# NATIONAL CERVICAL CANCER SCREENING PROGRAM IN MALDIVES

(National Action plan for Implementation and Strategic Planning)

Supported by:

UNFPA

Health Protection Agency
Ministry of Health

# FOREWORD

Cancer is a major public health problem throughout the world. Cervical cancer is the second most frequent cancer after breast cancer among women.

Human papilloma virus (HPV) infection is the most common viral infection of the reproductive tract among those who are sexually active. Although the infection is a self-limiting disease, a small percentage of the infections, by some virus types, leads to cervical cancer. Most sexually active women and men are infected at some point in their lives and some may be repeatedly infected.

Southern Asia region of which Maldives is a member, has the highest incidence of cervical cancer (25/1 00,000) in Asia. There is limited data related to cervical cancer in Maldives. Typically we possess only a partial picture of risk factors and overestimate both the incidence of cervical cancer and the efficacy of screening.

Women don't have to die from cervical cancer, but unfortunately the disease remains a leading cause of death, next only to breast cancer among women of Maldives. Screening can detect cancer at an early stage and timely initiation of appropriate treatment has a high potential for complete cure.

The national cervical cancer screening protocol is a strategy for cervical cancer screening program in the Maldives. This protocol is more community oriented, feasible even at the remote islands and has good linkage between different services related to screening , diagnosis and treatment.

When screening detects pre-cancerous lesions, they can easily be treated and cancer can be avoided. It is important to monitor the impact of such a program on the incidence and mortality from cervical cancer.

I would like to acknowledge the strong support provided by United Nations Population Fund (UNFPA), Health Protection Agency (HPA) and Indira Gandhi Memorial Hospital (IGMH) for this programme. The first phase of this project funded by UNFPA is implemented at "Dhamana Veshi" with the assistance from IGMH and HPA.

Immense gratitude goes to all those who contributed their time, knowledge and expertise to reduce cervical cancer in Maldives.

Dr Sheeza Ali
Director General of Health Services

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# EXECUTIVE SUMMARY

One of the foremost priorities of the government of Maldives as stated in the National Framework for Development 2009-2013 is to provide affordable and quality healthcare to all the citizens of the country. It is important to formulate evidence based health policies that align with the national development goals and be consistent with international commitments such as the Millennium Development Goals. From this viewpoint cervical cancer prevention is an important health priority in the country.

Maldives has a population of 120,000 women aged 15 years and older who are at risk of developing cervical cancer and this poses a major public health problem for the country. There is no national data regarding the incidence rate of cervical cancer and the mortality from the disease. Maldives is situated in South East Asia that has highest age standardized incidence rate of cervical cancer (25/100,000 women) among all the regions of the continent. It is likely that the incidence of the disease in Maldives will also be as high as in the neighboring countries. Due to the lack of proper early diagnosis facilities most of the women are detected at chronic stage of the disease and die at an early age.

Cervical cancer can be prevented through organized screening program. The existing program of Maldives based on Pap smear cytology is ineffective due to several reasons – low coverage of the population, lack of appropriate follow up of the screen positive women, unorganized treatment facilities, absence of coordination between stake holders or related service providers etc. According to the World Health Organization guidance note on cervical cancer prevention the resource limited countries should initiate screening of women at the age of 30 years and judicially select a screening test that is affordable, feasible and can achieve high coverage of the target population.

The present document suggests a strategy for cervical cancer screening program in Maldives that will be more community oriented, feasible even at the rural islands and have proper linkage between different services related to screening, diagnosis and treatment. It is proposed that cervical cancer screening using VIA should be offered to 30 to 50 year old women at an interval of 5 years. Screening will be done by trained nurses or health workers using Visual Inspection after Acetic Acid Application (VIA) test. The advantages of VIA are that the test is more sensitive than Pap smear, inexpensive, does not require a laboratory set up and the test result is immediately available. The VIA positive women will be referred for colposcopy for further evaluation at a convenient location. If any abnormality is detected on colposcopy by the clinician, the woman will be treated appropriately without waiting for biopsy confirmation ('see and treat' approach). If it is not feasible for a VIA positive woman to reach a colposcopy facility, she may be treated by cryotherapy on the basis of the VIA findings ('single visit approach') by a clinician.

For the successful implementation of the screening program the following components are crucial and should be appropriately organized:

- Mass based education campaign to create community awareness and ensure high participation rate
- Competency based training of different levels of service providers
- An operational plan for program monitoring, evaluation and quality assurance
- Creation of a National Advisory Body to oversee the program and engaging one National Coordinating Officer who will be directly responsible to implement the pro gram nationally with support from other stakeholders

Primary prevention of cervical cancer by immunizing the adolescent girls against Human Papillomavirus (HPV), the causal agent for cervical cancer, is a safe and effective option for comprehensive cervical cancer control. Following the World Health Organization (WHO) recommendations Maldives should explore the possibilities of introduction of this vaccine in the near future provided it is logistically feasible and financially sustainable.

## Cervical Cancer Screening Program in Maldives – The Key Issues

- An organized screening program can significantly reduce cervical cancer incidence and deaths
- The target age for screening, frequency of screening test, choice of test method are decided based on the judicial assessment of existing infrastructure, expertise available, capabilities of the health system and the available financial resources
- The new program of Maldives will aim to screen women in the age group of 30 – 50 years every 5 years
- VIA will be used as the primary screening test and the nurses and health workers will be trained to do the test
- Screen positive women will be referred for diagnostic test (colposcopy and biopsy) and treatment. In absence of such diagnostic facilities the VIA positive women will be assessed for cryotherapy at the same visit
- Appropriate training of all levels of health care providers will be arranged along with periodic refresher training.
- Periodic monitoring, communication between different levels of health care systems and meticulous attention to maintain quality at each level of service are crucial to make the program successful
- The program will be most cost-effective if there is greater coverage of the target population and high compliance of the screen positive women to treatment. This can be ensured by making all services accessible to the women

# 1.0 INTRODUCTION

Cervical cancer is a significant health issue worldwide as it is the second most common cancer among women and the number one cause of cancer deaths. It is estimated that worldwide more than 250,000 deaths occur every year from cervical cancer and majority of these deaths are in low and medium income countries. In some parts of the world, mortality rates from cervical cancer are higher than the maternal mortality rates. Cervical cancer causes a significant number of deaths among women in Maldives.

Cervical cancer is preventable, since there is a detectable precancerous condition (cervical intra-epithelial neoplasia; CIN) that takes nearly 10-15 years to transform to invasive cancer. If detected and treated at the precancerous condition, the risk of progression to malignancy can be substantially reduced. To detect the disease at the precancerous stage all women within a certain age group are recommended to have cervical cancer screening tests at regular intervals. There is strong evidence that effective early detection and treatment will result in significant reduction in mortality and morbidity from cervical cancer.

Various methods for screening, diagnosis and treatment of cervical cancer have been evaluated and are currently being used in different countries. Each strategy has strengths and limitations that need to be considered in the national context. The most successful strategy for the control of cervical cancer is to combine appropriate screening with effective treatment of precancer conditions ensuring high coverage of the target population.

Pap smear cytology has been successfully used as a screening test in many developed countries. However, many of the low/medium resource countries have failed to replicate the same model of cytology based screening program since cytology has several limitations in such settings. The sensitivity of cytology is moderate to poor unless stringent quality control mechanisms are ensured at every step. It requires functioning laboratories that is difficult to set up in primary or secondary health care levels. It is difficult to get adequate number of trained cyto-technicians and pathologists to interpret large number of slides. The cost of Pap smear cytology is high for many countries to provide the test free of cost to the entire target population. Due to these shortcomings of conventional cytology, several alternative screening tests have been extensively evaluated over the last decade. Visual inspection after application of acetic acid (VIA) has shown a lot of promise since the sensitivity of the test is superior to cytology in most studies. The test can be performed in primary health settings even by trained midwives or nurses. No laboratories are required and the necessary consumables are available easily and are inexpensive. The results are instantly available so that the women can be advised or referred immediately after the test. This reduces inconvenience to the women and improves their compliance. Many of the countries in Asia-Pacific region, Latin America and Africa have already launched national cervical cancer screening program using VIA as the screening test. (Figure 1)

**National Programs**

Bangladhesh
Bolivia
Cambodia
China
Colombia
El Salvador
Gautemala
Guyana
Indonesia
Kenya
Malawi
Morocco
Mozanbeque
Nicaragua
Panama
Praguay
Peru
Phillippines
Rwanda
Suriname
Tanzania
Thailnd
Uganda
Vietnam

**Pilot Prorams**

Angola
Bangladhesh
Benin
Bhutan
Botswana
Burkino Faso
Cameroon
Cote d'Ivoire
Ethiopoa
Ghana
Grenada
Guinea
Haiti
Honduras
India
Lesotho
Madagascar
Maldives
Mali
Myanmar
Namibia
Nepal
Nigeria
Republic of Congo
Rwanda
South Africa
St. Lucia
Sudan (North)
Turkey
Vanuatu
Zambia
Zimbabwe

Figure 1. Countries using VIA as the screening test

A safe and highly effective vaccine against Human Papillomavirus, the causative agent for cervical cancer is now available. The vaccine is recommended to be administered to the adolescent girls between 10 to 13 years of age. More than 50 countries in the world have introduced the vaccine in the national immunization program and many of them have successfully negotiated with the manufacturers to obtain a very preferential pricing. However, the vaccine is not yet available in Maldives and is not being considered currently for introduction in the national immunization program.

The present document focuses on the plan of implementation of a community based organized cervical cancer screening program for Maldives using VIA as the primary screening test. The document was drafted after discussions with Director General of Health Services, representatives from Ministry of Health, Obstetricians and Gynaecologists, Pathologists and members of the Nurses Association. The document has to be approved and ratified by the appropriate health authorities prior to implementation. A document on the quality control and quality assurance of a VIA based screening program has also been included for reference in the Appendix.

### 1.1 Justification for cervical cancer screening in Maldives:

- Cervical cancer is most common cancer among women in Maldives causing significant morbidity & mortality
- It has a recognized precursor stage that can be detected and treated in safe and effective manner

- The time between the appearance of precancerous lesions and the occurrence of cancer is long (about ten years), leaving ample time for detection and treatment

- Treatment of precancer lesions is simple and much less expensive compared to the management of invasive cancer. This is more pertinent in Maldives where the treat ment facilities for cancer are limited and women have to travel abroad for treatment with government support
- Cervical cancer screening prevents deaths of women in reproductive age and improves quality of life of women

## 2.0 Cervical Cancer Burden and Control Initiatives in Maldives – A Situation Analysis

### 2.1 Demographic Profile

The total population of Maldives is 341,848 of which little less than half are females. The number of women between 30 to 50 years (who will require cervical cancer screening) is approximately 40,000 and the number of girls between 10 to 14 years (who may be considered for HPV vaccination) is approximately 10,000. The population density is among the highest in the world (1330/Sq. Km). The life expectancy of females at birth is high (73 years) and the majority of the adult population is literate (96.3%).

### 2.2 Cervical cancer burden

The accurate cervical cancer incidence and mortality data are not available from Maldives since there is no population based cancer registry. Maldives is situated in South Asia with very high incidence of cervical cancer in many of the countries. Due to similar socio-demographic characteristics and similar prevalence of various risk factors it is likely that Maldives also has high burden of cervical cancer.

### 2.3 Cervical cancer screening

There is no organized cervical cancer screening program in Maldives. Pap smear cytology is advised by the gynecologists to the women attending the tertiary Hospitals with symptoms suggestive of lower genital tract infections or cancer. The number of women undergoing Pap smear is insignificant due to the opportunistic approach. The number of pathologists in the country is very limited. There are no cytotechnicians in the country. There is little possibility to train and recruit large number of cytologists or cytotechnicians required for a nationwide Pap smear based screening program.

The facilities for colposcopy are also very limited. Only one tertiary care hospital (Indira Gandhi Memorial Hospital; IGMH) in Male' has a colposcope. Even this unit is non-functional due to lack of trained colposcopists and insignificant number of referrals.

The facilities for treatment of cervical precancer, except hysterectomy are non-existent in the country. Cryotherapy equipment is available in some of the hospitals and is primarily used to treat ectropions and cervicitis. Carbon-di-oxide gas and nitrous oxide gas are available and the refilling facility exists. Electro-surgical Unit for Loop Electrosurgical Excision Procedure (LEEP) is available

only at IGMH. Even at this center LEEP is not practiced due to the lack of supply of the loop electrodes and other consumables.

Other key elements of an organized screening program e.g. a strategic plan to improve coverage, linkage between various levels of service, program evaluation and quality assurance, a dedicated program manager etc. are also absent.

### 2.4 Management of Cervical Cancer & Palliative care Facilities

There are no facilities for radical surgery to treat early cervical cancers or radiation therapy to treat more advanced cases in Maldives. The patients travel to neighbouring countries for treatment and the cost of travel and treatment is supported by the Government.
There is no palliative care unit in the country. Morphine tablets are not available in the country for the relief of cancer pain. Only morphine injections are available.

## 3.0 National Strategic Plan for Cervical Cancer Screening

The Government of Maldives is committed to offer cervical cancer screening facilities to the population. The present document on screening protocol and program implementation plan has been developed based on the recommendations of World Health Organization (WHO), UNFPA and International Federation of Gynecology & Obstetrics (FIGO). The new strategy has also taken into consideration the capacity of the health system and the feasibility of introduction of a new program.

### 3.1 Objectives of the strategy for Cervical Cancer Screening

Ensure one round of screening of at least 80% of the target population within 5 years of implementation of the program through strengthening the capacity of health system to deliver standard screening, diagnosis and treatment services for cervical precancer and cancer.

Such intervention is expected to reduce the mortality from cervical cancer by nearly 40% at the end of 5 years.

### 3.2 Guiding Principles

The lower part of the uterus is known as cervix and is divided into ectocervix (outer part) and the endocervix (inner part). (Figure 2)

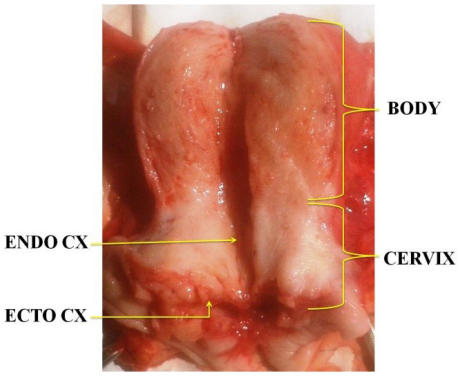


Figure 2. Cervix is the lower part of uterus and ectocervix is the commonest site of cancer

Cancer of uterine cervix develops slowly over 10 to 15 years following infection of Human Papillomavirus (HPV). The epithelial covering of the cervix first undergoes a precancerous change known as Cervical Intraepithelial Neoplasia (CIN). At this stage the abnormal cells are restricted to the epithelium and depending on the severity; the disease is graded into CIN 1, CIN 2 or CIN 3. If left undetected and untreated, CIN can progress to invasive cancer within a few years. In invasive cancer the abnormal cells break through the boundaries of the epithelium and spread to deeper tissues and other organs.

Once the disease becomes invasive, the treatment becomes cumbersome, time-consuming and expensive. The cure rate of cancer even after treatment can vary between 90% in stage I to 15% in stage IV. Compared to that, treatment of CIN is simple and inexpensive with high cure rate. So the objective of cervical cancer screening is to apply a simple test on all the women in a defined age group to detect the disease at the precancerous stage and to treat them. It is well established that detection and treatment of CIN through organized cervical screening programs can reduce the incidence of cervical cancer and the mortality from the disease by 60-80% in the long run.

Screening should be followed by confirmation of diagnosis through colposcopy/biopsy and treatment of screen detected precancers and cancers. The managers of the screening program should ensure availability of these crucial service components along with training of the service providers and periodic evaluation of the program. (Figure 3)

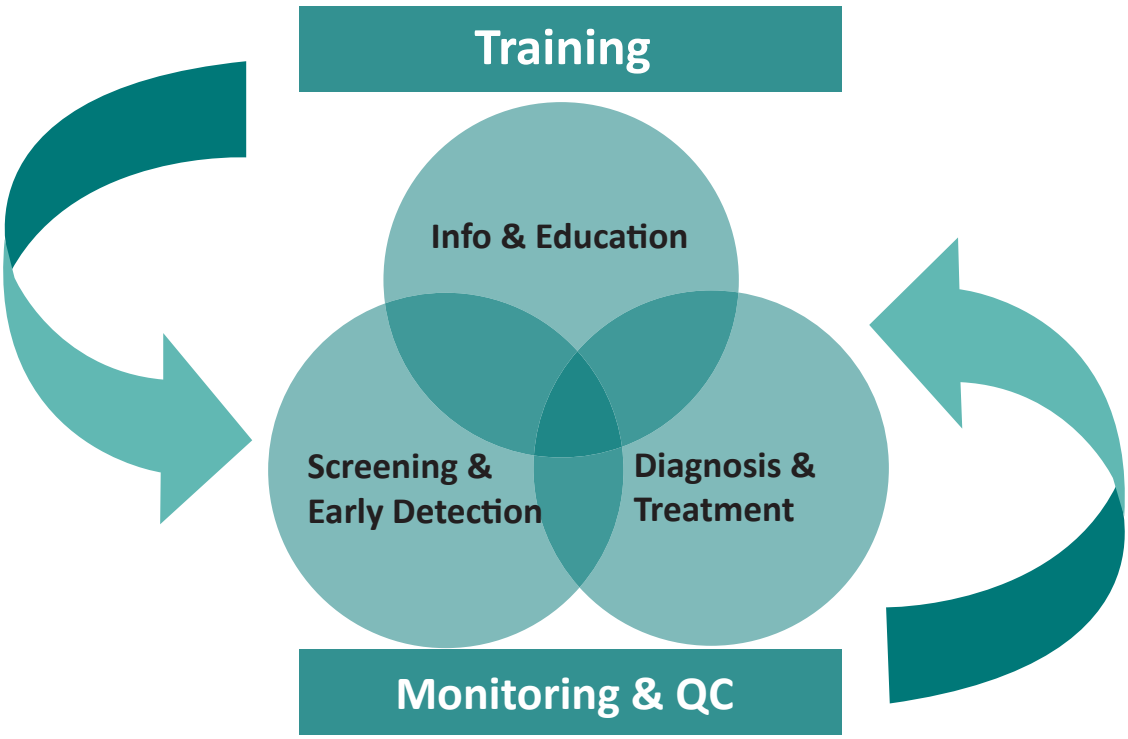


Figure 3. Components of a Cervical Cancer Screening Program

Over the last few years, various research studies as well as demonstration projects have established that cervical cancer screening is feasible in low to medium resource countries using low technology, inexpensive yet effective screening tests. Screening strategies that involve less frequent screening and less number of visits to the clinics by the screened women have been proved to be most efficient and cost-effective. The key elements for the success of the screening program are high coverage of the target population and ensuring treatment of the screen positive women.

### 3.3 Health Infrastructure of Maldives relevant to Cervical Cancer Screening

The proposed cervical cancer screening program will be integrated to the existing multi-tiered health system. The structure and the staff pattern of the health delivery system of Maldives relevant to the screening program is given in Figure 4.

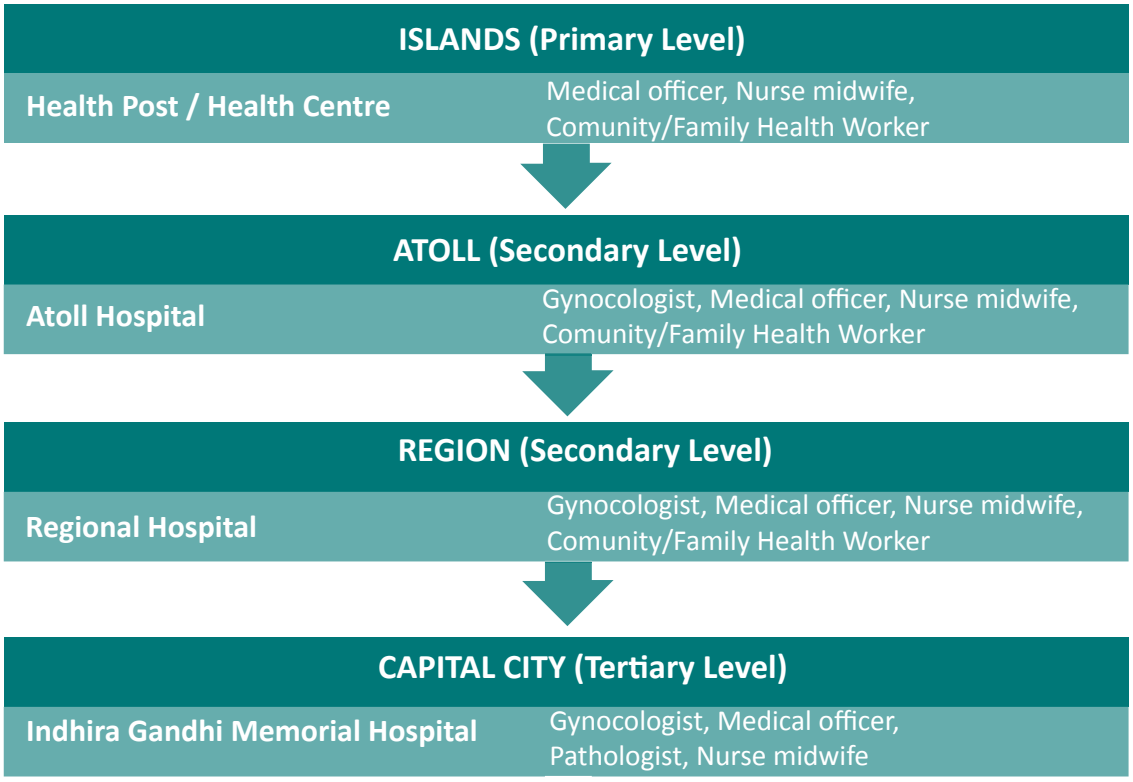


Figure 4. The Health Delivery System at primary, secondary and tertiary levels in Maldives

The Health Posts and the Health Centers are at the lowermost level of the health system based in the islands. The Atoll Hospitals serving a group of islands provide primary level of care and some of them have specialist gynecologists. Each of the seven provinces of the country has one Regional Hospital where in-patient care can be provided by specialist gynecologists. Indira Gandhi Medical Hospital (IGMH) is the tertiary referral hospital at the capital city of Male though there are no radical surgery or radiotherapy facilities.

The proposed Cervical Cancer Screening Program will be integrated into the existing health delivery system to ensure optimal utilization of resources and make cervical cancer screening services accessible to all.

### 3.4 Target population for screening & screening frequency

The women are usually asymptomatic at the stage when they have cervical precancers. The precancers can be detected only by routine screening of women, irrespective of whether they have any complaints or not. All women who have ever been sexually active are at risk of cervical cancer. In an organized program the target age group for cervical screening and the frequency of screening are decided based on the realistic assessment of the capability of the health services, need of the local women and the available resources.

Cervical cancer is rare before the age of 30 years. Screening women at younger age detects many low grade lesions that will never progress to cancer. Unnecessary treatment of these abnormalities will cause inconvenience to the women and will deplete the limited resources of the program. Best utilization of the resources is possible if screening is limited to the age group at which there is maximum possibility of detecting the high grade precancer lesions (CIN 2 and 3) and early invasive cancers. That is why it is proposed to limit the age of screening between 30 to 50 years. The sensitivity and specificity of VIA is optimum at this age. The number of women in this age group in Maldives who will require screening is approximately 40000.

Screening women too frequently puts a heavy burden on the limited manpower and financial resources with minimal incremental benefit. It is recommended that women at Maldives should be screened once every 5 years. Achieving a good coverage of the target women determines the success of the screening program rather than the frequency of test.

### 3.5 Recommended screening tests

An ideal screening test should be simple, painless, inexpensive and able to detect the disease effectively. Till date Pap smear (cytology) has been used most frequently in Maldives in a low intensity opportunistic setting. However, Pap smear has certain drawbacks that limit its usefulness. Pap smear sensitivity to detect CIN 2+ is at best moderate (~50%). It is a laboratory based test and needs infrastructure and skilled manpower that may not be easily available in the country. The stringent quality control required for optimum performance of the test may not be possible since the health facilities are not equitably distributed. Besides, Pap smear does not provide the result immediately and the positive women need to be recalled after the results are available from the laboratory. This is inconvenient for the women and will increase the dropout rates.

Visual Inspection after Application of Acetic Acid (VIA) is a low technology test that is feasible to be implemented in most health infrastructural situations. Many of the low/medium resource countries like Bangladesh, Thailand and Peru etc. are successfully implementing cervical cancer control programs using VIA as the screening test. It is inexpensive, does not require highly skilled manpower and has sensitivity better than cytology. VIA will be used to screen women in Maldives.

### 3.6 Procedure of Visual inspection after application of acetic acid (VIA)

VIA involves naked eye examination (without magnification) of the uterine cervix after application of freshly prepared 5% acetic acid (vinegar), under a good light source. VIA test definitions are provided in the Table 1.

| VIA Category | Description |
|---|---|
| **Negative** | No aceto-white lesions<br><br>Transparent lesions or faint patchy lesions without definite margins<br>Nabothian cysts becoming aceto-white<br><br>Faint line like aceto-whitening at the junction of columnar and squamous epithelium<br><br>Aceto-white lesions far away from the transformation zone |
| **Positive** | Distinct, opaque aceto-white area<br><br>Margin should be well defined, may or may not be raised<br><br>Abnormality close to the squamo-columnar junction in the trans formation zone and not far away from the os. |
| **Invasive cancer** | Obvious growth or ulcer in the cervix.<br><br>Acetowhite area may not be visible because of bleeding |

Table 1: Criteria for categorizing VIA test results

### 3.7 Screening Centers and Test Providers

For the convenience of the women and to ensure better compliance, the cervical cancer screening facilities should be made available at places close to their places of residence. The Atoll and the Regional Hospitals are best suited for setting up such facilities. At the capital city of Male VIA test facilities will be made available at the newly set up Urban Health Center (DHAMANA VESHI) along with other preventive health services.

The screening test can be performed by the nurses, the health workers (FHW and CHO) and the clinicians after appropriate training at these screening centers. It is logistically convenient for the women as well as the providers to run the VIA clinics on fixed days of the week. The frequency of such clinics will depend on the demand for the service.

### 3.8 Referral Facilities for Colposcopy & Biopsy

All women with positive VIA test results should ideally have colposcopy to confirm the disease. With a colposcope the doctor can have a magnified view of the cervix after application of 3-5% acetic acid

and Lugol's Iodine and can take biopsy if any abnormality is suspected. The biopsy specimen should be put in formaldehyde solution in a labeled container and sent to the laboratory for histology. Colposcope is already available at the Gynecology Department, IGMH. This facility is to be augmented and made functional so that it can serve as the apex national referral center. Colposcopy units should also be set up in select regional hospitals depending on the logistic feasibility and convenience for the women. Gynecologists as well as non-specialist clinicians (medical officers) will be trained to do the colposcopy at these hospitals. Each Center performing VIA should be linked to a designated colposcopy center that will be convenient for the women to attend and the VIA positive women should be referred to the designated centers only. The VIA negative women should be advised to have repeat test after 5 years unless they cross the upper age limit of screening (50 years) by that time.

### 3.9 Management of cervical pre-cancers

All cases of CIN 2 and CIN 3 should be treated. As most of the CIN 1 lesions regress even without treatment, such patients may be followed up. If the CIN 1 persists or becomes worse after one year or if there is colposcopic suspicion of higher grade of abnormality, it should be treated.

Decision to treat the woman with precancer is made usually on the basis of the biopsy reports. However, treatment can be offered on the basis of colposcopy findings in the same sitting. This 'see and treat' approach is convenient to the patients, cost-effective and should be followed in the program at Maldives as much as possible.

The cervical cancer precursors can be treated either by Loop Electrosurgical Excision Procedure (LEEP) or by Cryotherapy. Initially the LEEP procedure will be performed at IGMH only by trained gynecologists. Cryotherapy should be practiced in all the colposcopy centers. Cryotherapy equipment and carbon dioxide gas should be made available in these centers so that the CIN 2 and CIN 3 cases suitable for cryotherapy can be treated. The procedure can be done by gynecologists or by non-specialist physicians. Cases those are not suitable for cryotherapy should be referred to IGMH for LEEP.

#### 3.9.1 Loop Electrosurgical Excision Procedure (LEEP)

In this procedure the entire abnormal area of the cervix is excised using current generated by an electrosurgical unit. The special electrodes used to excise the abnormal part are called Loops. The surgery is done usually under local anesthesia and the patient does not require hospitalization. However, if the lesion is too big or if the patient is not cooperative, general anesthesia and hospitalization may be necessary.

#### 3.9.2 Cryotherapy

Cryotherapy is a safe, simple and effective technique to treat CIN lesions. The abnormal epithelium is destroyed by cooling them to very low temperature (-600 to -800 C) using a cryotherapy equipment. Nitrous-oxide or carbon-di-oxide gas is required for the cooling effect. The advantages of the technique are: no anesthesia or hospitalization is required, can be done even in the Atoll Hospitals, does not require electricity or sophisticated machines, the technique is very easy to learn and

complications are very few. Cryotherapy is almost as effective as LEEP in the treatment of CIN 1 to CIN 3 if the cases are appropriately selected. The selection criteria for cryotherapy are:

- The entire lesion is visible on the ectocervix
- Lesion does not extend on to the vaginal wall or into cervical canal beyond the reach of cryoprobe
- The lesion is not occupying more than three quadrants of the transformation zone
- There is no suspicion of cancer or glandular abnormalities

In remote islands where organizing colposcopy and histology services are not available, cryotherapy of the VIA positive women ('screen and treat' approach) may be considered provided the lesions are purely ectocervical, can be covered by a cryoprobe and is not suspicious of invasive cancer. Some of the regional hospitals not having colposcopy unit should have cryotherapy facility to perform treatment of the VIA positive women. The different algorithm for managing VIA positive women is shown in
Figure 5.

### 3.9.3 Hysterectomy

Hysterectomy should not be performed as primary treatment of the CIN 2 or CIN 3 lesions. It can be done only if there is incomplete excision after LEEP or if there is a recurrence after LEEP. In both situations invasive cancer should be ruled out.

### 3.10 Follow up of women after treatment

Women treated for CIN 2 or CIN 3 should have first follow up 8-12 months after completion of treatment when they can be screened by VIA or may have colposcopy. They should have yearly screening till two consecutive tests are negative. After that they may be asked to follow the 5 yearly screening protocol.

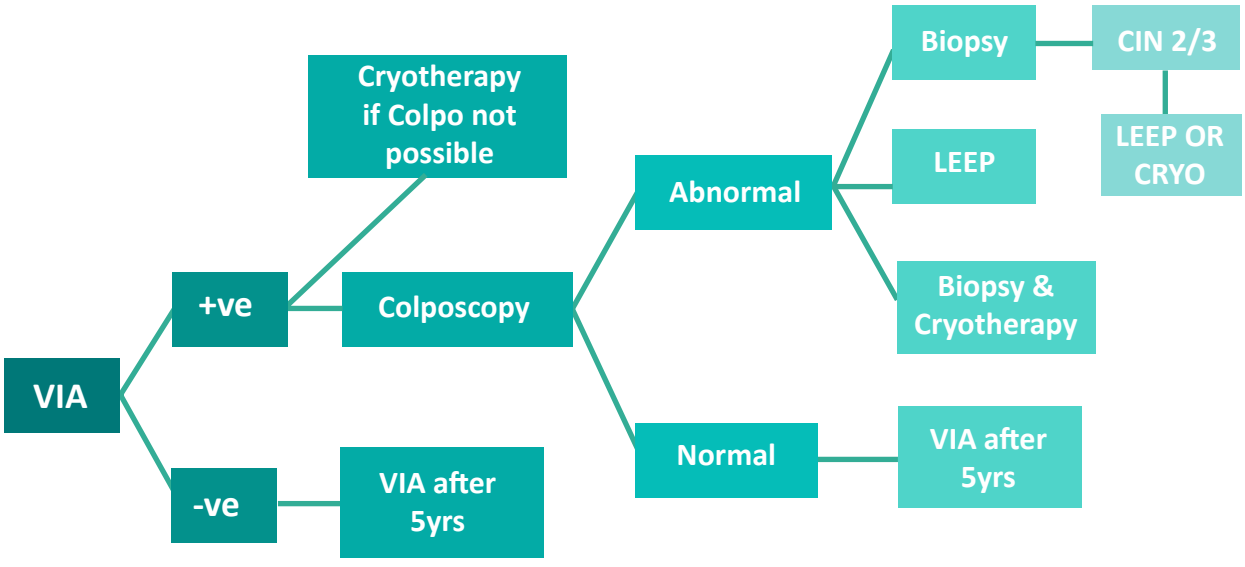


Figure 5: Screening and management protocol flowchart

### 3.12 Histology facilities

In Male histology facilities are available at the IGMH. The laboratory technicians and the pathologists at these centers will need an orientation training to be competent enough to process and interpret cervical punch biopsies as well as the LEEP specimens.

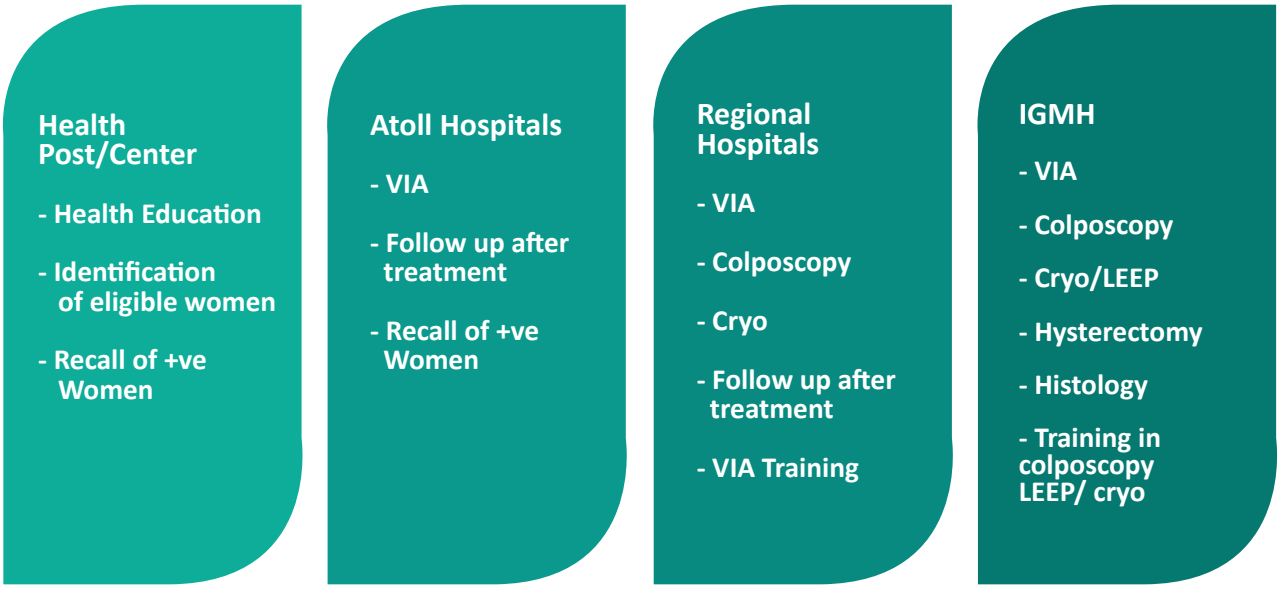


Figure 6. Functions of different health setups in the Screening Program

### 3.13. Screening of the Special Populations

Pregnant women may be screened by VIA in any trimester of pregnancy provided they are in the eligible age group. However, the providers have to be extra careful while exposing the cervix and performing VIA so that no swab is introduced in the endocervix. Colposcopy can be done in the pregnant women in the usual way. However, biopsies should be taken from a colposcopically detected lesion only if there is suspicion of invasion. Otherwise colposcopy may be repeated 6-8 weeks after child birth. If the lesion is persistent even at that time the biopsy can be obtained. Treatment of cervical precancer either by cryotherapy or by LEEP is contraindicated in pregnancy. Such treatment should be planned 6-8 weeks after childbirth only. Invasive cancers need to be treated by the usual protocol at any trimester of pregnancy.

The HIV positive women are at higher risk of developing cervical cancer and the progression of the disease in these women from cervical precancer to cancer is usually much faster. HIV positive women should have screening from the earlier age of 25 years and should ideally be screened yearly. VIA, colposcopy and treatment can be done following the usual principles and guidelines.

The expatriate groups of women, especially if they are not married to Maldivian men have limited health benefits. They are vulnerable group of women who tend to hide their disease conditions and present only at the late stage of the disease. Efforts should be made to bring them also under the free VIA services cover.

## 4.0 Program Management and Quality Assurance

The new program will be integrated into the existing health infrastructure of Maldives. An identified National Focal Point should be engaged with the responsibility to oversee and implement the cervical cancer screening program in the entire country. A National Advisory Body has to be formed to provide technical guidance to the program and to monitor the progress. The Advisory Body should have representatives from the Ministry of Health, IGMH, Faculty of Health Sciences, Medical Council, Nursing Council and other stakeholders. Each region should have a Regional Nodal Officer to coordinate the activities in the region in close liaison with the National Focal Point. A Clinical Coordinator should be identified at IGMH who will supervise the colposcopy, treatment and training facilities in close liaison with the National Coordination Officer. The flow chart showing the hierarchy of program management is shown in Figure 7.

**Responsibilities of National Focal Point**

- Develop educational materials and adopt them in the program
- Organize training of different categories of staff
- Ensuring that VIA and Colposcopy clinics are appropriately equipped & staffed
- Ensuring timely and adequate supply of consumables to the clinics
- Collecting and analyzing the quality control data from the VIA and colposcopy clinic on regular basis
- Share the information with the National Advisory Board and implement any corrective measures suggested by the Board

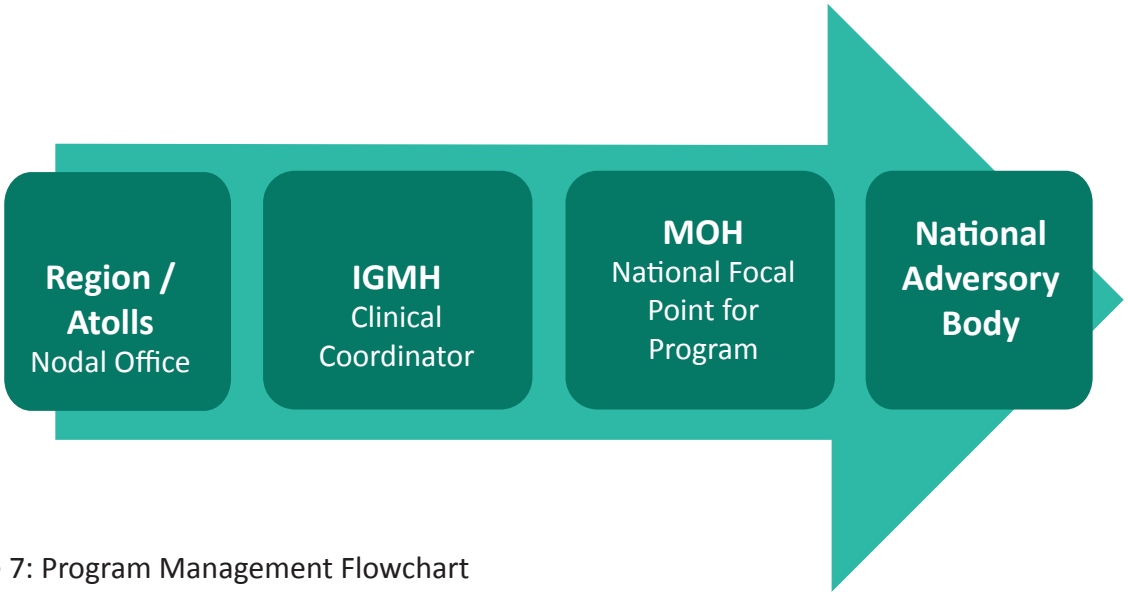


Figure 7: Program Management Flowchart

### 4.1 Improving Coverage & Compliance

All Maldivians are given a unique identity number at the time of registration of birth. A list of citizens enlisted with unique identity numbers can be very useful to identify women who are eligible for screening. The Nodal Officer at the Atoll / Region can do this if he/she has access to such list.

The Community Health Workers and the Family Health Workers will counsel and motivate eligible women during their home visits. Broad based educational campaigns utilizing the mass media (like television social media and newspaper) will also help to increase the uptake of the program. The Health Protection Agency of Ministry of Health will be involved in the media campaign. The Medical association and Nursing Association, NGOs can propagate the message through group meetings and special awareness campaigns.

At the screening center cervical cancer screening facility should preferably be set up in a dedicated clinic on fixed days of the week for the convenience of the women. A registration card will be issued to each woman who attends the clinic for screening and the results should be documented in the card as well as in a register to be maintained at the center. The unique citizen identification number should be used to register the women to facilitate tracking of the positive cases. Screen positive women should be properly counseled and referred to the designated colposcopy center for further investigation and treatment. Appropriate records should be maintained in registers at the Colposcopy Clinic.

A linkage should be established between the colposcopy clinics and the screening centers to ensure tracking of the non-compliant women. The Colposcopy clinic in charge should periodically check the list of positive women sent from the screening centers to identify the non-compliant women. A mechanism of recalling the non-compliant women either by calling them over phone or by informing through their CHW/FHW should be enforced. Maintaining records in a computerized database can be useful to assess coverage and identify the non-compliant women.

### 4.2 Monitoring, evaluation and quality assurance of the program:

The quality assurance plan should be built in the program right from onset. There are some short term and some long term indicators to evaluate the program. The long term indicators are reduction of incidence of cervical cancer and reduction of death from disease. It will take few years to observe the impact of the program on these indicators.

To evaluate the short term performance indicators, reports should be generated periodically by the screening/colposcopy centers using the annual report forms given in Appendix V. The National Focal Point can identify the gaps and suggest corrective actions by collating and analyzing the reports. The cervical screening database should preferably be computerized and linked to the Health Information System of the country. A detailed quality assurance exercise plan for a VIA based screening program is provided in the Appendix II. The common performance indicators that need to be monitored are as follows:

- Coverage of the target population (Number of women in the target age group screened/ Total number of women in the target age group X 100)
- Screening test positivity (Number of women positive on screening test/ Number of women screened X 100)
- Compliance to Colposcopy (Number of women undergoing colposcopy/ Number of women positive on screening test)
- Compliance to treatment (Number of women treated for CIN2+ on colposcopy or biopsy/ Number of women detected to have CIN2+ on colposcopy or biopsy X 100)

- Detection rates of CIN2 or worse disease (Number of CIN2 or worse disease detected/Total number of women screened)
- Positive predictive value of the test to detect CIN 2 or worse disease (Number of CIN 2 or worse disease detected/Total number of women tested positive on screening test)

### 4.3 Training of Service Providers

Training of all categories of service providers is a key factor in quality assurance of the program. IGMH should be designated as the Cervical Cancer Screening Resource Center to conduct and coordinate all training programs. The Regional Hospitals are most suitable to organize VIA training of the nurses and health workers. The duration of VIA training is 5-7 days. Since VIA is a subjective test, it is imperative that all the service providers receive refresher training for 2-3 days every year.

The specialist gynecologists attached to IGMH, the regional hospitals and the atoll hospitals should be trained in VIA, Colposcopy, cryotherapy and LEEP. The non-specialist clinicians can also be trained to provide these services. The training can be organized at IGMH over a period of one week.
The CHOs and the FHWs will perform counseling to motivate the women when they make home visits. These workers should also be given the basic knowledge of cervical cancer screening and its usefulness through short orientation training of one day.

### 4.4 Infection Control Measures

To maintain strict infection control the instruments used for various procedures should be treated in the following manners before they are reused

- Instruments that come in contact with cervix or vagina like specula, biopsy forceps, gloves (if disposable gloves not available): These should be immersed in a bowl con taining 0.5% chlorine solution immediately after use. The solution can be produced by diluting 1 part bleaching powder to 9 parts water. Leaving the instruments for 10 minutes in the solution will reduce the contamination with micro-organism and will inactivate HIV (AIDS causing virus). The instruments should then be thoroughly cleaned using a detergent and rinsed with boiled water. The next step is to sterilize them in an autoclave machine that uses superheated steam (120-130 degree C) under pressure to destroy all micro-organisms. If autoclave facility is not available the instruments are immersed in boiling water in a sterilizer and left there for at least 20 minutes. Sharp instruments like punch biopsy forceps should be immersed in 2% Gluteraldehyde solution for at least 20 minutes instead of putting them in sterilizer.
- The probes used for cryotherapy and the Loops used for LEEP: These should be decontaminated by keeping them in chlorine solution, cleaned and put in 2-4% Gluteraldehyde solution for at least 20 minute before reuse.
- The halogen light source, colposcope, cryotherapy machine, surface of examination table: These should be decontaminated daily after the end of the clinic by wiping with 60-90% ethyl alcohol.

## Plan of Action:

- Identify the Program Manager (National Focal Point)
- Form a National Advisory Body
- Formally get the project implementation strategy accepted by the members of the National Advisory Body & the Ministry of Health
- Identify the screening and the colposcopy centers to launch the program in a small scale
- Procure equipment's & consumables to initiate the program in the identified centers
- Identify & train the nurses & midwives in VIA
- Train the doctors in Colposcopy, LEEP & cryotherapy
- Ensure availability of histology services
- Set up VIA & colposcopy centers at the identified facilities
- Initiate education campaign among the target population
- Evaluate the performance after one year and plan for up scaling to include more regions

# APPENDIX I

Equipment & Consumables Required for the Program:

Requirements for VIA:

Equipment's:

- Halogen focusing light for examination (two per clinic)
- Cusco's self-retaining Speculum (10-15 per clinic)
- Sterilizer (one per clinic)
- Measuring cylinder (two per clinic)
- Small Bowl (four per clinic)
- Instrument Tray (Four per clinic)

Consumables:

- Examination gloves
- Cotton tipped swabs
- Glacial acetic acid (Merck)
- Distilled water
- 0.5% Chlorine solution
- Ethyl alcohol
- Gluteraldehyde (Cidex) solution
- Forms & other stationaries

Requirements for Colposcopy; Cryotherapy & LEEP

Equipments:

- Halogen Focusing light for examination (one per clinic)
- Binocular Colposcope with tilt/height adjustment facilities and variable magnification with camera and image capturing facility (one per clinic)
- Tischler Cervical Punch biopsy forceps (two per clinic)
- Cusco's self-retaining Speculum (10-15 per clinic)
- Vaginal sidewall retractors (one per clinic)
- Endo cervical speculum (two per clinic)
- Insulated self-retaining speculum with smoke extraction channel (three per clinic)
- [If LEEP facilities are set up]
- Endo cervical curette (two per clinic)
- Sponge holding forceps (four per clinic)
- Small Bowl (four per clinic)
- Instrument Tray (Four per clinic)
- Sterilizer (one per clinic)
- Measuring cylinder (two per clinic)

Portable Cryotherapy equipment with shallow, conical (20mm & 25mm) flat-tipped probes (the valve connecting to the gas cylinder should be compatible with the valve system in MALDIVES) (one per clinic)
Carbon di-oxide cylinders (four per clinic)
Electrosurgical unit (one per clinic) [If LEEP facilities are set up]
Suction apparatus (one per clinic) [If LEEP facilities are set up]

Consumables

Examination gloves
Cotton tipped swabs
Lubricant Jelly
Glacial acetic acid (Merck)
Lugol's iodine (iodine crystals; potassium iodide crystals; distilled water)
Monsel's solution
Formaldehyde solution
0.5% Chlorine solution
Ethyl alcohol
Gluteraldehyde (Cidex) solution
1% Inj. Lignocaine with adrenaline [If LEEP facilities are set up]
Syringe for local anesthesia (dental syringe with needles very useful)
Loop electrodes (size 10 to 15mm) [If LEEP facilities are set up]
Ball electrodes [If LEEP facilities are set up]
Diathermy pencils with hand switches [If LEEP facilities are set up]
Forms & other stationaries

# APPENDIX II

**Quality Control and Quality Assurance for Visual Inspection after Acetic Acid Application (VIA) as a Screening Test for Cervical Cancer**

## INTRODUCTION

### Visual screening for cervical neoplasia

VIA involves naked eye examination of the uterine cervix under bright light (preferably a halogen focus lamp) one minute after application of 5% dilute acetic acid. VIA has been extensively evaluated through cross-sectional studies, prospective randomized trials and demonstration programs. VIA is currently being used as a screening test for the national cervical cancer screening programs of some countries like Bangladesh. The present document will be dealing with the quality control issues and quality assessment parameters related to VIA-based screening programs.

Visual screening tests are simple, widely feasible and affordable. They provide immediate results enabling diagnosis and/or treatment to be carried out in the same session for screen positive women. They can be provided by a wide range of health professionals including doctors, nurses, midwives and primary health care workers after a short period of training. The infrastructural need is minimal and the consumables are universally available.

The purpose of this document is to define a core set of performance indicators for VIA-based organized cervical cancer screening programs.

## Limitations of VIA

The visual tests are subjective in nature and provider dependent, resulting in a wide variation of performance in different settings. Quality assurance for visual screening is a challenging task specially because there is limited information on the test performance in multi-provider real programmatic setting. VIA is dependent on the full visibility of the transformation zone of the cervix. However, the transformation zone moves into the endocervical canal after menopause and may be totally invisible with aging, limiting the utility of visual tests in postmenopausal women. Moreover, the interpretation of VIA is difficult in postmenopausal women due to the atrophy of the cervical epithelium. Low specificity and suboptimal positive predictive value of VIA will result in unnecessary referrals and/or treatment which can offset the perceived low cost of the tests. There are several training issues related to VIA such as the duration of training, structure and content of the competency based course and post-course evaluation need to be standardized.

### Accuracy of VIA: range in sensitivity and specificity

The sensitivity of a test to detect a particular disease is the proportion of individuals truly harbouring the disease (true positives) who are correctly identified by the screening test. The specificity of the test is the proportion of individuals free of the disease (true negatives) who are correctly detected negative by the test. Sensitivity is a measure of the probability of correctly diagnosing a case and specificity is a measure of the probability of correctly identifying a non-diseased person with a screening test. Positive predictive value is the proportion of people with a positive test who have the disease in question. It is a measure of the probability that a patient with

a positive screening result has the disease. Negative predictive value is the proportion of people with a negative test who do not have the disease. For the efficient running of the program the screening test should have high sensitivity as well as specificity though the minimum threshold of sensitivity and specificity required for a test to be inducted in a screening program may vary from one setting to another.

A systematic review of the accuracy of conventional cytology reported that, in 12 studies with the least biased estimates, sensitivity ranged from 30% to 87% and specificity from 86% to 100%. A critical review by Pan American Health Organization (PAHO) in 2003 observed the sensitivity of VIA to range from 29-95.8% and specificity to range from 64.1 to 97.7% with CIN 2 as the threshold for positive diagnosis. Most of these studies had verification bias since all the women with negative test were not evaluated by the reference standard. International Agency for Research on Cancer (IARC) conducted cross-sectional studies involving 56,939 women aged 25–65 years in Burkina Faso, Congo, Guinea, India, Mali and Niger to evaluate the accuracy of VIA performed by health workers. In all these studies same definitions were used to characterize the test outcomes and all the VIA negative women had gold standard test of Colposcopy to avoid verification bias. The pooled sensitivity, specificity, positive and negative predictive values for VIA in these multi-centric studies were 76.8% (95% CI: 74.2–79.4%), 85.5% (95% CI: 85.2–85.8%), 9.4% (95% CI: 8.8–10.8%) and 99.5% (95% CI: 99.4–99.6%), respectively. The accuracy of VIA was similar or higher than that of Pap smear in such studies where both visual tests and cytology were concurrently evaluated.

## VIA TEST PROCEDURE

### Pre-test counseling

The test procedure and the implications of the test results are explained to the woman before proceeding to examine her. She is assured that the discomfort associated with the procedure is minimal. Adequate privacy should be maintained in the examination room. Such measures will ensure that the woman is fully relaxed during pelvic examination. Some programs may require the woman to sign an informed consent prior to the procedure.

### Steps of VIA

The woman is made to lie in lithotomy position or dorsal supine position with legs flexed. A good focusing light, preferably one containing a halogen bulb should be used to visualize the genitalia and cervix. The external genitalia are inspected for any excoriation, skin changes, ulceration, wart or growth before proceeding to insert the lubricated self-retaining bivalve speculum. The cervix is gently exposed and any evidence of infection such as purulent, curdy white or greenish yellow or malodourous discharge, vesicles, redness and inflammation are looked for. The cervical os and the squamocolumnar junction (SCJ) are identified. If there is any cervical polyp or ulcer or growth it should be noted. A cotton swab is used to apply 4 to 5% acetic acid generously on the entire cervix for one minute before the aceto-white changes are looked for. Discharge or mucus, if any, on the cervix is gently removed while applying the acetic acid. The cervix is examined for any well-defined, well-demarcated, opaque acetowhite areas abutting the SCJ or the external os or extending into the endocervical canal. After the completion of examination any acetic acid collected in the posterior vaginal fornix should be removed with a dry swab. The speculum should be gently withdrawn. The test findings should be explained to the woman and she should be appropriately advised if any abnormality is detected. Meticulous attention should be given to ensure infection control.

## Reporting VIA test results

Aceto-whitening is not specific to neoplasia. It can be associated with immature metaplasia, inflammation, regenerating epithelium and human papilloma virus (HPV) infection. Aceto-whitening associated with cervical neoplasia are localised in the transformation zone of the cervix, invariably arising from the SCJ, have a smooth well demarcated margin and are densely white.
Different authors have used different criteria to define the VIA outcomes. In the present document we have used the test definitions as per the IARC technical manual where VIA is reported as negative, positive or invasive cancer.6 A negative report implies that screening test is normal and no further evaluation is necessary. The woman should be referred for Colposcopy if VIA is reported positive or invasive cancer.

VIA is reported Negative when any of the following features are seen:

- No acetowhite lesions on the cervix;
- Thin transparent aceto-white lesions or faint patchy lesions or lesions without definite margins;
- Polyp protruding from the os taking up acetowhite;
- Nabothian cysts taking up aceto-white and appearing as whitish acne;
- Faint line-like acetowhitening at the junction of columnar and squamous epithelium;
- acetowhite lesions away from the transformation zone;
- Streak-like acetowhitening;
- Dot like areas in the endocervix, which are due to grape-like columnar epithelium transiently staining with acetic acid;

VIA is reported Positive when any of the following features are seen:

- Distinct, well defined, dense, opaque or dull white or oyster white acetowhite areas touching the squamo-columnar junction (SCJ) or touching the external os (if SCJ not seen)
- The lesion should have a well-defined margin may or may not be raised from the surface
  VIA is reported Suspicious of Invasive Cancer when any of the following features are seen:
- Visible growth or ulcer on the cervix that bleeds on touch
- The growth or ulcer may or may not be aceto-white after acetic acid application

## QUALITY CONTROL & QUALITY ASSURANCE FOR VIA

### Principles of Quality Control

To make the cervical cancer screening program efficient and cost-effective appropriate monitoring and periodic performance evaluation should be done. The ultimate 'impact' of cervical cancer screening program is the reduction of incidence of cervical cancer and mortality from the disease. Initially the program is likely to detect many of the undiagnosed prevalent cancers that may be reflected as an apparent increase in the incidence. There will be a stage-shift of the detected invasive cancers with more and more cases being diagnosed at earlier stages. As the cervical precancers are detected and treated, there will be a gradual reduction in new cases of invasive disease. However, reduction in incidence and mortality as an impact of screening program may take a decade to be evident. In the meantime, evaluation of the performance of the program can be done by assessing the following performance indicators:

- Coverage of the target population
- VIA positivity and positive predictive value
- System capacity (time to Colposcopy, compliance to Colposcopy etc.)
- Colposcopy performance (i.e., biopsy rate, colposcopy-histology agreement)
- Pre-cancer detection rate
- Disease extent at diagnosis
- Treatment performance (compliance to treatment, cure rate after treatment)

Critical information required to assess the above-mentioned parameters have to be generated in a timely way on regular basis and need to be analyzed by the program managers. The ideal way to study the cervical cancer incidence and mortality among the screened population is to have a population based cancer registry (PBCR) covering the screened population. The trend in the incidence and mortality can be linked to the information about the screening uptake and outcome to get the best evaluation of the screening program. However, many of the settings where VIA will be used as screening test may not have a PBCR. They have to depend on other process and outcome measures mentioned earlier.

Program performance is influenced by different program elements and these elements may vary between programs in several ways. These include the organization of the program, the target population, service access and provision, reporting thresholds for test results, follow up and treatment, and screening interval recommendations. Factors external to the program can also affect the screening program performance such as number and availability of health care providers and facilities for diagnostic assessment and treatment. Therefore, program comparisons must take into consideration how the screening programs have been operationalized in addition to relevant external factors. The performance indicators should cover the entire screening spectrum starting from the invitation to the women to the treatment of the positive cases. At the same time the measures should be available on regular basis and regular monitoring of the measures should be beneficial and feasible.

### Objectives of Quality Control for VIA

VIA being an observer dependent test requires stringent quality control for optimum performance. The quality standards and the performance indicators should take into consideration all the components of a VIA-based screening program rather than the test in isolation. The Quality Control and Quality Assurance document for a VIA-based screening program should:

- Clearly define the measurable indicators that will help assess the performance of the program in achieving the stated targets and goals
- Provide a framework to identify the strengths and weaknesses of the ongoing program as well as report and resolve problems at the earliest
- Help continuous improvement in quality for all aspects of cervical screening service delivery

The performance indicators should cover all levels of services – public education and outreach, screening facilities, colposcopy and treatment facilities, pathology laboratories and training program. Some of the quality standards may not be universal and may vary from one programmatic setting to another. Over time, with regular monitoring and reporting of the various performance indicators, an evidence base will generate that will permit the setting of targets for individual program. Data obtained from a well-designed pilot study prior to launching a population based screening program can serve as quality standards for future evaluation of the program.

## Performance Indicators for VIA based screening program

### Coverage of the eligible population

- **Definition:** Percentage of eligible women in the target population with at least one VIA test in a three to five years period depending on the specified screening interval.

- **Method of calculation:**

$$\frac{\text{Number of women who have had VIA in last N years}}{\text{Number of eligible women}} \times 100$$

N = Specified screening interval in the program

- **Explanation:** Ensuring the participation of the majority of the eligible women in the screening program is one of the key determinants of success of the program. The age at which screening will be initiated and the age at which screening will be discontinued need to be predetermined depending on the capacity and the resources available. Similarly, the interval between two rounds of screening may vary from program to program. The program manager will have to ensure that all the women within the specified age group have access to VIA and majority of them undergo the test on regular basis. In an opportunistic program with low participation rate usually the low risk women undergo too frequent rounds of screening while those with significantly higher risk are left out. For significant reduction of mortality from cervical cancer 70-80% eligible women should have regular cervical screening.

  If possible, the coverage should be calculated by 10-year age groups. Screening of women with VIA beyond the specified age range should be discouraged and should be as low as possible. In many of the newly launched programs in low/medium resource countries it may be impractical to fix a coverage rate initially. The number of women screened per screening center (or region) per year can serve as an

indicator of performance. The program managers have to set a realistic target de pending on the number of providers and the available hours of work at the screening centers. On an average a trained provider can perform 6-10 VIA per hour.

### VIA Test Positivity

- **Definition:** Percentage of women reported positive/invasive cancer on VIA.
- **Method of calculation:**

$$\frac{\text{Number of women reported positive/invasive cancer on VIA}}{\text{Number of women screened}} \times 100$$

- **Explanation:** The positivity of VIA depends on the age distribution of the screened women, prevalence of cervical neoplasia in the target population, skill and experience of the VIA providers. The test positivity will be high in younger women, especially those below 30 years, due to the metaplastic changes in the cervix and high prevalence of low grade intraepithelial lesions. In various studies it has been observed that the test providers tend to report higher positivity initially. As they acquire skill and gain confidence, the test positivity tends to come down and stabilizes at a rate appropriate for the population. The optimum VIA test positivity is 5-10% in women between 30-60 years of age. The providers need retraining if the test positivity becomes too low (possibility of missing disease) or too high (possibility of high false positives). If possible, the test positivity should be calculated by 10-year age groups.

### Compliance to Colposcopy

- **Definition:** Percentage of VIA positive women undergoing colposcopy following a positive VIA test.

- **Method of calculation:**

$$\frac{\text{Number of VIA positive women who had colposcopy within N months}}{\text{Number of women reported positive on VIA in a 12 months period}} \times 100$$

(N = 1-3 months of index VIA test, depending on the program capacity and specification)

- **Explanation:** Ideally all screen positive women should have colposcopy for confirmation of the disease status that will lead to appropriate treatment. Linkage between screening and colposcopy/treatment is essential for the success of the screening program. A major advantage of VIA is that the report is immediately available and the positive women can have colposcopy in the same sitting or can be advised for colposcopy immediately. The program managers will have to decide on the permissible interval between VIA test and colposcopy depending on the program capacity. More than 80% of the VIA positive women should have colposcopy within the specified time.

Some of the programs may decide to follow the 'screen and treat policy' where VIA positive women are assessed immediately for suitability of cryotherapy. If suitable, cryotherapy is performed in the same sitting. Only those women who cannot be treated by cryotherapy are referred for colposcopy and subsequent management. In such setting the compliance to colposcopy should be calculated as follows:

$$\frac{\text{Number of women who had colposcopy within N months of index VIA}}{\text{Number of women referred for colposcopy in a 12 months period}} \times 100$$

Biopsy rate and adequacy of biopsy specimens

- **Definition:** Percentage of VIA positive women who received a histological diagnosis in a 12 months period is defined as the biopsy rate. The proportion of all the biopsies obtained during colposcopy that are reported unsatisfactory by the histopathologist is the measure of inadequate biopsies.

- **Method of calculating Biopsy rate:**

$$\frac{\text{Number of women with a histological diagnosis after VIA} \times 100}{\text{Number of VIA positive women in a 12 months period}}$$

- **Method of calculating Inadequate Biopsy rate:**

$$\frac{\text{Number of women with a diagnosis of inadequate biopsy} \times 100}{\text{Number of VIA positive women in a 12 months period}}$$

- **Explanation:** Punch biopsies are obtained from cervix if cervical neoplasias are suspected during colposcopy of the VIA-positive women. Biopsy is obtained through Loop Excision if 'see and treat' policy is practiced during colposcopy. A low biopsy rate usually indicates poor predictive value of VIA or inadequate follow up. The biopsy rate also depends on the skill and thoroughness of the colposcopist to rule out neoplasias. Sometimes the women themselves refuse biopsy. The minimum biopsy rate acceptable as a performance measure is to be specified in individual program setting and to be monitored over time. High inadequate biopsy rate indicates use of inappropriate punch biopsy forceps or inadequate skill of colposcopist to obtain a good biopsy. Failure to preserve the specimen or to process the specimen correctly in the laboratory can also lead to a report of unsatisfactory biopsy. The rate of inadequate biopsies should be as low as possible and corrective measures should be taken promptly if a high rate is detected.

## Detection Rate for Cervical Cancer Precursors

- **Definition:** Number of pre-cancerous lesions detected per 1,000 women who had a VIA test in a 12 month period. Commonly the detection rate of CIN 2 and CIN 3 are calculated due to the clinical and programmatic relevance of the high grade precursor lesions..
- **Method of Calculation:**

$$\frac{\text{Number of women with CIN 2 and CIN 3 on histology}}{\text{Number of women who had VIA in a 12 months period}} \times 1000$$

- **Explanation:** Detection rate of CIN, especially CIN2 and CIN3 lesions, can serve as a surrogate for the sensitivity estimate of VIA test. The detection rate of CIN2+ lesions in the population also depends on the prevalence of the disease in the population and capability of the colposcopists to identify the disease correctly. The detection rate has to be monitored over time. A decline in the rate indicates suboptimal sensitivity of VIA or inadequate work up of the VIA positive women. The detection rate of CIN 2 and CIN 3 usually varies from 3-10 per 1000 screened population.

### Stage of Invasive Cancer at Diagnosis:

- **Definition:** Proportion of screen detected invasive cancers in early stage (stage I; confined to cervix)
- **Explanation:** One of the major indicators of effectiveness of screening program is the ability to detect the cervical cancers in the preclinical or early stage when the cancer is curable in more than 90% cases. In an unscreened population the majority of cancers are detected in advanced stage. With implementation of screening program the number should come down gradually.

- **Method of calculation:**

$$\frac{\text{Number of cancers of cervix in stage I}}{\text{Number of cancers detected in a 12 months period}} \times 100$$

## Incidence of cervical cancer

- **Definition:** Age standardized incidence of cervical cancer in the screened population.

- **Explanation:** As organized screening program become established the rates of cervical cancers come down due to intervention at the pre cancer stage of the disease. The incidence rate is recorded by a population based cancer registry operating among the screened women and is expressed as age-standardized rate. A reduction in incidence (and mortality) rate of cervical cancer is the best outcome

indicator for cervical cancer screening program but may not be feasible to obtain in many of the low/medium resource settings due to non-availability of population based cancer registry.

- **Method of calculating**
  To calculate age standardized incidence rate information regarding the number of cancers detected in one year, their age distribution and the age distribution of a standard population.

**Appropriate infection control and sterilization procedures should be practiced**

## Individual VIA Provider Performance evaluation:

VIA is an observer dependant test. For correct interpretation of the post acetic acid application changes appropriate training of the test providers is essential. The structured training modules should contain theoretical knowledge of anatomy of normal cervix, physiological changes induced by hormonal status at various phases of life, lower genital tract infections, pathology of cervical precancers as well as cancers, management of cervical neoplasias and infection control measures. Normal cervix, non-neoplastic changes of cervix due to metaplastic changes and infections, various grades of precancers and invasive cancers should be demonstrated using photographs (without much magnification). VIA training manuals developed by IARC, JHPIEGO may be used. The duration of training varies between 5-7 days during which the candidates should have exposure to adequate number of VIAs being performed by the trainer as well as by him/her. The minimum number of VIAs required to be observed and to be performed under supervision to gain adequate competency to perform the procedure independently is not yet standardized. It is generally agreed that the number should be between 50-100 of which at least half of the procedures should be done by the trainee himself or herself.

It is essential that after completion of training each trainee should undergo competency based evaluation. During such evaluation the trainee should perform adequate number of VIAs while being observed by a trainer. The trainer has to evaluate the trainee using a checklist that can assess the trainee's skill in counseling (before and after VIA), positioning of the woman, steps of VIA, interpretation of the appearance of the cervix before and after application of acetic acid and following appropriate infection control measures. The minimum number of VIAs to be performed by the trainee for such a competency based evaluation is not standardized. It is important to have adequate number of cases with abnormal VIA findings to judge the trainee's understanding of the procedure. After successful completion of evaluation all trainees should be certified by appropriate authority. The program managers have to ensure that only the certified VIA providers perform the test.

All VIA providers need a reorientation training at least once a year. The agreement between the VIA results obtained by the provider and those obtained by the trainer can be assessed during such reorientation training. Such agreement should be at least 80%.

| | | | | |
|---|---|---|---|---|
| **AM (2½ Hours)**<br>**Opening: 60 min**<br>• Welcome and introductions<br>• Overview of the course (Goals, Objectives, Schedule)<br>• Review course materials<br>• Participant expectations<br>• Precourse questionnaire<br>• Identify individual and group learning needs | **AM**<br>Agenda and opening activity<br>Recap<br>Lecture 5: Steps of Colposcopy 30 min<br>Activity: VIA practice:<br>• Image projection<br>• CD-ROM | **AM**<br>Agenda and opening activity<br>Recap: Chapters 1–5<br>Lecture 9: Single Visit Approach 30 min<br>Lecture 10: Treatment of Cervical precancer by LEEP 30 min<br>Lecture: Treatment of Invasive Cancer | **AM**<br>Lecture 11: Organization of cervical cancer screening program 30 min<br>Lecture 12: Quality assurance of a VIA based cervical cancer screening program 30 min<br>Preventing Infections in Healthcare Workers | **AM (4 Hours)**<br>Course evaluation<br>Discussions |
| **PM (3½ Hours)**<br>Precourse Skills Assessment<br>Assess each participant's skills:<br>• Counseling (role play)<br>Lecture 4: VIA – steps & interpretations of findings 30 min<br>Discussion/ Demonstration: | **PM (3½ Hours)**<br>Lecture 7: Treatment of Cervical precancers with cryotherapy 30 min<br>Discussion: Clinical work preparation:<br>• Norms and conduct<br>• Assignment to groups | **PM (3½ Hours)**<br>Client Assessment and VIA Testing<br>Clinical Practice: Observe and provide services in the clinic:<br>• Counseling client<br>• VIA<br>• Cryotherapy | Hands on practical training in VIA, Colposcopy, Cryotherapy & LEEP | |

# APPENDIX IV

**CLINICAL SUPERVISION OF VIA TRAINEES**

| | |
|---|---|
| **A.** | **FOR EACH VIA PROVIDER, COMPLETE THE FOLLOWING** |
| **NAME OF FACILITY:**_____ | **DATE**_____ |
| **NAME OF SUPERVISOR:**_____ | |

***Directions:***

- Each form can be used to evaluate the trainee for performing VIA on 5 women
- Place "S" in case box if step/task is performed Satisfactorily,
- Place "U" if it is performed Unsatisfactorily,
- Place "X" if Not observed. (Step, task, or skill not performed by participant during the evaluation)

| **VIA counseling and clinical skills evaluation Observations** | | | | | |
|---|---|---|---|---|---|
| **Pre-VIA counseling** | **Case 1** | **Case 2** | **Case 3** | **Case 4** | **Case 5** |
| 1.Greets the woman respectfully and with kindness. | | | | | |
| 2.Provides cervical cancer screening counseling.<br>a. Provides accurate information about cervical cancer prevention (what/where is cervix, how cervical cancer is detected, what is the benefit of screening).<br>b. Uses effective counseling skills (actively listens, is supportive, helps woman make her own decision, keeps-messages simple, answers questions directly). | | | | | |
| 3. Responds to woman's needs and concerns | | | | | |
| 4. Describes the procedure and what to expect. | | | | | |

| Pre-VIA activities | | | | | |
|---|---|---|---|---|---|
| 1. Checks that instruments, supplies, and light source are available and ready for use. | | | | | |
| 2. Check the eligibility, proper filling of case form and card. | | | | | |
| 3. Has the woman undress from the waist down. Helps her get on to examining table and drapes her. | | | | | |
| 4.Puts one pair of new examination or high-level disinfected surgical gloves on both hands. | | | | | |
| 5.Arranges instruments and supplies on high-level disinfected tray or container. | | | | | |
| **VIA activities** | | | | | |
| 1. Inspects external genitalia | | | | | |
| 2. Inserts speculum and fixes blades so that entire cervix can be seen clearly. | | | | | |
| 3.Moves light source so cervix can be seen clearly. | | | | | |
| 4. Checks the cervix for cervicitis, ectropion, tumors, Nabothian cysts, or ulcers; and cleans cervix with cotton swab if necessary. Disposes of swab. | | | | | |
| 5. Identifies the cervical os, SCJ, and transformation zone. | | | | | |
| 6.After telling the patient that she might feel a mild stinging sensation, applies acetic acid. Waits precisely for one minute to allow colour changes to develop. | | | | | |
| 7. Checks if cervix bleeds easily. Checks for any raised and thickened white plaques or dense acetowhite epithelium with well-defined margin. | | | | | |
| 8. Correctly diagnoses the VIA findings | | | | | |
| 9. Removes any remaining acetic acid from the cervix and vagina with a swab. Disposes of swab. | | | | | |
| 10. Removes speculum and places it in appropriate container for disinfection. | | | | | |

| Post-VIA activities | | | | | |
|---|---|---|---|---|---|
| 1. Wipes light source with 0.5% chlorine solution or alcohol. | | | | | |
| 2. Immerses both gloved hands in 0.5% chlorine solution. Removes gloves by turning inside out. | | | | | |
| 3. Discusses the results of VIA test with woman and answers any questions | | | | | |
| 4. a) If VIA test is negative, tells woman when to return for repeat VIA testing.<br>b) If VIA test is positive or cancer suspected, discusses recommended next steps. After counseling, provides appropriate referral. | | | | | |
| 5. Records the VIA test results and other findings in woman's record and provide the card to the woman and asks her to retain it.<br>a) Documents cervical lesion findings on cervical map.<br>b) If required, documents referral and reason for referral.<br>c) If treatment/referral is refused at time of screening, documents reason for delaying/refusing treatment/referral. | | | | | |

**COMMENTS:**

**PRE-VIA COUNSELING:**

**PRE-VIA ACTIVITIES:**

**VIA SKILL:**

**POST VIA ACTIVITIES:**

**OVERALL PERFORMANCE:**

**RECOMMENDATIONS:**

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