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Guidelines on the Management of Abnormal Cervical Cytology

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1 INTRODUCTION

The Guidelines on the Management of Abnormal Cervical Cytology was revised in 2002 because of the revision of the Bethesda System in 2001 and the introduction of HPV testing in the management of atypical squamous cells. This revision is based on new information being available, including the ASC-US/LSIL Triage Study (ALTS) and the use of HPV testing as an adjunct in cervical cytology. In this guideline, HPV testing refers to testing for high-risk HPV types [1,2,3].

In this revision, the recommendations for atypical squamous cells (ASC) and low-grade squamous intraepithelial lesion (LSIL) are essentially unchanged, except in special populations such as adolescents, pregnant women, immunocompromised women and postmenopausal women. The management in these categories is being updated, such as adopting a more conservative approach with repeat cytology rather than immediate colposcopy in adolescents unless high-grade intraepithelial lesions (HSIL) are encountered. There are minor modifications for management for HSIL and atypical glandular cells (AGC). The use of HPV testing has been expanded, such as as an adjunct to cervical cytology screening in women aged 30 years and older.

2 RATIONALE FOR CERVICAL SCREENING

2.1 Cervical carcinoma, which is largely preventable, still affects 376 women and causes the death of 126 women in Hong Kong in the year of 2005 according to Hong Kong Cancer Registry. It is the 9th commonest malignancy in females and ranks 9th as a cause of cancer death in females in the year of 2005.

2.2 Cervical cytology screening can reduce the incidence and mortality of cervical carcinoma. Its effectiveness is increased when it forms part of an organized programme of screening [4].

2.3 The long latency which normally exists between the emergence of precursor lesions and occurrence of invasive, life threatening disease provides the foundation of the screening program for cervical cancer [5].

3 TARGET POPULATION AND SCREENING INTERVAL

3.1 The target population encompasses all women from age 25 or the time of commencing sexual activity (whichever is later) until they reach 65 years of age. In view of the rarity of cervical carcinoma in women below 25 years of age and the relatively high proportion of cytological abnormalities that spontaneously regress, screening before this age is less cost-effective and could result in unnecessary interventions. Nevertheless, women aged below 25 years with high-risk profile may be screened. Screening may be discontinued in women aged 65 or more if 3 previous consecutive cytology tests are normal. Women over 65 years who have never had cervical cytology, or who request a cervical cytology test, should be screened.

Taking a cervical cytology sample during pregnancy may induce bleeding and cause anxiety to the woman and hence this is not the best time to perform cervical screening. For those who have never had screening before pregnancy, this may be an opportunity to perform a cytology test.

3.2 The percentage reduction in the cumulative incidence of cervical cancer

is 93% with an annual or biennual screening interval, 91% if performed every 3 years, 84% if performed every 5 years and 64% if performed every 10 years. Screening at 3-yearly intervals is less costly and does not significantly reduce the efficacy of preventing invasive cervical cancer compared to that achieved with annual screening[6]. Screening at 3-yearly intervals, after 2 consecutive normal annual cytology tests, is recommended. However more frequent screening may be considered for persons at higher risk of developing cervical carcinoma more rapidly e.g. immunocompromised women.

3.3 Particular emphasis should be given to recruit those women at greatest risk of developing cervical cancer - those who have never had cervical cytology screening, and those who have not had one for more than 3 years.

3.4 Women who have hysterectomy with removal of cervix for benign diseases without prior history of cervical dysplasia can discontinue screening.

3.5 Although the use of HPV 16, 18 vaccines may reduce ~70% of cervical cancer, the same cervical cytology screening strategy is still recommended for vaccinated women.

4 METHODS OF SCREEINING AND OPTIMIZATION OF EFFECTIVE SCREENING METHOD

There are various methods of screening for cervical cancer. These include cervical cytology, cervicography, HPV typing and Visual inspection with acetic acid (VIA) / with Lugol's iodine (VILI). Apart from cervical cytology, the effectiveness of the other methods has not been established in cervical cancer screening. The effectiveness of cervical cytology in cervical cancer screening has been well established. The use of HPV testing alone or with cytology in women 30 years and older has been suggested by recent studies to improve the sensitivity. However, there is insufficient data to prove that this combination of tests will improve the outcome of a screening program or reduce the cost of screening. At the moment, cervical cytology remains the standard method for cervical cancer screening. Nevertheless, it must be understood that the cervical cytology test and the HPV test, like any other test, has inherent limitations and is neither 100% sensitive nor 100% specific.

4.1 Cervical cytology sample collection

4.1.1 The quality of the cytology sampling has a major influence on the sensitivity of the cervical cytology. The presence of inflammatory cells, blood or debris, the type of cell collector used and the skill of the operator will affect the quality of the cytology. Cytology sampling during menstruation should be avoided.

4.1.2 Use of a broom type device will optimize cell sampling from the endocervical canal & ectocervix & thus the transformation zone but it is more expensive than the Ayres' spatula.

4.1.3 Despite adequate collection of cervical cells, poor and uneven transfer of cells to the slide may hamper assessment because of insufficient cells or a thick smear. Mucus, blood or inflammatory cells may also obscure the cervical cells.

4.1.4 The cytology smear should be immediately and properly fixed after the slide is prepared, either in 95% alcohol or using a spray fixative.

4.1.5 Liquid based preparations minimize the problems mentioned above and have reduced the rate of unsatisfactory cytology sampling but at a price[7]**.** Liquid based cytology also has the advantage of allowing "reflex" HPV testing be performed if necessary. Liquid based specimens should be collected according to the manufacturer's instructions.

4.1.6 Factors that are important and can affect the interpretation of a cytology test include age, hormonal status, use of hormonal contraceptives or an IUCD, pregnancy and the

date of last menstrual period. Such information should be indicated on the request form. The sample should be properly labeled.

4.1.7 The use of oestrogen in postmenopausal women and the treatment of pre-existing infection may improve the quality of a cytology sample.

4.2 Laboratory screening

4.2.1 Cytology samples should be screened in a laboratory run by competent and qualified personnel and with documented good quality control.

4.2.2 The Basic Criteria for a Cervical Cytology Screening Laboratory composed by the Hong Kong College of Pathologists can serve as a guide for the basic requirements, performance standards and reporting guidelines for cervical cytology.

4.2.3 The Cervical Cytology Practice Guidelines of Hong Kong Society for Cytology provides good practice points in performing cervical cytology screening.

4.2.4 The laboratory accreditation system, such as the Hong Kong Laboratory Accreditation Scheme (HOKLAS), encourages high quality laboratory work to be performed.

4.3 HPV Testing and cytology screening

4.3.1 HPV testing should only target at high-risk oncogenic HPV types.

4.3.2 The use of HPV testing alone in primary screening is not recommended.

4.3.3 HPV testing should not be used for routine screening before the age of 30 years.

Women who are negative by both cytology and HPV testing can consider a longer screening interval.

Both cytology and HPV testing should be repeated at 12 months for cytology negative but HPV positive women.

Colposcopy is acceptable if HPV test is persistently positive; while those develop cytological abnormalities can be managed according to the present guideline.

4.3.4 The role of HPV genotyping assays remains to be elucidated.

5 REPORTING OF ABNORMAL CERVICAL CYTOLOGY

5.1 Various terminologies have been used in the reporting of cervical cytology. An understanding of the meaning of a cytology report is essential for proper management of abnormal results.

5.2 Most laboratories in Hong Kong report cervical cytology using the current Bethesda system (TBS)[8]. The strength of this system is that it provides an evaluation of the adequacy of the specimen and encourages a descriptive diagnosis of abnormalities. For uniformity, this should be the default reporting system in a cervical screening program.

5.3 The cytological terms low- & high-grade squamous intraepithelial lesion (LSIL and HSIL) correlate with, but is not diagnostic of, the histological diagnosis of HPV/CIN I & CIN II/III respectively.

5.4 The term Atypical Squamous Cells (ASC) applies to cytological changes that are suggestive of squamous intraepithelial lesion but are qualitatively or quantitatively insufficient for a definitive diagnosis. It is the most commonly reported category of abnormal cytology in a screening population [9]. TBS 2001 further indicate cases more likely to have high-grade lesions using the term ASC-H as compared to ASC-US (undetermined significance).

5.5 Significant pathologies including high-grade CIN, ACIS (adenocarcinoma in-situ), hyperplasia and carcinoma of the corpus and extrauterine carcinoma have been found in patients with AGC (Atypical glandular cells)[10]. Colposcopy, endocervical and endometrial sampling should be performed.

6 MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY

6.1 Criteria for referral for colposcopy

The decision to refer for colposcopy depends on the likelihood that a patient has CIN II/III or more advanced disease. The following table is a guide to this decision.

Cervical Cytology	Significance	Suggested actions
Normal (± inflammation)	0.1% CIN II-III	Normal screening program (Once every 3 years after 2 normal annual cytology tests)
ASC- US	5-17% CIN II-III[11] 0.1-0.2% invasive	Reflex HPV testing is preferred especially in postmenopausal women if cervical cells were collected with liquid based cytology. The alternative is to repeat cytology in 6 months. Refer for colposcopy if abnormality persists
ASC-H	24-94% CIN II-III[11]	Refer for colposcopy and biopsy
Low grade squamous intraepithelial lesion (LSIL)	15-30% CIN II-III[11] 0.1% invasive	Refer for colposcopy and biopsy
High grade Squamous Intraepithelial lesion (HSIL)	70-75% CIN II-III [11] 1-2% invasive	Refer for colposcopy and biopsy Immediate LEEP can be offered if frank high-grade lesion can be seen (Adolescent is an exception). Review of cytology slides is recommended if no high grade lesion could be found
HSIL-cannot exclude invasion		Early referral for colposcopy and biopsy
Invasive cancer	53.8% invasive	Biopsy if frank growth, otherwise early referral for colposcopy and biopsy
Abnormal glandular cells		Refer for colposcopy and biopsy, endocervical sampling. Cone biopsy and endometrial sampling may be required.(Exception: endometrial sampling first for AGC-NOS, endometrial cells) For AGC –favour neoplasia and AIS – if there is no significant pathology explaining the source of the abnormal cells, a diagnostic cold knife cone is recommended to obtain an intact specimen with interpretable margins without thermal artifacts. Ablative procedure is unacceptable
AGC-NOS	9-41% CIN2-3,AIS,Ca[11]	
AGC-favor neoplasia	27-96% CIN2-3, AIS, Ca[11]	
AIS	48-69% AIS[11] 38% Adenocarcinoma[11]	
Benign looking endometrial cells		
a/ women after menopause	28% benign pathology, 12% significant pathology[12] (hyperplasia, endometrial carcinoma, sarcoma)	Investigation recommended
b/ women greater or equal to 40 years of age		For asymptomatic women with benign endometrial cells, no further evaluation is recommended.
c/ women < 40 years of age		Treat as normal

6.2 Management in special category

6.2.1 Adolescent (20 yrs or less):

High prevalence of HPV infections is found in adolescence. The cytological abnormalities are usually of minor-grade (ASC & LSIL) and the prevalence of cervical cancer is very low in this population.

Because most HPV infections clear spontaneously within 2 years, so immediate colposcopy for minor cytological abnormalities in adolescents is discouraged, as there could be potential harm due to over-investigation and over-treatment.

For ASC-US/LSIL, repeat cervical cytology 12 monthly. If ≥ HSIL or persistent abnormal cytology for 2 years, colposcopy should be performed.

Colposcopy should be performed for HSIL. If CIN3 is confirmed, LEEP is indicated. For CIN2, observation is suggested. Cytology should be repeated 6 monthly and colposcopy should be repeated at least once every 12 months. If CIN2 or HSIL persisted for 2 years, LEEP should be offered.

If no CIN2/3 was found on a satisfactory colposcopy examination, cytology should be repeated 6 monthly. If HSIL persists at one year, colposcopy should be repeated.

If colposcopy for HSIL is unsatisfactory, cytology and colposcopy should be repeated in 6 months. If HSIL persists and colposcopy is still unsatisfactory at one year, LEEP should be offered.

6.2.2 Pregnant women

The only indication of therapy for cervical neoplasia in pregnant women is invasive cancer.

Cancer risk is relatively low among pregnant women with ASC-US/LSIL; hence deferring colposcopy for ASC-US/LSIL is acceptable (at least beyond 6 weeks after delivery).

Pregnant women with HSIL/AGC should have a colposcopic examination as non-pregnant women to rule out malignancy. Endocervical curettage is contraindicated. Repeat colposcopy at early 3rd trimester may be considered.

Treatment for high-grade disease can be deferred to the postpartum period.

Colposcopy guided biopsy or cone biopsy is indicated only if malignant lesion is suspected.

6.2.3 Immunocompromised

ASC-US is common in HIV-infected women.

Earlier reports of high rate of HPV infection and increased cervical pathology were disputed. Hence management of immunocompromised women with abnormal cytology should be the same as immunocompetent women.

6.2.4 Postmenopausal

HPV testing is less frequently positive in postmenopausal women, so reflex HPV testing for LSIL in these women in triaging for colposcopy if HPV positive, may be considered. Women who have negative HPV test may be followed up by cytology in 6 months.

Further studies are needed before HPV testing is used in the management of postmenopausal women with ASC-H.

6.3 Colposcopy examination

The colposcopist's role is to examine the transformation zone, define the extent of the lesion, and biopsy the most abnormal area for tissue diagnosis. In

addition to the cervix, the vagina should also be examined.

Histological confirmation of the colposcopic diagnosis is advisable before treatment. In patients with a colposcopic diagnosis of high-grade lesion, a "see and treat" approach[13] i.e. perform loop excision without a biopsy, is adopted by some colposcopists. Although this practice decreases the need for another visit, it carries the risk of over-treating patients with low-grade lesions. The rate of overtreatment depends on the expertise of the colposcopist.

6.4 Role of HPV detection in Management of Abnormal Cytology

6.4.1 High risk HPV can be detected by polymerase chain reaction (PCR) and dot-blot, sequencing or commercial kits. Only analytically and clinically validated HPV tests should be used.

6.4.2 Patients who present with ASC and LSIL and are positive for high risk HPV-types, are more likely to carry high-grade lesions (CIN II-III).

6.4.3 High risk HPV can be found in around 50% of ASC-US and 82-85% of LSIL[14-15] Reflex HPV testing in triaging patients with ASC-US is an alternative to repeat cytology at 6 months in decision for colposcopy referral[14] except in women 20 years of age and younger. On the other hand, HPV testing has limited role in triaging patients with LSIL for colposcopy because over 80% of LSIL has high risk HPV[15].

Reflex HPV testing for the triage of postmenopausal women with LSIL is an acceptable choice.

6.4.4 HPV testing may be used as an adjunct to cytology testing in the follow up management after colopscopy or treatment. It can be used as a test of cure at 12 months after colposcopy.

6.4.5 Future of HPV tests

In the future, HPV genotyping may play important role in the triage and management of women with HPV-related diseases.

HPV 16 and 18 are associated with majority (70%) of cervical cancer. As tests become available and gain FDA approval, data may support triage of HPV-positive women using tests to specifically identify HPV 16 & 18.

6.4.6 Full impact of HPV vaccine on cervical cancer screening and prevention is still unfolding.

6.5 Treatment for CIN & basis of treatment

6.5.1 Majority of low grade lesions (HPV, CIN I) will regress spontaneously over 2 years and immediate treatment may not be necessary[16-17]. About 15% of patients may progress to CIN II or III and require treatment later.

If a low-grade lesion is confirmed by colposcopy and biopsy, the patient can be followed-up with cytology every 6 months. If LSIL / ASC-US persist, colposcopy can be repeated between 12 to 18 months.

Patients can resume 3-yearly screening after having 3 consecutive normal results. Cytology examination every three years should be continued for at least 3 times even if women has reached the age of 65.

If HPV testing is available, follow up at 12 months with HPV testing and cervical cytology is acceptable. If both results are negative, another negative HPV testing or cervical cytology is required at 24 months before returning to routine screening. If either test is positive during the 24 months period, colposcopy may be recommended.

In patients with CIN 1 lesion involving more than 2 quadrants of the cervix or if the patient is

unable or unwilling to return for follow-up, then treatment should be considered. If the lesion persists for more than 2 years, treatment is recommended.

6.5.2 The reason for treating high-grade cervical intraepithelial neoplasia (CIN II or III) is that these lesions could progress to invasive cancer if left untreated. The time of progression to cancer is variable and can take from months to years[1]. The risk of CIN III progressing to an invasive lesion is about 12% over a period of 10 years[(18)].

6.5.3 Treatment for CIN can be carried out under local anaesthesia on an outpatient basis in 90% patients.

6.5.4 Ablative methods including electrocoagulation diathermy, cryosurgery, cold coagulation and laser vaporization, are undesirable because they do not provide a specimen for histology examination.

The current recommended method is the loop electrosurgical excision procedure (LEEP). This has the advantage of providing a tissue specimen that is generally of sufficient quality for histological exclusion of occult invasion. Complications include intraoperative and postoperative bleeding (1-8%), infection, cervical stenosis (1%), cervical deformity and cervical incompetence[(18)] and rarely injury to vagina, bladder and ureter. Recent reports showed an association with preterm delivery, low birth weight and premature rupture of membranes but there was no significant increase in neonatal morbidity[(19)].

6.5.5 Hysterectomy is not recommended for the treatment of CIN II/III unless there are concomitant gynaecological problems that warrant a hysterectomy. Hysterectomy should not be performed for cytological abnormality without proper colposcopy examination & biopsy.

6.5.6 The diagnosis and indication for treatment, treatment procedures & possible treatment complications, should be discussed with the patient before colposcopic examination & treatment. All counseling, cytology /histology /colposcopy results, consent, and the management plan should also be documented.

6.5.7 After treatment for high-grade CIN, patients should be followed up by cervical cytology for 3 times at 6-months intervals & then annually for 10 years, then return to life long 3-yearly screening.

If patient has ASC-US/LSIL on cervical cytology within 12 months, continue follow up with cervical cytology is acceptable. If the low-grade cytological abnormalities persist for more than one year, colposcopy has to be repeated. Colposcopy should be repeated any time when HSIL is found on cervical cytology.

If HPV testing is available, follow up using cervical cytology in combination with HPV testing is acceptable. At 6 months after treatment, follow up with cervical cytology only is recommended.

If HPV testing is available, follow up at 12 months with HPV testing and cervical cytology is acceptable. If both HPV testing and cervical cytology are negative at 12 months, HPV testing and/or cervical cytology should be repeated at 24 months before returning to 3-yearly screening after 10 normal annual cervical cytology results. If HPV testing is positive and cervical cytology is negative at either 12 or 24 months, cervical cytology should be repeated 6 months later. Colposcopy is indicated any time when HSIL or if patient has ASC-US/LSIL on cervical cytology after 12 months.

6.5.8 If patients had hysterectomy for CIN with clear margin, vaginal cytology should be taken at 6 & 18 months. If both results are normal, no further vaginal cytology is necessary. If excision was incomplete or clearance of margin is uncertain on hysterectomy, or if the patients had VAIN, vaginal cytology should be taken at 6 and 12 months then yearly for 10 years followed by life long 3-yearly cytology tests.

7 CALL-RECALL SYSTEM

7.1 For a cervical screening programme to be effective, it is essential to have in place a call-recall system. A call system ensures that eligible women are invited to have cervical cytology, and a recall system reminds women who are due for screening and those who do not respond to abnormal cytology results.

7.2 The Department of Health of HKSAR launched a territory-wide Cervical Screening Programme in March 2004 in collaboration with other health care professionals to facilitate and encourage women to have regular cervical cytology. Personal data and cytology results of women who have joined the programme are entered into the Cervical Screening Information System (CSIS). The CSIS is a computerized central cervical cancer screening registry for storing all the data related to cervical cancer screening. The functions of the CSIS include maintenance of a call-recall system, allowing sharing of cytology results among relevant health care providers for better patient care, tracking of utilization, evaluating the programme coverage, and supporting epidemiological and/or service-related research. Women can view their own records online, and registered health care providers as well as laboratory technicians can also use the CSIS to view the test records of their clients.

8 AUDIT

The results of the management of abnormal cytology should be audited regularly. Auditing should include the quality of treatment, the quality of service, the adequacy of follow-up and the clinical outcome. The College has guidelines on standard of colposcopy services and program on colposcopy service audit.

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This guideline was produced by the Hong Kong College of Obstetricians and Gynaecologists as an educational aid and reference for obstetricians and gynaecologists practicing in Hong Kong. The guideline does not define a standard of care, nor is it intended to dictate an exclusive course of management. It presents recognized clinical methods and techniques for consideration by practitioners for incorporation into their practice. It is acknowledged that clinical management may vary and must always be responsive to the need of individual patients, resources, and limitations unique to the institution or type of practice. Particular attention is drawn to areas of clinical uncertainty where further research may be indicated.

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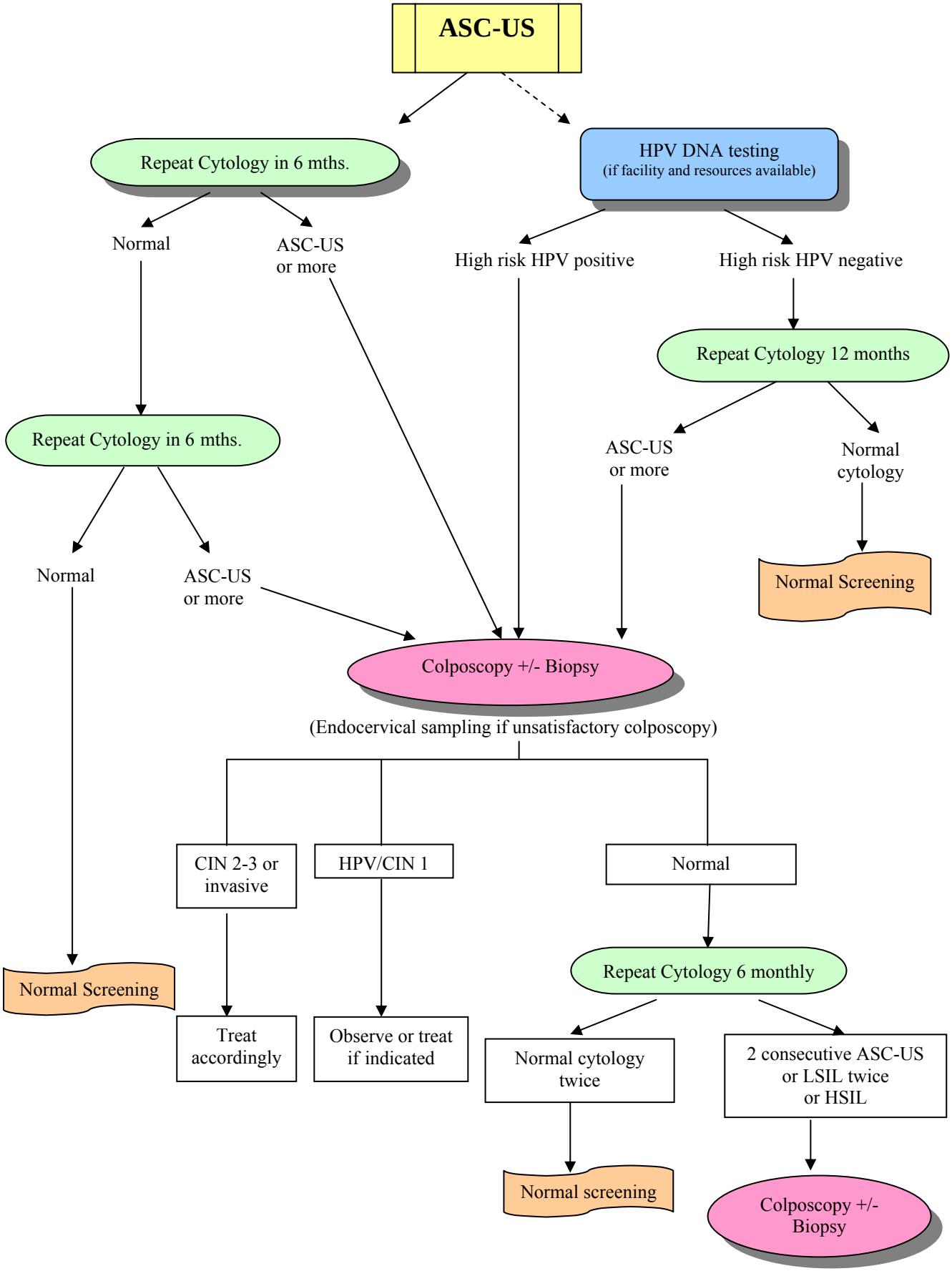
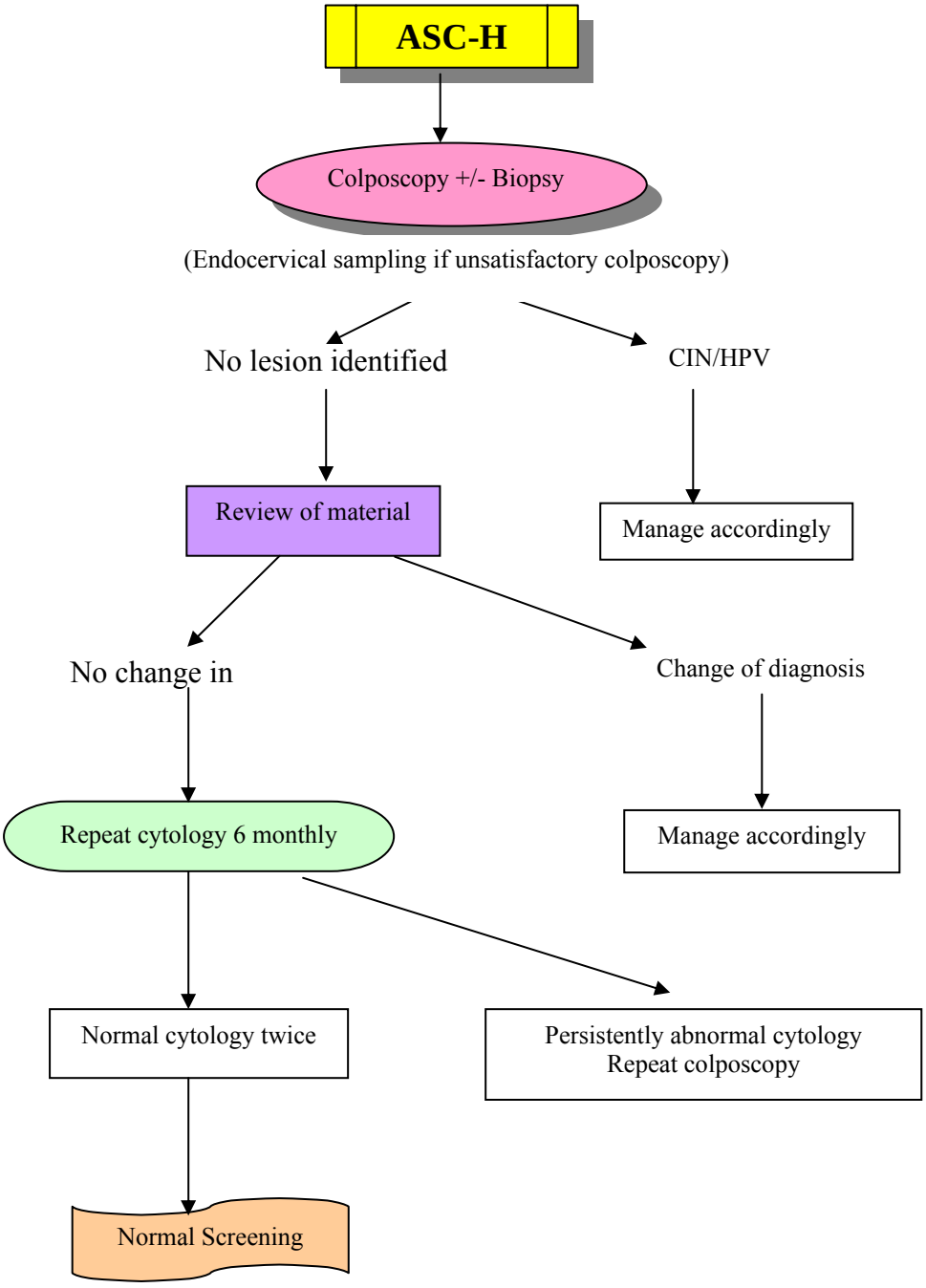
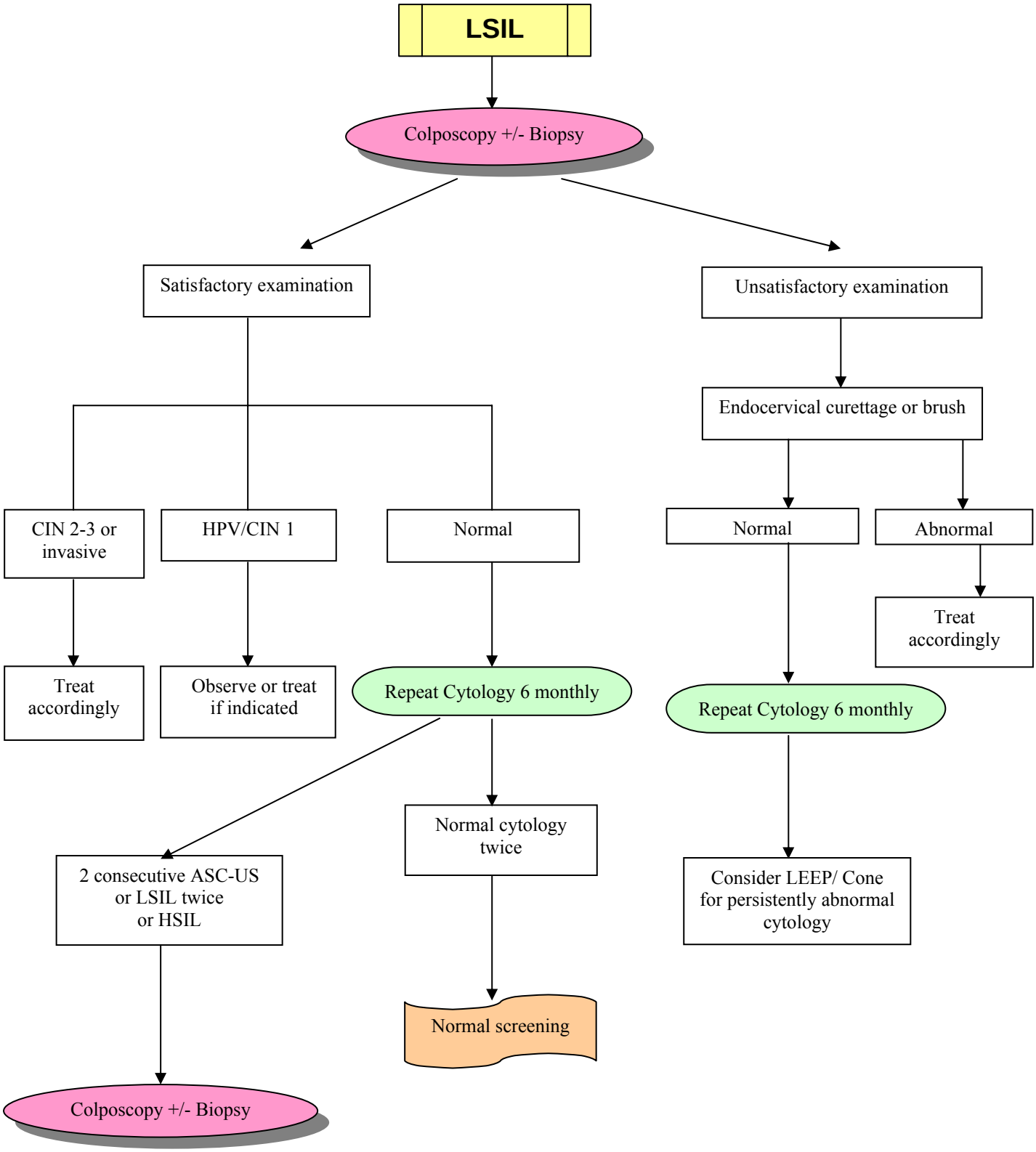
Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US)



Management of women with Atypical Squamous Cells-Cannot Exclude High grade SIL (ASC-H)



Management of women with Low Grade Squamous Intraepithelial Lesion(LSIL)



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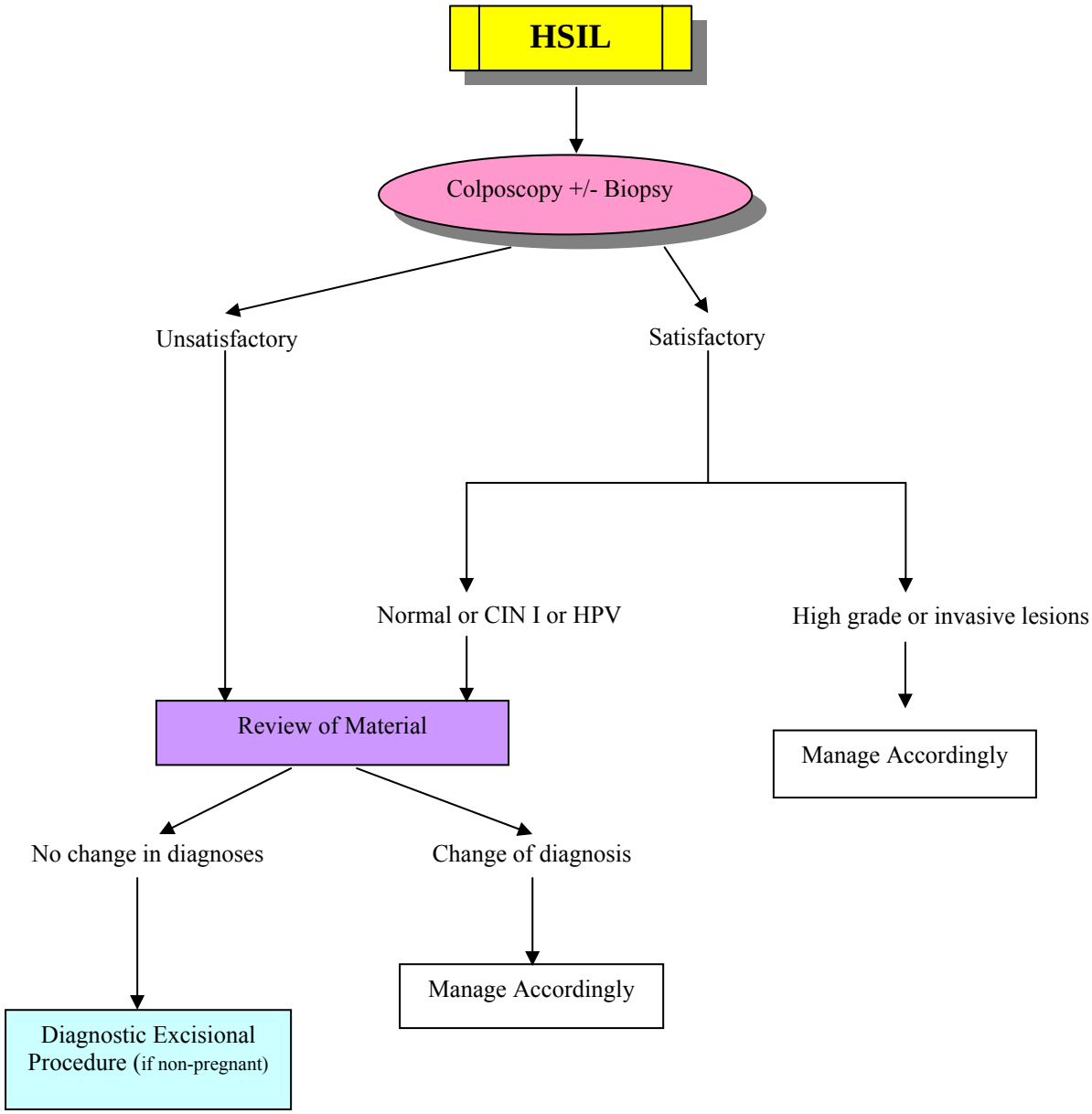
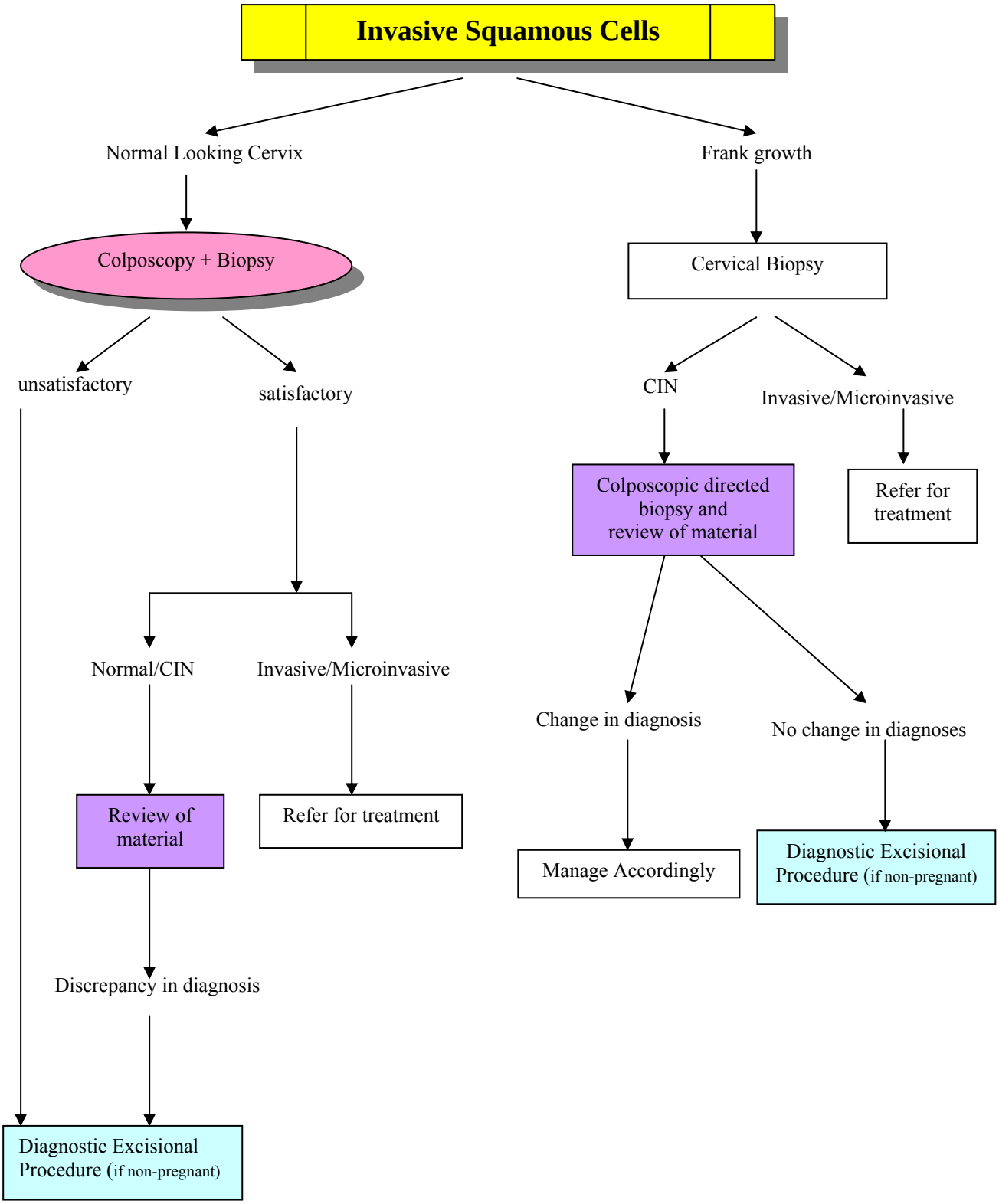


Management of women with Cytology showing Invasive Squamous Cells



Management of women with Cytology showing Atypical Glandular Cells