NATIONAL GUIDELINES

FOR

CERVICAL CANCER

PREVENTION AND CONTROL

Ministry of Health
Jamaica

August 2011

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Director, Health Promotion and Protection

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Director, Health Services Planning and Integration

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Chief Medical Officer

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NATIONAL GUIDELINES

FOR

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PREFACE

The National Guidelines for Cervical Cancer Prevention and Control came about as a result of the work of various dedicated persons and with the input of specialists in the field of obstetrics and gynecology. This protocol had been going through stages of development since 2002 and presents a set of best practices for the Jamaican situation.

The guidelines ensure that health professionals in the public health system, who are concerned with the prevention and control of cervical cancer, are guided by a standard modus operandi. The message is that cervical cancer is preventable and therefore no woman should die from it.

As ongoing measures are employed to strengthen the Cervical Cancer Prevention and Control programme, the use of this protocol by health professionals should positively impact the rates of cervical cancer screening, and the management of abnormal pap smears should significantly improve. This will rebound in the fight against non-communicable diseases, in particular, cervical cancer.

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INTRODUCTION

INTRODUCTION

Cervical cancer has a major impact on the lives of women worldwide, particularly those in developing countries. According to the latest global estimates, 493,000 new cases of cervical cancer occur each year among women, and 274,000 women die of the disease annually. About 83 percent of new cases are in developing countries; in most of these countries, cervical cancer is the leading cause of cancer deaths among women.

This is due in part to the lack of effective screening programmes to:

- Detect Cervical Cancer before it becomes clinically apparent
- Detect pre-cancerous changes of the cervix in need of treatment
- Treat and/or refer and follow up all women who need further investigation or treatment before they progress to invasive cancer
- Prevent deaths from Cervical Cancer

The regions hardest hit by cervical cancer are among the world's poorest. Central and South America, the Caribbean, sub-Saharan Africa, parts of Oceania, and parts of Asia have the highest incidence rates—over 30 per 100,000 women. These rates compare with no more than 10 per 100,000 women in North America and Europe. Incidence rates are reported to be 69 per 100,000 in Tanzania, 55 per 100,000 and in Bolivia, from Cervical Cancer.

If it is not detected and treated in a timely way, cervical cancer is nearly always fatal. In developing countries, mortality rates are reported at 11.2 per 100,000 women on average; almost three times the rate of developed countries.

Cervical Cancer is the second most common type of cancer among Jamaican women (Cancer Registry in Kingston and St. Andrew 1993-1997). It is surpassed only by breast cancer. The Age-Standardized Rate (ASR) is 25.2/100,000 women. This is better than the figure of 34.8/100,000 among Caribbean women in the year 2000 and for South and Central America, Eastern Africa, and Western Africa with more than 40/100,000, but high when compared with North America, Northern and Western Europe, Australia, New Zealand, Cuba and China with under 10/100,000.

Cervical Cancer is preventable and is usually curable if found and treated early. Where Pap smear screening is well organized and women are screened at regular intervals, cervical cancer incidence can be reduced dramatically. Well-organized cervical cancer programmes can reduce the incidence and mortality by at least 60%, to a maximum of 80%. In Iceland, a national programme for cervical cancer screening that was launched in 1960 reached almost all women in the country and resulted in an 80 percent decrease in cervical cancer deaths over a 20-year period. In the United States, where coverage is less comprehensive, the cervical cancer death rate decreased by 70 percent in the 50 years after screening was introduced.

NATURAL HISTORY

NATURAL HISTORY

The most current models for the natural history of Cervical Cancer suggest that the direct precursor of cervical cancer is high-grade dysplasia, which can progress to cervical cancer over a period of up to 10 years. Most lower grade dysplasia regress or do not progress, particularly lower grade incident cases in younger women.

Human Papilloma Virus (HPV) which is a common sexually transmitted infection is the primary underlying cause of Cervical Cancer. Less than 5% of women infected with HPV ultimately develop Cervical Cancer if they have no access to treatment. However, certain types of HPV are more strongly associated with Cervical Cancer and persistent HPV infection tends to lead to high grade dysplasia and cancer. There are some factors which may influence whether a woman with dysplasia is likely to develop Cervical Cancer. These include:

- Smoking
- Immune Suppression, particularly related to HIV infection
- Some hormonal factors, such as use of hormonal Contraceptives
- High parity
- Increased number of lifetime partners

Other risk factors like age, first intercourse and number of sexual partners may more likely be related to HPV exposure.

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SCREENING FOR CERVICAL CANCER

SCREENING FOR CERVICAL CANCER

When to Initiate Screening?

The incidence of invasive cervical cancer in the <25 years age group is very low in most countries. It increases at about age 35-40 years and reaches a maximum at about age 50 to 60 years. The Jamaica Lifestyle survey 2008 indicated that 34.3% of women 15-74 years old had never had a pap smear.

- Cervical Cancer Screening should begin within 3 years after a woman begins sexual activity.

There is no evidence to support Cervical Cancer screening in women less than 18 years of age.

Target Population and Frequency of Screening

Cervical Cancer most often develops slowly from pre-cancerous lesions. Screening can therefore take place relatively infrequently and still have significant impact on morbidity. The target age group is women 25-54 years, especially those who have never been screened.

- Women in the 25-54 years age group who have had 2 consecutive normal Pap test results should test every 3 years to age 65 years.
- Screening may be discontinued at age 65 if the following criteria are met: the woman has been regularly screened, has had two satisfactory smears, and has had no abnormal smears within the previous nine years. For all women over age 65 who have not been previously screened, three normal annual smears should be documented prior to discontinuation of screening. Mathematical modeling estimates suggest that screening past age 65 is inefficient and may be discontinued in women who have a history of regular negative smears.
- Recommendation may be made for more regular Pap test if a woman has certain risk factors e.g. HIV infection or a weakened immune system.
- Recommend: Annual Pap smear unless otherwise indicated.

POTENTIAL REDUCTION OF CERVICAL CANCER RATES WITH DIFFERENT SCREENING FREQUENCIES

Frequency of Screening	*Percent Reduction in Cumulative Rates*
1 year	93
2 years	93
3 years	91
5 years	84
10 years	64

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SCREENING IN SPECIAL CIRCUMSTANCES

SCREENING IN SPECIAL CIRCUMSTANCES

SITUTATION	ACTION
Post hysterectomy with HSIL as an incidental finding	
Subtotal (supra-cervical) hysterectomy	Cervical smears should be taken at the same interval as is recommended for women without hysterectomy
Total hysterectomy for benign disease	If there is no past history of dysplasia screening is not recommended
Post hysterectomy for HSIL	Vaginal vault smears at the same interval that is recommended for routine screening (e.g. every years)
Post radical hysterectomy to treat uterine or ovarian cancer	Annual vault smears for 5 years after surgery to help detect any recurrence. If all smears are negative, vault smears should be done at regular intervals (every three years)
Post radiotherapy for cervical cancer	Pap smears are not recommended (within 6 months of last treatment)
HIV–infected women	Screen every 12 months.

Referrals for HIV infected women	All HIV –positive women with abnormal cytology (ASCUS and above) should be referred for gynaecological evaluation.
Women who had a hysterectomy but have an immune system disease (such as HIV/AIDS) or are taking medicines to suppress the immune system	Women who are immunosuppressed should have pap smears every 12 months and thereafter for life.
Women age 70 years and older who have never had a Pap test	Women over 70 years old who have never had a Pap test should have one Pap test. If this is normal, the determination of subsequent screening is on an individual basis.
Abnormal Pap smear in Pregnancy	Women who were unscreened should be screened at the prenatal visit.
HSIL, CINII & III.	Refer for Colposcopy.

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TAKING A PAP SMEAR

TAKING A PAP SMEAR

Methodology

1. Inform client on the purpose of the Pap smear and the procedure.
2. Vaginal suppositories. Creams and foams should be avoided for one (1) week before the examination
3. Women should not have sexual intercourse, or douche the day before Pap test.
4. The best time to schedule a Pap test is between menstrual periods.
5. Record all patient information required on the cytology request form. Ensure that carbon paper is placed correctly to complete the information in duplicate.
6. Secure Ayre spatula, or sponge forceps, cotton balls, cytofixative, transport box, glass slide, pencil, bivalve speculum and adequate lighting.
7. Print the name of the patient legibly at the frosted end of the clear glass slide.
8. Explain the procedure for pelvic examination to the patient.
9. Take the Pap smear before digital vaginal examination.

Use of the cytobrush is not recommended during pregnancy. A spatula should be used.
It is not necessary to terminate pregnancies in order to treat pre-invasive disease.

Procedure

1) Moisten a bivalve speculum with water or a small amount of water-based lubricant (e.g. K-Y Jelly). Do not use oil-based lubricants because they may cause cell clumping on the slide and interfere with cytological screening.
2) Label slide immediately to clearly identify the woman from whom the sample is taken (e.g. name and registration number). These should match the information on the registration form

3) Place speculum in the vagina gently until the cervix is adequately exposed.
4) Use sponge forceps with cotton (if required) to remove excess cervical mucus by a gently swiping motion.
5) Place Ayre spatula so that the longer wing is inserted into the external os.
6) Rotate through 360 degrees using a little pressure so that the surface cells of the ectocervix are retained. For an optimal test endocervical cells as well as squamous cells must be included.
7) Apply smear in middle of glass slide with one motion. Care should be taken that the smear is not too thick, not air dried, not too bloody.
8) Fix smear by using the spray fixative held 15 to 20 cm away from the slide. When the aerosol is held too far from the slide an inadequate amount of fixative reaches the surface, and drying distortion results. If the spray is held too close to the preparation, the cells may be distorted as a result of freezing due to low temperature of the solvent as it rushes from the nozzle. Alternatively, the smear may be fixed in fresh 95% alcohol.
9) All smears should be dispatched with their accompanying request forms to the laboratory as soon as possible.
10) Give the client a return date of six (6) weeks.

The Pap smear should be taken in a manner consistent with the standards required for any gynaecological examination.

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PAP SMEAR REPORT – COMPLETING THE FORM, STRUCTURE AND INTERPRETATION

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MANAGEMENT OF ABNORMAL PAP SMEARS

MANAGEMENT OF ABNORMAL PAP SMEARS

Result	Management
Unsatisfactory	Repeat Pap smear in 6 weeks. If there are two (2) consecutive unsatisfactory smears refer for colposcopy.
Negative for Intraepithelial	Satisfactory Smear-routine screening every 3 years.
Lesion or Malignancy (NIL)	Satisfactory with qualifiers – Where there are inflammatory changes, if the pathogen is identified, treat the infection. If no specific is identified, there should be syndromic management of discharge.
LSIL (Low Grade Squamous Intraepithelial Lesion)	Repeat smears every 6 months for 2 consecutive years (4 smears); if any of these smears is ASC-US or worse, refer for gynecological evaluation. If smears in follow-up period are all NIL return to routine annual screening months.
ASC-H	Refer for gynecological evaluation consideration for colposcopy.
HSIL (High Grade Squamous Intraepithelial Lesion)	Refer for gynecological evaluation with consideration for colposcopy

Result	**Management**
Women with HSIL, ASC-H or glandular abnormalities	Gynecological evaluation within 6 weeks of receipt of the abnormal Pap smear results.
Invasive Cancer	Refer to hospital for specialist care.

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ABNORMAL PAP SMEAR IN PREGNANCY

ABNORMAL PAP SMEAR IN PREGNANCY

LSIL	Re-assess after delivery by repeating Pap smear at six weeks after delivery and treat according to results.
HSIL	Colposcopy without cervical biopsy; if not invasive, treat after delivery. Visual inspection with Acetic Acid (VIA) may also be done with punch biopsy or observe until after delivery, where colposcopy is not available.
Reactive, atrophic and inflammatory	Repeat at the normal interval.
Changes suggestive of HPV but no CIN	Annual pap especially in young women.

It is not necessary to terminate a pregnancy or to do a delivery by a C-Section for the pre-invasive disease.

All clients with a positive test, indicating result must be referred for diagnostic investigations and appropriate treatment. Early diagnosis and treatment will increase the possibility of a cure.

When the diagnosis is confirmed, it is necessary to further assess the patient to determine the extent to which the cancer has spread the appropriate therapy and when therapy should be stopped.

There are various approaches to treatment, the specific approach will be determined by availability of human, physical and financial resources bearing in mind that the aim is to facilitate rehabilitation and the objectives of treatment are to:

- Cure the cancer
- Prolong useful life
- Improve quality of life.

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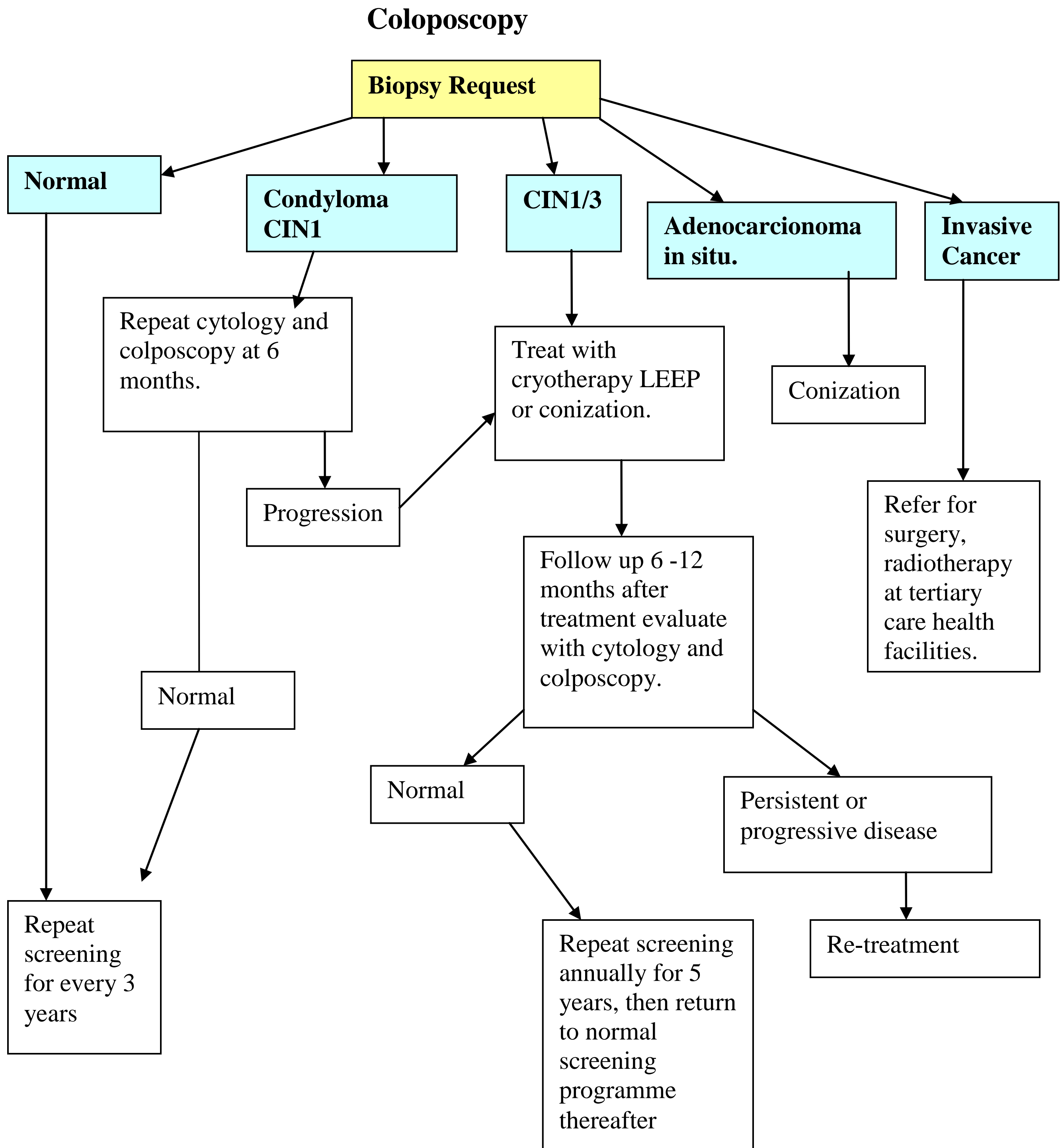
GUIDELINES FOR REFERRAL

Coloposcopy



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INDICATIONS FOR COLPOSCOPY

INDICATIONS FOR COLPOSCOPY

1. Pap smear showing High Grade Squamous Intra-epithelial Cell Lesion (HFSIL) – CIN II, CIN III.

2. More than two (2) consecutive ASCUS.

3. Any two abnormal pap smears done at 6 monthly intervals in a 2-year period.

4. A single Pap smear showing ASCUS or low grade SIL in a patient who is non- compliant.

5. Persistent inflammation after treatment of proven infection. Most Pap Smears especially in women who have children will show inflammatory changes, without any infection requiring treatment

6. Unexplained cervical lesion, regardless of Pap smear result.

7. Unexplained or persistent cervical bleeding regardless of Pap smear result.

8. Atypical glandular cells (especially in post-menopausal women) will need endocervical curettage (ECC).

9. *Note:* Colposcopy is strongly indicated in young women, in order to avoid invasive procedures that may affect fertility. Any hospital that has no colposcopy can proceed to cone biopsy in women who have completed their childbearing years.

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FOLLOW-UP AFTER COLPOSCOPY

FOLLOW-UP AFTER COLPOSCOPY

Biopsy proven low grade squamous intra epithelial lesion – LGSIL

Adequate colposcopy/lesion entirely seen	Follow up Pap smears every 6 months x 3 If all smears negative and satisfactory.
	Return to routine screening interval

Note: Adequate colposcopy includes cells from the transformation zone.

Any abnormal smears or patient not complaint	Colposcopy and Cryosurgery or Loop excision
	Repeat Pap smear at 6 and 12 months. If both smears are satisfactory and negative, and:
Excisional treatment was offered	Return to regular screening interval
Ablative treatment was used	Repeat Pap smear at 6 monthly interval for one more year.
a. Inadequate Colposcopy-Lesion not entirely seen	Cone Biopsy or Loop Excision
	Repeat pap smear at 6 monthly intervals for 2 years. If all smears are negative and satisfactory, return to regular screening interval.
b. Biopsy proven high grate intra epithelial lesion …HGSIL If the colposcopy is considered inadequate	Follow up by Loop excision or Cone biopsy if lesion is not entirely seen or repeat Pap smears.

Repeat pap smear at 6 monthly intervals for 2 years If all smears negative and satisfactory return to regular screening interval

c. Invasive Cancer of Cervix

Refer immediately to Oncologist or Gynecological Clinic for intervention. Ensure active follow-up of cases

Tracking

After treatment, clients should be monitored by their health facility and all services, intervention and outcome documented, including entries in the cervical cancer register and submitting timely reports.

Education/counseling of client and family members should precede referral to provide information, relieve anxiety, clarify issues and allow for informed choice.

Clients must be followed up by the referring health facility to ensure that she has in fact carried through the appointment for care. To effect follow-up care, referrals should be made through the existing referral systems from primary care or family physician for specialist care and back to primary care provider with regular reviews by specialist as needed.

Referral for palliative care must also be considered where necessary.

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WHERE SERVICE CAN BE PROVIDED

WHERE SERVICES CAN BE PROVIDED?

- Health Clinics and Centres
- Hospitals
- Private Physician's offices
- Jamaica Cancer Society
- Satellite clinics or outreach programmes – health fairs with clinical facilities, at workplace, mobile units.

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SERVICE STANDARDS

SERVICE STANDARDS FOR CERVICAL CANCER SCREENING USING "PAP SMEARS"

Introduction

It is to be recognized that all who come in contact with persons seeking health care has a responsibility to facilitate such a request. Further, that the actions of all those who come in contact with persons seeking care impact significantly on the standard of care offered and received. Therefore these service standards are intended to apply to individuals and facilities offering and or performing "Pap smears" as a part of a cervical cancer screening programme.

General requirements

Persons or facilities offering and or performing "pap smears" should:

1. Inform themselves of the National Guidelines for Cervical Cancer Screening
2. Ensure that all employers be informed about the National Guidelines for Cervical Cancer Screening as appropriate
3. Be able to meet the general requirements for the performance of a gynaecological examination
4. Have appropriate facilities for securing the personal data of clients with the intent of preserving the confidentiality of such information
5. Have in place arrangements for the reading of the "pap smear" with a reasonable turn around time (suggested not more than 3 months from date of creation of the smear)
6. Have in place a system of follow up of "smears" submitted for evaluation to ensure receipt of results
7. Have an established system for recall of patients for results and reminders
8. Have an established system for referral where this is necessary

<u>Special requirements</u>

1. The individual performing the procedure should have training in the taking and preservation of the sample
2. The individual performing the procedure, where not a registered physician, should have access to such an individual if necessary
3. The person or facility offering "pap smears" should have a facility for the sterilization of reusable equipment used in the procedure where this is applicable
4. Where 95% alcohol is used as a preservative the facility should have a safe and secure storage facility for this product
5. The person performing the procedure should be trained in the interpretation of the results or where not so trained, have easy access to a person so trained

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INTERPRETING HISTOLOGY

GUIDELINE: INTERPRETING HISTOLOGIES		
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FREQUENTLY ASKED QUESTIONS

FREQUENTLY ASKED QUESTIONS

What is cervical cancer?

Cervical cancer is a disease in which some cells in the cervix (the lower, narrow end of the uterus that opens into the vagina) display abnormal, uncontrolled growth and can damage healthy parts of the body. Cervical cancer is a major cause of death among women aged
40 years over, but can be prevented.

How can I prevent cervical cancer?

You can have a Pap smear screen done at least once every three years. Screening can help identify early signs that can be treated thereby preventing the development of cancer.

If I feel healthy, do I need to be screened?

A WOl1lancannot tell if she has an abnormal area on-her cervix as she may feel fine. By examining the cervix before there are any symptoms, abnormalities can be found and treated so that cancer is prevented.

I am embarrassed -do I really need this exam?

If you are within-the recommended age range of 25-54 years and have never had a Pap smear in the last three years, yes, you should be screened.

Will the examination hurt?

The examination may be a little uncomfortable but it will not be painful. You may feel some discomfort when the health care provider inserts the speculum. Staying relaxed and keeping your muscles loose can help ease the discomfort.

Will I be examined for other sexually transmitted infections (STIs)?

No. You are only being tested for abnormal areas on your cervix that could lead to cancer. It is possible that your clinician may notice signs of a vaginal or cervical infection and recommend treatment.

Will the examination tell me if I have cancer?

No. The examination results will tell if the cervical cells are abnormal. If so, you will be referred for further examination to find out what is wrong and get treatment.

What does a negative result mean?

The examination did not detect any of the abnormal signs that come before developing cancer.

What does a positive result mean?

It means that you may have abnormal areas on your cervix that may require treatment so that they do not turn into cancer. You may need some additional testing to confirm these results.

Adapted from Alliance for Cervical Cancer Prevention (ACCP), May2003
Celebrating Health: It's all about...what I put in; what I keep out and how much I do
Health Promotion and Protection Division
Ministry of Health,
March 20

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TERMINOLOGY

TERMINOLOGY

The formal classification used for cytological identification cervical cancer precursor conditions.

Table 1

ASC-US	Atypical squamous cells of undetermined significance
ASC-H	Atypical squamous cells, cannot exclude HSIL
LSIL	**Low-grade squamous intraepithelial lesion** Encompasses: HPV-related changes, mild dysplasia and mild CIN
HSIL	**High-grade squamous intraepithelial lesion** Encompasses: Moderate and severe dysplasia, moderate and severe CIN and Carcinoma in situ

GUIDELINE: TERMINOLOGY		
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DEFINITIONS

DEFINITIONS

Colposcopy

Colposcopy is the examination of the vagina and cervix using an instrument (Colposcope) that magnifies the tissues allowing direct observation and study of the vaginal and cervical tissues.

Loop Electrosurgical Excision Procedure (LEEP)

LEEP, also known as large loop excision of the transformation zone **(LLETZ)**, is a method of outpatient excisional biopsy and treatment that is used to remove the entire transformation zone of the cervix.

LEEP's primary advantage over ablative techniques is that it removes rather than destroy suspicious tissue, thus producing a histological sample for pathological review. LEEP also has been used to perform a cone biopsy on an outpatient basis.

Cryotherapy

The use of extremely low temperatures (-60^{0}C – 90^0) to freeze and destroy abnormal tissue on the cervix.

GUIDELINE: DEFINITIONS		
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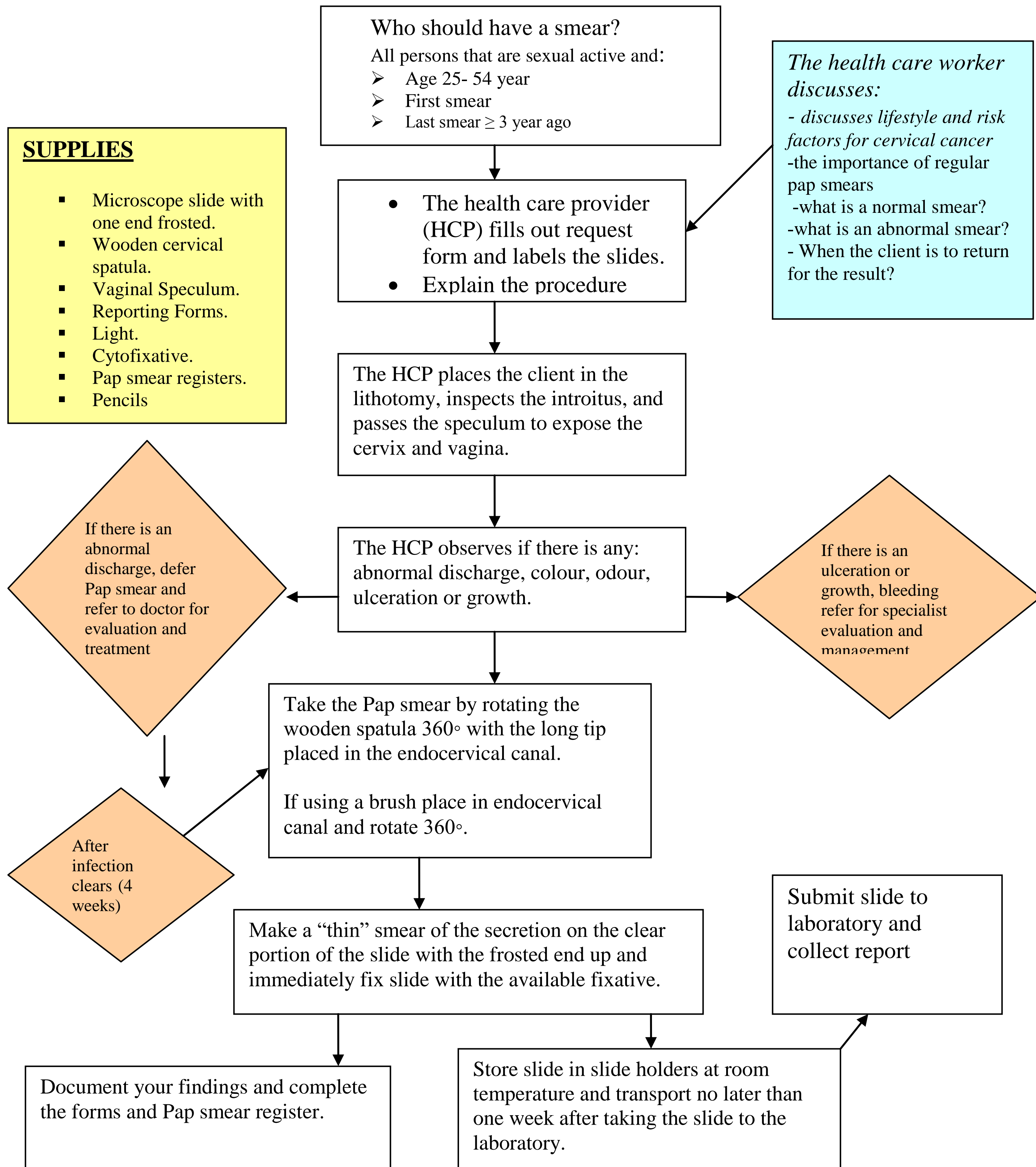
ANNEX

HOW TO TAKE A PAP SMEAR



MANAGEMENT OF ABNORMAL SMEAR

Definition: An abnormal smear is one which shows cellular abnormalities corresponding to intra-epithelial lesions (low grade and high grade).

Key points:

All abnormal smears should be referred to the doctor.

The Doctor discusses the findings on the pap smear and implications with the client.

Explains what SIL & ASCUS is.

The likelihood of progression and regression.