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MINISTRY OF HEALTH-ETHIOPIA

የዜጎች ጤና ለሃገር ብልጽግና!
HEALTHIER CITIZENS FOR PROSPEROUS NATION!

GUIDELINE FOR CERVICAL CANCER PREVENTION AND CONTROL IN ETHIOPIA

April 2021

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Contents

Abbreviations

AEFI	Adverse Event Following Immunization
AIDS	Acquired Immune Deficiency Syndrome
BCC	Behavior Change Communication
CDC	Center for Disease Control and Prevention
EPI	Expanded Programme for Immunization
FMOH	Federal Ministry of Health
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 Electro surgical Excision Procedure
LMIC	Low- and Middle-Income Countries
NCD	Non-communicable Disease
Ob/Gyn	Obstetrician and Gynecologist
PLHIV	People Living with HIV
RCH	Reproductive and Child Health
RHMT	Regional Health Management Team
ROC	Reproductive Organ Cancer
RRCHCO	Regional Reproductive and Child Health Coordinator
SCJ	Squamo-columnar Junction
SDG	Sustainable Development Goals
STI	Sexually Transmitted Infection
STA	See-and-Treat Approach
SVA	Single Visit Approach
TA	Thermal Ablation
USAID	United States Agency for International Development
VIA	Visual Inspection with Acetic Acid
WHIS	Woreda Health Information System
WHO	World Health Organization
WRCHCO	Woreda Reproductive and Child Health Coordinator

Foreword

Cancer of the cervix is the fourth most common cancer among women worldwide, with about 569, 847 new cases diagnosed and over 311,000 deaths every year. In low- and middle-income countries (LMIC), cervical cancer is the commonest cancer affecting reproductive organs and also the leading cause of death from cancer among women.

In Ethiopia, cervical cancer is the second most common cancer among women with over 6,200 new cases every year and with a mortality close to 5,000 (Globo can 2018). According to Addis Ababa Population Based Cancer Registry (2012-2015), the leading cause cancer type among women is breast cancer (32.3%) followed by cervical cancer (14.5%).

The Health Policy of Ethiopia boldly states that the health needs of women and children deserve particular attention. The FMOH launched the first national cervical cancer prevention and control guideline in 2015.Over the last five years, several progresses have been made including introduction of Human Papilloma Virus (HPV) vaccination into the routine immunization program and the scale-up of national cervical cancer screening and treatment using the 'see and treat' approach. To date over 500,000 women age 30-49 (3.3%) have been screened with a treatment coverage of 96% among those with precancerous lesion.

The government's strategy is to strengthen the existing services including scale-up of secondary cervical cancer screening and treatment to ensure service access in the country. In line with this, efforts have been made to improve the low coverage of cervical cancer screening in collaboration with stakeholders through demand creation at national and regional level, capacity building, adoption of better screening and treatment technologies, and continuous quality improvement.

The second revision of National Cervical Cancer Prevention and Control Guidelines provide the most current up-to-date knowledge and direction on cervical cancer screening, treatment and management in line with World Health Organization (WHO)strategy to eliminate cervical cancer by 2030. The guideline provides a solid foundation from which service providers in all health facilities can provide quality and standardized cervical cancer prevention and treatment services. The FMOH encourages the use of this guideline by managers, policymakers and training institutions and partners.

I urge all health managers and health care providers to promote cervical cancer screening and treatment services to save lives and reduce the suffering of many women from cervical cancer.

Dereje Duguma (MD, MPH)
State Minister of Health
Federal Democratic Republic of Ethiopia

Acknowledgments

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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 estimated population of Ethiopia for 2019 is 102,850,793. The male to female ratio is 0.96 to 1. Ethiopia has a very young population with 47% between 0-14 years and 48% between 15-64 years of age. The proportion of population 65 years and above is nearly 5%. The proportion of women age 30-49 constitute about 19.2% of total female population. This will help us address the increasing needs of expanding the cervical cancer prevention.

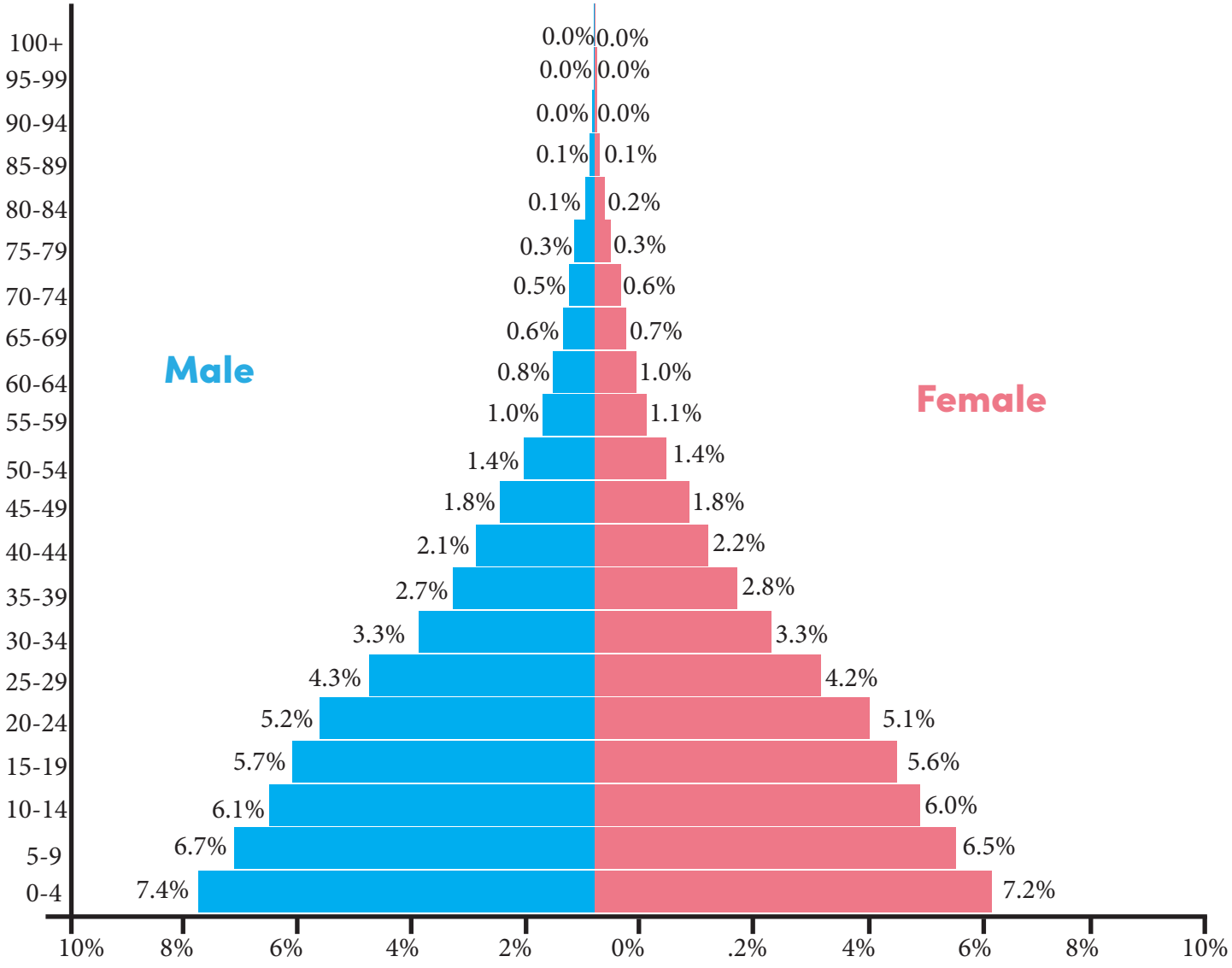


Figure 1.1 The population pyramid of Ethiopia

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 lowat0.29 (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 girls, 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 enrollment rate for girls at primary level increased to 95.5% in 2016/17.

1.2 Global and National Burden of Cervical Cancer

Cancer of the cervix is the fourth most common cancer among women worldwide, with about 569, 847 new cases diagnosed and over 311,000 deaths every year. In low- and middle-income countries (LMIC), including Ethiopia, cervical cancer is the commonest cancer affecting reproductive organs and also the leading cause of death from cancer among women. In Ethiopia, cervical cancer is the second most common cancer among women with over 6,200 new cases every year and with a mortality close to 5,000 (Globocan 2018). According to Addis Ababa Population Based Cancer Registry (2012-2015), the leading cause cancer type among women is breast cancer (32.3%) followed by cervical cancer (14.5%).

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.

Ethiopia launched the first ever national guideline on cervical cancer screening and treatment in2015. This guideline served a period of five years until 2020. During the past five years, the national coverage of cervical cancer screening and treatment for women age 30-49 hit only 5%. As a number of advancements are evolving around global cervical cancer screening and treatment in terms of technical refinement in screening and accuracy of treatment, the Ministry of health reviewed the exiting guideline based on the advances around the world and adapt a new strategy to guide the national program. The new strategy also takes into consideration the WHO global cervical cancer elimination goals by 2030. This guideline also takes into consideration new technological screening and treatment advances such as HPV DNA testing and thermal ablation treatment option based on WHO 2019 recommendations to increase access to screening and treatment in Ethiopia.

1.3 Ethiopia's Experience in Cervical Cancer Screening using Visual Inspection with Acetic Acid (VIA)

Breast cancer is the top leading cancer type by 33.2% followed by cervical cancer at 13%. The estimated coverage of cytology-based cervical cancer screening in Ethiopia is 1.6% in urban settings and 0.4% in rural areas (WHO household survey, 2003).

Visual Inspection with Acetic acid (VIA) screening combined with access to cryotherapy was piloted in Ethiopia by the FMOH in collaboration with Pathfinder International through CDC support. 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 11additional 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 by the end of 2014.

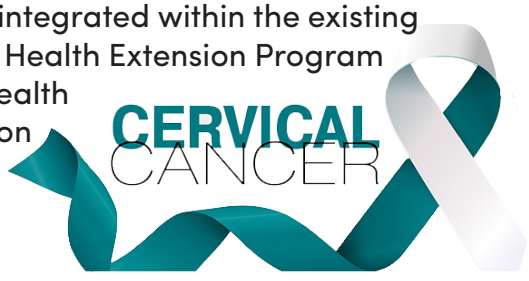
Based on the lessons learned from the pilot (obtained through careful documentation and efforts to examine and understand the success and challenges faced), the FMOH decided to scale up the service further into public healthcare facilities to create access for the general public irrespective of HIV status. Accordingly, the Ministry developed comprehensive cervical cancer prevention and control guideline along with preparation of VIA and cryotherapy training materials.

An estimated 12,000,000 women age 30-49 are eligible for cervical cancer screening in Ethiopia. Over the last five years, a number of progresses have been made including introduction of HPV (human papilloma virus) vaccination into the routine immunization program and the scale up of national cervical cancer screening and treatment using the 'see and treat' approach. To date over 500,000 women age 30-49 (3.3%) have been screened with a treatment coverage of 96% among those with precancerous lesion. Currently around 800 health facilities are providing cervical cancer screening and treatment by using VIA screening and cryotherapy treatment.

1.4 Rationale

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 in to 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. 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 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 ROC 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 ROC, 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 ROC. 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.

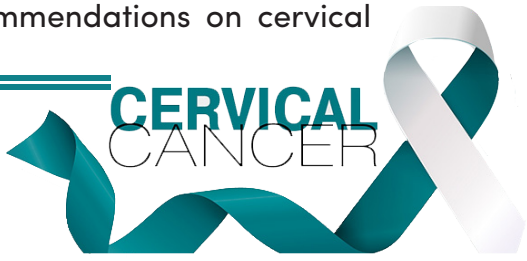
1.5 Goal, Objectives, and Target Audience

Goal: To guide the national cervical cancer prevention and control program in Ethiopia.

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 layout a standardized strategy for the implementation of cervical cancer prevention, screening and treatment options.
- To guide the country to improve access to cervical cancer prevention and control initiatives.
- To provide guidance and coordination for the prevention and control of cervical cancer in Ethiopia among different stakeholders.
- To provide a platform for updated evidence-based recommendations on cervical cancer screening and treatment in Ethiopia.



Target Audience:

The guideline is intended for use by healthcare providers, trainers, managers, supervisors, teaching institutions including universities and health science colleges, implementing partners 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.

1.6 About the Current Guideline

The revised guideline is based on the first guideline Ethiopia endorsed in 2015. The revised guideline addresses new developments in cervical cancer screening and treatment based on best practices both in the country and around the globe. Experience from program implementation of the first guideline was explored and lessons extracted to guide the new version.

New additions to the revised guideline are mainly introducing additional screening option using HPV DNA testing and additional treatment option using thermal ablation. It also provides a detailed algorism for VIA and HPV DNA screening.

The Ethiopia Guidelines for Cervical Cancer Prevention and Control include the three main 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 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. Furthermore, the guidelines provide guidance on monitoring and evaluation including the necessary tools and registers. The guideline will be reviewed periodically to include updated information and inform public policy.

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.

The Federal Ministry of Health, at National level, with all implementing partners shall coordinate national level program design and implementation. The ministry shall use all existing coordination mechanisms (e.g. Joint Steering Committee - JSC) meetings to monitor overall cervical cancer screening and treatment program implementation at national level. Similarly, Regional Health Bureaus (RHBs) will facilitate re-

gional coordination, cascade implementation at all levels down to community level, ensure program ownership, adaptation, monitoring and ensuring implementation to maximize success from cervical cancer program implementation.

Chapter 2: Communication, Advocacy and Co-ordination

2.1 Definition and Scope

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.

Communication, advocacy 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 the 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 improve understanding of both HPV and cervical cancer amongst health care workers, educators, policymakers, parents, adolescent girls 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 adolescent girls, 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. However, it may also be possible to conduct health education and awareness creation via mobile and electronic media using m-Health and e-Health platforms.

Facility-based	Community-based (outreach)	Media-based
One-on-one and/or group education to inform patients who are attending health facilities	One-on-one and/or group education to inform people in the home and community settings	Using radio, television and print media to convey messages to a larger and more dispersed audience

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

1. Conduct advocacy meetings: at different levels, such as women groups, policymakers, politicians, development partners, religious leaders and community champions.
2. 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.

2.2 Communication Channels and Target Audience

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 and Internet
- Printed materials: newspapers, posters and brochures
- Cultural and festival activities
- The following audiences or agents 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
- Schools
- People living with HIV (PLHIV)
- Peer educators
- Health extension workers and health development army

2.3 The Role of Stakeholders in Demand Creation, Program Implementation and Coordination

The National Cervical Cancer Prevention and Control Program is a Ministry of Health initiative but requires collaboration with many sectors and partners to be successful.

2.3.1 The Federal Ministry of Health (FMOH)

The FMOH will provide the overall policy formulation, strategy development and revision, development and review of guidelines and standard operating procedures, asses and organize training, program management and coordination, quality assurance, monitoring and evaluation as well as ensuring institutionalization of the program into routine service delivery. In addition, the Ministry should guide and assist RHBs 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. The Ministry would ensure uninterrupted supply to cervical cancer screening and treatment supplies including ensuring availability and local production of quality and standard acetic acid solutions.

Disease Prevention and Control Directorate is in charge of co-ordination of all the national activities and all stakeholders with an interest in cervical cancer prevention activities and ensuring linkages with other government sectors and non-governmental organizations. The EPI team under the RMNCH Directorate will also be responsible to undertake and sustain routinization of HPV vaccination for eligible target girls. All concerned bodies at the ministry will work hand-in hand for the success of wholesome efforts towards the prevention and control of cervical cancer.

The Head of the DPC Directorate will chair co-ordination meetings and will be responsible for presenting program issues to NCD technical working group (TWG)convening quarterly and annual reviews as well as the mid-term and end of program evaluation.

Under the leadership of the ministry, the national TWG will support the FMOH and RHBs in providing technical guidance and direction as it relates to cervical cancer prevention and control including advise on new directions, global development and evidence based local data generation, analysis and recommendations. The TWG will also play key role in developing and revising as appropriate the national guideline, training materials, Standard Operating Procedure (SoP), program monitoring tools,

job aids and IEC materials.

2.3.2 The Ethiopian Public Health Institute (EPHI)

EPHI plays a role in supporting the Government's effort in cervical cancer screening and control by building the capacity building of HPV DNA testing laboratories, facilitating the implementation and validation of laboratory procedures for HPV molecular testing, ensuring quality and proficiency testing, supporting quantification of supplies (reagents), supporting validation and maintenance of HPV testing equipment, monitoring, and supervising laboratories. The institute in collaboration with other stakeholders and regional institutes implements surveillance and research activities to inform the national cervical cancer program.

2.3.3 Ethiopian Pharmaceuticals Supply Agency (EPSA)

Strong procurement Supply management is important to ensure sustainable supplies and responsive cervical cancer program. The FMOH, in close collaboration with EPSA, will do regular quantifications of necessary commodities for prevention and control service delivery. EPSA will also coordinate the quantification, procurement and distribution of the necessary commodities by integrating into existing supply chain management system. Reporting and requisition formats will be updated to incorporate commodities needed for cervical cancer VIA and cryotherapy/thermal ablation services.

Most of the items required to start the service are already in place like examination coach, speculum, and drums and so the FMOH will be responsible for quantifying the equipment required for service expansion (Cryotherapy/thermal ablation and CO2 cylinder). Ongoing drugs, supplies and medical equipment needs will be covered by the regional health bureaus as deemed necessary. EPSA will procure the required items according to the quantification.

2.3.4 The Regional Health Bureaus (RHBs)

RHBs adapt the technical guidelines from the Ministry to implement interventions on the prevention and control of cervical cancer and provision of screening (VIA or HPV testing) and treatment (cryotherapy/thermal ablation/LEEP (Loop Electro surgical Excision Procedure)) services in their own regional context. The RHBs therefore, are in charge of planning, implementing, coordinating, monitoring and evaluation of the screening and treatment services in particular and prevention and control of other cervical cancer activities including routinization of HPV vaccination within the regions. The regions are expected to establish a management team to oversee the above functions.

2.3.5 Zonal Health Offices

VIA and cryotherapy/thermal ablation services can be provided at a lower-level health facility. Most of these facilities are located within a zonal and woreda level health structure. After trainings are cascaded it is very crucial to ensure quality of services through continuous supervision, monitoring and evaluation of services provided to patients. Zonal level health system can play an important role in assuring quality and develop a better uptake through wider awareness creation and community engagement. The regions are expected to establish a management team to oversees the above functions.

2.3.6 Woreda Health Offices

By its very nature cervical cancer prevention and control program can benefit hugely from early screening, diagnosing and treatment with a very high cure rate if treated early. There is a great need for high level of awareness by women to be undergo regular checkups at the nearby health facility. Woreda level health system can play important role in sharing information and mobilizing women for the service and facilitating HPV vaccination for the target girls. Monitoring and evaluation system can also be done at this level by ensuring a continuous flow of information for program improvement and decision-making. The woredas are expected to establish a management team to oversees the above functions.

2.3.7 Health Facilities

Health facilities (hospitals and health centers) has a role in demand creation and provision of VIA and cryotherapy/thermal ablation services for eligible women in their catchment areas. In addition,selected high load hospitals will provide LEEP service that covers other nearby health centers through referral networking.

They will ensure the following:

1. Availability of commodities, supplies and equipment to facilitate cervical cancer screening in their specific sites; and ensure that equipment is always in good condition (servicing and repairs as necessary)
2. Follow-up of clients (especially screen positive clients) to ensure that they complete treatment and adhere to management protocols
3. Completion of the requisite data tools /registers and submission reports in a timely, accurate and consistent manner
4. Community mobilization activities in their areas of operation and availability of IEC / BCC materials and technical support
5. Outreach and in reach cervical cancer screening and treatment activities
6. Administer HPV vaccination for eligible girls as per the national immunization schedule

2.3.8 The Ministry of Women, Children and Youth

The ministry of women, children and youth have a wider community level representation through various networks of women. Using these networks, the screening service can reach out to women even in peripheral settings. Moreover, the screening program can be integrated with other community services targeting women. Women have a very strong role in childcare and usually visit health facilities with young children. This is a golden opportunity to counsel women at the same time for possible screening for cervical cancer.

2.3.9 Development partners, stakeholders and private sectors

A variety of non-governmental organizations, civil society organizations, and Faith-based organizations and the private sector health care agencies and businesses have interests in cervical cancer prevention.

The NCD team within the directorate of disease prevention and

control will coordinate with partners at the national level, while the regional health bureaus will designate a focal person in their management teams to coordinate with groups at regional and district levels.

The FMOH will coordinate and monitor the activities implemented by the partners in their area of operation within the country.

Professional Associations will play a critical role in advocacy and dissemination of new policies and technical information to their membership.

The Ministry will also work closely with potential partners in the area of resource mobilization and service provision.

The NGOs, CSOs and private sector will be critical in the promotion of community involvement and in community mobilization for utilization of services.

2.3.10 Training Institutions

Medical training institutions including the Universities will provide basic trainings for health care workers. They ensure that health care workers on completion of training have the necessary knowledge and skills to implement and integrate screening and treatment services wherever they are deployed according to national guidelines and standards. The Ministry in collaboration with other partners will provide Training of Trainers (ToT) trainings. All trainings should be conducted based on the qualification and competency indicated in each of the training manuals developed by FMOH.

2.3.11 Research Institutions

Research institutions in close collaboration with EPHI will conduct research to inform practice in the area of cervical cancer prevention and control in line with the FMOH research agenda. They will disseminate research findings to relevant stakeholders and support capacity development of interested partners in operations research.

2.3.12 Health Extension Workers

In Ethiopia HEWs play a critical role in promoting health at community level. There are over 39,000 HEWs currently active in Ethiopia. HEWs will use their existing systems to enhance awareness on the risk factors for cervical cancer including promoting safer sex practices and also will register the eligible women (age between 30-49) living in their catchment area then link to the health center. The school-based HPV vaccination program will be coordinated by the HEW at community level and eligible out of schoolgirls will be referred to health facility for vaccination. They will educate their members on availability of screening services and where to obtain them, and especially men to support/facilitate accessing of these services as well as adherence to treatment protocols.

They will also develop and maintain systems that facilitate timely referral and transfer of patients that need hospital care and in addition. They will provide home based care and support for patients with overt cervical cancer. They will conduct community mobilization activities in their areas of operation and availability of IEC/BCC materials and technical support. Participate in facilitating outreach and in reach cervical cancer screening and treatment activities.

2.3.13 Schools

Schools are important vehicle for community mobilization activities as informed students take messages to their respective families and neighbors. Schools are an important entry point for school-based vaccination program for HPV. With the main entry point being the schools, the Ministry of Education is a key stakeholder in ensuring smooth implementation in primary schools.

2.3.14 Media

Media plays in an important role in promotion and enhancement of social services including health care delivery. Screening is done in a relatively healthy community. Therefore, coming forward for screening demands a great deal of awareness and self-decision to promote one's own health through early detection of potentially difficult or expensive to treat health conditions.

2.4 Advocacy, Information and Communication for HPV Vaccination

Development of an advocacy, information and communication package related to an 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 cancer sand 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, schools, women, men and the community at large. It would be critical to engage religious and clan leaders as well as local administrations mainly to reach out of schoolgirls residing in remote and pastoral communities. 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.

Chapter 3: Cervical Cancer Prevention and Control: A Comprehensive Approach

The core principle of a comprehensive approach to cervical cancer prevention and control is to act across the life course using the natural history of the disease to identify opportunities in relevant age groups to deliver effective interventions (Figure 3.1).

Vaccination against human papilloma virus, screening and treatment of pre-cancer, early detection and prompt treatment of early invasive cancers and palliative care have proven to be effective strategies to address cervical cancer across the continuum of care. These interventions are embedded in the targets and indicators of the WHO Global Action Plan for the Prevention and Control of non-communicable Diseases 2013–2020, support realization of the 2030 Sustainable Development Goals (SDGs) and are aligned with the Global Strategy for Women's, Children's and Adolescents' Health (2016–2030), the Global Health Sector Strategies on HIV, Hepatitis and Sexually Transmitted Infections (2016–2021) and health systems strengthening for social protection and universal health coverage as set out in United Nations General Assembly resolution 72/81. Each strategy is supported by cost-effectiveness recommendations and WHO technical guidance.

At the national level, a comprehensive approach to cervical cancer prevention and control benefits from being multidisciplinary. As this approach is made up of several key components ranging from community education, social mobilization, vaccination, screening, and treatment to palliative care, it is important to involve representatives from various disciplines and national health programs such as immunization, reproductive health, cancer control and adolescent health.

This guideline takes into consideration the WHO target for cervical cancer elimination. A global effort to eliminate cervical cancer is in alignment with the 2030 SDGs, which lay out ambitious targets for improving human health and well-being worldwide. The strategy defines an incidence threshold, below which cervical cancer would be eliminated as a public health problem. It is then organized around three key pillars: primary prevention, secondary prevention, and tertiary management of cervical cancer. The ministry of health's national guideline on cervical cancer prevention and control is expected to align and contribute to the global effort of WHO initiative for cervical cancer elimination.

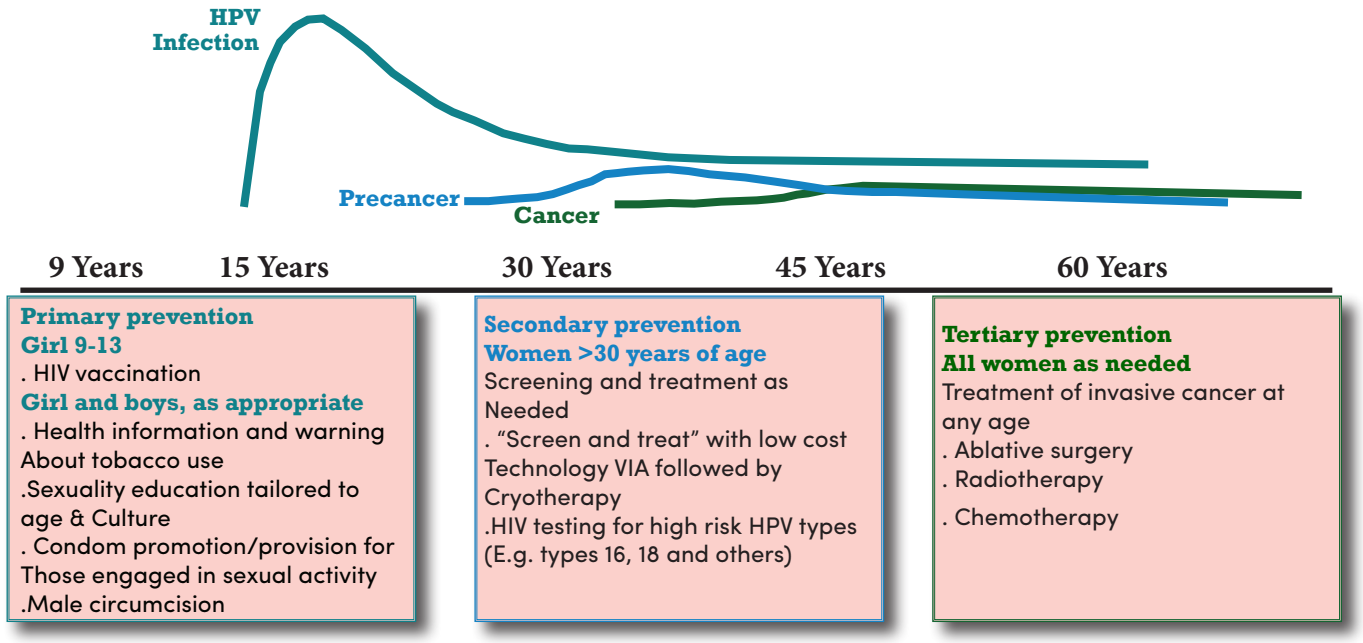


Figure 3.1. Intervention across the life course to prevent HPV infection and cervical cancer.

3.1 Primary Prevention

3.1.1 Primary Prevention of HPV Infection and Cervical Cancer

Primary prevention of cervical cancer involves prevention of infection with HPV. Cervical cancer occurs mainly 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 three types of HPV vaccines: the bivalent vaccine (Cervix), which protects mainly against HPV genotypes 16 and 18, the quadrivalent vaccine (Gardasil), which protects against genotypes 6, 11, 16 and 18 and the nonavalent (Gardasil 9) which give protection against 5 additional HPV subtypes(31,33,45,52,and 58). These three 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 and the other stereotypes known to cause cervical cancer.

Data from clinical trials and initial post-marketing surveillance conducted in several continents show all three vaccines to be safe.All the three vaccines been shown to be effective in preventing cervical precancerous lesions.

The primary target group in most of the countries recommending HPV vaccination is young adolescent girls, aged 9-14. For all three vaccines, the vaccination schedule depends on the age of the vaccine recipient.

- Females <15 years at the time of first dose: a 2-dose schedule (0, 6 months) is recommended.
    - If the interval between doses is shorter than 5 months, then a third dose should be given at least 6 months after the first dose.
- Females ≥15 years at the time of first dose: a 3-dose schedule (0, 2, 6 months) is recommended.

NB: *A 3-dose schedule remains necessary for those known to be immuno compromised and/or HIV-infected.*

3.1.2 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 (< USD10-25). 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 9-14 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 strategies. Following a two year HPV demo project in two districts of Oromia and Tigray regions, Ethiopia was formerly planned to vaccinate the MAC (Maulti Age Cohort) between 9-14 years. However, the country opted to vaccinate single age cohort of 14-year-old girls due to the global vaccine constraint and the national roll-out occurred in December 2018 with quadri-valent HPV vaccine. During the first dose of HPV introduction of the total 1,226,291 fourteen years old target girls 1,179,522 vaccinated showing administrative coverage of 96.2%. Among these, 96.7% were vaccinated in schools and the remaining 3.3% were vaccinated out of school. A total of 1,174,845 doses of HPV vaccine were used showing vaccine wastage rate of 0.3%. During the provision of the vaccine, 19 mild Adverse Event Following Immunization (AEFI) cases were reported and managed accordingly.

Second dose of HPV vaccination was initiated six months later and implemented from June through October 2019. It was administered for girls who received the first dose of HPV vaccination. During this period, a total of 1,113,395 target girls were vaccinated showing administrative coverage of 90.8% from the total target and 94.4% from those who received the second dose. No AEFI case were reported during this period (Technical report of HPV vaccine introduction in Ethiopia, Dec 2018- October 2019).

3.2 Secondary Prevention

3.2.1 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 3.2).

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). In Ethiopia, women are dis proportionally affected by HIV – more than 63% of the adults living with HIV are estimated to be women in 2020 (EPHI 2018). Nevertheless, the Ethiopia Population-Based HIV Impact Assessment (EPHIA) 2017-2018, showed that only 16% of HIV-positive women aged 30-49 years were screened for cervical cancer in urban settings. which has significant implications for the national program.

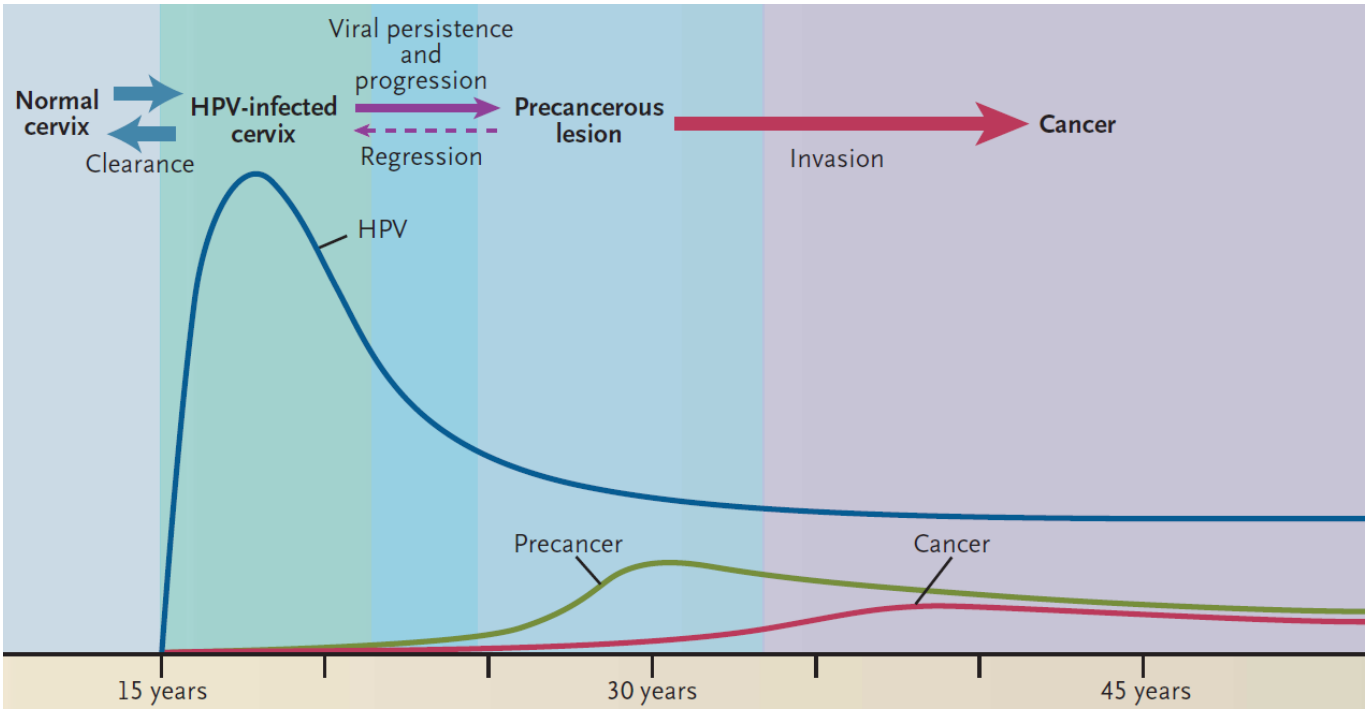


Figure 3.2. Natural history of HPV infection and cervical cancer development

3.2.2 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 cryptologic screening to detect cervical cancer precursors, followed by treatment to prevent progression to cancer. For secondary prevention strategies to be effective, validated screening tests and treatment. Procedures must be widely available and implemented at the programmatic level. The large health disparities for cervical cancer prevention in LMIC reflect barriers of access to healthcare, lack of technologies appropriate for these settings

and disparities in the delivery of screening and other prevention services. These barriers must be addressed in order to meet the WHO 2030 cervical cancer elimination goals.

WHO recommends three types of screening tests: HPV testing for high-risk HPVTypes, conventional Pap smear and liquid-based cytology (LBC), and VIA. As pre-cancerous lesions take many years to develop, repeated screening is recommended for every woman above age 30 (frequency depends on the screening test and risk category) (WHO 2014).

Screening tests for cervical cancer such as cytology (Pap smear) evaluation, visual tests, and tests for HPV infection are all capable of identifying women with high probability of having cervical intra epithelial neoplasia (CIN), squamous intra epithelial lesions (SIL), or preclinical invasive cancer. The objective of cervical screening is to prevent invasive cervical cancer by detecting and treating women withCIN 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.

3.2.2.1 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 acceptable 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 intervals during a given period). The number of screening tests done is not coverage, since this number 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 possi-

ble proportion of women at risk and to ensure appropriate follow-up for those who have a positive or abnormal test results. 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

3.2.2.2 Choice of screening test to be used

The choice of screening test or tests to be used is usually made at the national 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; and
- 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 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. WHO recommends VIA has alternative to cytology comparable sensitivity and specificity 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 must weigh the extent of disability and death caused by different diseases, and the efficacy, cost and impact of diagnosing and treating them. While decisions 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.

3.2.2.3 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 a 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, who 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.)

3.2.2.4 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. Hav-

ing 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.

3.2.2.5 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

3.2.3 Screening methods

Depending on the availability of resources, this guideline recommends the following types of screening methods:

1. Visual inspection: with acetic acid (VIA) or Lugol's iodine (VILI)
2. HPV DNA test
3. Cytology: conventional (Pap smear) and liquid-based

3.2.3.1 Visual methods

Two visual methods are available:

a. Visual inspection with acetic acid (VIA)

b. 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.

Advantage	Disadvantage
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.	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 post menopausal 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.

Table 3.1 Advantages and disadvantages of visual methods

Who are the providers?

Trained nurses, nurse-midwives, nurse assistants, physicians and other health workers with adequate and ongoing support and supervision can perform VIA. Training takes 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 of use

VIA and VILI are indicated for all women in the target age group specified in this guideline, provided that:

- They are premenopausal. Visual methods are not recommended for post menopausal 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.

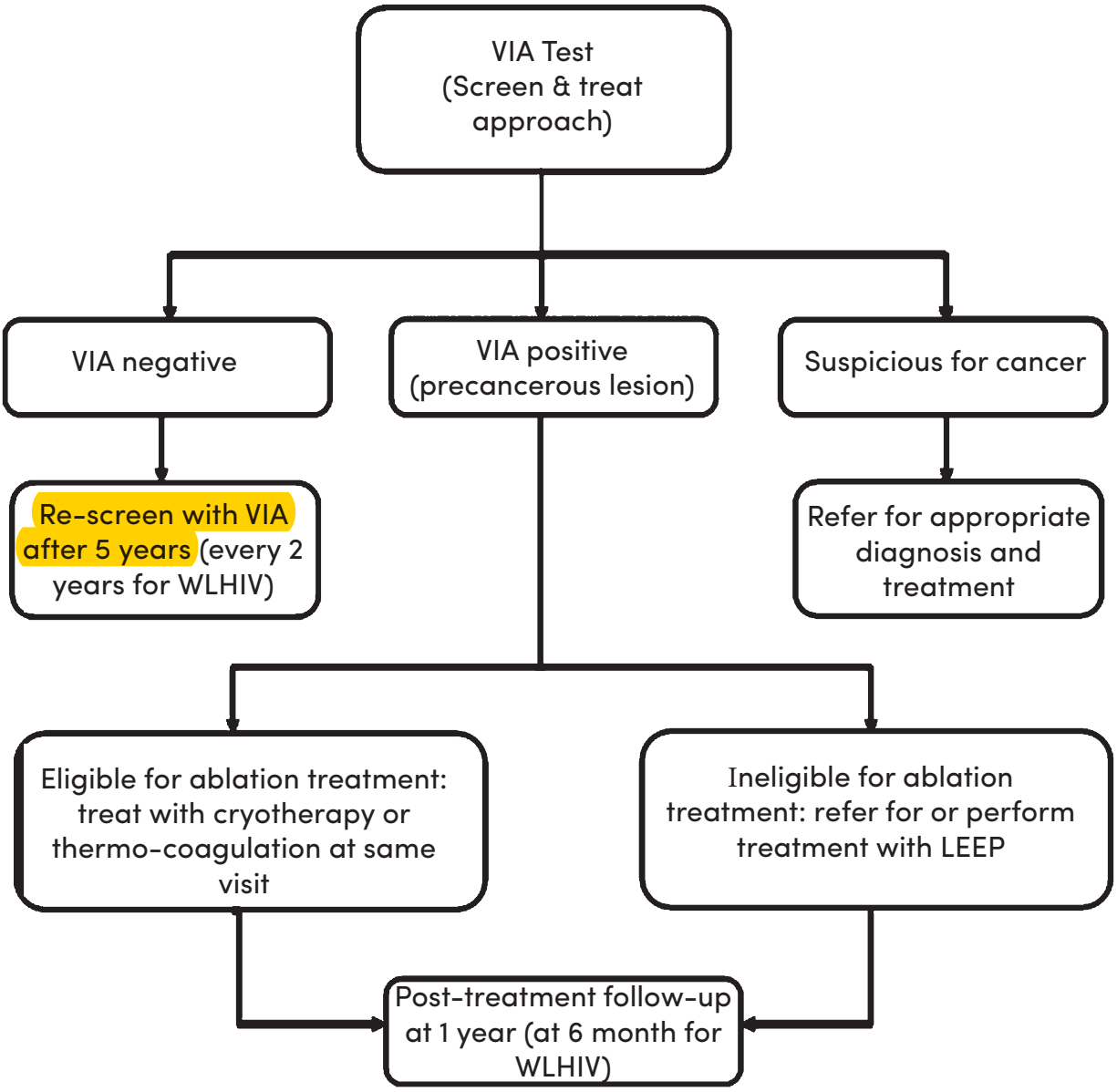


Figure 3.3. Screening with VIA testing using see and treat approach

NB: *For WLHIV Follow up after ablative therapy should be after 6 months*

Target population

The program will focus efforts on screening and treating women between the ages of 30 and 49 years, unless HIV-positive (see below). The target age group could be expanded (e.g., to ages 25-59 years), 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).

Women Living with HIV (WLHIV) are at a much greater risk for developing cervical cancer and require a more frequent screening. Start screening at the time of HIV diagnosis, regardless of age, once sexually ex-

posed. WLHIV should be screened every two years as part of routine care for HIV-positive women. Anti retro viral (ART) clinics should be closely linked with VIA clinics or sites providing cervical cancer prevention services, or ideally, provide the services themselves.

Screening frequency

The FMOH recommends screening every five years following normal results except WLHIV that should be re-screened every two years. 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 5-year period. Based on the population census, the 2020 projected estimate of women aged 30 to 49 years comprises approximately 19.2 % of the female population of 52 million, yielding an estimate of 9.98million women who would need to be screened.

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.

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

Screening by itself will not prevent 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. Screened women must be informed of the test results and advised on follow-up screening based on the recommendations of the guideline. Follow-up is essential 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).
- Facilities should use appointment calendar and provide appointment cards to every client
- 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:
- Telephone women at home or at work;
- Ask health extension workers and case managers 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 trace women with abnormal results if they do not return for scheduled appointments. Appointment calendars system should be used to monitor women who need re-screening (appendix 7).

3.2.3.2 HPV DNA-based Screening Methods

It has been established that cervical malignancy is associated with HPV infection. HPV DNA has been detected in more than 90% of cervical carcinomas in situ, squamous carcinomas, and adenocarcinoma. There are many types of HPV; the types that are most frequently associated with malignancy of the cervix are types 16, 18, 31, 45, 56. Other frequently detected types include HPV 6 and 11. The oncogenic potential of the latter two viruses seems to be low. The prevalence of HPV infection ranges from 10% to as high as 46% in some countries. In common with other sexually transmitted diseases, younger women tend to have a higher rate of infection than older women and are more likely to be transiently infected with HPV. The majority of HPV infections seem to be latent with no production of viral particles. Transient infections tend to contain a low copy number of viral DNA particles (low viral load) and are less likely to progress to malignancy. Persistent infection, however, is associated with a high copy number of DNA molecules (high viral load), a high-risk HPV type, a higher risk of malignant transformation and an older age group of women.

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. 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% to95%, 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.

With the emergence of HPV DNA testing as a primary screening modality, promising and affordable new tests of HPV are available for cervical cancer prevention in LMICs. WHO recommended VIA triage of women who test positive for HPV as a screen-and-treat strategy in LMICs, especially where resources are limited, or quality assurance is not maintained for cytology programs (WHO 2013). Accordingly, the ministry will consider application of various HPV DNA testing modalities depending on the availability of resources. Point-of-care HPV DNA testing using WHO approved GeneXpert PCR tests can be used to support rapid scale-up of VIA triage using single visit approach de-

pending on availability of resources, and considering other program testing platform such as TB, HIV-VL and infant HIV virology testing. On the other hand, the government has been piloting OncoE6 testing as additional option of screening for future consideration based on research findings and global recommendation.

Who are the 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.

HPV testing does not necessarily require visualization of the cervix. A health-care provider can collect a sample of cells by inserting a small brush or other appropriate device deep in to the vagina, and then placing it in a small container with an appropriate preservative solution; it may also be collected at the time of a speculum examination. Sample can also conveniently be self-collected by the client herself.

Indications for Use

HPVDNA testing is not generally used on its own as the primary screening test. It is mainly used in combination with other tests like cytology or VIA to improve the sensitivity of the screening. It is also used as a triage tool to assess which women with borderline Pap results need to be referred for colposcopy. When combined with cytology, 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. In a setting where HPV DNA testing is feasible, primary HPV DNA testing followed by VIA is recommended to improve sensitivity and specificity of the see and treat approach strategy (Fig 4.3).

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 followed by VIA in a see and treat strategy are recommended to use where necessary facilities and human power are available. Based on availability of resources, efforts will be made to maximize efficient use of the existing HIV viral load testing platforms at selected sites in conjunction with VIA or cytological or other screening tests. HPV DNA-based screening should not begin before 30 years of age. The recommended age is between 30-49 years; and women should be rescreened for HPV every five years. For women living with HIV who are sexually active, HPV testing is recommended staring from 25 years of age and should be rescreened every two years. HPV testing is being incorporated into cervical cancer prevention programs in high-resource settings as a primary screening test.

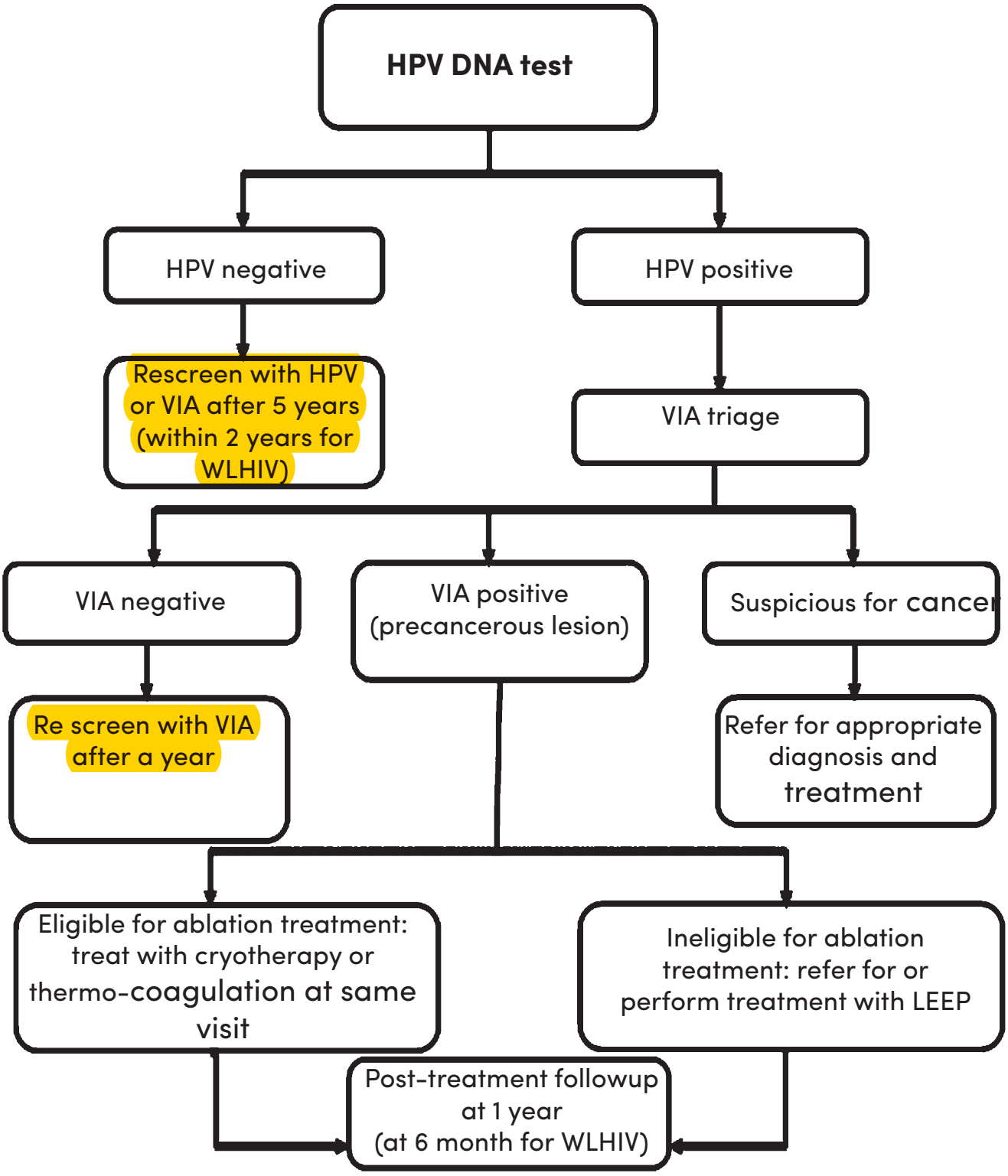


Figure 3.4 Screening with HPV testing followed by VIA triage algorithm

NB: *For WLHIV Follow up after ablative therapy should be after 6 months*

3.2.3.3 Cytology

a) 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

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 microscope to determine whether the cells are normal (see figure 3.2) 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%.

b) 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 a slide, 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 staff 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.

Who are the providers?

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

Indications for use

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 3 or more years ago (or accord-

ing to national guidelines).

- Women whose previous Pap smear was reported as inadequate or showed a mild abnormality.
- Women who have been found to have abnormalities on their cervix.
- Women who are positive for HPV DNA testing.

3.2.4 Screening activities at different levels of the health system

3.2.4.1 Community level

The below activities are executed by community workers by health extension workers. In addition, volunteer care givers and other community workers can also play these roles to promote demand creation on cervical cancer screening.

- Educate and inform the community, promote the screening program, and encourage women to attend.
- Refer eligible 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.
- Health development armies are supposed to collaborate with health extension workers

3.2.4.2 Health center

- Screen, using methods specified by national guidelines (VIA)and integrating screening into other services (see and treat approach).
- 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.
- Implement prompt client referral to the next level of care as per the guideline.

3.2.4.3 Primary hospital

- Carry out screening activities as per national guideline (see and treat approach).
- Inform and counsel women with positive screening test re-

sults, 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.
- Train medical personnel, and support and supervise providers in lower-level health facilities.
- Manage referral and links with lower levels of the health system.
- Provide LEEP service if available.
- Perform biopsy services if available

3.2.4.4 General hospital

- Carry out screening in outpatient clinics where women are seen (see and treat approach).
- Maintain central cytology, pathology, and molecular laboratories, as feasible.
- Receive referrals from HC and give feedback to referring facilities
- Train medical personnel, and support and supervise providers in lower-level health facilities.
- Involve in training and mentorship.
- Provide LEEP service if available.
- Perform biopsy services

3.2.4.5 Specialized hospital

- Carry out screening in outpatient clinics where women are seen (see and treat approach).
- Receive and treat advanced cases.
- Maintain central cytology, pathology, and molecular laboratories, as feasible.
- Perform HPV DNA testing or cytology followed by colposcopy, if available.
- 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.
- Involve in training and mentorship.
- Provide LEEP and advanced cervical cancer service

3.2.5 Treatment of Precancerous Lesions

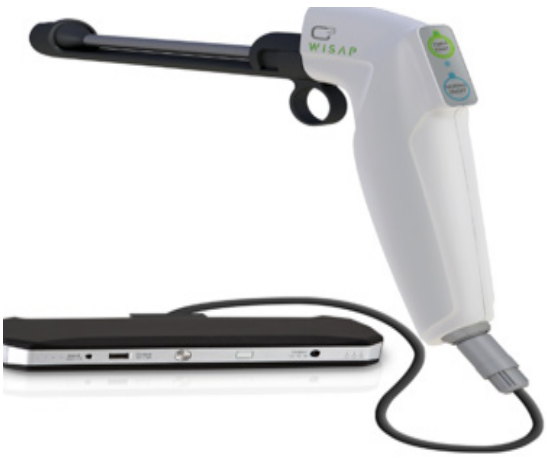
3.2.5.1 Cryotherapy

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 single visit approach 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 thecryo-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.

3.2.5.2 Thermal ablation

Thermal ablation is another novel ablative treatment of option for precancerous lesions and is sometimes called "cold coagulation" or "thermo coagulation". WHO and the guideline development group decided to use the term thermal ablation, as it describes most closely what the treatment is. The equipment is fairly simple, and treatment is based on a 20–30 second application of a reusable metallic probe that is electrically heated to approximately 100 °C, leading to epithelial and stromal destruction of the lesion. Conventional desktop devices weigh about 5 kg and are reasonably portable. Newer handheld, battery-operated devices weigh less than 2 kg, and are compact enough to carry in a backpack which makes for easy implementation in LMIC. The treatment time is shorter with thermal ablation and also the use of thermal ablation overcomes one major disadvantage of cryotherapy which is the need for a refrigerant gas (N2O or CO2). The gas containers are bulky and heavy to transport and some areas of LMIC may have supply issues. In addition, frequent refilling of freezing gas can be costly. The use of thermo coagulation for the treatment of CIN is as effective as other methods, such as cryotherapy and LEEP, with the advantage of being rapid and is also associated with low occurrence of side effects (Dolman et al, 2017). Currently thermal ablation is increasingly being adopted as an alternative to cryotherapy and along generated evidence is accumulating to support the inclusion of thermal ablation for the treatment of cervical precancer lesions and WHO also issued recommendation on its use (WHO 2019).



Advantages for Healthcare Provider

- **No gas required**
- **No power-grid required**
- **No autoclave required**
- **Simple handling**
- **Timer function**
- **Heat protection**

Figure3.5. Handheld thermal ablation device (electrically charged with power bank)

3.2.5.3 Loop Electro Surgical Excision Procedure (LEEP)

LEEP is reserved for precancerous lesions that are not eligible for cryotherapy or thermal ablation. 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.

3.2.5.4 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.

3.2.6 Management of treatment complications

Cryotherapy, thermal ablation 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, WHO 2019). 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 feaces through vagina (very rare)

3.2.7 Provision of care

The services will be primarily provided in static facilities. To improve coverage, outreach clinics will be considered. See Table 4.1 for outline of the health system by level, services provided and cadre. Cryotherapy and thermal ablation 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 and thermal ablation services can be provided at all levels of the health service delivery system, provided the facility meets the Health Facility Readiness Assessment.

LEEP services can be provided from the primary to tertiary level of the health service delivery system; provided the facility meets the Health Facility Readiness Assessment. 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 program person integrating the activities with other RH services.

Healthcare delivery level	Service provided	Cadre
Tertiary hospital	VIA/cryotherapy/thermal ablation,-PAPsmear, colposcopy, LEEP biopsy, histopathology ra-diotherapy, radical surgery chemotherapy and palliative care	Nurse,midwives,health officer, MD residents and specialists (gyn/obn, gynoncologists)
Regional/general hospitals	VIA/cryotherapy/thermal ablation,-PAPsmear, colposcopy LEEP biopsy histopathology, radical surgery and palliative care	Nurse,midwives,health officer, MD residents and specialists (gyn/obs, gynoncologists)
District hospitals / primary hospitals	VIA/cryotherapy/ thermal ablation, biopsy, palliative care	Nurse,midwives,health officer, MD
Health centers	VIA/cryotherapy/ thermal ablation, palliative care	Nurse,midwives,health officer

Table3.2. Healthcare delivery level by type of service and cadre of health workers

3.2.8 Referrals and Laboratory/pathology Investigations

Referral linkage

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 (as per technical training material) or thermal ablation will be referred for LEEP service
- 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 (Ob/Gyns).

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 recommended that when cervical cytology is feasible, it will be provided in situations where the SCJ cannot be visualized, which is common in post menopausal 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.

3.2.9 Integration of Cervical and Breast Cancer Screenings at Health Facility Level

3.2.9.1 Introduction and Rationale for Integration

Globally, breast cancer is ranked 2nd in cancer incidence with 2,088,849 cases (accounting for 11.6% of all new cases). In African women, breast cancer incidence peaks between the ages of 35 and 45 years, approximately 10 –15 years earlier than peak incidence for western countries outside of the western Africa region. Overall, breast cancer is the leading cancer in Ethiopian accounting for 32.3% of all cancer types followed by cervical cancer at 14.5%. Cancer dis-proportionally affects women with staggering share of 67% of all cancer types.

The WHO Global Breast Cancer Initiative (GBCI) aims to reduce global breast cancer mortality by 2.5% per year, thereby averting 2.5 million breast cancer deaths globally between 2020 and 2040. Reducing global breast cancer mor-

tality by 2.5% per year would avert 25% of breast cancer deaths by 2030 and 40% by 2040 among women under 70 years of age. The three pillars toward achieving these objectives are: health promotion for early detection; timely diagnosis; and comprehensive breast cancer management.

The national cervical cancer screening program of Ethiopia presents a unique opportunity to reach as many women as possible through the well-established screening program for cervical cancer. To date, more than 1000 public health facilities are providing cervical cancer screening and treatment program throughout the country. This platform can easily be accessed to leverage on breast cancer screening and contribute towards the global initiative by WHO.

The incidence of breast cancer is on the rise. Screening for early detection therefore is an important aspect in the control of breast cancer. The primary goal of screening is to increase detection of breast cancer in its early stages and hence improve prognosis and reduce mortality.

The goal of an integrated screening of breast and cervical cancer is to avail the opportunity for the women who come for cervical cancer to have a check for breast cancer at the same time and get connected to the next level of screening and confirmation as per the national breast cancer screening and care (guideline under development).

Cervical cancer screening and treatment providers will have an integrated and scheduled training on basics of breast cancer screening during the basic training for cervical cancer screening and treatment. Special reference will be made to the breast cancer clinical examination guideline for primary health workers.

Chapter 4: 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 multidisciplinary 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 tobe used by tertiary-level providers, but rather to help first- and second-level providers to understand different treatment modalities for early referral.

4.1 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 a 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 describes health care service provision in terms of what is recommended and what is available currently in Ethiopia.

Intervention	Level of care	Cadres of health providers
Surgery for precancerous Conization/LEEP	Regional/tertiary hospitals	Gyn/Obs, oncologists
Surgery for early invasive disease radical hysterectomy with pelvic lymphadenectomy	Tertiary hospital	Gynecologic oncologists
Radiotherapy-external beam therapy	Tertiary hospital/ recommended at regional hospitals	Radiotherapy oncologist Radiotherapist technician Medical Physicist/dosimetrist
Chemotherapy in combination with surgery or radiotherapy	Tertiary hospital	Medical oncologist Nurse oncologist
Palliative care	All levels	All cadres, faith based spiritual based leaders, psychologist and psychiatrist

Table 4.1. Health service provision and cadre of health workers for cervical cancer

Reasons for referral	Clinical service required	Level of referral facility
Client testing positive for precancerous lesion	Cryotherapy or thermal ablation	This service is mainly given at a primary health care level but with potential referral to 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

Table4.2. Referral hierarchy for cervical cancer services in Ethiopia

4.2 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 fami-

lies. 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 5: Infrastructure, Equipment and Supplies

Essential infrastructure, equipment, supplies and logistics requirements to provide high-quality cervical cancer prevention and control services are detailed on the technical training materials. 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 8.1), as well as using the essential equipment and supplies lists (see Appendix 8.2) that are considered essential to performing cervical cancer prevention services.

The procurement of all equipment and supplies will be conducted through the Ethiopian Pharmaceuticals Supply Agency (EPSA) and should follow the existing Integrated Logistic System (ILS). A mechanism should be in place to anticipate demands, especially during scale-up of the program, to avoid interruption of services due to stock-outs. Cryotherapy is performed using either nitrous oxide (N2O) or carbon dioxide (CO2) gas. Nitrousoxide costs approximately four times as much as carbon dioxide. Reportedly, CO2 is also relatively more readily available. Given these findings, the current recommended gas for cryotherapy is CO2. It is recommended that each site providing cryotherapy services has at least two 25 kg CO2gas tanks. The number of cryotherapy treatments which it is possible to perform per 25 kg tank is approximately20-22 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 a 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,thermal ablation and LEEP machines require troubleshooting, basic maintenance and care. Thermal ablation treatment is also an additional option for treatment of pre-cancerous cervical lesion being scaled-up.

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 cryotherapy, thermal ablation and LEEP machines.
- Every health facility should liaise or be a member of the drug and therapeutic committee (DTC) of the facility to raise issues related to supplies and commodities for cervical cancer prevention and control program.
- Ensure local production and manufacturing of frequently required supplies and diagnostic tools.

Chapter 6: Monitoring and Evaluation

6.1 Introduction and Target Setting

Monitoring is the regular collection of information about all project activities. It is an ongoing activity that should be incorporated into everyday service/ program activities.

It shows whether things are going to plan and helps project managers to identify and solve problems quickly. It keeps track of project inputs and outputs such as:

- Activities
- Reporting and documentation
- Finances and budgets
- Supplies and equipment.

An evaluation asks whether a project is achieving what it set out to do, and whether it is making a difference. It Evaluations keep track of key outcomes and impacts related to the different project components, assessing whether the objectives, aims and goals are being achieved. Evaluations take place at specific times during interventions.

This section provides guidance for health care providers, program planners, 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 help 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.

The National Cervical Cancer Prevention Program under the NCD Case Team uses standardized national forms that have been approved by the FMOH and are linked to the current DHIS system. The Health Information System (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 DHIS in Ethiopia, which is operational from the facility to the central level.

Target setting:

The 2019 WHO strategy to eliminate cervical cancer proposes:

- Vision of a world where cervical cancer is eliminated as a public health problem
- Threshold of 4 per 100,000 women-year for elimination as a public health problem
- The following 90–70–90 targets that need to be met by 2030 for countries to be on the path towards cervical cancer elimination
    - 90% of girls fully vaccinated with the HPV vaccine by age 15.
    - 70% of eligible women in the target age group get screened
    - 90% of women identified with cervical disease receive treatment (90% of women with pre-cancer treated; 90% of women with invasive cancer managed).

See annex 8.13regarding how to calculate targets.

6.2 Health Information System 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 aggregate data. Documentation of services provided, should be done by trained VIA with cryotherapy/thermal ablation as well as LEEP service providers on a daily basis. Information gathered from the registers will be used to calculate monthly statistics based on the indicators. The health facility cervical cancer focal person will be responsible to monthly compile, analyze and report cervical cancer screening and treatment performance to the health facility HIS officer. Health facility management needs to ensure monthly analysis and review of cervical cancer prevention performance data against facility level targets on monthly basis. In addition, the health facility HIS officer will regularly update cervical cancer screening and treatment data on DHIS regular bases. If DHIS is not functional, health facility HIS officer will be responsible in sharing the report to the Woreda NCD focal person using HMIS focal person.

6.3 Health Information System at Woreda

The Woreda NCD coordinator will be responsible for sharing the targets to the respective Health facilities. The target shared from FMOHare based on the Woreda-based planning and selected health facilities in the Woreda will be responsible to screen all eligible women living the Woreda. Other health facilities in the Woreda are expected to refer eligible client to the selected cervical cancer screening HF in the Woreda (VIA and cryotherapy/ thermal ablation center). Moreover, Woreda NCD coordinators will be responsible in checking on time reporting of cervical cancer screening and management activities by health facilities in the Woreda by following the DHIS report. If DHIS system is not functional, the Woreda NCD coordinator will ensure HF share the manual HMIS report. In addition, the Woreda NCD coordinator will be responsible in analyzing the performance of health facilities in their respective catchment on monthly basis against target, and support health facilities to develop performance improvement plans for gaps identified. Woreda NCD focal person will also regularly conduct supportive supervision and quality assurance for HF with cervical cancer screening service.

Other responsibilities of the Woreda NCD focal persons include:

- Following the performance and reporting cervical cancer screen services conducted in non-governmental (NGO) and private HFs in the

Woreda.

- Ensuring distribution, continues availability and appropriate utilization of CCP M&E tools, CEMs, PST in the selected cervical cancer screening and treatment HFs the Woreda.

6.4 Health Information System at Zone/ Sub city level

The Zonal/ Sub city level (SC) NCD coordinator will be responsible in ensuring that Woreda have shared the Woreda level targets to the selected cervical cancer screening health facilities in the respective Woredas. Zone/SC will also be responsible in following cervical cancer screening performance of Woreda in the respective zones/SCs and monitor performance trends against target. Moreover, Zone/SC NCD coordinators will be responsible in checking the on-time reporting of cervical cancer screening and management activities by respective Woreda in the zone by following the DHIS report. In addition, the Zone/SC NCD coordinator will be responsible in analyzing the performance of the respective Woreda on monthly basis and support Woredas/health facilities to develop performance improvement plans for gaps identified. In addition, Zone/SCNCD coordinator will regularly conduct supportive supervision (SS) and quality assurance visits to Woreda and HFs with cervical cancer screening and NCD services, by giving focus on high impact HFs. Based on the SS finding the Zonal/SC NCD coordinator will be responsible in identifying best practices and implementation gaps. In addition, ZHD will be responsible in ensuring cervical cancer screening and management performance activities are included in the regular Zonal review meetings.

Other activities of Zonal/SC NDC coordinator include ensuring:

- Post training follow up of newly trained HCPs,
- Smooth initiation of cervical cancer screening services in new health facilities starting CCP service.
- Availability minimum requirement for service initiation of cervical cancer screening service and management services.
- Competency of newly trained HCPs by linking them with experienced service providers.
- Distribution continues availability and appropriate utilization of M&E tools in the health facilities.

6.5 Health Information System at Regional level

Regional NCD case team /cervical cancer focal person will be responsible in ensuring that Zones/SC are following cervical cancer screening performance of all Woreda in their respective Zone/SC and monitor performance trends against target. Moreover, regional NCD case teams/cervical cancer focal person will also be responsible in checking on time reporting of cervical cancer screening and management activities by the respective Woreda and Zones by following the DHIS report. In addition, the regional NCD case team/ cervical cancer focal person will be responsible in analyzing the performance of the respective Zones on monthly basis and provide support the re-

spective Zones in developing performance improvement plans for gaps identified. They are also responsible on timely reporting of activities to FMOH. In addition, regional NCD case team/cervical cancer focal person will regularly conduct SS and quality assurance for health facilities with cervical cancer screening service and NCD services, by prioritizing high impact Zones, Woreda and health facilities in cervical cancer screening and NCD services. Besides, regional NCD case team/cervical cancer focal person will be responsible in identifying best practices and implementation gaps. Additional activities of regional NCD case team/cervical cancer focal person includes:

- Planning and implementation on expansion of cervical cancer prevention activities.
- Planning and implement basic and refresher trainings on cervical cancer prevention as well as LEEP training.
- Identify and regularly update pool of trainers on cervical cancer prevention,
- Lead advocacy and social mobilization activities concerning cervical cancer prevention at regional, Zonal and Woreda level.
- Advocate on resource mobilization and effective utilization of resource for CCP activities, Support Zones to strengthen referral linkage of clients for cervical cancer screening and management services at each level.
- Ensure cervical cancer screening and management performance activities are included in the regular regional review meetings.
- Ensure printing, distribution, continues availability and appropriate utilization of cervical cancer prevention M&E tools.

6.6 Health Information System at FMOH

FMOH NCD case team/cervical cancer focal person will be responsible in ensuring that RHBs are following cervical cancer screening performance of all Zones/SCs and monitor performance trends against target. In addition, the FMOHNCD case team / cervical cancer focal person will regularly analyze the performance of the respective regions on monthly basis and support regions to develop performance improvement plans for gaps identified. Besides, FMOHNCD case team / cervical cancer focal person in collaboration of RHBs will regularly conduct SS and quality assurance of cervical cancer screening services

6.7 Cervical Cancer Prevention and Control Program Implementation and Monitoring Tools

The main tools for implementation and reporting/monitoring results for the National Cervical Cancer Prevention Program will include:

6.7.1 Eligibility assessment, triage and referral linkage

To strengthen linkage of eligible women for cervical cancer screening service among women from the general population, health facilities need to use cervical cancer eligibility screening and linkage form both at

triage or at each service delivery points where potentially eligible clients for cervical cancer screening are seen (ART, PMTCT, FP unit, OPDs, MCH, Wards).HCPs will ensure linkage of all cervical cancer screening eligible clients identified during triage or in the service delivery points (SDPs). Please see the client flow to strengthen integration and linkage of cervical cancer screening and management services for all clients who come to the health facilities (appendix 1).

In the triage unit and service delivery points, the HCPs will ensure availability and usage of cervical cancer eligibility assessment (appendix 2) and linkage form (appendix 4). This form helps to make quick eligibility assessment of the client for cervical cancer screening by checking her age, previous history of screening, pregnancy status (those pregnant and within 3 months of post-partum should not be included in the screening unless they have clear symptoms suspicious of cancer).

For ART clients getting cervical cancer screening and management services, besides documentation on client charts, and registers, cervical cancer related services given for ART clients need to be updated on ART EMR database which has a feature to capture cervical cancer screening and management services provided to ART clients by data clerks. This would make monitoring of cervical cancer screening and management service at health facility level including use of data for informed decision making for program improvement. As the use of EMR database for other health facilities expand, this guideline recommends updating of cervical cancer screening and management services given to all groups clients in the respective health facilities.

Note: *Health facility cervical cancer focal person should ensure continues availability and usage of M&E tools annexed in this guideline.*

6.7.2 Cervical cancer screening and treatment register

Cervical cancer screening and management register (annex 5) is a register put in the cervical cancer-screening unit. The HCP working on cervical cancer screening unit completes this form for each client who got cervical screening service. Instructions on how to use the register is put in the first page of the register. In addition, to avoid repeated back and forth checking of instruction on the first page of the register, the copy of instructions on how to fill the register can be posted in cervical cancer screening unit notice board or desktop. This would help, HCPs to easily refer to the instructions while documenting on the cervical cancer register. The register has columns to capture important information on:

- Client identification,
- Risk factors for cervical cancer,
- Eligibility for risk-based HIV status including ART status of those who are HIV positives,
- Cervical screening with HPV DNA testing as well as VIA screening including cervical cancer screening outcome,
- Follow up of clients who got cervical cancer screening service as well as
- Referral of clients for further evaluation and treatment.

NB: *CxCa screening HCP should complete the register at the time of the client visit in the same day. Information from the register should be used to prepared monthly reporting summary form.*

6.7.3 Cervical cancer screening and treatment service reporting form

Cervical cancer screening, management and referral service reporting form (appendix6) summarizes the performance of cervical cancer screening service among eligible women cervical cancer screening. The reporting tool helps to generate information on cervical cancer screening and management service provided for general population. The reporting format helps to generate data on cervical cancer screening management services given for:

I. New clients,

II. Routine re-screening client

III. One-year post-treatment follow-up clients

The following key program, indicators are included in the reporting format, which can be used for program improvement. The indicators are:

- Number Screened with HPV DNA
- Number HPV DNA positive
- Number screened with VIA
- Number VIA positive
- Number identified for cervical abnormalities on VIA testing with disaggregation on eligibility for cervical cancer and suspicious for cancer
- Number treated for cervical abnormalities disaggregated by type of treatment as well as those treated on the same day
- Number of clients referred disaggregated by reasons for referral

NB: *In addition, reporting format includes disaggregation of all indicators by HIV status age categories.*

Other tools used to enhance program monitoring of cervical cancer screening and management service are appointment card (appendix7) and appointment calendar (appendix8). For each client appointment is given, HCPs need to complete appointment cards and give it to client. Some of the appointment given for clients who got cervical cancer screening are long for example clients who became negative for VIA test long appointment dates. Hence, in addition to appointment cards, it important to use appointment calendars so that it would be easy for providers to have information on how many clients they expect for follow up visit on each day and make necessary preparations. Moreover, the use of appointment calendar would help to identify those who missed appointment and make appropriate interventions to track clients so that they came back to get the service they are appointed for.

6.7.4 Strengthening referral linkage

Provision of VIA and cryotherapy/thermal ablation 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 referral linkages are extremely important. The National Cervical Cancer Prevention Program will use the national protocol for referral.

6.7.5 National Program Indicators

The National Cervical Cancer Prevention Program will track key program indicators through the above-described reporting system. The following key indicators will be incorporated with the DHIS reported national health indicators.

Core Indicator1 Screening rate: Percentage of women aged 30–49 years who have been screened for the first time with VIA/ HPV in reporting period. This monitoring indicator measures how many VIA screenings were performed in the reporting period against target of women aged 30–49 years.

CoreIndicator2 VIA/HPV test positivity rate: Percentage of VIA/ HPV –screened women aged 30–49 years with appositive result

Core Indicator3 Percentage of women who received treatment for precancerous lesion (Cryo/TA/LEEP)

CoreIndicator4 Percentage of women who got follow up for VIA re-screening service after one year of treatment during the reporting period

Table 6.1. Core indicators to follow cervical cancer screening program

1. Proportion of women aged 30–49 years who have been screened for cervical Ca

Definition	Proportion of women between ages 30 – 49 screened either with VIA or HPV DNA test for cervical cancer	
Formula	Number of women aged 30–49 years who have been screened for cervical ca in reporting period	X 100
	Estimated Number of women aged 30–49 years in the catchment	
Interpretation	This indicator is intended to monitor trends in provision of counseling and screening services for cervical cancer. Data should be generated by counting the total number of individuals who received screening service at service delivery points (family planning clinics) from health facilities providing the service. Recent developments in technologies adapted to low-resource settings make screening and treatment of cervical pre-cancer lesions feasible and highly cost-effective for all countries. Additionally, Ethiopia has also introduced HPV DNA test as additional screening test in addition to VIA screening test previously in use. Early detection and treatment of precancerous lesions can result in massive improvements of survival and are especially important in developing countries where access to expensive cancer treatment is limited. There is sufficient evidence that cervical cancer screening can reduce cervical cancer mortality by 80 per cent or more among screened women. The service is provided integrated with family planning service and during the service cervical intake form will be used to document the required information during screening. HPV DNA test positive only tells us the presence of human papilloma virus infection. Therefore, women whose HPV DNA test turned positive should undergo VIA screening to identify presence of lesion.	

Disaggrega-tion	Screening type: VIA, HPV DNA Result for VIA - Normal cervix - Precancerous lesion - Suspicious for cervical Cancer				Result for HPV DNA test - Positive - Negative	
Data source	Cervical Cancer Screening and Treatment Register					
Frequency of reporting	HP	HC	Hospital	WorHO	ZHD/SHO	RHB
		Monthly	Monthly			

2. Number of women screened 1 year after treatment follow up

Definition	Number of women screened 1 year after treatment follow up					
Formula	Number of women 30-49 years re-screened					X 100
	Number of women 30-49 years received treatment last year in the same re-porting period					
Interpretation						
Disaggrega-tion	Screening type: VIA, HPV DNA Result for VIA Result for HPV DNA test - Normal cervix - Precancerous lesion - Suspicious for cervical Cancer				- Positive - Negative	
Data source	Cervical Cancer Screening and Treatment Register					
Frequency of reporting	HP	HC	Hospital	WorHO	ZHD/SHO	RHB
		Monthly	Monthly			

3. Proportion of eligible women who received treatment for cervical lesion

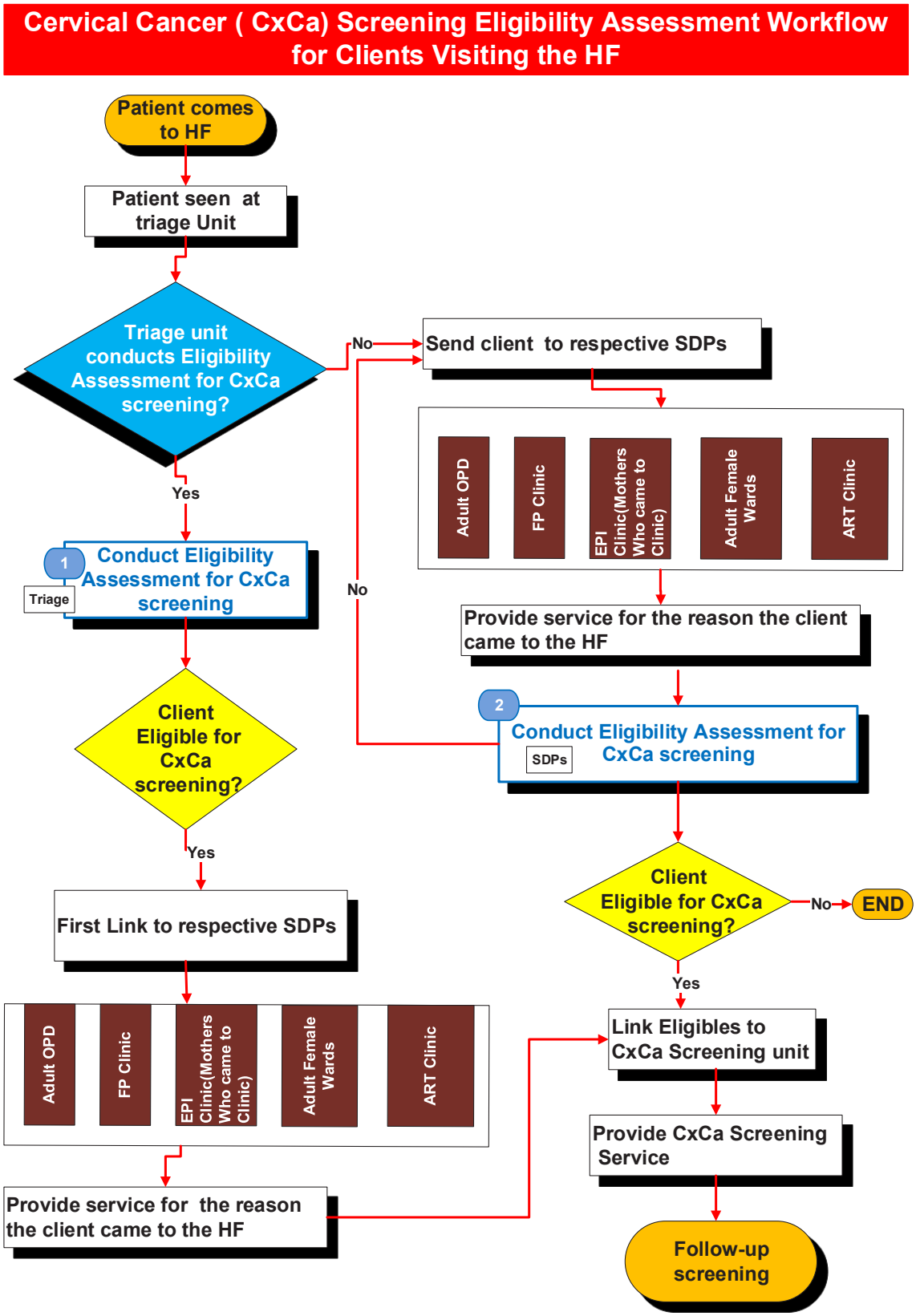
Definition	Percentage of women with precancerous lesion on VIA test who received treatment					
Formula	Number of women 30 - 49 years with cervical lesion treated					X 100
	Number of women 30 - 49 years with identified pre-cancerous cervical lesion					
Interpretation	This indicator is intended to monitor the proportion of women with precancerous cervical lesion who received treatment of precancerous lesions with treatment approach such as cryotherapy, LEEP or thermal ablasion. This can result in massive improvements of survival and are especially important in developing countries where access to expensive cancer treatment is limited.					
Disaggrega-tion	TTreatment type: - Cryotherapy - LEEP - Thermal Ablasion				HIV status - Positive - Negative - Undocumented	
Data source	Cervical Cancer Screening and Treatment Register					
Frequency of reporting	HP	HC	Hospital	WorHO	ZHD/SHO	RHB
		Monthly	Monthly			

Chapter 7: Surveillance and Research

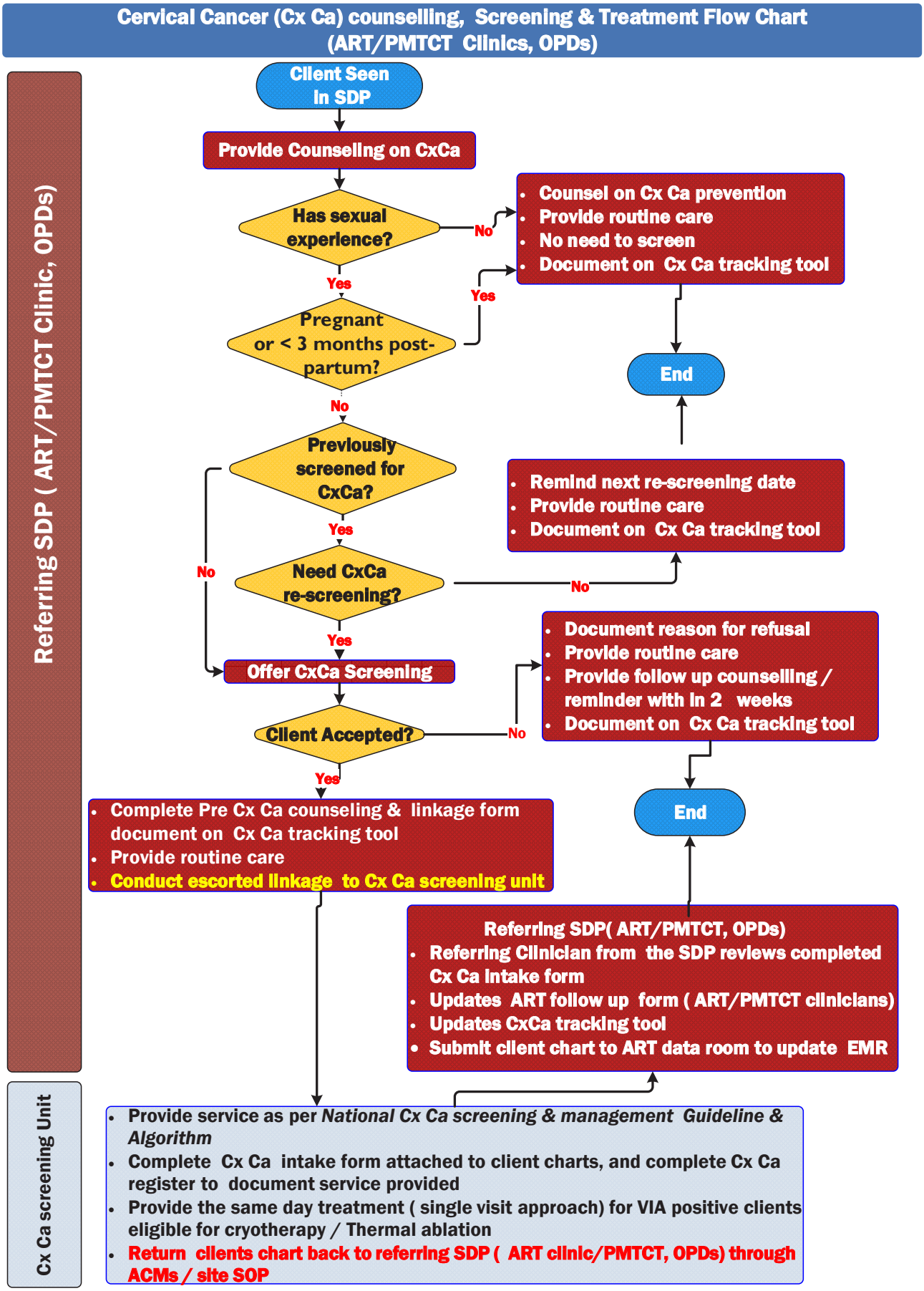
As a fundamental element of any cancer-control strategy, surveillance and research provides the foundation for advocacy and policy development. The strategy focuses on enhancing cancer surveillance systems at all levels of the health system, especially cancer registration. It suggests ways to improve research capacity, and the dissemination and use of research findings. For more details on cancer surveillance and research strategies, plans and activities, please refer to the national cancer control plan. The national cancer control of Ethiopia recommends establishment of at least facility based cancer registry in all the expansion sites. Cervical cancer program would benefit from this establishment.

Appendix

Appendix 1: Cervical cancer screening eligibility assessment and linkage workflow



Appendix 2: Cervical cancer screening eligibility assessment and linkage workflow



Appendix 3: HF triage/service delivery point cervical cancer (Cx Ca) screening eligibility and linkage form for women visiting the HF

I. Eligibility criteria

1.Is the age of the client between 30-49 years or age 25-49 for HIV positives (inclusive)?

Yes ☐ No ☐

2. Does the client have sexual experience?

Yes ☐ No ☐

3. Has the client been screened for Cx Ca in the past5 years or in the past 2 years for HIV positives?

Yes ☐ No ☐

4. Is the client currently pregnant or less than 3 months post-partum?

Yes ☐ No ☐

II. Is the client eligible for to Cx Ca screening?

Yes ☐ No ☐

NB:

- *If the answer is, Yes for Q# 1 and 2 question and No for Q# 3 &4. The client would be eligible for screening on this visit*
- *All eligible clients for to Cx Ca screening need to be linked to cervical cancer screening unit (preferably through escorted linkage)*

.....

III. If eligible, Is the linked to cervical cancer-screening unit?

Yes ☐ No ☐

Appendix 4: Client intake form

CLIENT IDENTIFICATION: MRN: _____ SN on VIA register No. _____ Date of visit_____/_____/_____

Name of client: _____Age: ___ Telephone: _____ _____

Educational Status (enter last grade completed): _____ Check box if illiterate

Reproductive history

Marital status: _____ Parity: _____ Current contraceptive(s): _____ Age at first intercourse: _____

Pregnant: ☐Yes (If pregnant, do not screen unless symptomatic for Cervical Cancer) ☐No

Menstrual Bleeding Pattern: ☐Regular (23-35 intervals). ☐ Irregular ☐ Menopause ☐Post-coital spotting or bleeding

Risk factor STI History: Number of sexual partner(s) of Client: ¬¬¬¬¬¬¬¬¬_____ Of spouse: _____

History of STI Client: ☐ Yes ☐ No – Partner: – ☐ Yes – ☐ No

HIV status – ☐ Positive ☐ Negative – ART status: – ☐ Yes – ☐ No

.....Other Risk Factors (Tick for applicable):

☐ History of smoking ☐ Previous abnormal Pap smear ☐ Chronic corticosteroid use

EXAMINATION

Result of pelvic examination	☐ Normal	☐ Abnormal (please describe details below)
Suspicious for cancer	☐ No	☐Yes (please describe details below)
SCJ was completely seen	☐ Yes	☐ No (please describe details below)
STI case	☐ Yes	☐ No, if yes treatment provided: _____

Type of screening visit

1. First time 2. Re-screening after previous negative result 3.Post Treatment follow-up screening

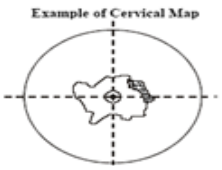
Screening method

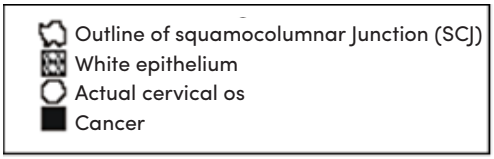
1. HPV DNA, sample collected date: _____/_____/_____ 2. VIA 3. HPV followed by VIA

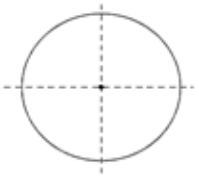
HPV DNA screening result HPV result received date: _____/_____/_____

1. Negative (if negative, go to Eligibility for risk based HIV testing section) 2. Positive 3. Unknown/ inconclusive

Cervical map: Draw the cervical findings on right circle using the instructions from the left circle







VIA screening result (Circle) Screened date:_____/_____/_____

1. VIA Negative, return for re-screening on ___/____/_____
2. VIA Positives: Eligible for Cryotherapy or thermocoagulation
3. VIA Positives: Non eligible for Cryotherapy or thermocoagulation
4. Suspicious cases for cervical cancer
5. Unknown screening result

Treatment services for precancerous lesions

1. No treatment 2. Cryotherapy 3.Thermocoagulation 4. LEEP service

For precancerous lesion: If Not treatment, Specify reason: _____

Date treatment given: _____/_____/_____ Next follow-up screening date: _____/_____/_____

N.B: As much as possible please provide same day treatment to implement single visit approach

Eligibility for Risk Based HIV Testing ☐ Yes ☐No

HIV/AIDS testing ☐ Positive (If new positive, link to ART clinic) ☐Negative ☐ Unknown.

Reason for Referral/linkage

1. Gyn OPD for LEEP 2. Gyn OPD for suspicious cancer evaluation
3. Referred for LEEP service 4. Referred for suspicious cancer evaluation
5. Other, specify: _____ Date of referral/linkage: _____/_____/_____

N.B: Criteria for LEEP service referral/linkage ☐ Lesion larger than cryoprobe/Thermoprobe > 2 mm ☐ Lesion > 75% ☐ Lesion extended inside os ☐ Client denied cryotherapy/ Thermal ablation

Providers Name_____ **Signature**_____

Appendix 5: Pre-cervical cancer screening and treatment counseling and linkage form

Pre-Cervical Cancer Counselling & Linkage Form

Completed by referring clinicians at SDPs (ART, PMTCT, OPD, etc.)

Visit Date: ____/_____/_____

Name: _____**MRN:** _____**UAN:** _____**Age:** _____

CxCa screening counselling offered? ☐ **Yes** ☐ **No**

CxCa screening counselling accepted? ☐ **Yes** ☐ **No**

Date accepted: ____/_____/_____

Have you ever been (previously) screened for CxCa? ☐ **Yes** ☐ **No** ☐ **Don't Know**

If yes, date screened: ____/_____/_____

Eligibility for screening on this visit

1. Never Screened
2. Screened negative before 2 years
3. Screened positive & Treated with Cryo/ thermocoagulation or LEEP before 6 months year
4. Other reasons for eligibility, specify: _____
5. Not eligible

If eligible, Is Cervical Cancer Screening service accepted? ☐ **Yes** ☐ **No**

Service Provider Name/Signature: _____

Person accompanied the client to CxCa Unit /Adherence Counselor

Is client linked to CxCa Screening unit?

☐ **Yes,** date linked to CxCa screening unit: ____/_____/_____

☐ **No,** If No, specify reason for not linked to CxCa unit

_____

Appointment date for CxCa Service: ____/_____/_____ Signature:_____

Cx Ca screening unit provider

Cx Ca screening done on the same date

☐ **Yes,** date CxCa screening unit: ____/_____/_____

☐ **No,** if no, specify reason for not screened on the same day_____

Appointment date for screening: ____/_____/_____

NB: As much as possible linkage as well as screening should be done on the same date

NB: *For WLHIV Follow up after ablative therapy should be after 6 months.*

Appendix 6. Cervical cancer screening and management treatment register

Cervical Cancer Screening and Treatment Register

Health Facility:____________________ **Woreda:** ____________________ **Zone/Sub City:** ____________________ **Region:**__________

Client Identification					Risk factors for CxCa			CxCa Screening and Treatment									Risk Based HIV Testing			Referal, Appointment and Follow-up Visits			
									HPV DNA			VIA Screening and Treatment											
CxCa SN#	Visit Date dd/mm/yy Linkage/ Referral status: Code (0-2)	Client Full Name Address (Woreda, Sub city, Kebele)	MRN Phone #	Age	Marital Status (Code 1-4) Education (Code 1-5)	History of STI (Self/Partner) # of Births	HIV status code (1-3) If known postive; on ART	Type of Visit (Code 1 -3)	HPV Sample collected	Collected Date Result Received date	HPV DNA Result Code (1-3)	VIA Result (Code 0-4)	VIA Screening Date VIA +Ve treatment date	VIA + Ve Treatment (Code 0-3)	Pathology Test (Code 0-5)	Breast Clinical Examination (Code 0-5)	Population Category (Code 1-7)	Eligible for risk based testing?	HIV test result Code (P/N)	Next Appointment for CxCa screening Follow up re-visit date	Referral reason Code (1-4)	Feedback received for refferred clients	Remark
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	
	__/__/__					☐ Y ☐ N	☐ Y ☐ N		☐Y ☐N	__/__/__ __/__/__			__/__/__ __/__/__					☐Y ☐N		__/__/__ __/__/__	__/__/__	☐Y ☐N	

Linkage/ Reffered in Status
0= Same Facility
1= Other facility
2= Comunity

Education
1= Illiterate
2= Can read and write
3= Elementary/junior
4= High school
5= Tertiary school

Marital Status
1= Unmarried
2= Married
3= Divorced
4= Widowed

HIV status (1-3)
1. Positive
2. Negative
3. Unknown

Type of Vsiit
1. 1st time screening
2. Re-screening after previous negative result
3. After one year of post treatment follow-up screening

HPV DNA Result
1. Negative
2. Positive
3. Unknown

VIA Result :
0. Not Done
1. VIA Negative
2. VIA Positive: Eligible for Cryotherapy/ thermocoagulation (TA)
3. VIA Positive: Non eligible for Cryotherapy/thermocoagulation
4. Suspicious cases for cervical cancer

VIA +Ve Treatment
0. No treatment
1. Cryotherapy
2. Thermocoagulation (TA)
3. LEEP service

Pathology Test Result
0. Not collected/Not done
1. Negative
2. CIN-1,2,3
3. Carcinoma insitu
4. Invasive Cx Ca
5. Others

Breast Clinical Examination
0. Not done
1. Normal
2. Lump
3. Visible bumps
4. Nipple crusting
5. Other Specify

Population Category
1. FSW
2. Long distance driver
3. Mobile/Daily laborer
4. Prisoners
5. Other MARPS
6. General population
7. Other specify

HIV test result
1. P=Positive; 2. N=Negative;
3. UN=Unknown

Referral reason
1. For LEEP service
2. For suspicious cancer evaluation
3. For breast cancer evaluation
4. Others

NB: *For WLHIV Follow up after ablative therapy should be after 6 months*

Appendix 7. Monthly report form

Cervical Cancer Screening and Treatment Monthly Reporting Form

MoH Cx Ca Monthly reporting form

Measures		Month (HMIS Period):									
		Type of Visit	HIV Negative			HIV Positive			HIV Unknown		
	Age		<30	30-49	50+	<30	30-49	50+	<30	30-49	50+
1	Number counseled for CxCa screening										
2	Number screened with HPV DNA test	1st time									
		Re-Screened from Previously -Ve									
		Post Tx FLUP screened									
2.1	# HPV DNA positive result	1st time									
		Re-Screened from Previously -Ve									
		Post Tx FLUP screened									
3	# screened with VIA	1st time									
		Re-Screened from Previously -Ve									
		Post Tx FLUP screened									
3.1	# VIA positive and Eligible for Cryotherapy /Thermal ablation	1st time									
		Re-Screened from Previously -Ve									
		Post Tx FLUP screened									
3.2	# VIA positive and Not eligible for Cryotherapy/ Thermal ablation)	1st time									
		Re-Screened from Previously -Ve									
		Post Tx FLUP screened									
3.3	# suspicious for cervical cancer										
4.1	# VIA +ve and treatment service with **cryotherapy**	Treated the same day of screening									
		Treated in another day									
4.2	# VIA +ve and treatment service with **Thermalablation**	Treated the same day of screening									
		Treated in another day									
4.3	# VIA +ve and treatment service with **LEEP**										
5	# referred since suspicious for cervical cancer										
6	# Referred for LEEP service										

Appendix 8: Consent form for cryotherapy / thermal ablation

የጤና ተቋሙ ስም: _____

አገልግሎቱ የሚሰጥበት ክፍል፡ _____

<u>የመሃፀን በር የቅድመ ካንሰር ህክምና ማካሄጃ የፈቃደኝነት መግለጫ ስምምነት</u>

እኔ በ ..... ሆስፒታል ውስጥ በፈቃደኝነት የመሃፀን በር የቅድመ ካንሰር ምርመራን (VIA) ያደረግሁ ሲሆን ምርመራውን ያደረገልኝ የጤና ባለሙያ የምርመራ ውጤቱ የቅድመ ካንሰር ምልክት ማሳየቱን ገልፆልኛል። ውጤቱንም አስመልክቶ በጤና ባለሙያው ተገቢውን የምክር አገልግሎት እና ለዚህ ተገቢ የሆነ፡

ክራዮቴራፒ (Cryotherapy) ☐

ተርማል አብሌሽን (Thermal ablation) ☐

የሚባል ህክምና በሆስፒታሉ እንደሚገኝ ተገልፆልኛል።

ህክምናውን አስመልክቶ በሚገባኝ ቋንቋ በበቂ ሁኔቴ የተገለፀልኝ ሲሆን፤ ስለህክምናው ያልገባኝ እና ተጨማሪ ማወቅ ስለምፈልገው ማለትም ስለ ተለዋጭ ህክምናዎች፤ የህክምናውን አፈፃፀም እና የህክምናውን ውጤት አስመልክቶ እንድጠይቅ እድል ተሰጥቶኛል። ለጥያቄዎቼም በቂ መልስ ተሰጥቶኛል። ህክምናውም በፈቃድ ላይ የተመረኮዘና ህክምናውን ያለመቀበል መብት እንዳለኝ እንዲሁም ባልቀበለው ከማንኛውም ተፅእኖ ነፃ መሆኔ ተገልፆልኛል።

በመሆኑም በባለሙያ የተሰጠኝን ምክርና አስፈላጊውን መረጃ በመገንዘብ ያለማንም ተፅዕኖ በራሴ ፈቃድ ህክምናውን ለማድረግ መስማማቱን በፊርማዬ አረጋግጣለሁ።

የታካሚው ስም_____ የጤና ባለሙያው ስም_____

ፊርማ _____ ፊርማ _____

ቀን _____ ቀን_____

Appendix 9: Consent form for LEEP service

የጤና ተቋሙ ስም፡_____

ቦታ፡_____

<u>የማህፀን በር የቅድመ ካንሰር ህክምና ማካሄጃ የፈቃደኝነት መግለጫ ስምምነት</u>

እኔ በ..... ሆስፒታል ውስጥ በፈቃደኝነት የማህፀን በር የቅድመ ካንሰር ምርመራን (VIA) ያደረግሁ ሲሆን ምርመራውን ያደረገልኝ የጤና ባለሙያ የምርመራ ውጤቱ የቅድመ ካንሰር ምልክት ማሳየቱን ገልፆልኛል። ውጤቱንም አስመልክቶ በጤና ባለሙያው ተገቢውን የምክር አገልግሎት እና ለዚህ ተገቢ የሆነ ሊፕ (LEEP) የሚባል ህክምና በሆስፒታሉ እንደሚገኝ ተገልፆልኛል።

ህክምናውን አስመልክቶ በሚገባኝ ቋንቋ በበቂ ሁኔቴ የተገለፀልኝ ሲሆን ስለህክምናው ያልገባኝንና ተጨማሪ ማወቅ ስለምፈልገው ማለትም ስለ ተለዋጭ ህክምናዎች፤ የህክምናውን አፈፃፀም እና የህክምናውን ውጤት አስመልክቶ እንድጠይቅ እድል ተሰጥቶኛል። ለጥያቄዎቼም በቂ መልስ ተሰጥቶኛል። ህክምናውም በፈቃድ ላይ የተመረኮዘና ሀምናውን ያለመቀበል መብት እንዳለኝ እንዲሁም ባልቀበለው ከማንኛውም ተፅእኖ ነፃ መሆኔ ተገልፆልኛል።

በመሆኑም በባለሙያ የተሰጠኝን ምክርና አስፈላጊውን መረጃ በመገንዘብ ያለማንም ተፅዕኖ በራሴ ፈቃድ ህክምናውን ለማድረግ መስማማቴን በፊርማዬ አረጋግጣለሁ።

የታካሚው ስም_____ የጤና ባለሙያው ስም_____

ፊርማ _____ ፊርማ _____

ቀን _____ ቀን_____

Appendix 10: Appointment card

FRONT OF THE CARD:

Appointment Card

Cervical Cancer Prevention Services Appointment Card

Medical Record Number/UAN:_____/_____

VIA Serial Number: _____

Name_____

Age: _____

Address: _____

Health facility Name: _____Region: _____ City/Town: _____

Date of First Visit to Cx Ca screening unit: _____

Date of Appointment	Signature of Provider (if seen on the appointment date)

Note: Do not forget to bring the appointment card with you when you visit the facility for follow up.

It is important for your health that you come on your appointment date.

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 sexual intercourse.
• Avoid smoking.
• Get an HPV vaccination, if available and applicable.

Appendix 11: Appointment calendar

Appointment Calendar for the Month of Nehassie 2012 E.C.(Sample)

Monday, Nessie 04,2012					
SN	Name	MRN	Attendance	Action Taken	Outcome
1					
2					
3					

Tuesday, Nessie 05,2012					
1					
2					
3					

Wednesday, Nessie 06,2012					
1					
2					
3					

Monday, Nessie 04,2012					
SN	Name	Unique ART No./ Card No./MRN	Attendance	Action Taken	Outcome
1					
2					
3					

Friday, Nessie 07,2012					
1					
2					
3					

Saturday, Nessie 08,2012 (Weekend Break)					
1					
2					
3					

Sunday, Nessie 09,2012 (Weekend Break)					
1					
2					
3					

Instruction for appointment calendar:

1. Name- write name of the client.
2. MRN: Write Medical Record Number.
3. Attendance: Write "√" if the clients attend as per the appointment or "X" if the client did not attend.
4. Action taken: For those who did not attend write "Telephone call" if the missed appointment client is contacted through phone and/or write "Home Visit" if Peer educator/other team members have contacted the missed appointment client using home visit. If he/she is not contacted at all due to lack of address or wrong address, write "Not contacted".
5. Outcome: Write the outcome of action taken fvor those clients who did not attend.
    - Return to care
    - Refused to return to care
    - Seen in other HF
    - Died
    - Unknown

Appendix 12: Comprehensive Baseline assessment checklist for CxCa screening & management program

Region: _____Zone_____ Town/SC: _____Date of Assessment conducted_____

Assessing Team members				
Name of Person conducting the assessment	Organization	Position	Contact address (Telephone)	Contact Address (Email)
1.				
2.				
3.				

RHB / Zone /Sub city/Facility Team contacted				
Name of contacted Person in the site supervised	Health Facility Name	Position	Contact Address (Telephone)	Contact Address(email)
1.				
2.				
3.				

Objective of the Assessment:

1. To assess the status of CxCa screening & management program implementation at RHB, Zone/Sub city & HF level
2. To review data on CxCa screening & management performance activities at RHB, Zone/Sub city & HF level
3. To develop PIP on the identified gaps & provide focused mentorship at the visited HFs &above site support

Section I: RHB /Zone /Sub city level Assessment			
1.Leadership, planning and coordination on CxCa screening and management			
Sr. no.	Activities / indicators	Availability	Remark /gaps Identified
1.1	Does the RHB have plan on CxCa screening And management activities? Check	Yes No	
1.2	Is Cervical Ca Coordinator/focal person assigned at RHB	Yes No	
1.3	Does the RHB have facility level target for CxCa? Shared to the HFs?..... Check	Yes No	
1.4	Is CxCa screening and management review meeting conducted? (Separate or integrated in the Regional RM), check minute	Yes No	
1.5	Is CxCa screening & management mentorship support integrated in the regional mentorship platform? Check mentorship checklist or report	Yes No	
1.6	Are demand creation activities on CxCa screening and management being conducted by RHB? How?	Yes No	
1.7	Total number of facilities with CxCa screening and management service in the region?		
2. Trainings, National Guideline, PSTs, and other tools availability			
2.1	Is National guideline for Cervical Ca screening & Management available?	Yes No	
2.2	Is Training manual for Cervical Ca screening & Management? (Cryo and TA) available?	Yes No	
2.3	Are Cervical Ca screening & Management PSTs (E.g. Flow chart, CxCa management algorithm, cue card etc.) available?	Yes No	
2.4	Are IEC /BCC materials available and distributed?	Yes No	
2.5	Is Training manual for LEEP available?	Yes No	
2.6	Are HCWs from the region attended TOT trainings provided by MOH on (write number trained)	Yes No	
2.7	Is Basic training provided on CxCa screening through VIA and LEEP training (write number trained)	Yes No	
3. CxCa Service monitoring & evaluation mechanism at RHB level			
3.1	Is there M&E system from facility to RHB level?	Yes No	
3.2	If yes, to 3.1, mention the reporting flow?		
3.3	Is Cervical Ca screening & Management Register available?	Yes No	
3.4	Is CxCa monthly reporting format being available (Both DHIS and DATIM format)	Yes No	
4. Partners support on CxCa screening and management			
4.1	List of partners supporting the regional CxCa activities including they focus and level of support		
4.2	Any other support needed.		

Section II: HF level assessment			
1. Leadership and coordination on CxCa screening and management			
Sr. no.	Activities / indicators	Availability	Remark /gaps Identified
1.1	Is Cx CA screening and management service available in the HF? Currently being provided?	Yes No	
1.2	Does the HF have plan on Cx Ca screening and management activi-ties? Check	Yes No	
1.3	Is CxCa focal person assigned in the HF?	Yes No	
1.4	Does the HF have facility level target for CxCa? Check	Yes No	
1.5	Does the HF received mentorship from external body on CxCa screening and management service? Check feedback	Yes No	
1.6	Did you review CxCa indicators on monthly PRM /PMT? Check minute	Yes No	
1.7	Are demand creation activities on CxCa screening and manage-ment being conducted in the HF? How?		
2. Trainings, National Guideline, PSTs, and other tools availability			
2.1	Is there a certified trained staff in Cx Ca screening & management using VIA and cryotherapy or TA, LEEP? If yes, # of trained staffs currently available for each training	Yes No	
2.2	Is National guideline for Cervical Cancer screening & management available?	Yes No	
2.3	Are Cervical Ca screening & Management PSTs (E.g.? Flow chart, management algorithm, cue card etc.) available?	Yes No	
2.4	Are IEC /BCC materials available and utilized?	Yes No	
2.5	Are all formats available in the HF? Intake forms, pre CxCa screening and linkage form, consent forms etc.	Yes No	
3. Infrastructures in the HF			
3.1	Is designated area for patient waiting and/or group education available in the facility?	Yes No	
3.2	Is Separate Examination and procedure rooms OR a large room with privacy screens/curtain assigned /allocated / for Cx Ca unit?	Yes No	
3.3	Is sink with tap/running/rainwater available in the CxCa screening unit?	Yes No	
4. CxCa Service Monitoring & Evaluation Mechanism			
4.1	Is Cervical Ca screening & Management Register available?	Yes No	
4.2	Is CxCa monthly reporting format available?	Yes No	
4.3	Is CxCa counselling tracking tool available and being utilized?	Yes No	
4.4	Does the facility review Cervical Ca Program performance on regular basis?	Yes No	
4.5	Does the facility submit (Monthly & Semi-annual) CxCa program reports regularly?	Yes No	
5. Service provision at ART /PMTCT clinic and CxCa Screening unit			
5.1	Is demand creation activity being done by ACMs regularly?	Yes No	

5.2	Is routine prevscreening counseling and linkage being done at ART /PMTCT clinic on regular basis?	Yes	No	
5.3	Is escorted referral linkage to CxCa screening unit being done in the HF? By who?	Yes	No	
5.4	Is CxCa tracking tool being utilized, completed and updated regu-larly?	Yes	No	
5.5	Is EMR data being updated for all clients on regular bases?	Yes	No	
6. Conduct chart and register review				
6.1	Review charts of clients at ART /PMTCT clients(Pullout 19 random charts of clients at ART / PMTCT clinic), *calculate the review findings in percentage*			
6.2	Is pre screening counseling and linkage form attached inside the client's charts? Fully completed? (Out of 19 charts)	Yes	No	
6.3	Is intake form is attached for eligible clients? Fully completed? (Out of 19 charts)	Yes	No	
6.4	Is the follow up form updated for CxCa screening status? (Out of 19 charts)	Yes	No	
6.5	Review CxCa tracking tool, is it fully completed and regularly updated? (Out of 19 recent clients visited the ART /clinic)	Yes	No	
6.6	Review CxCa national register, is it fully completed and regularly updated? (Out of 19 recent clients visited CxCa screening unit)	Yes	No	
7. Equipment and Supplies (Availability and Utilization)				
7.1: Equipment and supplies for VIA service (check availability and utilization)				
7.1.1	**Equipment & Instruments**			
	Thermal ablation machine	Yes	No	
	Carbon dioxide tank	Yes	No	
	Cryotherapy unit with Cryo machine	Yes	No	
	Autoclave or other sterilization machines	Yes	No	
	Speculum small, medium and large size (10)	Yes	No	
	Small basins for instruments/supplies	Yes	No	
	Sponge forceps	Yes	No	
	Trolley	Yes	No	
	Large plastic buckets for decontamination of specula/ instrument	Yes	No	
	One gynecological examination couch with stirrup	Yes	No	
	Torchlight or halogen lamp	Yes	No	
	Shelf for supplies/drugs	Yes	No	
7.1.2	**PPE**			
	Isolation gowns	Yes	No	
	Face mask for HCPs (especially in the context of COVID)	Yes	No	
	Non-sterile gloves (appropriate size for providers)	Yes	No	

	Utility gloves for handling contaminated instruments(cleaning)	Yes	No	
	Plastic apron – for instrument processing and preparation of chlo-rine solution	Yes	No	
7.1.3	**Antiseptic & disinfectant Solutions**			
	Chlorine solution	Yes	No	
	Alcohol-based hand sanitizer or soap	Yes	No	
	Cidex (2-4% glutaraldehyde) Isopropyl	Yes	No	
	Alcohol 60-90%	Yes	No	
	Monsel' solution	Yes	No	
7.1.4	**Medications**			
	Panadol	Yes	No	
	Ibuprofen; medications for cervicitis treatment	Yes	No	
7.1.5	**Other supplies**			
	Timer/watch	Yes	No	
	K-Y Jelly/lubrication	Yes	No	
	Wooden spatulas	Yes	No	
	Condoms	Yes	No	
	Drapes/sheets	Yes	No	
	Large cotton-cotton swabs/cotton balls/gauze cut in small pieces	Yes	No	
	Small cotton swabs	Yes	No	
7.2 Additional List of Equipment and Supplies for LEEP sites only				
7.2.1	Machine	Yes	No	
	LEEP machine	Yes	No	
	Foot switch with pencils and adapter	Yes	No	
7.2.2	Accessories for LEEP	Yes	No	
	Smoke filter	Yes	No	
	Lugoli's Iodine	Yes	No	
	Lietz (insulated) Graves speculum	Yes	No	
	Lietz (insulated) tissue forceps	Yes	No	
	Lietz (insulated) vaginal wall retractor	Yes	No	
	Lietz (insulated) tenaculum	Yes	No	
	Tischer biopsy punch titanium	Yes	No	
	Monsel's solution	Yes	No	
	Disposable loop	Yes	No	
	Surgical gloves	Yes	No	
	Clean gloves	Yes	No	
	Cotton	Yes	No	
	Sanitary pads	Yes	No	

Section III. HF Cx CA screening & management Performance data reporting & review template for clients on ART

Indicators/ Measures	Performance	Achievement # (%)	Remark
# Female clients on ART aged > 15 years			
# Counselled about CxCa screening			
# Eligible for CxCa screening			
# CxCa screening done (total)			
4.1 # screened with HPV followed by VIA			
4.2 # screened with VIA only			
# VIA positive			
# VIA positive eligible for cryotherapy or TA			
# VIA positive not eligible for cryotherapy or TA			
# suspicious for CxCa			
# Treated with Cryotherapy or TA			
# VIA positive not eligible for cryotherapy treated with LEEP			
# VIA positive not eligible for Cryotherapy referred			

Section IV. Identified gaps/challenges and action plans developed for Improvement

Focus Area	Identified Gap	Proposed action item	Responsible person	Timeline

Appendix 13: How to calculate targets for providing Cx Ca screening service to the general population

- Let us say Woreda X has a population of 100,000 of which 51% are females
- 19.2% are women between ages 30-49
- 70% screening coverage is expected in 5 years
- # Female population in Woreda X = 100,000* 51= 51,000
- # Of eligible women = 51,000x 19.2% =9792
- 70 % of eligible women for Cx Ca screening in 5 years=9792 x 70% = 6854
- Annual target would be= 6854/5= 1370
- Monthly target =1370/12= 114

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