



GUIDELINE FOR SCREENING OF GASTRIC CANCER, CERVICAL CANCER & BREAST CANCER



Health Flagship Project
Ministry of health
Royal Government of Bhutan



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Executive Summary

The current health system with its focus on primary health care has remained the backbone of health services in the country and contributed immensely to health outcomes in the past 5 decades, with Bhutan achieving most of the Health MDG goals. The rapid socio-economic development, the national goal of Universal Health Coverage and the epidemiologic transition of diseases to more NCDs and Cancers has resulted in more demand for tertiary healthcare services, expansion of health facilities and increasing patient referrals, leading to escalating costs for healthcare provision. The budget allocation for health services has not seen a corresponding increase; in fact, the Health Ministry's annual budget allocation has been decreasing over the years as a proportion of the annual government budget. Recognizing that Gastric and Cervical cancers contribute to most of the cancer burden and mortality, this Flagship project specifically targets prevention of Gastric, Cervical and Breast cancers, by introducing early screening programs for Gastric and Breast cancers and improving on the existing cervical cancer screening program. The strategies involve the introduction of new screening tests with the goal of reaching all the target populations and providing treatment, sustained health advocacy, and having adequate human resources in place. The health flagship project is one of the many flagship-projects the government has committed. The health flagship project has allocated funds of Nu. 1109.572 million and the project has to be completed by 2023.

For a successful implementation of the project, a separate Project Management Unit (PMU) for the health flagship project is established in MoH. The overall target of the project and implementation strategy will be based on the project blueprint approved by Gross National Happiness Commission (GNHC). However, in order to have a robust and evidence-based screening program in the field, it is imperative to have a technical

good guideline in place. So, the Technical Working group (TWG) for the program has developed the guideline for screening gastric and breast cancer before the actual implementation of the screening program. The TWG is a group expert from various medical fields formed to give technical guidance to the PMU during the implementation of the project. The guideline is developed in reference to available scientific evidence, international screening documents and at the same time considering our own context in terms of availability and capacity of infrastructure and human resources.

Background

As per the population-based cancer registry of Bhutan 2014-2018, the age-adjusted incidence rate per 100,000 populations is 64 and 89.8 for male and female, respectively. The cumulative risk of getting cancer among females is 1 in 9 (11%) and among male is 1 in 11 (9%). The top five cancers in male are Stomach, Oesophagus, Liver lung and Rectum cancer whereas Cervix Uteri, Stomach, Breast, Thyroid and Ovary cancers are five leading cancers in females. Around 62% of cancer cases were referred out of the country for treatment and confirmation of diagnosis. By district wise, the highest number of stomach cancer case was from Paro, followed by Wangdue Phodrang, Punakha, Trashigang and Haa, whereas the highest number cervical cancer case was from Trashigang, followed by Mongar, Wangdue Phodrang, Chukha and Samtse. The age-adjusted cancer mortality rate in Bhutan per 100,000 populations is 30.7 and 31.5 for male and female, respectively. The leading cancer death in males is due to stomach cancer, followed by Oesophagus, Liver, Lung and Gallbladder cancer and in females is due to cervix uteri, followed by Stomach, Lung, Ovary and Liver cancer. The First Report on the Prevalence and Epidemiology of *Helicobacter pylori* in Bhutan has shown almost all Bhutanese carry *H. pylori* bacteria, with the prevalence rate of 66% to 82%. Through genotyping, *H. pylori* strains in Bhutan are found to be very virulent which are responsible for causing gastric cancer.

Objectives:

The health flagship will contribute towards the above goals through the following objectives:

- Reduce Gastric cancer incidence and mortality through early screening and prevention
- Reduce Cervical cancer incidence and mortality through early screening and prevention
- Reduce Breast cancer incidence and mortality through early screening and prevention

Target:

The health flagship will aim to achieve the following measurable targets by 2023

A. Gastric cancer

- All target population are screened for *H. pylori*
- All screened population (*H. pylori* positive) receive triple therapy treatment
- All high-risk target population are screened for gastric cancer and managed

B. Breast cancer

- All target population are screened for breast cancer and managed

C. Cervical cancer

- All eligible women are screened for cervical cancer
- All screened positive women receive treatment/management

GASTRIC CANCER

I. Introduction:

Gastric cancer is one of the common malignancies worldwide and it is still the 3rd leading cause of cancer-related deaths globally. In Bhutan gastric cancer is the commonest malignancy in male with an incidence rate of 8.3 per 100000 population and the second commonest malignancy in females after cervical cancer with an incidence rate of 5.2 per 100000 population. At the same time, gastric cancer is also the leading cause of cancer mortality in male with an incidence rate of 8.3 per 100000 population. (*Source: Population based cancer registry 2014-2018*).

II. Risk factors for Gastric cancer

The cause of gastric cancer is multifactorial.

- *H. pylori* infection
- High salt intake and salt preserved food
- Smoking
- Low dietary fibre intake
- Family history of gastric cancer

III. Prevention of Gastric cancer

a) Primary prevention-

- Lifestyle changes
- cessation of smoking
- reducing salt intake
- more fruits and vegetables
- Eradicating *H. pylori*

b) Secondary prevention-

- Detection of precancerous lesion, atrophy, intestinal metaplasia, dysplasia and early gastric cancer through the screening program.

IV. Screening Programs:

1. MASS ERADICATION OF H. *PYLORI* IN BHUTAN

Modalities for diagnosis of H. *pylori*

- Stool antigen test
- Urea breath test
- Rapid Urease test in biopsy specimen by UGIE
- Histopathology
- Culture

a) Target Population:

All population age 18 years - 75 years

b) Method:

Steps for screening and treatment for H.pylori is given in the flow chart (figure 1)

- » Test for H. *pylori* by stool antigen
- » Treat all positives by CAP regimen
- » Retest for eradication using stool antigen
- » Second line treatment if still positive after treatment
- » Refer for UGIE if still positive after a second line treatment

2. GASTRIC CANCER SCREENING PROGRAM

a) Target Population:

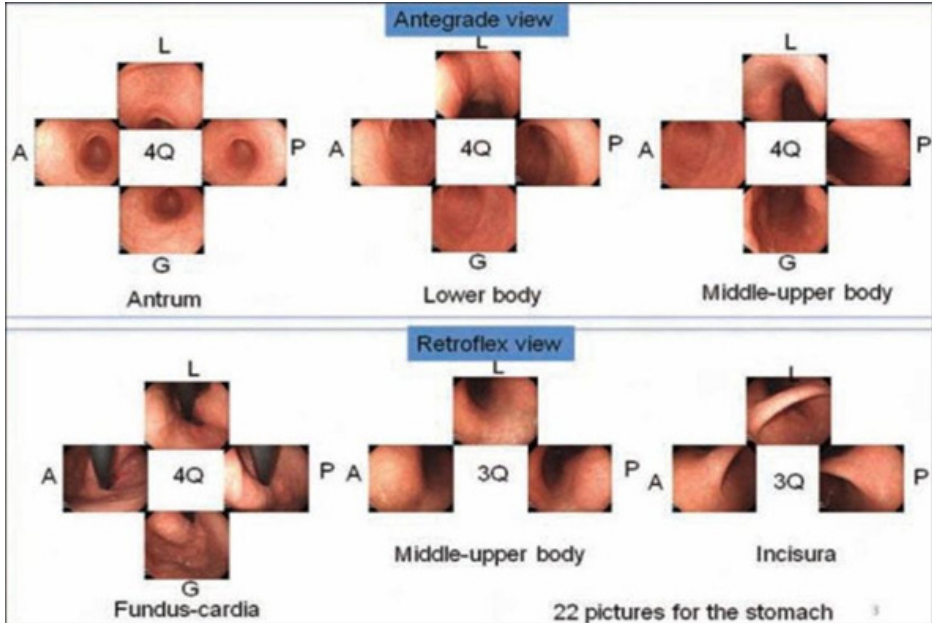
1. Age 40- 75 years
2. People with history of atrophic gastritis
3. History of H.Pylori infection
4. People with history of gastric cancer in the family
5. Any patient with history of dyspepsia with alarm features

b) Method:

- Steps for screening for gastric cancer is given in the flow chart (figure 1)
 - » Do viral markers before subjecting to endoscopy procedure
 - » Do Upper Gastrointestinal Endoscopy (UGIE)
 - » Take tissue biopsy for a suspicious lesion
 - » Do rapid H.pylori test if the person has not undergone the H.pylori test and give the H.pylori eradication therapy
 - » If the biopsy report is malignant, refer to Oncosurgeon
 - » For severe atrophic gastritis/metaplasia, repeat UGIE after one year
 - » For dysplasia, repeat UGIE after six months

- **Endoscopic Procedure:**

The systematic screening of stomach is mapping the stomach into 22 sites and pictures of the 22 sites need to be taken and examined carefully to search for any signs of early gastric carcinoma. All the endoscopists follow this protocol while doing endoscopy for screening in a uniform manner.



A-Anterior wall of stomach; *P*-Posterior wall of stomach; *L*-Lesser Curvature of stomach; *G*-Greater Curvature of stomach; *Q*-Quadrant

Figure 1: Systematic Screening of Stomach (SSS) during endoscopy (22 pictures to be taken to map the entire stomach) (picture courtesy; Prof Kenshi Yao, Japan)

- Biopsy during endoscopy:
 - » Tissue biopsy for all suspicious lesion to be taken
 - » All patients who have not undergone H.pylori test to undergo tissue biopsy for rapid H.Pylori test
 - » Biopsy to be examined by the pathologist at the facilities.
 - » Methods to collect the biopsy report: -by the concerned focal person in the centre/ CSO
 - » If the biopsy comes positive: Further evaluation for staging by

CT abdomen and follow up with Oncosurgeon or Oncologist as applicable.

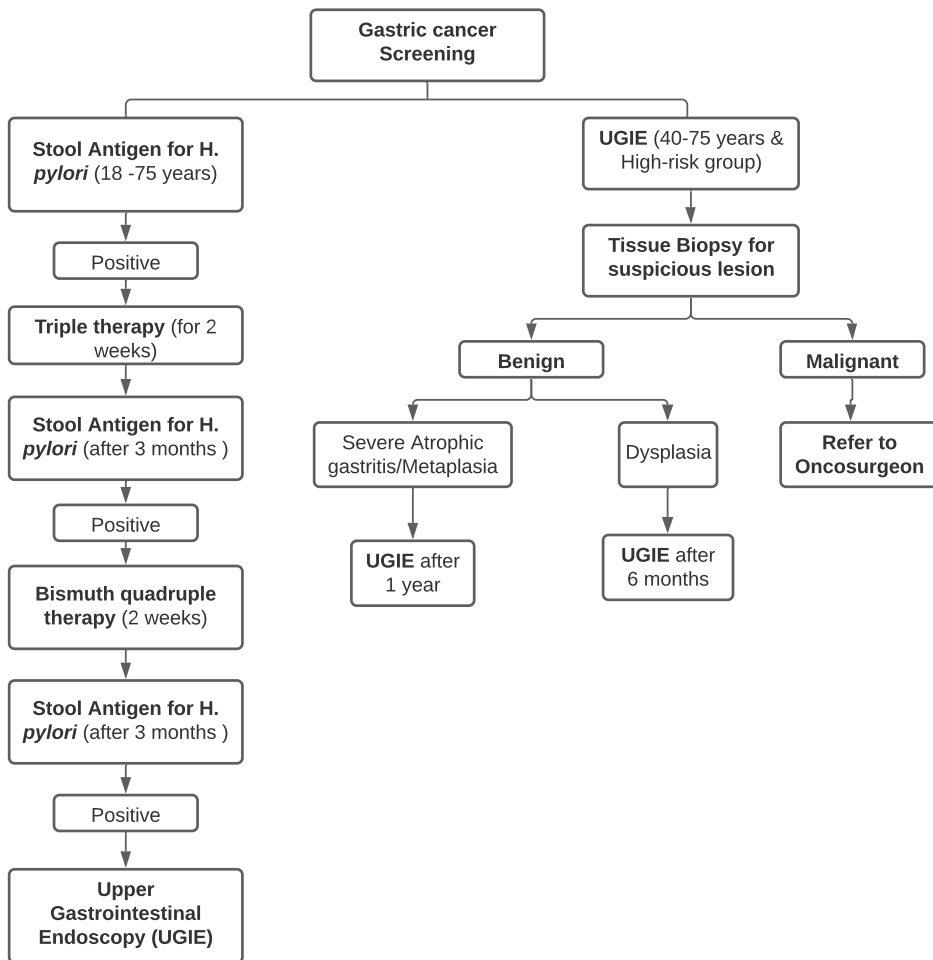


Figure 1: Flowchart for gastric cancer screening

Definitive treatment

a) For H.Pylori positive patients, initiate Triple therapy. Best proven regimen for Bhutan is 14 days duration (CAP Therapy)

1. Clarithromycin 500 mg bd
2. Amoxicillin 1g bd
3. Pantoprazole 40 mg bd

b) 2nd line therapy for patients with recurring positive -duration14 days (quadruple therapy to be avoided in pregnancy)

1. Tetracycline 500mg qid
2. Bismuth Subsalicylate 520mg qid/Bismuth Subcitrate 120mg -one tablet qid
3. Pantoprazole 40mg bd
4. Metronidazole 400mg qid

c) UGIE with biopsy and culture for H.pylori, if resistant to 2nd line therapy

d) For patients with negative biopsy but with suspicious lesions

1. For dysplasia- follow up endoscopy after 6 months
2. For Atrophic gastritis and metaplasia- follow up endoscopy after one year

Resource Requirement:

a) Human Resource

1. Endoscopists
2. Endoscopy nurse
3. Pathologist

4. Histotechnician
5. Receptionist

b) Medical infrastructure

1. Endoscopy set
2. RUT kit
3. Pathology Equipment: Tissue processor; Auto-stainer; Microtome
4. Necessary Consumables

Note:

- Get the consent from the patient before performing the procedure
- Use the requisition for gastric cancer screening
- Detailed patient data must be maintained in the register
- Follow the screening algorithm given in Figure 1
- Refer SOP for early gastric cancer screening

Advocacy programs

- Health advocacies and education must be given to both health workers and the public
 - A. Training and educating health worker on prevention, early detection and treatment
 - B. Public awareness on gastric cancer through National TV programs, National events etc.
 - C. Public education by local health workers and CSOs

BREAST CANCER

I. Introduction

Breast cancer is one of the top cancers in women both in the developed and the developing world. It is estimated over 2.08 million new cases of breast cancer worldwide and 627000 women died in 2018 due to breast cancer (*Source: GLOBOCAN 2018*). The low survival rate in less developed countries can be explained mainly by the lack of early detection programmes, resulting in a high proportion of women presenting with late-stage disease, as well as by the lack of adequate diagnosis and treatment facilities. Currently, breast cancer is the 3rd most common cancer in Bhutanese females with an incidence rate of 6.8 per 100000 population. Breast cancer can affect males also but it is very rare. Amongst the different screening methods available for breast cancer, mammography has been proven to be the most effective. However, it is very costly and is feasible in countries with good health infrastructure that can afford long-term organized population-based screening programmes. Low-cost screening approaches, such as clinical breast examination, could be implemented in limited resource settings. Breast cancer, if detected early and adequately treated, is curable.

II. Risk Factors for Breast Cancer

Several risk factors for breast cancer have been well documented. However, for the majority of women presenting with breast cancer it is not possible to identify specific risk factors (*IARC, 2008; Lacey et al., 2009*)

- Family history of breast cancer , uterine and ovarian cancer
- Genetic predisposition (BRCA1, BRCA2 and p53)
- Early menarche, late menopause, advanced age at first childbirth
- Prolonged (>10 years) use of oral contraceptive and hormone replacement therapy. (*IARC, 2008, Lacey et al., 2009*).

- History of chest radiation
- Modifiable risk factors including alcohol use, obesity, sedentary lifestyle and smoking
- Previous history of breast cancer

III. Prevention and control

Advocacy

- » Control of specific modifiable breast cancer risk factors
- » Early detection
- » Timely diagnosis and treatment
- » Rehabilitation and palliative care
- » Breastfeeding and pregnancy before 30 years has a protective effect (*Source: Helewa M et al.*)

IV. Early detection and diagnosis.

a) Screening: Many women with breast cancer have no symptoms. Therefore, a systematic application of ascreening test in a presumably asymptomatic population is recommended; which aims to identify individuals with an abnormality suggestive of cancer.

b) Early diagnosis: Advocate awareness of early signs and symptoms in symptomatic populations in order to facilitate early diagnosis and treatment.

Following are some of the signs and symptoms of breast cancer;

- Lump/swelling in breast or arm pits
- Pain in the breast or nipple
- Nipple discharge
- Nipple retraction
- Change in skin color and texture of the breast

- Eczema of nipple and or areola
- Breast shrinkage or enlargement

V. Screening Program

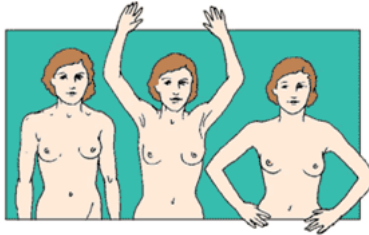
1. BREAST SELF EXAMINATION (BSE)

Breast Self-Exam

1. Examine your breasts in the shower.



2. Examine your breasts in the mirror with your arms down, up, and on your hips.



3. Stand and press your fingers on your breast, working around the breast in a circular direction.



4. Lie down and repeat step 3.



5. Squeeze your nipples to check for discharge. Check under the nipple last.



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Image 1: Breast Self Examination

Note: BSE is recommended for raising awareness among women rather than as a screening method.

2. CLINICAL BREAST EXAMINATION (CBE)

Once the woman has signs and symptoms in the breast, this examination is conducted by a physician.

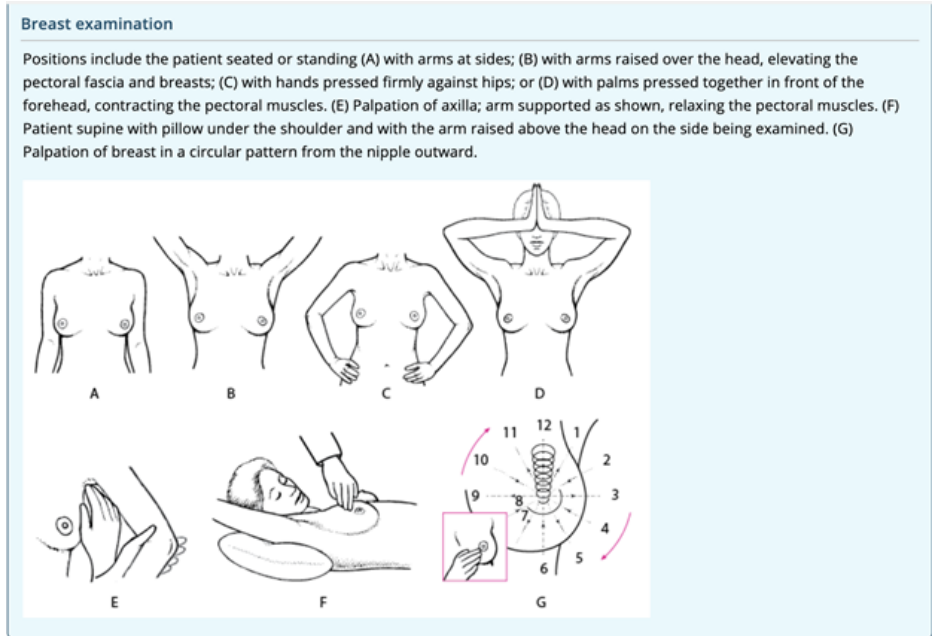


Image 2: Method of Breast Clinical examination

(Picture courtesy: Kosir MA (2018) Evaluation of breast disorders. Merck Manual Professional Version.)

Note: Clinical breast exams are not recommended for breast cancer screening among average-risk women at any age.

3. BREAST CANCER IMAGING

i. Mammography

Mammography screening is the only screening method that has proven to be effective in reducing mortality. Mammography utilizes low-dose X-rays for breast imaging. Regular mammograms can help detect breast cancer at an early stage, when treatment is most successful. A small possibility of being over diagnosed (false positive) exists. It is important that women getting mammograms know what to expect and understand the benefits and limitations of the screening.

a) Target group for mammography:

1. Females aged 40- 65 years without risk factors.
2. Females aged < 40 years with high risk factors
3. Females aged > 65 years with high risk factors

b) Method

i. Mammography to check for microcalcification(s).

- » For benign microcalcification, follow up mammograms every year.
- » For suspicious microcalcification, perform core needle biopsy
- » If malignant, refer to onco-surgeon .
- » When requested by a surgeon, perform wire localization or radio-isotope insertion and refer back to the surgeon for axillary nodal assessment and necessary surgical procedure.
- » After the surgical excision and post surgical treatment, necessary follow up mammography advised as per the surgeon's instructions.

Check list :

- Develop separate requisition and consent forms for breast cancer screening
- Get written consent signed by the patient before performing any invasive procedure
- Detailed patient data must be maintained in the Cancer Registry
- Follow the screening algorithm given in figure 2
- Core needle biopsy and wire localization or radio-isotope insertion to be performed by a Radiologist/Surgeon/Interventionist.
- Breast biopsy is the confirmatory test for breast cancer. Types of Breast biopsies: Fine needle aspiration biopsy/cytology (FNAB/C), core needle biopsy (CNB) and surgical (open) biopsy.
- Axillary lymph node (ALN) and Sentinel lymph node (SLN) biopsy can be performed with CNB or surgical (open) biopsy to rule out spread of disease.

For microcalcification negative, advise patients to practice breast self examination and do follow up mammograms every 6 months for high-risk groups. For the target population (40-65 years), advise a second mammogram after a year and if still normal, every 2 years.

ii. Ultrasonography

Ultrasound is used as an adjunct imaging modality for any breast abnormality. It is useful for looking at some breast changes, such as lumps (especially those that can be felt but not seen on a mammogram) or changes in women with dense breast tissue. It also can be used to re-look at a suspicious area that was seen on a mammogram. Ultrasound can differentiate between fluid-filled cysts and solid masses which mammography can not. Ultrasound can also be used to help guide a biopsy needle into the specific area so that tissue can be taken out and tested for cancer.

iii. MRI

MRI is used in instances where mammography is inconclusive such as in young females with dense breasts and females with difficult breast morphology. Breast MRI may sometimes be used in women already diagnosed with breast cancer, for more detailed assessment of the malignant breast lesion, look for other tumors in the breast, and to check for tumors in the contralateral breast.

iv. CT

Once breast cancer is confirmed by biopsy, CT is done for staging of the disease.

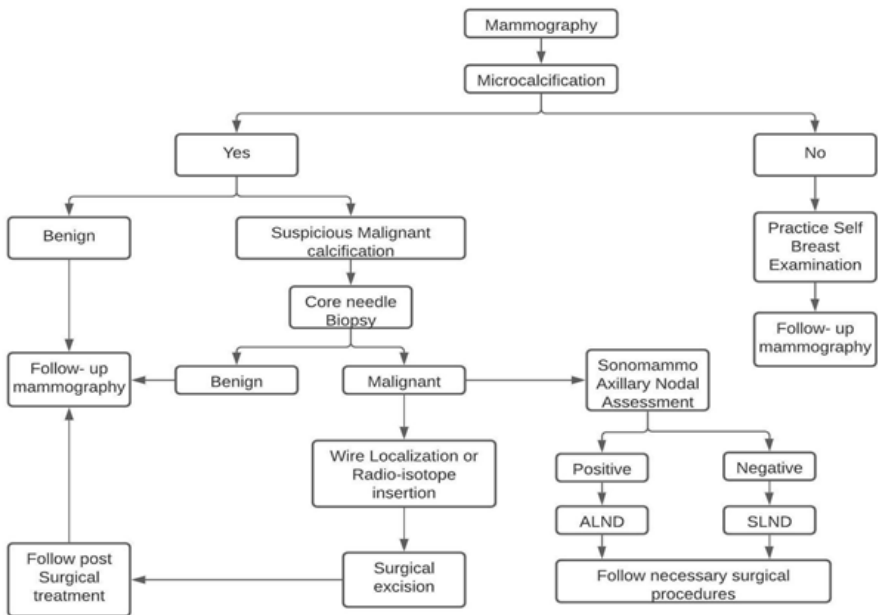


Figure 2: Flowchart for mammo sonography (Breast cancer Screening)

VI. Treatment

Early breast cancer detected on screening needs a less radical surgical approach to treatment. Surgical excisional biopsy is often adequate to treat the early condition while conserving most of the affected breast.

VII. Resource requirement:

a) Medical Infrastructure

1. Digital mammography machine with stereotactic biopsy facility- at least 1
2. USG machine - 2
3. Portable digital mammography machine in large mobile vehicle - 1
4. Portable ultrasound machine - 1
5. Robust Picture Archiving and Communication System (PACS) and electronic Patient Information System (ePIS)
6. Digital printer for films
7. Sentinel lymph node detection hand-held gamma probes (eg. truencode)
8. Intraoperative specimen X-ray (eg. Faxitron)

b) Human resource

1. Radiologist
2. Surgeon
3. Pathologist
4. Radio-technologist/Radio-technician (mammography and ultrasound)
5. Histotechnologist/Histotechnicians
6. Mammography nurse
7. OT scrub Nurse
8. Receptionist

VIII. Advocacy programs

- Health advocacies and education must be given to both Health workers & Public.

(a) Health workers

- » Training on breast health advocacy
- » Training on performing screening mammography
- » Training on Mammography interpretation.
- » Training on stereotactic biopsy

(b) Public

- » Public awareness on breast cancer through National TV programs, National events, other media etc.
- » Training of village health workers, local leaders and CSOs regarding breast health
- » Public advocacy by village health workers, local leaders and CSOs regarding breast health
- » Promote breast self examination
- » Promote exclusive breastfeeding

CERVICAL CANCER SCREENING

I. Introduction

Worldwide, cervical cancer ranks as the fourth most frequently diagnosed cancer and also the fourth leading cause of cancer deaths in women. In the year 2018 there were 5,69,847 new cases (*Source: Globocan 2018*). It is the most frequent cancer diagnosed among Bhutanese women with peak incidence in women at 40-49 years of age. PBCR 2014-18 shows an age adjusted incidence rate of 20.5/100,000 and mortality rate of 5.3 per 1000,000 women in Bhutan.

Bhutan has had a cytology-based screening program with conventional Pap smear since 2006, but the STEPS survey in 2019 showed 60% coverage only. Besides, sensitivity to detect CIN III with conventional Pap smear is only 50%. According to WHO, to eliminate cervical cancer, 90% girls must be vaccinated, 70% of women must be screened with a high precision test like HPV testing and 90% of women with pre-cancers and cancers must be treated. More than 90% of our young women are covered by HPV vaccine. For vaccinated women, HPV testing should be the primary screening method with cytology either as triage for HPV positive women or as co-test. When these 2 methods are used, screening intervals can be increased to 5 years.

II. Risk Factors

- Early age at sexual debut
- Early age at first child birth
- Multiple sexual partners.
- Multiparity
- Smoking
- Immuno-suppression

- Prolonged OCP use

Symptoms of cervical cancer

- Cervical cancer is frequently asymptomatic in the very early stage of the disease.
- Abnormal vaginal bleeding – It can be inter-menstrual, postcoital, postmenopausal or a woman may have just heavier and more prolonged menstrual flow than usual.
- Excessive or foul-smelling vaginal discharge may be there due to superadded infection of necrotic tissue.
- There may be urinary frequency, urgency and backache.
- In advanced cases, there may be:
 - Pain in the pelvic region and/or lower limbs
 - Swelling of lower limbs
 - Renal failure in late stages
 - Passage of urine and faeces per vagina (fistula formation)

III. Prevention

1. Primary prevention with HPV vaccination
2. Secondary prevention with cytology, visual tests and HPV DNA tests

IV. Cervical Cancer Screening Program

- a) Types of screening
 1. Visual test
 2. Pap-smear screening/Cytology
 3. HPV DNA testing:

Cervical cancer is a rare complication of HPV infection. HPV is a common STI in young sexually active women, but in most, it is cleared in the next

2-3 years by host immunity. In 10-20% of women, HPV persists and leads to development of precancerous lesions. Screening helps to detect these pre-cancers. HPV testing has higher sensitivity in detecting CIN II/III lesions compared to cytology. It detects more than 90% of CIN II/III and invasive cancers. It is less specific in young women and should not be used as a screening method in women younger than 30 years. It has higher negative predictive value with longer protection against cancer which translates to increased screening interval (5-7 years compared to 3 years in cytology).

b) Method of screening

- HPV testing with/without genotyping: as primary screening method for women 30-65 years old women with reflex LBC for HPV positive women.
 - The screening algorithm is given in the flow chart (Figure 3)
 - Liquid based cytology for women between 25-29 years old as primary screening (for whom the HPV testing is not recommended as the primary screening), with HPV testing as for high risk types as triage for borderline smears (ASCUS/LSIL) (Figure 4).
-
- » HPV DNA testing on vaginal or cervical sample
 - » If negative for HR- HPV, repeat HPV DNA test after five years. If positive for High-risk HPV (HR-HPV), do reflex cytology or genotyping.
 - » For abnormal cytology or positive for HPV 16/18 genotype, refer for colposcopy and accordingly give a treatment
 - » For normal cytology, repeat HPV DNA test in 12 months and if positive for HR-HPV, refer for colposcopy and give treatment accordingly.
 - » If negative for HR-HPV, repeat HPV DNA test after five year.

- **Handling of sample for HPV testing**
- » A cervical or vaginal sample must be collected with a special brush and immersed in the medium. Samples may also be collected by women themselves at home (self sampling).
- » Samples can be stored and transported without cold chain if ambient temperature is less than 30 degree centigrade. In hot places, samples are stored and transported in cold boxes or vaccine carriers
- » Genotyping, reflex cytology (LBC) can be done using the same sample used for HPV test. So samples are not discarded whatever test is done.

Note:

- HPV testing or LBC should not be done in menstruating women.
- In pregnant women, do HPV testing/LBC 6 weeks after delivery/ miscarriage
- Women who had hysterectomy for reasons other than CIN or cervical cancer need not do HPV testing. Her HPV report of hysterectomy should not have CIN II/higher.
- Management of women with abnormal cytology results will be done as per ASCCP guidelines
- For women where HPV testing is not recommended as the primary screening, follow the method given in flow chart (Figure 4)

VI. Treatment

Method of treatment of pre-cancers are:

a) Ablative methods

1. Cryotherapy
2. Thermocoagulation

b) Excisional method

1. Loop electrosurgical excision procedure (LEEP)
2. Cold knife conization (CKC)

Note: Hysterectomy is reserved only for those women not eligible for above procedures

VII. Resource Requirement

a) Medical Infrastructure/Supplies

» For HPV testing

1. HPV DNA testing platform/machine
2. HPV Reagent
3. Sample collection medium and cyto-brush
4. Gloves and mask
5. Hand sanitizer
6. Chlorine solution
7. Waste disposal bags
8. Screening cards, registers and requisition/record forms

» For Liquid based cytology (LBC)

1. LBC processor/machine
2. LBC Reagent

3. Sample collection medium and cyto-brush
4. Registers /report form
5. Different Stains
6. Ethanol
7. Clearing agents
8. Mountant
9. Slides and cover slip

» **For Colposcopy**

1. Colposcope
2. Mini-bite biopsy forceps
3. Bivalve speculum
4. Sponge holding forceps
5. Instrument tray
6. Gloves
7. Swab sticks
8. Normal saline
9. Acetic acid
10. Lugol's iodine
11. Monsel's solution
12. Formalin
13. Chlorine
14. Biopsy vials

» **For Cryotherapy**

1. Cryo gun
2. Cryo-probe of different sizes
3. Carbon Dioxide or Nitrous oxide cylinders and wrench

4. Bi-valve speculum of different sizes
5. 5% Acetic acid/Lugol's iodine to demarcate lesions
6. Water soluble lubricant gel
7. Stopwatch/wall clock

» **For Thermocoagulation**

1. Thermocoagulator
2. Thermo-sounds of different sizes

» **For Loop electrosurgical excision procedure (LEEP)**

1. Cautery machine
2. Smoke evacuating speculum
3. Sponge holding forceps
4. Long tissue forceps (non toothed)
5. Dental syringe
6. Loop electrodes of different size
7. Ball cautery
8. Monsel's solution
9. 5% acetic acid or Monsel's solution
10. Local anaesthetic drugs
11. Spinal needles (23/24G sizes)

» **For Cold knife conization (CKC)**

1. Sim's speculum
2. Sponge forceps
3. Long suture cutting forceps
4. Long needle holder
5. Endocervical curette

6. Uterine sound
7. Knife handle
8. Syringe (5/10 ml)
9. Spinal needle (23/24G)
10. Adrenaline/Epinephrine
11. Suture
12. No. 11 blades
13. Monsel Solutions

b) Human Resource

- i. Gynecologist
- ii. Pathologist
- iii. Nurse
- iv. Cyto-technologist/technician
- v. Histo-technologist/technician

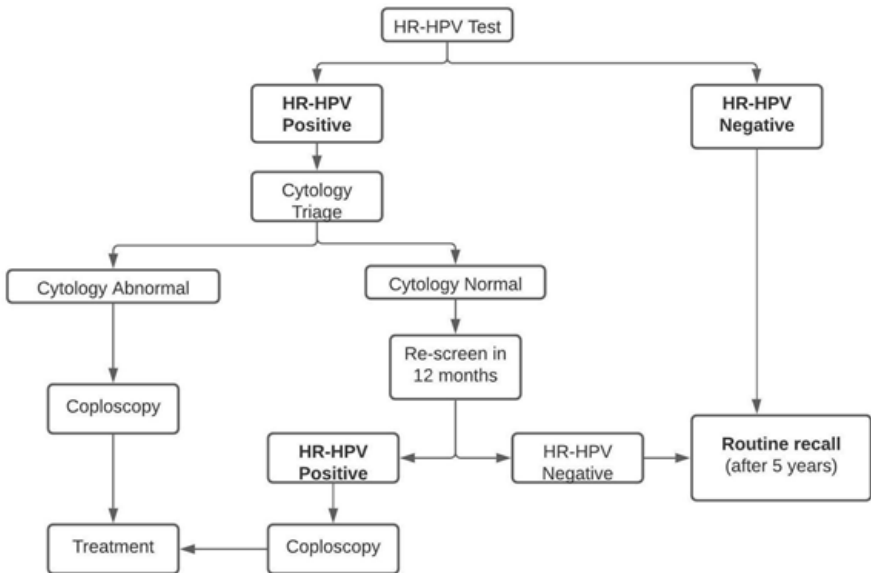


Figure 3: Flowchart for cervical cancer screening (with HPV testing)

system)

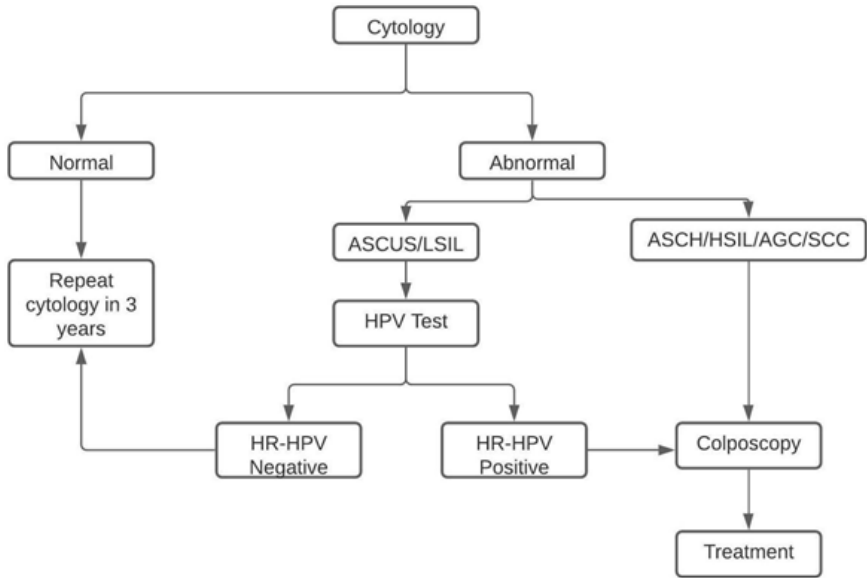


Figure 4: Flowchart for cervical cancer screening (for age 25-29 years old)

Note:

- Get the consent from the patient before performing the procedure
- Use the requisition for breast cancer screening
- Detailed patient data must be maintained in the register

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