NATIONAL GUIDELINE FOR

CERVICAL CANCER
SCREENING PROGRAMME
Introduction
Cancer of the cervix is the second most common form of cancer amongst South African women. Approximately one in every 41 women will, within their lifetime, develop this form of cancer. Papanicolaou smears (Pap smears) to detect cervical abnormalities are the best known form of secondary prevention.

Population-based screening programmes, even in countries where screening is less than perfect, has significantly decreased the incidence of cervical cancer in large parts of the world. There are few examples of screening programmes in less-developed countries. The success of screening programmes is dependant on good attendance rates by women at high risk. The best predictor of high risk is age. This policy reflects the best attempt to reduce the incidence and mortality of cervical cancer by more than 60% within the resources available.

Natural history of the disease
Cancer of the cervix is now thought to be associated with certain strains of a sexually transmitted virus, human papillomavirus. The role of other sexually transmitted infections is unclear. To date studies on the association between invasive cancer of the cervix and HIV infection are inconclusive. Other related risk factors include early age of onset of sexual intercourse and parity.

Cancer of the cervix develops over time from a precursor lesion which, although seemingly invisible to the naked eye, can be diagnosed by special investigations (cervical cytology). Progression of the disease is slow and may take as long as 10-20 years before the disease becomes invasive.
Younger women (under 30 years of age) tend to present with a milder degree of precursor and there is evidence that the majority of these low-grade lesions will spontaneously regress to normal.

A new classification, the Bethesda system, has been introduced whereby the precursors are named squamous intra-epithelial lesions (SIL), which are divided into low-grade SIL (similar to CIN I) and high-grade SIL (for CIN II and CIN III).

In older women, however, the regression rate decreases, resulting in lesions that are more likely to progress to high-grade precursors and ultimately to cancer. The mean age of patients with high-grade SIL is approximately 30 years, whilst the time interval for the progression to cancer is approximately 10 years. The fact that the precursor stage develops slowly (10-20 years) implies that a single smear performed within this period will diagnose the disease should the smear's sensitivity be adequate. Therefore, when reducing the number of smears per lifetime, a serious attempt must be made to ensure the highest possible sensitivity.

The success of the screening programme in reaching its aims is dependent on achieving adequate coverage. While the screening programme will be introduced incrementally depending on health service capacity, the ultimate goal is to screen at least 70% of women, nationally, within the target age group within 10 years of initiating the programme.
MANAGEMENT OBJECTIVES

- to reduce the incidence of carcinoma of the cervix, primarily by detecting and treating the pre-invasive stage of the disease
- to reduce the morbidity and mortality associated with cervical cancer
- to ultimately reduce the excessive expenditure of scarce health funds currently spent on the treatment of invasive cancer of the cervix

TARGET POPULATION FOR SCREENING
Women 30 years and older.

HEALTH SERVICE TARGET
Primary level health-care facilities with adequate infection control and quality assurance measures in place.

MANAGEMENT

PRIMARY PREVENTION
Primary prevention is supportive of efforts to increase public knowledge and the ability of individuals to make healthy lifestyle choices as well as creating environments that assist individuals in making healthy choices.

Women should:

1. Stop smoking or preferably never start smoking. There is evidence that women who smoke are more susceptible to cervical cancer than women who do not smoke.
2. Use barrier methods during intercourse to prevent the spread of the human papillomavirus and other sexually transmitted diseases.
3. Postpone sexual activity to older age.
4. Effectively manage sexually transmitted diseases.
5. Decrease parity.
SECONDARY PREVENTION
Secondary prevention aims at detection and treatment of precursors. Cervical cancer is one form of cancer that can be prevented.

1. SCREENING
1.1 General

- Cervical cytology (Pap) smear is proposed for the programme.
- Three (3) free smears per lifetime are proposed.
- Women screened for the first time at age 55 or more will have only one smear if first smear is normal.
- A woman with an inadequate smear should be re-screened. If the second smear is also inadequate, the patient should immediately be referred to a known competent screening service.
- A smear as a diagnostic investigation is not regarded as an element of the screening programme.
- Should more than three smears be requested by a woman, the extra cost will have to be carried by her.

1.2 Screening Interval Options

Women aged 30 years or older will be screened three times in succession, utilising cervical cytological (Pap) smears.

The World Health Organisation (WHO) supports the concept of reducing the number of smears per women per lifetime in favour of more women in the population having fewer smears.
<table>
<thead>
<tr>
<th>Number of years between Pap smears</th>
<th>Total number of smears per lifetime</th>
<th>Reduction in cumulative incidence of cervical cancer (%)</th>
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<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>94</td>
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<tr>
<td>3</td>
<td>10</td>
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<td>64</td>
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The WHO has recommended a minimum requirement of one (1) adequate smear per lifetime in women older than 35 years of age.

Based on the above, the Department of Health proposes three (3) smears per lifetime, with a 10-year interval between each smear, commencing at not earlier than age 30 years.

1.3 Referral Criteria

- A referral system to be in place.

- Clients with a normal smear to be informed of next smear date, according to the proposed programme.

- Clients with atypical smears:
  - Low-grade SIL and atypical squamous cells (ASCUS): repeat the smear in 12 months’ time. If the diagnosis remains the same or worsens, the patient is to be referred to a colposcopy clinic. If negative on the second smear, the client will fall into the normal screening cycle.
  - High grade SIL and/or atypical endocervical (glandular) cells (AGUS): refer to a colposcopy clinic. If negative on colposcopy and cytology, the client can be discharged. If positive, treat.
Any patient with a macroscopically suspicious lesion, whatever the cytological result may be, should be referred for colposcopy.

1.4 Follow-up Criteria

- An effective follow-up system to be in place.
- Screened women to be informed to return to the specific screening facility to obtain the result. The time lapse between screening and follow-up should be 1-4 weeks, depending on circumstances. Every attempt possible to be made to find those patients with positive results who do not return voluntarily. This responsibility rests with the provider institution of the cervical screening service.
- Patients who do not keep their appointments at colposcopy clinics to be traced by the original screening institution.

2. QUALITY ASSURANCE AND INFECTION CONTROL

2.1 Quality Assurance

The adequacy rate of a screening facility is to reach at least 70%. Cytological laboratories to audit and control the proportion of adequate smears from each screening facility and inform the facilities of adequacy rate. Should a facility consistently achieve below 70% adequacy, the staff is to be retrained.

NB: An adequate smear should contain both ecto- and endo-cervical cells, cervical mucus and minimal amounts of blood, pus and debris. The Aylesbury spatula is the recommended screening device.

2.2 Infection Control

Refer to Annexure A.
INFECTION CONTROL RELATED TO HUMAN PAPILLOMAVIRUS (HPV)

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

HPV is a very stable, hardy virus, and therefore more difficulty is experienced in sterilizing instruments adequately, e.g. vaginal specula used in Pap smear collection. This virus is not enveloped and the methods aimed at dissolving lipid envelopes are unlikely to be effective in sterilization procedures. It has been found that HPV is relatively resistant to ether and acids.
EFFECTIVE DISINFECTION OPTIONS FOR HPV

General
Clean non-disposable instruments/specula thoroughly in hot water with soap and a brush. Cleaner must wear gloves for own protection. Splashes of water should be avoided as HPV may possibly be transmitted to staff in this manner.

Options in order of preference
1. **Single-use disposable instruments/specula are the preferred option.**
2. Instruments/specula to be autoclaved (small autoclaves are available and are appropriate for use in clinics) at 121 °C at a pressure of 15 psi for 15-20 minutes. This is the ideal method of sterilization.
3. Boiling at 100 °C for 60 minutes is effective, **but** care is necessary to ensure that items are **completely immersed** and that the instrument is exposed to boiling water for the **required time**. The boiling water bath should preferably have a **timing mechanism** or else an alarm clock can be used.
4. The use of chemical disinfectants are not recommended.
The Department of Health wishes to thank all the people who were involved in the development of the National Guideline for Cervical Cancer Screening Programme.

Special thanks to the following stakeholders:

- National and provincial colleagues within the Department of health
- The South African Institute for Medical Research
- Women's Health Project
- Cancer Association of South Africa
- National Institute for Virology
- Medical Schools