parliamentarians
- People living with HIV infections (PLHIV)
- Peer educators
- Health extension workers and health development army

2.5 Advocacy, Information and Communication for HPV Vaccine

Development of an advocacy, information and communication package related to an HPV vaccine program presents specific challenges and opportunities. One challenge is to produce a balanced public education package about HPV, cervical cancer and other HPV-related cancers and diseases, and to explain the benefits and limitations of the vaccines. The messages should be aligned to specific target audiences and with the stages of introducing the vaccine program. Advocacy for HPV vaccine should target key stakeholders, policymakers, health professionals, adolescents, women, men and the community at large. It is also important to avoid focusing exclusively on girls who are targeted to receive the vaccine; appropriate messages have to target boys as well.

2.6 Counseling for Screening and Control of Cervical Cancer Program points

Counseling is face-to-face, personal, confidential communication, in which the counselor helps the client to make decisions and act on them. Counseling is a two-way communication between a client and provider to identify and address the client's needs and concerns. Counseling requires listening and conversational skills and knowledge of the subject being discussed.

Counseling can help a person to make decisions only if:

There is mutual trust between the client and the counselor;

There is a two-way transfer of relevant, accurate and complete information.

The content of counseling about cervical cancer will vary according to the client's problem or concern and her individual circumstances. It can cover prevention, screening, follow-up, referral, diagnosis, treatment of precancerous conditions, and treatment of invasive cancer. The depth and detail of communication will vary according to the patient's situation and needs and the category and level of provider.

Counseling should be structured to educate the woman, review the results of screening and follow-up, present alternative services and procedures, and discuss any follow-up she may need. This will give the woman the tools she needs to make rational decisions for herself.

Counseling can also help patients and their families to cope with a diagnosis of invasive cancer and terminal disease. Such counseling may involve only the patient, or also her partner and other family

members, especially if decisions concerning severe disease or costly treatment need to be made.

A good counselor uses verbal and non-verbal communication skills, and helps the client feel at ease by empathizing with her situation, reassuring her, and fostering a sense of partnership in helping her solve her problem.

An effective counselor should also have the ability to listen, up-to-date knowledge, build mutual trust with the patient and understand the sensitivity in addressing and discussing private topics, particularly related to sexuality and behavior.

Who needs to be counseled?

All women who have to decide whether to have a service should receive counseling, as well as those who have chosen to have the service and need information on what it entails and how it relates to their present and future health.

CHAPTER 3

Primary Prevention

3.1 Primary Prevention of HPV Infection and Cervical Cancer

Primary prevention of cervical cancer involves prevention of infection with HPV. Almost all of cervical cancer is due to HPV infection, a virus transmitted through sexual contact. There are a number of varieties of subtypes of HPV that can cause cervical cancer but, the predominant subtypes are 16 and18. Primary prevention can be achieved through behavioral change approaches and the use of biological mechanisms, including HPV vaccination. Abstinence from sexual exposure, being mutually faithful and consistent condom use can reduce the risk of HPV transmission. Condoms only offer partial protection against HPV transmission, because the virus can exist on body surfaces not covered by the condom, such as the perianal area and anus in men and women, the vulva and perineum in women, and the scrotum in men. Despite this, consistent and correct condom use is highly recommended.

Currently, there are two types of HPV vaccines: the bivalent vaccine (Cervarix), which protects mainly against HPV genotypes 16 and 18, and the quadrivalent vaccine (Gardasil), which protects against genotypes 6, 11, 16 and 18. These two vaccines have been evaluated in large clinical trials and proven to prevent the two most important high-risk HPV types—genotypes 16and 18—which are known to cause up to 70% of cervical cancers. These vaccines also provide cross-protection against other oncogenic HPV genotypes.

Both Cervarix and Gardasil have been shown to be effective in preventing cervical precancerous lesions over the period of more than ten years since they have been in use. Both vaccines are given in a series of three0.5 ml intramuscular injections within six months, and require storage and transport in a cold chain system. Table 3.1 summarizes the characteristics of the two vaccines.

NOTE: HPV vaccines are not intended to treat women with past or current HPV infection

Table 3.1: HPV Vaccines

	Quadrivalent Vaccine - Gardasil	Bivalent Vaccine - Cervarix
Manufacturer	Merck	GlaxoSmithKline
Virus-like particles of genotypes	6, 11, 16, 18	16, 18
Schedule: 3 doses at interval of	0, 2 and 6 months	0, 1 and 6 months
Recommended age of 1st dose	9-15 yrs	10-14 yrs

Source: WHO 2007

3.2 HPV Vaccine Introduction

The recommendations in this chapter have been made in accordance with WHO recommendations for resource-poor countries (WHO 2006, 2009A, 2009B). While the HPV vaccine holds promise for cervical cancer prevention, a number of programmatic issues need to be addressed before introducing the vaccine. HPV vaccination program may be cost-effective in countries where high-quality screening is not widespread, vaccination coverage is high (>70%), and the cost of a three-dose course is low (< US$10-25). If used, HPV vaccination should be a part of a coordinated strategy, including appropriately targeted messages to different audiences, and should not undermine or divert funding from effective screening program.

It would be wise to remember any effect of a vaccine on the incidence of cervical cancer would not be noticeable for some decades after introduction of the HPV vaccine. Therefore, widespread screening for cervical cancer needs to continue, even after an HPV vaccine program is fully implemented, in order to detect cervical abnormalities in the unvaccinated and previously infected population, as well as cancer caused by other serotypes of the HPV and to monitor and evaluate progress towards the goals of the vaccination program.

Generally, adolescent girls of age 9 – 13 years are the current target for HPV vaccinations. Delivering HPV vaccine to these target groups requires a systematic approach such as school based, health facility based, outreach or a combination of either structures. So far, HPV immunization has not been introduced in the public sector in Ethiopia however, the country is in an active phase of introducing the HPV vaccine as a demonstration phase which eventually will be launched nationwide.

CHAPTER 4

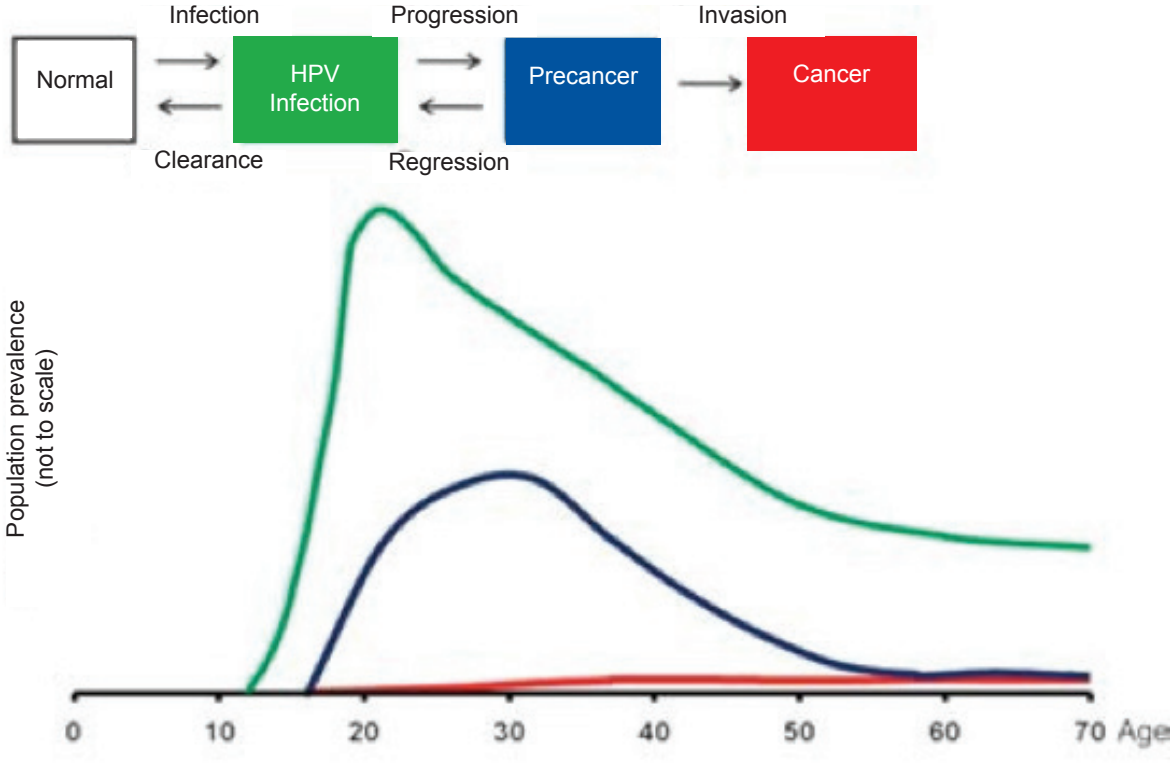
Secondary Prevention

4.1 Introduction

Secondary prevention aims to prevent invasive cervical cancer by detecting and treating precancerous lesions of the cervix before they progress to cancer. Cervical cancer has a long precancerous period, usually taking more than 10 years to progress from precancerous lesions to invasive cancer. As a result, it is rare for cervical cancer to develop in a woman less than 30 years of age (WHO 2006). This long precancerous stage provides an excellent opportunity for effective intervention measures (see Figure 4.1).

HIV-positive women are at an even greater risk for developing cervical cancer. A number of factors can increase cervical cancer risk in HIV-positive women, as compared to their HIV-negative counterparts (Branca, 2003; DeVuyst, 2008 &Parham, 2006). Ethiopia had an HIV prevalence rate of 1.9% amongst women aged 15–49 yrs, which has significant implications for the national program (UNAIDS 2008).

Figure 4.1: The timeline and natural history of cervical pre-cancer and cancer development



4.2 Elements of Secondary Prevention (Screening Programs)

Secondary prevention stops the progression of disease once it has already started. A good example of secondary prevention is cytologic screening to detect cervical cancer precursors, followed by treatment to prevent progression to cancer. Screening tests for cervical cancer such as cytologic evaluation, visual tests, and tests for HPV infection are all capable of identifying women with a high probability of having cervical intraepithelial neoplasia (CIN), squamous intraepithelial lesions (SIL), or preclinical invasive cancer. The objective of cervical screening is to prevent invasive cervical cancer by detecting and treating women with CIN 2/3 lesions (high-grade cervical cancer precursor lesions), and the effectiveness of screening is evaluated by the reduction in cervical cancer incidence and mortality observed following screening.

What is screening?

Screening is a public health intervention used on a population at risk, or target population. Screening is not undertaken to diagnose a disease, but to identify individuals with a high probability of having or of developing a disease. Women targeted for screening for cervical cancer may actually feel perfectly healthy and may see no reason to visit a health facility. Not all diseases can be screened for. The following criteria should be met by any disease that is the object of a screening program:

- ✓ The disease must have serious public health consequences.
- ✓ The disease must have a detectable preclinical stage (without symptoms).
- ✓ The screening test must be simple, non-invasive, sensitive, specific, inexpensive and ac ceptable to the target audience.
- ✓ Treatment at the preclinical stage must favorably influence the long-term course

Screening programs will only be successful if the following elements are present

- ✓ High coverage (80%) of the population at risk of the disease (“Coverage” is the proportion of women in the target age group who are screened at the recommended inter vals during a given time period). The number of screening tests done is not cover age, since this num ber may include women outside the target age, and women screened more often than recommended.
- ✓ Appropriate follow-up and management for those who are positive on screening.
- ✓ Efforts to increase coverage will be wasted if those who test positive are not followed up correctly;
- ✓ Effective links between program components (e.g. from screening to diagnosis and treatment);
- ✓ high quality of coverage, screening tests, diagnosis, treatment, and follow-up;
- ✓ Adequate resources.

Cervical cancer screening aims to test the largest possible proportion of women at risk and to ensure appropriate follow-up for those who have a positive or abnormal test result. Such women will need

diagnostic testing and follow-up or treatment. Colposcopy and biopsy are often used to reach a specific diagnosis of the extent of the abnormality in women with a positive screening test

Choice of screening test to be used

The choice of screening test or tests to be used is usually made at the national or regional level. Nevertheless, providers should have some basic knowledge of all the available screening tests.

Decisions on the test or tests to be used may be based on:

- the organization of the health system;
- the funds available;
- the number and type of health workers;
- the availability of laboratory services and transport;
- The availability and cost of the various screening tests.

The test used may also be determined based on the physical proximity of services to women; for example, it might be decided to use the Pap smear (which requires women to return for their test results) in urban areas and visual inspection with acetic acid (VIA) (for which results are immediately available) in more inaccessible rural areas in the same country. The most extensive and long-term experience in cervical cancer screening is with cytology, which has been used in numerous countries since the 1950s. Cytology-based screening and treatment programs have reduced cervical cancer incidence and mortality by as much as 80% in Canada, the USA and some Nordic countries, and by 50–60% in other European countries.

It has been difficult to replicate this success in low-resource settings, because of the inherent requirements of a cytology-based program. These include highly trained personnel, well equipped laboratories, transport of specimens, and an effective system for collecting information and following up patients. In addition, the demands of other competing health needs often result in a lack of resources or political will to make cervical cancer screening a priority.

Because of the problems of implementing quality cytology-based screening, alternative methods, such as visual inspection, have been developed. These methods have shown promise in controlled research settings but have not yet been widely implemented. Their ultimate impact on cervical cancer incidence and mortality will not be known until large ongoing population-based studies are completed. HPV-based tests are now also commercially available, but have disadvantages, including the need for sophisticated laboratory facilities and high cost.

Ethical issues

Decisions on how best to use scarce resources have to weigh the extent of disability and death caused by different diseases, and the efficacy, cost and impact of diagnosing and treating them. While deci-

sions about priorities are usually made at national level, providers should understand the reasons for the decisions; so that they are motivated to implement them and can explain them to their patients. If well planned and integrated into other sexual and reproductive health activities, screening for cervical cancer has the potential to both strengthen the health care

system and improve the health of women, particularly women over childbearing age, whose health is often relatively neglected.

Before a screening program is implemented, the following elements should be considered to ensure an ethical and equitable approach:

- ✓ Screening should be accessible to all women in the target group, including the poorest, most vulnerable, and hardest to reach.
- ✓ Patients, providers and communities should receive health education to ensure informed decision-making on screening and treatment.
- ✓ Patient record systems should ensure confidentiality.
- ✓ Diagnostic tests, follow-up, and treatment should be available and accessible.
- ✓ Providers should have clear guidelines on follow-up and management of women with positive screening results.
- ✓ A referral system should be in place for other health problems, including gynecological disorders, discovered during the screening process.

Informed choice and Informed Consent

Informed choice and informed consent are based on the ethical principles of autonomy and respect for the individual. In many cultures, the notion of consent may be collective decision-making process involving others, such as partner, family, and village leaders. Accurate information provided through health education and counseling can ensure that women and their extended families understand the facts about cervical cancer, which is at risk, how screening can reduce risk, and any potential harm related to screening. Before consenting to screening, women should be given information on the specific test to be used, the meaning and consequences of a positive test, and the availability of treatment. In addition; when results are not available immediately (as they are with visual screening methods), informed consent should include explicit permission to be contacted at home or at work. Respect for autonomy requires that the choice to be screened is voluntary and free of coercion.

(Informed consent is not equivalent to informed choice. Consent refers to the explicit permission given by a person for a procedure or test, once she (or he) has received sufficient information to make a rational personal (informed) choice.)

Client assessment

All clients attending for screening should have a basic assessment before proceeding to the screening

test. This assessment should include information and counseling, informed consent, a social and clinical history, and a physical examination. The history can provide useful information for guiding decisions about management or additional examinations or tests that might benefit the patient. Because of the stigma associated with genital problems, women are often reluctant to talk about their concerns or symptoms and signs. To establish and maintain trust and respect, confidentiality and privacy must be explicitly guaranteed to each woman who presents for screening before she is asked about her history. For cervical cancer screening, the essential components of the pelvic examination are visual inspection of the external genitals and speculum examination. Providers should explain what is being done at each step during the examination; if an abnormality is noted, the provider should inform the woman without alarming her. Having female providers perform the physical examination, if possible, can greatly reduce reluctance to be examined and can play a major role in making screening acceptable. When the provider is a man, the woman may request that a female companion or clinic attendant is in the room.

Sexual and reproductive health problems detected during history-taking and examination

An integrated approach to management of sexual and reproductive health problems during screening can help improve the health of women, especially older women. The provider should pay particular attention to signs and symptoms suggestive of cancer, STI, or other diseases detected during history-taking and pelvic examination. In addition, women should be offered an opportunity to raise personal concerns regarding sexual and reproductive health issues. Women with abnormal findings can be treated or referred for further investigation, as appropriate.

Infection prevention in cervical cancer screening

In screening, as in all clinical activities, scrupulous attention should be given to infection prevention. Pathogens, including HIV, can be transmitted if guidelines on hand washing, handling of instruments, and disposal of used supplies, including gloves, are neglected. Universal precautions against spreading infection should be used with all patients, whether they appear sick or well, and whether their HIV or other infection status is known or not. In this way, providers protect both their patients and themselves. Providers should use only uncontaminated instruments, and should wear latex gloves on both hands when performing speculum or bimanual examinations and taking specimens, and when performing procedures such as cryotherapy.

Screening Tests

A good screening test should be:

- ✓ accurate;
- ✓ reproducible;
- ✓ inexpensive;
- ✓ easy to perform and easy to follow up;
- ✓ acceptable;
- ✓ safe

The following tests meet the above criteria to a greater or lesser extent:

1. Cytology: conventional (Pap smear) and liquid-based;

2. HPV DNA test;

3. Visual inspection: with acetic acid (VIA) or Lugol's iodine (VILI).1.

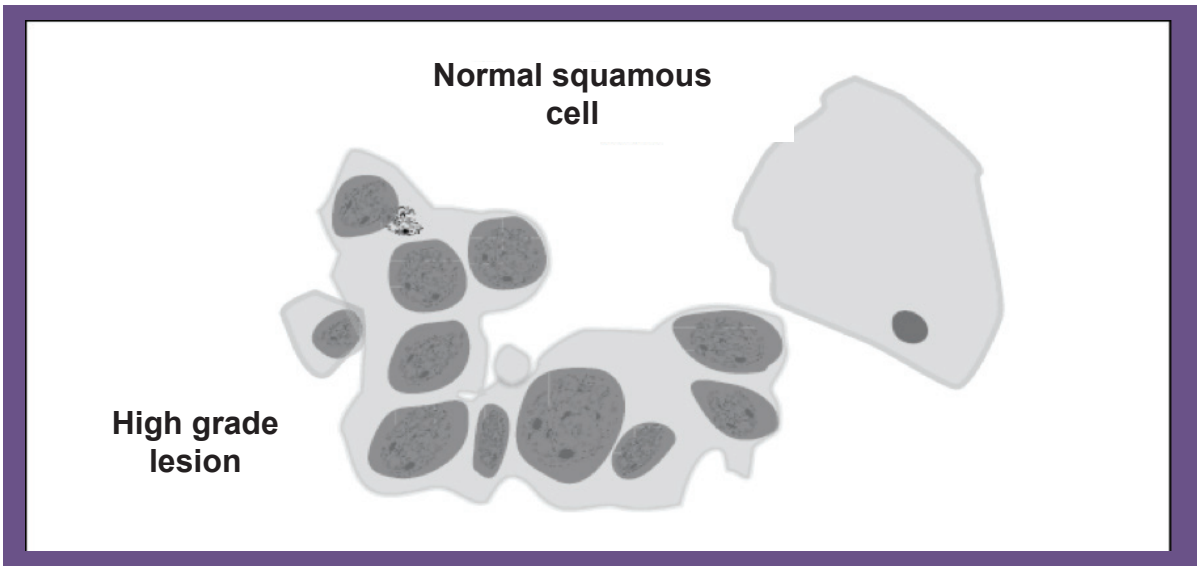
1. Cytology

1.1 Conventional Pap smear

In the Pap smear test, a sample of cells is taken from the transformation zone of the cervix using an extended-tip wooden spatula or brush; using a cotton swab is no longer recommended. The entire transformation zone should be sampled since this is where almost all high-grade lesions develop. The sample is then smeared onto a glass slide and immediately fixed with a solution to preserve the cells. The slide is sent to a cytology laboratory where it is stained and examined using a microscope to determine whether the cells are normal (see figure 4.1) and to classify them appropriately, using the Bethesda classification. The results of the Pap smear are then reported to the clinic where the specimen was taken. Health workers are responsible for ensuring that the woman is informed of her result and that she receives appropriate follow-up. The Pap test takes less than 5 minutes to perform, is not painful, and can be done in an outpatient examination room. It is advisable to postpone taking a Pap smear if the woman is menstruating actively, has a clinically evident acute inflammation, or is pregnant. A satisfactory smear requires adequate numbers of well-preserved squamous epithelial cells and an adequate endo-cervical/transformation zone component. Each smear should be legibly labeled.

The accuracy of cytological testing depends on the quality of the services, including sampling practices (taking and fixing the smears), and preparation and interpretation of smears in the laboratory. Under the best conditions in high-income countries or research settings, conventional cytology can detect up to 84% of pre-cancer and cancer. However, under poor conditions its sensitivity can be as low as 38%. The specificity of the test is usually over 90%.

Figure 4.2: Graphic representation of normal and abnormal epithelial cells



1.2 Liquid-based cytology (LBC)

This refinement of conventional cytology was introduced in the mid-1990s and is increasingly used in high-resource settings. Instead of smearing cervical cells on aside, the provider transfers the specimen from a brush to a preservative solution. The specimen is sent to a laboratory where the slide is prepared. LBC is more expensive than conventional cytology and laboratory staffs need to be specially trained. However, it appears to have a number of advantages over conventional methods.

- ✓ The specimens obtained are more representative of the areas sampled with fewer false negatives.
- ✓ There are fewer unsatisfactory specimens.
- ✓ Each specimen requires a shorter interpretation time, leading to increased efficiency and cost-effectiveness.
- ✓ The material collected can also be tested for HPV DNA.

Several studies have shown that LBC is more sensitive than Pap smear and has almost the same specificity.

Providers

After a short training course; any provider who knows how to do a speculum examination (nurse, auxiliary or assistant nurse, midwife, clinical officer, medical doctor) can take a Pap smear.

Indications

The following groups of women should be offered screening:

- ✓ Any woman between the ages of 25 and 65 years, who has never had a Pap smear before or who had one 3 or more years ago (or according to national guidelines).
- ✓ Women whose previous Pap smear was reported as inadequate or showed a mild abnormality.
- ✓ Women who have abnormal bleeding, bleeding after intercourse or after the menopause, or other abnormal symptoms.
- ✓ Women who have been found to have abnormalities on their cervix.

Interpretation of smears

Smears are read in a laboratory by trained cyto-technicians, under the supervision of a pathologist, who has final responsibility for the reported results. Correct interpretation of slides is crucial to a successful program. To maintain proficiency and avoid fatigue, cyto-technicians should spend a maximum of 5 hours a day at the microscope and should review a minimum of 3000 slides per year. Quality assurance is crucial and should be established in all cytology laboratories. The two most commonly

used methods are rapid review of all negative slides and full rescreening of a 10% random sample of slides originally reported as negative. In both methods, the review is done by another cyto-technician, with confirmation of abnormal smears by the supervising pathologist. Current evidence shows that, of the two methods, rapid review of all negative smears is more effective and more cost-effective. Laboratories should be equipped to read a minimum of 15 000 smears annually.

Therefore, cytology services should not be decentralized to primary health care clinics or to small laboratories. Reliable transport of slides and test results to and from the laboratory is essential. Cytology is recommended for large-scale cervical cancer screening programs, if sufficient resources exist.

2. HPV DNA-based screening methods

New screening procedures are based on the detection of high-risk HPVDNA in vaginal or cervical smears. A sample of cells is collected from the cervix or vagina using a swab or small brush, and placed in a small container with a preservative solution. The specimen can be collected by a health care provider or by the woman herself, inserting a swab deep into the vagina. Studies comparing the two collection methods have shown that self-collection is less sensitive than provider-collection. In either case, the specimen containers are transported to a laboratory where they are processed. HPV DNA-based tests currently require sophisticated and expensive laboratory equipment, although work is under way to develop a more affordable and less complicated test that can be carried out in lower level settings. Detection of high-risk HPV does not necessarily mean that precancer or cancer is present; it indicates simply that there is an HPV infection. As mentioned earlier, HPV infections are extremely common in women under 35 years, and most of them resolve spontaneously. When detection of HPV is used as a primary screening test, the sensitivity for detection of precancer and cancer varies from 50% to 95%, with most studies reporting high sensitivity of 85% or more. The specificity ranges from 50% to 95%, with an average of 84%. In women aged 35 years or older, HPV DNA tests perform better because in these women a positive test is more likely to be due to a persistent infection than in younger women. The average sensitivity and specificity in this group are 89% and 90%, respectively. The combination of cytology and HPV testing has very high sensitivity and negative predictive values approaching 100%. It might therefore be possible to increase the interval between screenings for women who are negative on both tests. However, performing the two tests together is expensive. The high cost, and the need for both a molecular laboratory and reliable methods of transport, present major challenges, and the feasibility of HPV testing has not been demonstrated in low-resource settings. A new, faster, highly sensitive and less costly test for HPV is under development but is not yet available.

Providers

HPV DNA testing can be done by trained providers at any level of the health care system, provided that there is an appropriate laboratory within a reasonable distance, and that reliable transport is available for specimens. Clinic needs for HPV testing are the same as for Pap smears and visual methods.

Indications

HPV is not generally used on its own as the primary screening test. It is mainly used in combination with cytology to improve the sensitivity of the screening or as a triage tool to assess which women with borderline Pap results need to be referred for colposcopy. The main indication is a Pap result of "atypical cells of undetermined significance" (ASC-US). Of the women with this lesion, only those who test positive for high-risk HPV will need to be referred for colposcopy and biopsy, significantly reducing the number of colposcopies.

Laboratory facilities

The HPV laboratory requires a special clean room to avoid contamination, and highly trained technicians. It also requires equipment and reagents as specified by the manufacturers of the test.

Recommendation

HPV DNA tests as primary screening methods, at this time, are recommended for use only in pilot projects or other closely monitored settings. They can be used in conjunction with cytological or other screening tests, where sufficient resources exist. HPV DNA-based screening should not begin before 30 years of age.

3. Visual methods

Two visual methods are available:

3.1 Visual inspection with acetic acid (VIA);

3.2 Visual inspection with Lugol's iodine (VILI)

Abnormalities are identified by inspection of the cervix without magnification, after application of dilute acetic acid (vinegar) (in VIA) or Lugol's iodine (in VILI). When vinegar is applied to abnormal cervical tissue, it temporarily turns white (aceto-white) allowing the provider to make an immediate assessment of a positive (abnormal) or negative (normal) result. If iodine is applied to the cervix, precancerous and cancerous lesions appear well-defined, thick, and mustard or saffron-yellow in color, while squamous epithelium stains brown or black, and columnar epithelium retains its normal pink color. Because they do not rely on laboratory services, VIA and VILI are promising alternatives to cytology where resources are limited. They are currently being tested in large, cross-sectional, randomized controlled trials in LMICs. Until data from these studies are available, VIA and VILI are recommended by WHO only for use in pilot settings, because the impact on cervical cancer incidence and mortality is still unproven. In research settings, VIA has been shown to have an average sensitivity for detection of precancer and cancer of almost 77%, and a range of 56% to 94%.The specificity ranges from 74% to 94% with an average of 86%. Low level magnification does not improve the performance of VIA over and above that of naked eye visualization. One study has shown that VILI can

detect 92% of women with pre cancer or cancer, a sensitivity considerably higher than that of either VIA or cytology. Its ability to identify women without disease is similar to that of VIA (85%), and lower than that of Pap smears. One study showed that VILI had a higher reproducibility than VIA. VIA and VILI can be performed in clinics and other outpatient facilities. They are both short procedures and cause no pain. Assessment is immediate, and no specimen is required.

Advantages

- ✓ VIA and VILI are relatively simple and can be taught to nurses, nurse-midwives and other health workers.
- ✓ Assessment is immediate and no transport, or laboratory equipment or personnel, is needed.
- ✓ The tests are likely to be less costly than other approaches in routine use.
- ✓ Results are available immediately, eliminating the need for multiple visits in most cases, and reducing loss to follow-up.
- ✓ They could potentially be used in an approach based on screening and treating women in a single visit.

Disadvantages

- ✓ Because of the low positive predictive value of the test, a considerable number of women who test positive do not have disease, resulting in excessive diagnosis and treatment, and unnecessary anxiety.
- ✓ Visual tests cannot be relied on in postmenopausal women, because the transformation zone of these women is often inside the cervical canal.
- ✓ There is no permanent record of the test that can be reviewed later.
- ✓ VIA has mostly been evaluated as an once-in-a-lifetime screening test, and its perfor mance in periodic screening has not been assessed.

Providers

Trained nurses, nurse-midwives, nurse assistants, physicians and other health workers with adequate and ongoing support and supervision can perform VIA. Training takes 5–10 days using a competency-based approach. To maintain quality services, it is important that an experienced provider conducts regular assessments. Studies show that immediately after training, providers have more false positive results. These decrease in a few months as the providers gain experience.

Indications

If adopted by a program as a screening method, VIA and VILI are indicated for all women in the target age group specified in national guidelines, provided that:

- ✓ They are premenopausal. Visual methods are not recommended for postmenopausal women, because the transition zone in these women is most often inside the endo-cervical canal and not visible on speculum inspection.
- ✓ Both squamo-columnar junctions (i.e. the entire transformation zone) are visible.

If the patient does not meet the above indications and no alternative screening method is available in the particular clinical setting, she should be referred for a Pap smear.

Recommendation

Visual screening methods (VIA and VILI) are recommended for use in resource limited but closely monitored settings. These methods should not be recommended for postmenopausal women.

Follow-Up

Follow-up and management of women with an abnormal (positive) test

Screening by itself will not prevent a single case of cervical cancer. An effective system for follow-up and treatment of women who test positive is perhaps the most important component of a successful cervical cancer prevention program. Ideally, all women should receive the results of their test, whether negative or positive. In practice, resources will sometimes be too limited to allow this. At the very least; women whose test results are positive or abnormal must be informed of the results and of what follow-up is needed. Follow-up is essential for the woman's welfare and for the success of the program and every effort should be made to contact women with positive test results.

The following actions will help ensure that women with an abnormal screening test can be reached for follow-up:

- ✓ The woman's address, or other information on how she can be reached, should be noted at the time of screening (with her consent).
- ✓ During counseling and after screening, providers need to emphasize the importance of coming back for results and follow-up care.
- ✓ Every clinic should have a directory of all women with abnormal test results, with an indication of whether they have received the results and been followed up. Clinics should designate someone to ensure that follow-up is done.

For women who do not return spontaneously as advised, providers can:

- ✓ Send a letter by mail;
- ✓ Telephone women at home or at work;
- ✓ Ask community health workers to contact women directly at home.

Health care managers and providers can develop other locally appropriate approaches to reach women with abnormal screening tests. Health facilities need to make every effort to find women with abnormal results if they do not return for scheduled appointments.

Record-keeping

Records should be compatible throughout a country, so that all the data collected by the cervical cancer control program can be compared. The information system should include every woman's clinical record, appointments scheduled, and those kept or missed. This can be a simple paper record or can be computer-based. A logbook can be used to register women screened and record their test results. If women need to return later for their results, a system must be in place to ensure that those with abnormal results are notified and that women who are hard to locate are traced.

4.3 Screening activities at different levels of the health system

In the community (by health development army in the community and health extension workers in health posts)

- ✓ Educate and inform the community, promote the screening program, and encourage women to attend.
- ✓ Refer appropriate women for screening
- ✓ Assist women to attend screening clinics.
- ✓ Assist in follow-up of women with a positive screening result to ensure that they return to the clinic for management.
- ✓ Support and supervise health development armies by HEWs

At the health center

- ✓ Screen, using methods specified by national guidelines (VIA) and integrating screening into other services.
- ✓ Train, support and supervise HEWs and HDA.
- ✓ Work with HEWs and HDA to educate women, and recruit them for screening.
- ✓ Participate in campaigns to bring women at high risk for testing.

- ✓ Provide counseling and health education in the clinic and community.
- ✓ Inform and counsel women with positive screening test results, and advise them on needed follow-up, diagnosis and treatment.
- ✓ Implement an accurate patient information system, to allow proper tracking and follow-up of women after treatment.

At the district hospital

- ✓ Carry out screening activities as per national program.
- ✓ Inform and counsel women with positive screening test results, and advise them on needed follow-up, diagnosis and treatment.
- ✓ Train, support and supervise providers at health center level.
- ✓ Manage referral systems with lower and higher levels of the health system.
- ✓ Carry out screening in outpatient clinics where women are seen.
- ✓ Maintain central cytology, pathology, and molecular laboratories, as feasible.
- ✓ Interpret screening and histopathology results and ensure that results reach the screening site.
- ✓ Train medical personnel, and support and supervise providers in lower-level health facilities.
- ✓ Manage referral and links with lower levels of the health system.

At the central hospital

- ✓ Carry out screening in outpatient clinics where women are seen.
- ✓ Maintain central cytology, pathology, and molecular laboratories, as feasible.
- ✓ Interpret screening and histopathology results and ensure that results reach the screening site.
- ✓ Train medical personnel, and support and supervise providers'in lower-level health facilities.
- ✓ Manage referral and links with lower levels of the health system.

Target Population

The program will focus efforts on screening and treating women between the ages of 30and 49 years, unless HIV-positive (see below). The target age group could be expanded (e.g., to ages 25-59years), as dictated by relevant national data, and if resources permit. Screening is not indicated in women with previous total hysterectomy for benign indications (e.g., uterine fibroids).

HIV-positive Women and Integration as Part of Routine Care

HIV-positive women are at a much greater risk for developing cervical cancer and require a more intensive screening. Start screening at HIV diagnosis, regardless of age, once sexually exposed and screen every five years be integrated with national policy as part of routine care for HIV-positive women. Care and treatment clinic (CTC) sites should be closely linked with sites providing cervical cancer prevention services, or ideally, provide the services themselves.

Screening Frequency

The FMOH recommends screening every five years following normal results irrespective of HIV status. Following abnormal results and/or treatment, repeat screening in one year. If follow-up screening is normal, return to screening every five years.

Screening Coverage

Every woman has the right to be screened for cervical cancer at least once in her lifetime. Aim to screen at least 80% of women in the target population over a defined period of time. Based on the population census, the 2014 projected estimate of women aged 30 to 49years comprises approximately 8.9% of the total population of 93 million, yielding an estimate of8.4million women who would need to be screened to achieve 80% coverage.

4.4Treatment of Precancerous Lesions

Cryotherapy

Cryotherapy is the treatment of choice for precancerous lesions that meet eligibility criteria. Treatment is to be offered without requiring biopsy diagnosis (screen and treat) in a SVA whenever feasible. Only providers who have demonstrated clinical competencies in cryotherapy are permitted to perform the procedure. Treat using a double-freeze (three minutes freeze, five minutes defrost, three minutes freeze) technique to achieve a 3-5 mm ice ball around the cryo-tip. Follow-up screening with VIA in one year.

Do not treat with cryotherapy during pregnancy. Reschedule the woman when she is more than 12 weeks postpartum.

LEEP

LEEP is reserved for precancerous lesions that are not eligible for cryotherapy. LEEP may be used in cases suspicious for cancer, but only as a diagnostic tool. LEEP is reserved for those who have demonstrated clinical competence in the procedure. LEEP requires anesthesia and is to be performed only in settings that can handle potential urgent complications related to the procedure (e.g., heavy bleeding).Follow-up screening with VIA in one year.

Conization (Cone Biopsy)

Conization is the removal of a cone-shaped area from the cervix, including portions of the outer cervix (ecto-cervix) and inner cervix (endo-cervix). Excision can be performed with a scalpel (cold-knife conization), laser, or electrosurgical loop. Cold-knife conization (also called “cone biopsy”) involves removing a large area of the cervix with a scalpel, and is usually done in the operating room under general or regional (spinal or epidural) anesthesia. It provides clean specimen margins for looking at under a microscope, but it is typically associated with more bleeding than laser or LEEP.

Conization is recommended for the treatment of lesions that cannot be treated with cryotherapy (large

or unknown extent of lesion) and unclear type of cervical abnormality to rule out invasive cervical cancer as it allows taking tissue for biopsy to confirm the diagnosis. The woman may be discharged from the hospital the same or the next day. Complications include bleeding, infection, stenosis, and cervical incompetence with possible decreased fertility.

4.5 Management of Complications

Cryotherapy and LEEP have been shown to be safe procedures when performed by qualified providers, with low rates of complications, (ACCP 2003, ACCP 2007, Charmot 2010, Jacob 2005, WHO 2006). Still, a small percentage of women will develop complications. It is important that women are counseled about these potential complications and the warning signs, and that providers have the knowledge and skills to manage these complications, or know when to refer appropriately.

Pain, vaginal discharge, bleeding and infection are the most common reported complications associated with cryotherapy and LEEP. Mild-moderate "crampy" pain, watery or non-purulent discharge and very light bleeding are not uncommon side effects from treatment with cryotherapy or LEEP. These side effects usually resolve without intervention, though pain should be managed with non-narcotic pain relievers, and can often be minimized with treatment before or at the time of cryotherapy or LEEP.

More severe signs and symptoms should be evaluated for the occurrence of minor or severe complications related to treatment. The following are warning signs that women should be counseled to look for, and to seek care if any of these occur.

Warning Signs (usually within the first 2-4 weeks)

- Fever for more than two days
- Severe lower abdominal pain, especially if you have fever
- Foul-smelling or pus-colored discharge
- Bleeding heavier than heaviest days of menstrual bleeding for more than two days
- Bleeding with clots

Warning Signs (usually 1-3 months following the procedure)

- Later onset of lower abdominal pain with fever
- Severe menstrual cramping with minimal or no menstrual bleeding
- Leaking of urine or faeces through vagina(very rare)

4.6 Provision of Care

The services will be primarily provided in static facilities. To improve coverage, outreach clinics will be considered. See Figure 4.2 for outline of the health system by level, services provided and cadre. Cryotherapy can be performed by the following cadres that have demonstrated competency according to national standards: nurses, midwives, health officers, general practitioners, residents and specialists. Cryotherapy services can be provided at all levels of the health service delivery system provided the facility meets the Health Facility Readiness Assessment (see Appendix 6.1).

LEEP can be performed by the following cadres that have demonstrated competency according to national standards: gynecologists only at the start of a program.

LEEP services can be provided from the district (general) to tertiary level of the health service delivery system; provided the facility meets the Health Facility Readiness Assessment (See Appendix 6.1). Supervision should be introduced at each level of the health system, as per the existing mechanisms. It is recommended to conduct supervision on both technical and programmatic aspects of program implementation and to conduct supervision in teams of one technical person and one programmatic person integrating the activities with other RH services.

Table 4.1: Table showing healthcare delivery level by type of service and cadre of health workers

Healthcare delivery level	Service provided	cadre
Tertiary hospital	VIA/cryotherapy, PAP smear, colposcopy, LEEP biopsy, histopathology radiotherapy, radical surgery chemotherapy and palliative care	Nurse, midwives, health officer, MD residents and (specialists(Gyn/Obs
Regional/general hospitals	VIA/cryotherapy,PAP smear, colposcopy LEEP biopsy, histopathology, radical surgery and palliative care	Nurse, midwives, health officer, MD residents and (specialists Gyn/Obs
District hospitals /primary hospitals	VIA/cryotherapy, biopsy, palliative care	Nurse, midwives, health officer, MD
Health centers	VIA/cryotherapy, palliative care	Nurse, midwives, health officer

4.7 Referrals

An efficient referral system is an essential component of a high-quality, comprehensive cervical cancer prevention and control program. Women receiving cervical cancer screening will be referred using the existing national referral system and forms. It is recommended that a referral form has a second page or tear-away section that facilitates feedback to the referring health facility. These national referral forms should be available at all levels of health facilities and service providers should be made aware of the existing referral forms.

Cases to be referred include:

- Suspicious for cancer
- VIA-positive, but not eligible for cryotherapy (for LEEP)
- For second opinion
- Any complication encountered following treatment

Biopsy

Cervical biopsy is indicated when suspicious lesions are seen on the cervix on speculum examination, and can be performed at district, regional and referral hospitals by appropriately trained GP, Residents and specialists (Gyn/Obs).

Colposcopy

Colposcopy is similar to VIA except that it uses a special instrument (colposcopy) that provides magnification and a strong light to visualize the cervix more closely than in VIA. It is typically used in conjunction with directed biopsies of abnormal appearing lesions of the cervix. Colposcopy requires specialized training, and it will be reserved for gynecologists at regional (general) and tertiary centers who have completed the requisite training.

Cervical Cytology (Pap smear)

It is recommend that when cervical cytology is feasible, it will be provided in situations where the SCJ cannot be visualized, which is common in postmenopausal women

Histology

Histological samples should be fixed with formalin and sent to tertiary hospitals for reading. All samples should be sent with appropriately filled-out forms.

CHAPTER 5

Tertiary Care for Cervical Cancer

A comprehensive cervical cancer prevention and control program should include primary prevention, secondary prevention and tertiary care. The components of tertiary care include surgery, radiotherapy, chemotherapy and palliative care. Invasive cervical cancer should be treated by specialists at tertiary-level facilities. Health care providers at all levels, however, should know the common symptoms and signs of cervical cancer. These providers are responsible for establishing a link amongst the different levels of the health care system, the patient, the family and the community. At these different levels of the health care system, the patient undergoes diagnosis, staging and treatment of invasive cervical cancer. Curative treatment for cervical cancer is possible for all except the advanced cases. Access to treatment improves prognosis and survival rates.

This section provides an overview of treatment modalities of invasive cervical cancer and provides specific recommendations for continuum of cervical cancer care. This chapter is not intended to be used by tertiary-level providers, but rather to help first- and second-level providers to understand different treatment modalities for early referral.

5.1 Treatment Modalities for Invasive Cervical Cancer

Treatment of invasive cervical cancer includes surgery or radiation therapy with or without chemotherapy.

Surgery

Curative surgery in cervical cancer aims to remove the primary tumor with all its extensions in single operation. The operation performed will depend on the clinical stage of the tumor, which is a measure of how far it has advanced and determines how it can be treated. Partial surgery is not recommended as it brings more harm than good. If radical surgery cannot be performed, radiation should be the management of choice for most advanced cervical cancers.

Radiotherapy

Radiotherapy plays a crucial role in the treatment of most invasive cervical cancer. In this aspect, the tumor is treated with ionizing radiation (a ray of light with higher energy) that is released as the ray penetrates the body, damaging and destroying the cancer cells. A combination of external and intra-cavitary radiation therapy is most useful to improve treatment outcome. Radiotherapy can be given as a curative or palliative dosage depending on the disease stage.

Chemotherapy

While chemotherapy is not a primary mode of treatment for cervical cancer, it has been shown to improve outcomes and may be used concurrently with radiotherapy; and it works synergistically by destroying the cancer cells.

The table below (Table 5.1) describes health care service provision in terms of what is recommended and what is available currently in Ethiopia.

Table 5.1: Health service provision and cadre of health workers for cervical cancer

Intervention	Place/site	Cadres of health providers	Services currently given in Ethiopia
Surgery for precancerous Conisation/LEEP	Regional/tertiary hospitals	Gyn/obs, oncologists	SPH,BLH,AYDER
ASSELA hospital			
Surgery for early invasive disease radical hysterectomy	Tertiary hospital	Gyn/Obs, oncologist	SPH,BLH,AYDER hospital
Radiotherapy external beam therapy	Tertiary hospital/ recommended at regional hospitals	Radiotherapy oncologist	
Radiotherapist technician Physist dosimetrist	BLH		
Chemotherapist in combination with surgery or radiotherapy	Tertiary hospital	Medical oncologist	
Nurse oncologist	BLH		
Palliative care	All levels	All cadres, faith based spiritual based leaders, psychologist and psychiatrist	none

Table 5.2: Referral hierarchy for cervical cancer services in Ethiopia

Reasons for referral	Clinical service required	Level of referral facility
Client testing positive for precancer	Cryotherapy	Primary secondary and tertiary facilities
	LEEP	Secondary and tertiary facilities
	CONE	Secondary and tertiary facilities
Major complications following treatment	Surgery to control bleeding	Secondary and tertiary facilities 24hrs and 7 days a week
Severe bleeding	Blood transfusion	Secondary and tertiary facilities 24hrs and 7 days a week
Acute infection	IV antibiotics	Secondary and tertiary facilities 24hrs and 7 days a week
Suspicious for cancer	Evaluation biopsy,colposcopy, laboratory services and treatment	Tertiary facilities and oncology centers

5.2 Palliative care to cervical cancer patients

Palliative care is an essential element of cervical cancer control. The goal of palliative care is to avoid unnecessary suffering and improve the quality of life of women with advanced cervical cancer and their families, through emotional support, symptom control, end-of-life care and bereavement care. It addresses the physical, psychosocial, and spiritual needs of patients and their families. Palliative care should begin as soon as cervical cancer is diagnosed, so that need can be anticipated, and preventive and treatment measures planned and put into effect. Please refer the FMOH palliative care guideline for further reference.

CHAPTER 6

Infrastructure, Equipment and Supplies

Essential infrastructure, equipment, supplies and logistics are required to provide high-quality cervical cancer prevention and control services. The procurement and maintenance of essential equipment and supplies should support and anticipate the needs of the service sites. A system ensuring that these materials are procured and maintained is critical to the success of the program. Prior to starting cervical cancer prevention services, it is important to ensure the readiness of health facilities. The facilities should be assessed using the Health Facility Readiness Assessment Tool (see Appendix 6.1), as well as using the essential equipment and supplies lists (see Appendix 6.2) that are considered essential to performing cervical cancer prevention services.

The procurement of all equipment and supplies will be conducted through the PFSA and should follow the existing Integrated Logistic System (ILS). Mechanism should be in place to anticipate demands, especially during scale-up of the programme, to avoid interruption of services due to stock-outs. Cryotherapy is performed using either nitrous oxide (N2O) or carbon dioxide (CO2) gas. Nitrous oxide costs approximately four times as much as carbon dioxide. Reportedly, carbon dioxide is also more readily available. Given these findings, the current recommended gas for cryotherapy is carbon dioxide. It is recommended that each site providing cryotherapy services has at least two 25 kg carbon dioxide gas tanks.

The number of cryotherapy treatments which it is possible to perform per 25 kg tank is approximately 22-26 treatments, but this needs to be tracked to anticipate needs for the program and service sites, as well as to provide an ongoing cost-analysis.

In preparation for the scale-up of the program, it is recommended that the management team should be informed of anticipated increased demands for carbon dioxide and gas tanks. They should also be involved in the planning for the demands of the program and the logistics of maintaining continuous supply of gas to the service sites. In addition, all regional and district management teams should include costs for purchase, refilling and transport of the gas tanks in their budgets. Continued optimal functioning of the cryotherapy and LEEP units requires basic maintenance and care.

To avoid interruption of services and costly repairs outside of the country, the following options are recommended: Through the distributor in the form of a post-sales service contract for major problems or working with existing repair and maintenance section of large tertiary care hospitals.

For routine repair and maintenance, train providers or technicians to service the equipment on a regular basis for both cryotherapy and LEEP units.

CHAPTER 7

Monitoring and Evaluation

This section provides guidance for health care providers, program planners and supervisors to improve monitoring and evaluation activities in the context of results-based management of the National Cervical Cancer Prevention and Control Program.

Monitoring and evaluation helps the management team to:

Determine the extent to which the program is meeting the stated goals, objectives, targets and make corrections accordingly

- Make informed decisions regarding program management and service delivery.
- Ensure the most effective and efficient use of resources.
- Evaluate the extent to which the National Cervical Cancer Prevention and Control
- Program is achieving desired outcomes and impact.

An effective Health Information System (HIS) is an essential tool for tracking clients and monitoring cervical cancer program performance. The monitoring and evaluation system will be guided by:

- Clearly-defined valid and measurable indicators;
- Standard data collection tools and methodologies;
- Clear procedures for filling out the forms; and
- Clear guidelines and protocols for data management including validity and consistency checks

The National Cervical Cancer Prevention Program under the Disease Prevention and Control unit (DPC) will have standardized national forms that have been approved by the FMOH and are linked to the current HMIS system. The HIS should be at the service delivery point (health-facility level) and centralized. The key to HIS effectiveness is routine collection of essential data and generation of regular monitoring reports. The Cervical Cancer Prevention and Control Program monitoring and evaluation protocol will follow the existing integrated HMIS in Ethiopia, which is operational from the facility to the central level.

7.1 Health Information System (HIS) at Facility Level

A facility-level HIS should be used to monitor and evaluate the specific services provided at the facility. A facility-level system relies largely on registers to collect and aggregate data collection should be done at the service delivery point on a daily basis by trained VIA/cryotherapy providers. Information gathered from the registers will be used to calculate monthly statistics based on the indicators. The health facility in-charge, in collaboration with the screening team, will be responsible for compiling

data on a monthly basis.

7.2 Health Information System (HIS) at District, Regional and National Levels

The Woreda/zone/sub-city MCH Coordinator will be responsible for compiling and aggregating the report at the Woreda level and reporting to the regional coordinator. The Regional mother and Child Health Coordinator (RMCHO) will be responsible for compiling/aggregating the data at the regional level and reporting to the Federal Ministry of Health through the Policy and Planning directorate. At the district and regional levels, data should be compiled on a quarterly basis using monthly summary forms and should be sent to the FMOH as indicated from the regions.

7.3 Cervical Cancer Prevention and Control Program Monitoring Tools

The main tools for reporting/ monitoring results for the National Cervical Cancer Prevention Program will be: registers, filled in for client level at service delivery site and summary forms, which aggregate data to facility level for submission to district: At the facility level, providers will be responsible for assigning a client ID and filling in the Client ID card, as well as filling in the register for every client who receives screening, treatment and/or referral for cervical cancer/HPV. Facility-level staff will also be responsible for filling in the monthly summary form to send to the Woreda/zone/sub-city. In addition, the focal person of the MCH unit at the facility will use the referral form and fill in the referral log every time they refer client to a higher level for management. Woreda/zone Level and Regional Level focal persons will be responsible for compiling the health facility summary forms and aggregating into the district summary form, which will be sent to the level above on a quarterly basis. Whereas the regional focal person will similarly aggregate district-level summaries into the regional summary and report to the FMOH level through the Reproductive and Child Health Section.

7.4 Data flow amongst health facilities and in referral

Provision of VIA and cryotherapy will be instituted at most, if not all, levels of service delivery in Ethiopia. However, the management of large lesions, suspect cancer and cancer will require a referral either to regional- or national-level facilities. However, in cases where management of clients requires referral, such as in situations where laboratory processing (biopsy, cytology) or referral for colposcopy or LEEP is required, effective data linkages are extremely important. The National Cervical Cancer Prevention Program in collaboration with other MCH activities will use the national protocol for referral.

7.5 Program Indicators

The National Cervical Cancer Prevention Program will track key program indicators through the above-described reporting system. Two key indicators will be incorporated with the HMIS Unit's annually reported national health indicators.

These are:

- Total number and % (of target population) of clients screened with VIA
- Total number and % of women screening positive on VIA treated with cryotherapy/LEEP

All other indicators to track the National Cervical Cancer Prevention Program will be derived from the reporting system described above. All indicators will be stratified by age and HIV status.

CHAPTER 8

Training and Competence Qualification

For the program to provide effective high-quality screening and treatment, it is important to build country capacity through training of a wide range of health care providers. A training system comprises a network of institutions that work collectively and in a coordinated manner to develop new providers and trainers. The goal of the training system is to provide a constant flow of competent trainers and providers who are trained to perform to standard. To maximize the potential of capacity-building, the FMOH recommends that training occur at both the pre-service and in-service level. The following section outlines key considerations for developing national training and qualification process.

8.1 In-Service Training of Service Providers

8.1.1 Selection Criteria for Trainees

Table 8.1 below summarizes key selection criteria that should be considered when selecting providers who will be trained to provide cervical cancer prevention services.

Table 8.1: Selection Criteria for Trainees by Service Provision

Area	Cadre	Character	Selection
VIA/CRYOTHERAPY	Nurse, nurse midwife,HO,MD,obs/gyn	Ability to be retained for one year at site	Health facility in charge
LEEP	Obs/gyn specialist	Work at site for one year	Health facility in charge
Biopsy	MD,HO,obs/gyn		
Colposcopy	Obs/gyn specialist		
Supervision monitoring and evaluation	Health facility in charge,nurse,nurse midwife, HO,MD	Certified TOT practicing VIA/CRYO,LEEP	District and regional trainers
Communication/ information and education	HEW/HDA		

Training should be conducted using a standardized course package that is approved by the FMOH and by trainers who are qualified to conduct the training. Following the training, ensuring performance to standard will occur through monthly or quarterly supportive supervision visits.

FMOH recommends incorporating pre-service training in cervical cancer prevention, including VIA and cryotherapy, at the various schools from which the anticipated providers will be emerging

8.2 Competency Qualification

Qualification for competency to provide VIA, cryotherapy and LEEP is achieved by participants following completion of a FMOH-approved course, and demonstrated competence in that skill. Training done prior to establishment FMOH approved courses, or outside of Ethiopia, will be considered by the MOH on a case-by-case basis. Competency qualifications to be done by approved trainers. The following criteria will be adopted to evaluate competency and qualification of the providers post-training:

8.2.1 Follow Up After Training

Transfer of learning occurs during training as well as after the training. It is the close monitoring phase of performance assessment that occurs immediately after training. This phase ensures that the new skills are applied in the service site, and links training and routine supportive supervision. Supportive supervision will consist of both technical and programmatic supervision.

Development of Trainers

Training of Trainers (TOTs) should be conducted to develop national, regional and district-level trainers.

8.2.2 Selection criteria for TOTs include:

- Has undergone MOH-approved, competency-based training in VIA/cryotherapy or

LEEP

- Demonstrated competency in VIA and cryotherapy, or in other skill such as LEEP or
- Colposcopy, for which they will be a trainer
- Has undergone MOH-approved TOT course
- Is competent and qualified as a trainer
- Has good facilitation skills
- Selection criteria for development of trainers include:
- Competent service provider of cervical cancer screening services
- Has undergone competency-based training on VIA/cryotherapy or LEEP
- Has good experience in provision of VIA/cryotherapy/LEEP services

Coordination of Training Activities

It is essential that the various training activities occurring throughout the country are coordinated and standardized to ensure consistent and high-quality training. The coordination of these training activities will be done by the FMOH. A training officer should be identified for this purpose. The RHC Unit will develop criteria for scale up, determining which regions to be trained first and how to expand. This unit will also maintain an inventory of people trained that will include: trainees, service providers, TOTs and supervisors of cervical cancer prevention programs.

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Appendixes

APPENDEX 1 HEALTH EDUCATION MESSAGES

APPENDIX 1.1 HEALTH EDUCATION MESSAGES

The following are key evidence-based messages that can be used to promote cervical cancer prevention. An effective cervical cancer prevention health educator and advocator should:

Have accurate, up-to-date knowledge about cervical cancer.

Good communication skills.

Provide consistent messages about cervical cancer, tailored to the educational and cultural background of the audience.

Be comfortable and non-judgmental when talking about sexuality and behavior that increases the risk of HPV infection.

Be comfortable explaining how to use male and female condoms.

Provide messages that are in line with national policy and appropriate to the local situation.

Key cervical cancer prevention messages for adolescents, women and men:

Cancer of the cervix is the second most common cause of cancer-related death in women worldwide, and is the most common cancer amongst women in Ethiopia.

- Cervical cancer is the leading cause of cancer deaths in women in their 40s, 50s and 60s in developing countries.
- Cervical cancer is preventable—a healthy lifestyle, screening of women 30 years of age and older, and vaccination of young girls are key prevention measures.
- Cervical cancer is caused by infection with HPV, a very common STI. This infection frequently occurs in young men and women.
- HPV has been demonstrated to be the cause of more than 99% of cases of cervical cancer and is involved in other cancers and diseases.
- Most HPV infections have no signs or symptoms. Most infected people are unaware that they are infected; yet, they can transmit the virus to a sex partner. Condom use offers partial protec tion from HPV and may lower the risk of developing HPV- related diseases, such as genital warts and cervical cancer. HPV vaccine offers protection against the two types of HPV that cause the majority of cervical cancers worldwide. If the vaccine is administered to girls before sexual debut, it is expected to prevent up to 70% of cervical cancer cases in this group.
- Most HPV infections do not persist and do not cause cancer.
- The few HPV infections that do persist may lead to precancerous lesions; if not diagnosed and treated early, these precancerous lesions may progress to cancer.
- It usually takes 10-15 years for HPV infection to cause precancerous lesions and years longer for these lesions to progress to cancer.
- Screening can detect precancerous lesions. Most abnormal conditions found during screening can be treated.
- Early detection and immediate treatment can save lives.Women aged 30 years and older are

more likely than younger women to have cervical precancerous lesions.

- Women should be screened every five years from age 30. All women should have screening at least once in a lifetime after age 35.
- Screening using VIA is relatively simple, quick and painless.
- Precancerous lesions can be easily treated, and a hospital stay is not usually required.
- If cancer is found and treated early, it can be cured.
- Women need to seek medical care promptly if they have abnormal discharge, vaginal bleeding, bleeding after sexual intercourse or any bleeding after menopause; these may be signs of cervical cancer.
- Women have a right to make their own decisions about their health (involving their partner or family if they wish).Women should not feel ashamed, guilty or "dirty" if they are diagnosed with HPV. They should not place blame or try to identify where and from whom the infection came, as this will only lead to less buy-in from both men and women for receiving diagnosis and treatment. While screening and follow-up are highly recommended, women should be free to refuse any test or treatment.

Messages about personal behavior:

- Delay first sexual intercourse: people who engage in early sexual activity are more likely to be infected with HPV. Younger women are more vulnerable to being infected with a single sexual act Women who have had five or more children have a higher chance of developing cervical cancer. Reduce the number of sexual partners: the more partners a person has, the greater the chance of becoming infected with STIs, including HPV and HIV, both of which increase the risk of cervical cancer.
- Avoid partners who have multiple partners: women whose partners have or have had multiple partners have a higher rate of cervical cancer.
- Use condoms: condoms have been shown to protect against STIs and to reduce the risk of cervical cancer.
- Avoid tobacco smoking: people who smoke have a higher risk of getting almost all cancers, including cervical cancer.
- Seek treatment immediately if you have symptoms of an STI or suspect that you have been exposed to an STI. Some STIs may facilitate the development of cervical cancer. Prompt treatment of STIs may protect against HPV and cervical cancer. If you are 30 years of age or older, get screened
- All women who have had sexual intercourse are at risk of having been exposed to HPV. Screening can detect early precancerous lesions that can be treated before they have a chance to progress to cancer.
- Women who are HIV-infected have a higher risk of developing precancerous lesions when

compared to HIV-negative women. Screening in this group is recommended to start at any age (as long as the client has been sexually active) and on a five year basis thereafter.

Special message to men and boys:

- Encourage men to reduce the number of sexual partners and if feasible to be circumcised, since this reduces the risk of cervical cancer in their female sexual partners.

Key messages for an HPV vaccine programme (in addition to the above key messages):

How HPV vaccination can reduce the risk of cervical cancer

Benefits and limitations of the vaccine

Why HPV vaccine is offered to a specific target group

Safety and side effects of the vaccine

Costs

APPENDIX 1.2 MATERIALS FOR HEALTH EDUCATION

Information on cervical cancer prevention through health education can be provided using the following materials, based on the local context:

Flip charts

Brochures

Slide shows

Drama and role plays

Videos

Radio and television program

Presentations by experts, politicians, community leaders and cervical cancer survivors who can communicate using non-technical language

APPENDIX 2

HEALTH FACILITY READINESS ASSESSMENT TOOL

Health Facility: _____ Date: ____ / ____ / ____

Assessor's Name: _____

Human Resources

Notes: ----------

A certified staff in VIA and cryotherapy----------

A nurse/nurse assistant----------

Infrastructure----------

Designated area for patient waiting and/or group education----------

Separate examination and procedure rooms OR a large room with privacy screens/curtain------

A sink with tap/running/rain water----------

Equipment

One carbon dioxide tank----------

One cryotherapy unit----------

Cytology brush (for cleaning cryo unit filter) optional----------

One autoclave or other sterilization----------

Speculum (10)----------

Small basins for instruments/supplies----------

Sponge forceps----------

Instrument trolley----------

Large plastic buckets for decontamination of specula/instruments----------

One gynecological examination couch with stirrup----------

Torch light or halogen lamp----------

Large plastic buckets for decontamination of specula/instruments----------

Trash bin with plastic bag for non- contaminated materials----------

One filer with lock for clinical records----------

Shelf for supplies/drugs----------

Personal protective equipment ----------

Non-sterile gloves (appropriate size for providers) Utility gloves for handling decontaminated instruments

Plastic apron – for instrument processing and preparation of chlorine solution

Solutions

Chlorine solution 0.5%----------

Alcohol-based hand sanitizer or soap----------

Cidex (2-4% glutaraldehyde)-

Isopropyl alcohol 60-90%

Monsel's

Stationary----------

IEC materials Register

Monthly summary forms

Post-cryotherapy instruction forms

Referral forms

Consent forms

Medications ----------

Panadol, ibuprofen; medications for cervicitis treatment

Timer/watch

K-Y jelly/lubrication

Wooden spatulas or condoms

Drapes/sheets

Large cotton-cotton swabs/cotton balls/gauze cut in small pieces

Small cotton swabs

Acetic acid (3-5%)

APPENDIX 3

ETHIOPIA CERVICAL CANCER PREVENTION

VIA/CRYOTHERAPY REGISTER

Please see reference manual

This register records basic information and test results on all clients required for screening.

It helps to monitor the program and identify patients with positive results requiring further investigation or treatment.

Register entries should be written ideally at the time of the client visit.

Where the register is completed, the information has to be transferred to the monthly summary form.

The entire page of the register should be completed before starting a new page. Do not start a new page for each day.

Client ID: This unique number is provided to the client when she is registered for VIA screening. Client ID should start with 001 for the first client.

Client Name: given names of the client, preferably three names

Contact Address: name of village/street/ten cell leader and phone number

Age: age of client in completed years

Parity: number of deliveries.

Visit type: this records the type of visit based on the cervical cancer screening services provided to the client.

VIA test and results: this column records VIA test results

Referral: this column describes the reason for referrals for clients who have undergone VIA test.

Treatment: this column records the type of precancerous lesion treatment given to the clien

APPENDIX 3.1 Client register

Identification	Family Planning and contraceptive services																		
Personal information	Registration	Counseling and testing	VIA screening		Fill app	Clinical exam and contraceptive services provided													
Serial No.	MRN	Sex (M/F)	Reg. date (DD/ MM/YY)	New acceptor at registration (√)	Repeat acceptor at registration (√)	HIV Test offered (√)	HIV Test performed (√)	HIV Test Result (R or NR or I)	HIV specific counseling / methods offered (√)	VIA screening for women age 30-49 (√)	VIA Test Result (Normal, PC, or Ca)	TT status checked (√)	Contraindication for hormonal method (√)	Contraindication for IUD (√)	Permanent method selected (TL or V)	Visit No.	Visit date (DD/MM/ YY)	Contraceptive provided	Remark/ Appointment
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
																1			
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APPENDIX 4

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ቦታ .....

የማህፀን በር የቅድመ ካንሰር ህክምና ማካሄጃ የፈቃደኝነት መግለጫ ስምምነት

እኔ በ ..... ሆስፒታል ውስጥ በፈቃደኝነት የማህፀን በር የቅድመ ካንሰር ምርመራን ያደረግሁ ሲሆን ምርመራውን ያደረገልኝ የጤና ባለሙያ የምርመራው ውጤት ቅድመ ካንሰር ምልክት ማሳየቱን ገልፆልኛል። ውጤቱንም አስመልክቶ በጤና ባለሙያው ተገቢውን የምክር አገልግሎት እና ለዚህ ተገቢ የሆነ ክራዮቴራፒ የሚባ ህክምና በሆስፒታሉ እንደሚገኝ ተገልፆልኛል።

ህክምናውን አስመልክቶ በሚገባኝ ቋንቋ በበቂ ሁኔታ የተገለፀልኝ ሲሆን ስለህክምናው ያልገባንንና ተጨማሪ ማወቅ ስለምፈልግ ማለትም ስለ ተለዋጭ ህክምናዎች ፤ የህክምናውን አፈፃጸም እና የህክምናውን ውጤት አስመልክቶ እንድጠይቅ እድል ተሰጥቶኛል። ለጥያቄዎቼም በቂ መልስ ተሰጥቶኛል። ህክምናውም በፈቃድ ላይ የተመረኮዘና ህክምናውን ያለመቀበል መብት እንዳለኝ እንዲሁም ባልቀበለው ከማንኛውም ተፅዕኖ ነፃ መሆኔ ተገልጦልኛል።

በመሆኑም በባለሙያ የተሰጠኝን ምክርና አስፈላጊውን መረጃ በመገንዘብ ያለምንም ተፅዕኖ በራሴ ፈቃድ ህክምናውን ለማድረግ መስማማቴን በፊርማዬ አገልፃለሁ።

የታካሚው ስም.....	የጤና ባለሙያው ስም.....
ፊርማ	ፊራማ ....
ቀን	ቀን .....

APPENDIX 5

Post-Cryotherapy Information Sheet

After receiving cryotherapy for treatment of cervical lesions, you need to know the following:

1. You may have short-lasting, mild, lower-level abdominal cramping. If you have mild pain, you can take any anti-pain medicine.
2. You will have watery vaginal discharge that lasts 4–6 weeks. The color of the dis charge will change from pale red to white over time. If the discharge has an un pleasant small and the color changes to yellow, you need to visit the health facility and get treatment.
3. You may have spotting (light bleeding) that lasts 1–2 weeks. If the bleeding is heavi er than on your heaviest days of menstrual bleeding, you need to visit the health facility and get treatment.
4. You are strongly advised to avoid sexual intercourse for about 1 month until the wound heals. If this is not possible, please use a condom regularly to prevent infection.
5. Please remember your follow-up appointment date carefully.

If you have any of the following warning signs, you should return to the health facility immediately. Do not wait for your appointment date.

Return to the facility immediately if you have:

1. Fever for 2 days or more.
2. Severe lower abdominal pain, especially if accompanied by fever.
3. Bleeding for more than 2 days that is heavier than your heaviest days of menstrual bleeding. 4. Bleeding with clots.
5. Vaginal discharge with a foul or unpleasant smell

APPENDIX 6

Cervical Cancer Prevention Services Appointment Card

FRONT OF THE CARD:

Medical Record Number: _____

VIA Serial Number: _____

Name: _____ Age: _____

Address: _____

Hospital Name: _____ Region: _____ City/Town: _____

Date of first visit: _____

Date of Appointment	Signature of provider (if seen on the appointed date)

Note:-

- Don't forget to bring the appointment card with you when you visit the facility for your follow up visit.
- It is important for your health that you keep your appointment.

BACK OF THE CARD:

HOW A WOMAN CAN DECREASE HER RISK OF GETTING

CERVICAL CANCER

- Get screened for cervical cancer regularly.
- Delay your first sexual intercourse.
- Limit your number of sexual partners.
- Use a condom every time you have intercourse.
- Avoid smoking.
- Get an HPV vaccination, if available and applicable.

APPENDIX 7

Quarterly Summary Report of Service Provision

Region name	
Facility name	

Reporting month/ Quarter/: From _____to _____Year_____

- New client

VIA testing, treatment, and referral for women in care

Months	Number counseled on CCP	Number tested with VIA	Number with no cervical lesion on VIA	Number with identified cervical abnormalities on VIA testing			Number of women who received treatment			Number referred for other treatment	
				Acetowhite lesion; eligible for cryo	Acetowhite lesion; not eligible for cryo	Suspicious for cervical cancer	Treated with cryo	Treated with LEEP	Received other treatment	Acetowhite lesion; not eligible for cryo	Suspicious for cervical cancer
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Total of the quarter											

- Clients for one year post-treatment follow-up

Months	Number counseled on CCP	Number re-tested with VIA	Number with no cervical lesion on VIA	Number with identified cervical abnormalities on VIA testing			Number of women received treatment			Number referred for other treatment	
				Acetowhite lesion; eligible for cryo	Aceto white lesion; not eligible for cryo	Suspicious for cervical cancer	Treated with cryo	Treated with LEEP	Received other treatment	Aceto white lesion; not eligible for cryo	Suspicious for cervical cancer
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Total of the quarter											

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