

2R. CORE REFERENCE

INTRODUCTION

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Regional Programme Co-ordinator (RPC)

Where there is reference to RPCs in the SOPPs; this could include delegated authority to the 'Clinical Lead' in CSAD, where such a post exists.

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2R.10. OBJECTIVES

2R.10.1. Overall aim

The aim of the cervical screening programme is to reduce the incidence of, and morbidity and mortality from, invasive cervical cancer. However, screening also has the potential to cause both physical and psychological harm to women invited. It is essential that this harm is minimised, so that the benefits of screening outweigh the costs. A balance must be struck between maximising effectiveness and minimising harm.

2R.10.2. Introduction

The National Service Framework (NSF) for the Cervical Screening Programme in Wales was introduced to ensure that cervical screening is delivered in a consistent manner across Wales; this includes the management and treatment of screen detected non-invasive disease.

The aim of the NSF is that all women should receive the same level of service and quality of care for the same level of need, regardless of location. The NSF covers not only what should be provided, but also how the programme, and each of its elements, should be organised and managed. Standard Operating Policies and Procedures, accepted throughout the service are, therefore, essential if this aim is to be achieved.

- Cervical Screening aims to identify pre-malignant changes in women, before they develop into cancer, enabling appropriate treatment to be offered
- Diagnosis is confirmed by the histopathological examination of biopsies taken during the colposcopic examination
- The aim of treatment is to reduce the level of morbidity and mortality from cervical cancer
- The success of treatment is indicated by the return of the woman to normal cytology and her subsequent reinstatement to normal recall within the cervical screening programme
- The quality of the screening service is measured by a high level of success in the eradication or removal of cervical intra-epithelial neoplasia (CIN) following treatment

A high level of compliance will have a major impact on the success of the cervical screening programme in Wales. The degree of compliance will depend very much on the acceptability of the process to women, their experience of colposcopy and the underlying satisfaction with the service whilst undergoing investigation.

Maintenance of quality is an essential part of the framework of clinical governance. The responsibility for clinical governance within the screening programme for all elements of the programme apart from the sample taking process lies with Cervical Screening Wales.

2R.10.3. Objectives

The National Health Service Cancer Screening Programme (NHSCSP) is responsible for setting standards and co-ordinating objectives for the cervical screening programme in England.

Wherever possible, CSW works to the same or similar standards and targets (see below) and contributes by way of payment to central initiatives such as the maintenance of the Exeter System and the organisation of national committees.

CSW acknowledges the advice and guidelines issued by the NHSCSP, but it is not subject to its direct control.

Standards for the NHS Cervical Screening Programme are defined in a series of publications, which can be found on the NHSCSP website (link below) or copies can be obtained through CSW.

<http://www.cancerscreening.nhs.uk/cervical/index.html>

2R.10.4. All-Wales Minimum Standards

The Cancer Services Co-ordinating Group issues minimum standards which “define the essential aspects of the service that should be provided for cancer services throughout Wales.”

http://howis.wales.nhs.uk/sites/documents/322/All_Wales_Minimum_Standards_2000_-_Gynaecological_Cancer_Services.pdf

CSW is not responsible for treating cervical cancers but will ensure that where cervical cancer is identified appropriate referral pathways are in place.

Further Guidance

2R.20. ALL-WALES CERVICAL SCREENING POLICY

2R.20.1. Aims of the Cervical Screening Programme

The aim of the cervical screening programme is to reduce the incidence of, and morbidity and mortality from, invasive cervical cancer. However, screening also has the potential to cause both physical and psychological harm to women invited. It is essential that this harm is minimised, so that the benefits of screening outweigh the costs. A balance must be struck between maximising effectiveness and minimising harm.

2R.20.2. The Eligible Population

- The target age group for cervical screening is women aged 20 to 64
- Women under 20 must not be screened

“The most recent mortality rates from cervical cancer in England and Wales in 1996 show no deaths from this disease in teenagers and only 5 of the 1,329 deaths were in women under 25 years of age. High grade CIN undoubtedly occurs in teenagers but is normally at a very early stage in its pathogenesis thus allowing ample time for its detection ... once the woman has left her teens. There are no indications for taking a smear in immunocompetent women under the age of 20. Indeed there may be more harm than good in this practice since a non negative smear may result from normal developmental changes in the cervix. If this apparent abnormality persists the teenager will be referred to colposcopy with all the negative sequelae of such an experience for little or no benefit.”

Guidelines for Clinical Practice and Programme Management NHSCSP 1997

- All women must be invited for the first time after their 20th birthday, but before their 21st birthday. In most cases, women will be invited for the first time shortly after their 20th birthday
- Woman in the eligible age group must only be discharged from the programme:
 - Following a total hysterectomy (see 4P.80 for further details)
 - Following a Manchester repair
 - If there is a congenital absence of the cervix
 - Following radiotherapy to the pelvis
 - At the request of the woman, provided that she has been provided with appropriate information and has signed and returned an opt-out form
- Women who are on routine recall (i.e. women who are not undergoing cytological surveillance, modified cytological surveillance or follow up after abnormal or inadequate cervical cytology or treatment) and will be 65 or over at the time of their next invitation will be discharged from the programme
- Women who have no screening history and will be 65 or over at the time of their next invitation will be discharged from the call and recall system, but may be screened opportunistically within the programme

2R.20.3. Recall Interval

- When normal recall is indicated women must be sent their next invitation 3 years after their normal test

2R.20.4. Opportunistic Smear Taking

- Opportunistic cervical sampling (that is cervical sampling that is not a direct result of a call or recall invitation or colposcopy assessment or follow-up) must only be carried out in the following circumstances:
 - Women who have reached their 20th birthday and have never been screened (including women aged 64 and over)
 - Women aged over 20 who were last screened more than 3 years previously
- Additional cervical cytology must not be taken from women:
 - During pregnancy or within 3 months following delivery, unless attending termination clinic and due for smear test (see smear taker guide 1.17)
 - Avoiding pregnancy by the use of contraception, hormonal or otherwise
 - Receiving hormone replacement
 - Undergoing investigation for genital infection including genital warts
 - With or having had multiple sexual partners

2R.20.5. 'Clinically Indicated' Cervical Samples

- Cervical cytology is a screening test and is not an appropriate diagnostic test. Therefore, the taking of a cervical sample is never 'clinically indicated' within primary care

"It is a misconception, but one which is widely held in the UK, that cervical smears are diagnostic. Their inappropriate use in the investigation of symptomatic women coupled with their unjustified use in various clinical situations results in a significant extra load for cytological laboratories with no particular benefit. It is important to remember that cervical cytology is a screening tool, that cervical screening aims at detecting pre cancerous conditions not cervical cancer and that pre cancerous conditions of the cervix do not produce symptoms."

Guidelines for Clinical Practice and Programme Management NHSCSP 1997

- A cervical sample may be taken from a woman with symptoms who has attended for screening as a result of a routine invitation, or who meets the criteria for opportunistic screening outlined above. It is, however, important that decisions about the subsequent management of the woman do not wait for, and are not made on the basis of, the cytology result obtained. It should also be noted that the symptoms may affect the adequacy of the smear for screening purposes

2R.20.6. Cervical Samples Taken Outwith this Policy

- Cervical samples taken outwith this policy should not be included within the screening programme. Such samples will continue to be screened, but

will be closely monitored. Efforts will be made, through education and contact with smear takers, to reduce significantly the number of such samples being taken. Teenage women may have abnormal cervical cytology. Referral for colposcopy is managed similarly to older women. Treatment for low grade disease is discouraged as the majority of such abnormalities will spontaneously regress

2R.20.7. Referral for Colposcopy

- Referral for colposcopy must be made:
 - After one cervical sample showing moderate or severe dyskaryosis, glandular abnormality, severe ?invasion or borderline ?high grade or borderline change in endometrial cells, borderline change in Endocervical cells, any grade abnormality where the woman is >64
 - After two cervical samples showing mild dyskaryosis or one cervical sample showing mild dyskaryosis and one cervical sample showing borderline changes or two samples showing borderline or mild changes where one or both of these shows borderline changes in endocervical cells (where the second abnormal smear occurs whilst under cytological surveillance)
 - After three cervical samples showing mild dyskaryosis or borderline changes, over any 10 year period or after two cervical samples showing borderline glandular neoplasia, over any 10 year period (without an intervening colposcopic investigation)
 - After one abnormal cervical sample, showing mild dyskaryosis or worse, whilst the woman is under cytological surveillance (i.e. Before being returned to routine recall) following colposcopy
 - After one abnormal cervical sample, showing borderline or worse, whilst the woman is under cytological follow-up (i.e. Before being returned to routine recall) following colposcopy After three consecutive cervical samples described as inadequate
 - When cervical cancer is suspected for cytological reasons
 - When a woman has a single mildly dyskaryotic or borderline cervical sample if it is anticipated that the woman will not comply with cytological follow-up

If cervical cancer is suspected for clinical reasons, the women should be urgently referred to the gynaecological service, without waiting for the results of any tests.

The above policy is outlined in greater detail within the Cervical Screening Wales management protocol (see 2R.31). The detailed protocol should be followed when determining the future management of an individual woman.

2R.20.8. Treatment

- CIN2, CIN3 and cGIN must be treated once diagnosed, unless it is agreed at an MDT meeting to manage a woman with CIN2 conservatively. CIN1

may be treated or kept under close surveillance for a limited period. HPV change on biopsy without CIN is managed as a borderline smear.

2R.20.9. Cytological Surveillance and Follow-Up (see 2R.31)

- Other than routine or opportunistic screening testing, as described above, cervical samples must only be taken from:
 - Women undergoing cytological surveillance following mild or borderline cervical samples
 - Women undergoing cytological surveillance following colposcopy where treatment was not carried out (CIN1 or no abnormality detected at colposcopy)
 - Women undergoing cytological surveillance following treatment of CIN1
 - Women undergoing cytological follow-up after the treatment of CIN2/3 or cGIN
 - Women undergoing cytological follow-up where no colposcopic abnormality was confirmed following referral for a high grade cytological abnormality
 - Women undergoing follow-up after the treatment of cervical cancer, where further smears are recommended by the woman's gynaecologist or oncologist. Such women will not be invited for screening as part of the call/recall system
- During cytological surveillance following a mild or borderline cervical sample, colposcopy where treatment for CIN1 was not carried out or following the treatment of CIN1, women must have a cervical sample taken 6 months after the abnormal cytology or colposcopy. If this sample is normal, a further cervical sample must be taken a further 6 months later and, if still negative, a further 12 months later, before the woman is returned to routine recall
- Following colposcopy for a low grade cytological abnormality where no colposcopic abnormality was found and the colposcopy was adequate, modified cytological surveillance is recommended. This does not include the circumstance where a biopsy is taken for suspected low grade abnormality
 - A cervical sample is repeated 6 months after colposcopy in colposcopy service (but need not be accompanied by colposcopic assessment)
 - If this is negative then return to normal recall
 - If this is borderline then repeat outwith the colposcopy service at 12 months
 - If this is mild then repeat with a colposcopy in 12 months

If the woman defaults the 6 month repeat cervical sample at colposcopy service she may have her cytology repeated in primary care. If this is negative she will be returned to normal recall.

- During cytological follow-up after the treatment of CIN2/3 or cGIN, women must have a cervical sample taken 6 months after treatment and, if normal, a further 6 months later. If still negative, cytology must be repeated annually for at least 9 further years, before the woman is returned to routine recall

- If a woman fails to attend for one or more of the follow-up cervical samples, she may still be returned to routine recall if she has had at least five negative cervical samples at least 12 months apart and the final negative sample is at least 10 years post treatment

The above policy is outlined in greater detail within the Cervical Screening Wales management protocol (see 2R.31). The detailed protocol should be followed when determining the future management of an individual woman.

2R.20.10. Vault Smears from Women following Total Hysterectomy or Manchester Repair (MR)

Women who have a sub-total hysterectomy will continue to be included in the cervical screening programme as their cervix is still present.

The following guidance applies to women who have undergone a total hysterectomy or a Manchester Repair (which involves amputation of the cervix).

Women who have had a total hysterectomy/Manchester repair (MR) more than 5 years ago and not had follow up will be ceased from recall.

Group 1 - Women who do NOT require vault smears post-hysterectomy or MR:

- Vaginal vault smears are not required when:
 - A woman has had a benign total hysterectomy/MR and
 - She has not had a high grade smear or histologically confirmed CIN2+/CGIN in the 10 years prior to her hysterectomy/MR and
 - She has no history of histologically confirmed CIN/CGIN without a subsequent correct return to normal screening recall

In this case, her recall for screening will be ceased and both she and her GP will be informed of this.

Other Groups - Women who DO require vault smears post-hysterectomy or MR.

Group 2 - A woman who has a benign total hysterectomy/MR but had a high-grade smear or histologically confirmed CIN2+/CGIN in the 10 years prior to it, or has a history of histologically confirmed CIN/CGIN without a subsequent correct return to normal screening recall:

- In this case, she will require a single vault smear 6 months after her hysterectomy/MR. If this is negative she will be ceased from the cervical screening programme
- Cervical Screening Wales will send her an invitation for this single vault smear which should be taken in primary care
- If the result is borderline or worse, she will be directly referred to colposcopy clinic by CSAD. She will be ceased from screening at the time the referral is made, and her colposcopist will determine her subsequent management

- The exception in this group is a woman who has CIN/CGIN or a high-grade smear in the six months prior to the hysterectomy. These women will be managed as in Group 3

Group 3 - A woman who has coincidental CIN/CGIN found at total hysterectomy/MR, which was completely excised (or CIN/CGIN/high-grade smear in the 6 months prior to the hysterectomy)

- In this case, she will require a vault smear 6 months after her total hysterectomy/MR and a second vault smear a further 12 months later
- Both of these should ideally be in colposcopy clinic, but if taken in primary care this will be acceptable
- If both these smears are negative, she will be discharged from the colposcopy clinic and be ceased from the cervical screening programme
- If either smear is borderline or worse, she will remain in (or be referred to) the colposcopy clinic. She will be ceased from screening at this time and her colposcopist will determine her subsequent management

Group 4 - A woman who has CIN/CGIN found at total hysterectomy/MR, but this was incompletely excised.

- In these circumstances, the woman will require a vault smear at 6 months after her hysterectomy/MR. Further follow up should be:
 - Vault smears at 6 and 12 months post-operation
 - Surveillance or follow-up depending on grade of CIN/CGIN found
 - Return to routine recall until 65 years
- Initial follow-up should take place within the colposcopy service
- The colposcopist may discharge to primary care if appropriate
- If any one of these results is borderline or worse, she will be managed within the colposcopy service. She will be ceased from screening at this time and her colposcopist will determine her subsequent management

2R.20.11. Cervical Cytology from Previously Ceased Women

- All previously ceased women who have a cervical sample reported as negative or inadequate will be re-ceased (see 5C.170)
- All previously ceased women who have a cervical sample reported as abnormal will be referred for colposcopy (see 5C.170)
- This excludes women who were ceased after signing a disclaimer

2R.20.12. Private Cervical Cytology and Cervical Cytology Reported Abroad

- When Cervical Screening Wales is notified of the result of a private cervical sample or a sample reported abroad, the result will be logged on the call/recall computer system.
 - Normal or inadequate private cytology results will not result in a change to the date on which the woman will be called or recalled for an NHS screening programme cervical sample
 - Women with abnormal private cervical sample results notified to Cervical Screening Wales will be included within the CSW FailSafe system

- Cervical cytology results from these sources will not be accepted unless the result is clearly stated (eg foreign language reports will not be translated)

2R.20.13. Women with HIV

- Annual recall is advised. CSW cannot provide FailSafe as HIV status is not routinely recorded on the cytology request (HMR 101) form. The best approach is to utilise the close relationship between these women and the medical team managing their care
 - As these women are seen on a regular basis the treating clinician should arrange for annual screening to be performed
 - The treating clinician should advise women that the result letter for a negative sample will state that they should have the next test in 3 years time. They should ignore this and be screened annually
 - Referral for colposcopy is as per the general population

2R.20.14. Immunocompromised Women

Women who are receiving maintenance immunosuppressant therapy following solid organ transplants should be screened as per the general population, but should be referred for colposcopy after a single abnormal smear of any grade.

Women who are receiving immunosuppressant therapy for any other reason (chemotherapy etc) should be screened and referred as per the general population.

Further Guidance

2R.30. ALL-WALES CERVICAL SCREENING STANDARDS

2R.30.1 Introduction

- The standards must be adhered to by each provider of services within the cervical screening programme in Wales
- It is accepted that in many cases, a failure to meet a standard does not necessarily indicate poor performance. In such cases, further investigation is required

2R.30.2 Coverage

- High coverage of the target population should be achieved
- Efforts must be made to get uniform coverage of the target population
- 5-year coverage >80% of women aged 25-64

2R.30.3 Time from Smear Taking to Receipt of Result

- All women and smear takers must receive their results in a timely manner.
- >80% of women and of smear takers receive result within 4 weeks of smear taking
- 100% of women and of smear takers receive result within 6 weeks of smear taking
- All cervical samples must be forwarded to the laboratory within 1 week of being taken
- 100% of cervical cytology results should be forwarded by the laboratory to the CSAD within 20 working days of receiving the cervical sample

2R.30.4 Call and Recall Arrangements

- All eligible women, registered with a general practitioner, must be identified and included in the programme
- Women in the eligible age group must only be discharged from the programme as specified in the All-Wales Cervical Screening Policy
- All eligible women must be called for the first time before their 21st birthday
- All eligible women for whom routine recall is indicated must be recalled after 3 years
- All women called or recalled must be sent a written invitation for screening
- All invitation letters must be sent out in the name of the woman's general practitioner
- All women who do not attend after their first invitation must be sent a written reminder within 6 months of the first invitation

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- The general practitioner of every woman who does not attend after an initial invitation and a reminder, must be notified
- All results letters must be dispatched to women within 5 working days of receipt of the report from the laboratory
- All screening data entered onto the call-recall system must be validated
- Cervical screening records must be transferred for every woman who moves to or from a health authority database

2R.30.5 Smear Taking

- All smear takers must be provided with appropriate training in cervical screening, with appropriate theoretical and clinical content, so that their role in making the programme acceptable to women, and the rationale behind the test, are clearly understood
- All doctors who intend to carry out cervical screening and are not formally trained in gynaecology or genitourinary medicine, or who have not received instructions in smear taking in a Family Planning course, should participate in a training course recognised by Cervical Screening Wales
- All staff involved in primary smear taking, including doctors, practice nurses, receptionists and practice managers, should take steps to update their knowledge and skills at least every 3 years
- There must be an agreed cervical screening procedure in every practice, with a designated person responsible for coordination
- All women must have access to:
 - A choice of venue
 - A welcoming accessible environment
 - A choice of appointment time
 - A choice of smear taker
 - A choice of a female smear taker, either in the practice or at a community clinic
 - An assurance of confidentiality and privacy
 - Clear written and verbal information
- All smear takers should ensure that women understand the benefits and limitations of the screening programme before a cervical sample is taken
- Smear takers must advise all women of how and when she will receive her test result
- Smear takers must check that all cervical cytology reports are received
- In every case where a test result is reported as being 'abnormal', the smear taker must ensure that the appropriate action has been taken

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- All practices must provide post-result support for women with abnormal cervical cytology results
- All practices must attempt to contact all women who do not attend for further investigation
- All practices must ensure that groups with special requirements are included in the screening programme
- All smear takers must be informed about the standard of their cervical sampling and where they stand in relation to other smear takers at least annually
- Action must be taken if the smear taking standards of an individual are persistently poor

2R.30.6 Cervical Cytology

Laboratory Accreditation

- All laboratories participating in the cervical screening programme must be registered with CPA and working towards accredited status within a time limit agreed with CPA (UK) Ltd. CSW will decide on the continued provision of service in cases where non-cervical cytology non-compliances affect departmental accredited status

2R.30.7 Staff Responsibilities

- Every laboratory or network of laboratories must be under the supervision of a consultant pathologist personally responsible for the reporting of abnormal cervical samples, including those showing borderline nuclear changes. This consultant must be contractually responsible for delivering a quality service to an agreed specification
- In every laboratory there must be clear documented evidence of who is responsible for what and who is accountable to whom
- The screening role must only be undertaken by suitably trained medical staff, biomedical scientists and cytoscreeners
- The checking role must ordinarily be undertaken by staff graded BMS2, or higher. In exceptional circumstances, notifiable to CSW, checking may be carried out by a BMS1
- All cervical cytology reports must be authorised by competent, trained laboratory staff
- All cervical samples considered to be abnormal and certain other specified cervical samples must be reported by a pathologist or advanced practitioner BMS

2R.30.8 Staff Qualifications and Training

- Existing screeners should be encouraged to acquire the NHSCSP Certificate in Cervical Cytology

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- All new screeners must acquire the NHSCSP Certificate in Cervical Cytology, prior to undertaking unsupervised primary screening
- All BMS Advanced Practitioners must hold the Advanced Specialist Diploma in Cervical Cytology awarded conjointly by the Institute of Biomedical Sciences and Royal College of Pathologists
- Provision must be made for continuing education for all scientific, technical and medical staff in non training grades
- All existing staff must receive and take part in continual update training
- All staff involved in primary screening must undertake a formal update course at least every 3 years
- Regular educational sessions must be held for the discussion of interesting and problem cases and new developments. All grades of staff must participate
- 1 day per quarter (4 days annually per WTE) must be dedicated for 'in house' updating of screening staff
- Update training and close monitoring of work must routinely follow when staff return to cervical cytology after a period of absence exceeding 3 months
- Relevant and up to date journals and text books must be available to all staff in all laboratories

2R.30.9 Staff Performance

- The performance of all laboratory staff must be monitored and documented, along with action taken to address problems
- All performance outwith standards must be dealt with in a sensitive and caring fashion. Anonymity must not outweigh consideration of the action to be taken
- Remedial action, such as retraining and re-testing, must always take place, when necessary to correct substandard performance
- Persistent substandard performance, or an unwillingness to accept advice on retraining, must result in the suspension of the individual concerned from the screening programme. This applies equally to primary screeners, checkers and consultants

2R.30.10 Workload

- All pathologists/advanced practitioners participating in the cervical screening programme must report at least 750 cases per year. This figure should include all cervical cytology, where the pathologist/AP issues a report. The benchmarking exercise for cytology has made provision for a realistic

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workload of 10% of the total throughput to be carried out by the pathologists/ APs, working within a laboratory/network

- National standards expect that all primary screeners must screen between 3,000 and 7,500 cases per year. The benchmarking exercise for cytology has made provision for a realistic, achievable target of 5000 samples to be screened by each screener
- All checkers, including Chief BMSs, must screen or check at least 1,000 cases per year
- Screening staff must not screen for more than 5 hours per day and must spend no more than 2 hours at a microscope without a break
- As far as possible, all primary screeners should be carrying out a similar workload
- Where standards are not met, and laboratory workload is believed to be a contributory factor, changes in laboratory workload or laboratory configurations will be required

2R.30.11 Quality Control and Quality Assurance

- All laboratories must have appropriate IQC arrangements
- All laboratories must have, and must follow, standard operating procedures, which document every laboratory process
- All laboratory procedures must be routinely monitored and their monitoring recorded
- All laboratories must rapid QA screen all negative and unsatisfactory slides, on a daily basis
- The integrity of all laboratory data must be validated and audited.
- All cervical cytology staff must participate regularly in an External QA scheme and any deficiencies must be corrected. A record must be kept of all deficiencies and corrective actions undertaken

2R.30.12 Reporting

- All laboratories must use the BSCC/CSW reporting terminology
- All laboratories must be monitored against current NHSCSP standard reporting ranges, which are recalculated and published each year
- All laboratories must be monitored against current NHSCSP performance indicators for sensitivity of primary screening, based on rapid review, and positive predictive value (PPV) of cytology:
 - Current ranges:
 - Sensitivity for all abnormalities: 90% or more

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- Sensitivity for high grade abnormalities: 95% or more
- PPV for CIN2 or worse: 65% -90%
- All performance outside standard reporting ranges and performance indicators must be fully investigated

2R.30.13 Recommended Management

- Subsequent management must be recommended in **all** cases, according to the CSW Quality Manual

2R.30.14 Laboratory Accommodation and Facilities

- Laboratory accommodation and facilities must meet the requirements of CPA and should comply with the BSCC Code of Practice and Medical Devices Agency recommendations

2R.30.15 Records and Slides

- HMR request forms may be disposed of immediately following reporting, provided that an adequate electronic or facsimile media record is retained
- The copy must be legible and capable of paper reproduction
- An adequate copy of the form must include any notes appended to the form on both the facing and reverse sides, or on any supplementary forms or attachments relating to the request or report
- Electronic and other media must be 'backed-up' via a documented procedure that provides adequate data resilience
- All slides must be filed accurately to facilitate retrieval for review
- All slides must be kept for a period 10 years from the date of reporting
- All slides including (abnormal samples) should be disposed of after 10 years of storage
- Documentation relating to laboratory IQC must be retained for a minimum of 10 years
- Slide disposal after 10 years must be documented

2R.30.16 Review of Previous Cytology

- A review of previous cytology must be undertaken in **all** cases meeting the conditions stipulated in current CSW SOPPs

2R.30.17 Colposcopy Information and Support

- All women referred for colposcopy must receive a personalised invitation and information leaflet prior to their first colposcopy visit
- Information and support must be provided as an integral part of the colposcopy service

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- All women needing treatment must be informed that treatment will be required and have that treatment explained. Their consent, either written or verbal, must be recorded
- At least 90% of women, and their referring practitioners, must have their results and management plans communicated to them within 4 weeks and 100% within 8 weeks of attendance at clinic
- The colposcopy service must always inform the general practitioner and the Cervical Screening Administration Department when treatment is completed
- The CANISC Colposcopy Information System (CIS) must be appropriately used for the collection of data regarding colposcopy services
- Any appointment visit detailing visit type/ attendance status must be entered onto CANISC within 5 working days

2R.30.18 Accommodation and Facilities

- All colposcopy services must be permanently sited with a specific room for colposcopy
- All colposcopy services must have the following facilities:
 - Dedicated private area with toilet and changing facilities
 - A suitable couch, colposcope and other equipment necessary for diagnosis and treatment
 - At least one method of satisfactory treatment of CIN or automatic referral to a unit where treatment is available
 - Resuscitation equipment and the ability and training to use it correctly;
 - A suitable recovery area
 - Written emergency guidelines with which all clinic staff are familiar

2R.30.19 Staffing and Workload

- All colposcopy services must have a named colposcopist with appropriate skills who leads the service
- All colposcopists must be certificated by the BSCCP or be recognised by the BSCCP as being a trainee
- All clinics must have a named clinic nurse with appropriate skills and without concurrent out-patients duties
- No more than 15% of colposcopy services should be cancelled by the hospital (excluding annual leave) once appointments have been sent to women
- Consent must always be obtained to the presence of non-essential clinic personnel eg trainees, under-graduates, visitors

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2R.30.20 Waiting Times for Colposcopic Assessment

- All women referred for colposcopy must have their first appointment in a timely manner
 - All referrals: >90% in less than 8 weeks from the date of receipt of referral
 - Women with moderately/severely dyskaryotic cervical cytology: >90% in less than 4 weeks from the date of receipt of referral
 - Women with severe dyskaryosis /? Invasive or ?glandular neoplasia must be seen within 2 weeks of receipt of referral

2R.30.21 Non-Attendees

- All clinics must have written protocols for the management of default
- All clinics should ensure that there are low levels of default
 - ≤15% of women fail to attend for first appointment
 - ≤15% of women fail to attend for follow-up appointment
- The colposcopy service must always inform the General Practitioner and the Regional Programme Coordinator when a woman fails to respond to a second invitation for colposcopy

2R.30.22 First Assessment and Diagnosis

- All women requiring treatment for an abnormal cervical sample must have prior colposcopic assessment
- The cytology report must always be available to the clinician at the time of the colposcopic assessment
- At least 90% of women with moderately or severely dyskaryotic cervical samples must have a biopsy (i.e. material excised and sent for histological interpretation)
- At least 90% of biopsies should be adequate for histological interpretation
- The visibility of the squamo-columnar junction must always be recorded
- The following colposcopic findings must be recorded in at least 90% of cases:
 - Presence or absence of a visible lesion
 - Colposcopic opinion regarding the nature of the abnormality and requirement for treatment
- Colposcopists should accurately predict high grade lesions or worse in at least 65% of cases

2R.30.23 Treatment

- All women must be managed according to the CSW Quality Manual

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- All treatments must be recorded
- All women must be treated in properly equipped and staffed clinics
- At least 90% of women should have definitive treatment for high grade CIN within 8 weeks of a diagnostic biopsy and 100% must be treated within 12 weeks. Pregnancy is an exception. The reason for delay must be specified
- All women must have had their histological diagnosis established prior to destructive therapy
- At least 90% of women treated at their first visit should have evidence of CIN on histology
- At least 80% of women should be managed as out-patients with local analgesia
- No more than 5% of treatments should be associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied
- No more than 2% of cases should be admitted as in-patients due to treatment complications

2R.30.24 Follow-Up

- All women must be managed according to the CSW Quality Manual
- At least 85% of treated women must have a follow up cervical sample, within the colposcopy service, within 6 to 8 months following treatment
- In at least 90% of cases, there should be no dyskaryosis on cytology in treated women at 6 months
- There should be no more than 5% of cases with histologically confirmed treatment failures within 12 months of treatment

2R.30.25 Cervical Histology

- The pathologist must always have the cytology and colposcopy results available at the time of reporting biopsy specimens
 - The pathologist must always provide the histopathological information needed to allow clinical management to be planned. Such details should include:
 - Specimen size
 - Number of segments
 - Margin status
 - Grade of CIN/ dysplasia
 - Presence or absence of cGIN/carcinoma
- If carcinoma is reported then the complete histopathology minimum dataset for carcinoma cervix should be provided

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2R.30.26 Links between Cytology, Colposcopy and Histology

- All cases in which the histology result is different from that expected from cytology must be further investigated
- All cases in which the histology result is different from that expected from colposcopy must be further investigated
- Where cytology and histology are carried out in different laboratories, there must be an efficient two-way flow of information between laboratories. Cytology results must be available when histology is reported and final histology results must be available to cytology laboratories, for correlation and audit purposes
- Joint audit between the relevant laboratories must also take place
- Decisions as to whether repeat biopsies are required should be multidisciplinary, as should decisions about future management in difficult cases. As a minimum, pathologists must be in a position to suggest a further biopsy specimen, if indicated
- Pathologists must ensure that formal arrangements are in place for regular discussion of cases with medical colleagues
- Any relevant clinical information on the outcome of women referred to colposcopy must be provided routinely to the relevant cytology laboratory
- Multidisciplinary audit across professional boundaries must be established

2R.30.27 FailSafe

- FailSafe procedures must ensure that all women are appropriately followed up, and their General Practitioner informed, in the following circumstances:
 - Non-attendance for a cervical sample (routine, repeat or follow-up)
 - Non-attendance for colposcopy (assessment, treatment or follow-up)
- The Regional Programme Coordinator must be informed of all women for whom all attempts at follow-up have failed
- Less than 5% of women not returned to routine recall should have an unknown outcome after 12 months

Further Guidance

2R.31 MANAGEMENT OF THE ABNORMAL CERVICAL SAMPLE

Cytological Surveillance:

Cytological Surveillance is a series of early repeat smear tests which is applied in the management of low grade abnormalities.

a) In its standard form it is the appropriate management protocol:

- After one smear showing mild dyskaryosis
- After one or two smears showing borderline changes in squamous cells only
- After colposcopic investigation where no abnormality was confirmed following referral for a low grade cytological abnormality unless modified cytological surveillance has been recommended (see below)
- After diagnosis of histologically confirmed HPV
- After diagnosis of histologically confirmed CIN1, whether treated or not
- After investigation of borderline glandular changes (endocervical or endometrial) or abnormal endometrial cells where no abnormality is identified and discussed and confirmed at MDT

Standard Cytological Surveillance is:

A series of three follow-up smear tests taken after the abnormal smear or colposcopy/treatment at 6, 12 and 24 months, all of which must be negative before a woman is returned to routine recall:

- A sample is taken six months after the abnormal smear or colposcopic investigation/treatment
- If negative, a repeat smear test is taken a further six months later
- If negative, another repeat smear test is taken a further twelve months later
- If negative, the woman is returned to routine recall
- This first sample following colposcopy/treatment should ideally be taken within the colposcopy service

b) In defined circumstances cytological surveillance is modified.

In its modified form it is the appropriate management protocol:

- Following a satisfactory colposcopic examination for low grade cytological abnormality (referral for recurrent borderline changes or mild dyskaryosis) where no colposcopic abnormality was found

Modified Cytological Surveillance is:

- Only used when requested by a colposcopist
- Only used following a satisfactory colposcopic examination where no colposcopic abnormality was found
- Not applicable where the colposcopic impression is low grade or worse, or where a biopsy has shown HPV changes or worse

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- A repeat sample, taken within the colposcopy clinic, six months after the colposcopic examination - the woman may only be discharged from colposcopy clinic if the result is negative or borderline

If the sample is negative the woman is discharged and returned to routine recall.

If the sample is abnormal this is considered a 'first' abnormal smear:

- For borderline changes
 - The woman is discharged from the colposcopy service
 - A repeat smear test is taken 12 months later in primary care
 - If borderline at the 12 month smear (ie 'second' abnormal) then continue standard cytological surveillance (see above)
- For mild dyskaryosis
 - The woman is not discharged from the colposcopy service
 - A repeat smear is taken in 12 months, together with colposcopic examination
- For moderate dyskaryosis or worse (high grade)
 - Urgent colposcopy is required

If colposcopy is delayed for more than six months after the referral smear then a repeat smear may be taken at colposcopy

Cytological Follow-Up:

Cytological Follow-Up is the appropriate management protocol following the treatment of:

- CIN2 or CIN3
- CGIN or SMILE
- A high grade cytological referral, which shows CIN1 or no abnormality

Cytological Follow-Up consists of a series of early repeat smear tests, which must all be negative before a woman is returned to routine recall.

The CSW follow-up protocol consists of:

- i. A smear test 6 months after treatment which ideally should be taken within the colposcopy service
- ii. If this test (i) is negative she should be discharged from the colposcopy service and have a repeat test in primary care a further 6 months later
- iii. If test (ii) is negative, repeat smear test a further 12 months later (2yrs after treatment)
- iv. If test (iii) is negative, then repeat samples annually up to 10 years after date of treatment

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- v. If final test is negative (exit smear) the woman is returned to routine recall

If a woman fails to attend for one or more of the follow-up tests, she may still be returned to routine recall provided that she has had:

- At least five negative smear tests
- Each of which were at least 12 months apart, and
- The final negative sample (the 'exit smear') is at least ten years post treatment

If any of these follow up tests shows borderline changes or worse she will be directly referred to the colposcopy service.

Suggested Management:

- Routine recall must be suggested following:
 - A negative result following call or whilst on routine recall
 - A negative result following an inadequate smear whilst on routine recall
 - A third consecutive negative result whilst under 'cytological surveillance' which meets the criteria for return to routine recall (see above)
 - A negative result, whilst under 'cytological follow-up' which meets the criteria for return to routine recall (at least 10 years post treatment – see above)
- Immediate repeat must be suggested following an inadequate result:
 - After one or two smear tests are reported as inadequate
 - Be repeated no less than 6 weeks after the original sample and usually within 3 months of the preceding test
 - Have any infection present treated prior to repeating the test
 - Take into account the reason for the previous inadequacy
 - Not be repeated before 12 weeks post partum (pregnancy, termination, miscarriage)
- An early repeat smear must be suggested (unless it is anticipated that the woman will not comply with cytological surveillance or follow-up) following:
 - One smear result showing mild dyskaryosis
 - One or two smear results showing borderline squamous change (excluding borderline ?high grade, or borderline changes in endocervical/endometrial cells see below)
 - A first or second negative smear test whilst under 'cytological surveillance' (see above)
 - A negative smear test whilst under 'cytological follow-up' (prior to the criteria for return to routine recall being met – see above)

Referral for colposcopic examination must be suggested following:

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- One result showing:
 - ?invasive carcinoma
 - Moderate or severe dyskaryosis
 - High grade glandular abnormality(6GC/6GM)
 - Borderline changes ? high grade (8H)
 - Borderline changes ? high grade/endocervical cells (8HC)
 - Borderline changes in endocervical cells (8GC)
 - Borderline changes in endometrial cells (8GM)
 - Any grade of abnormality whilst under cytological follow up
 - Mild dyskaryosis or worse whilst under cytological surveillance post colposcopy
 - Any grade of abnormality for a post transplant woman on maintenance immunosuppressant therapy
 - Any grade of abnormality where the woman is 65 or over, or has no cervix

- Or
 - Two tests showing mild dyskaryosis
 - One test showing mild dyskaryosis and one test showing borderline changes (or vice versa)

NOTE: in these cases the second abnormal test occurs whilst under 'cytological surveillance' of the first

- Or
 - Three tests showing mild dyskaryosis or borderline changes, over any 10 year period (without an intervening colposcopic investigation)
 - After three consecutive smears described as cytologically inadequate
 - When cervical cancer is suspected for clinical reasons
 - When a woman has a single mildly dyskaryotic or borderline smear if it is indicated that the woman will not comply with cytological surveillance or follow-up

De Novo Borderline Changes:

The occurrence of borderline changes in a smear test is considered a new and separate episode when a woman who has not had previous high grade disease has been colposcopically investigated for low grade cytology/histology and has had a subsequent negative smear

Further Guidance

FOR SPECIFIC GUIDANCE SEE 2R.80

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Summary of Recommended Management for Cervical Samples

The following table (Suggested Management – 2R.80) can be used to determine clinical management or follow-up.

The appropriate management (column three)
is based on
The previous history prior to current test result (column two)
and
The current test result (column one)

Table 1 Suggested Management

CURRENT TEST	PREVIOUS HISTORY	MANAGEMENT
Negative	<ul style="list-style-type: none"> ▪ No previous screening history or following routine recall ▪ Following inadequate smear (unless under cytological surveillance or follow up) ▪ Under cytological surveillance after a borderline or mild dyskaryosis smear or after colposcopy: <ul style="list-style-type: none"> – Following initial borderline changes, mild dyskaryosis or colposcopy – Following one previous negative smear – Following two previous consecutive negative smears ▪ Under cytological follow up after colposcopy (CIN2/3) <ul style="list-style-type: none"> – Following colposcopy – Following one or more previous negative smears – Unless following five or more previous consecutive negative smears at least 12 months apart, where the current smear is at least 10 years post treatment 	<ul style="list-style-type: none"> ▪ Routine recall ▪ Routine Recall ▪ Repeat in 6 mths ▪ Repeat in 12 mths ▪ Routine recall ▪ Repeat in 6 mths ▪ Repeat in 12 mths ▪ Routine recall
Inadequate*	<ul style="list-style-type: none"> ▪ No more than one previous consecutive inadequate* test ▪ Two previous consecutive inadequate* results 	<ul style="list-style-type: none"> ▪ Immediate repeat ▪ Refer colp (8 weeks)
Borderline Changes	<ul style="list-style-type: none"> ▪ No more than one previous mild or borderline squamous smear, within ten years** (unless under cytological surveillance or follow-up: see below) ▪ Two previous mild or borderline smears within 10 years** ▪ Under cytological surveillance after a single borderline smear or de novo borderline after CIN1 and a negative follow-up smear ▪ Under cytological surveillance after a mild or borderline endocervical smear ▪ Under cytological surveillance (if 3rd borderline) or follow-up (if 1st borderline) after colposcopy 	<ul style="list-style-type: none"> ▪ Repeat in 6 mths ▪ Refer colp (8 wks) ▪ Repeat in 6 mths ▪ Refer colp (8 wks) ▪ Refer colp (8 wks)
Borderline Endocervical (8GC)	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer Colp(8 wks)
Borderline Endometrials(8GM)	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer Colp(Urgent 4 wks)
Borderline ?High Grade (8H)	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer Colp(Urgent 4 wks)
Borderline Endocervical ? High Grade (8HC)	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer Colp (Urgent 4 wks)
Mild Dyskaryosis	<ul style="list-style-type: none"> ▪ No more than one previous borderline smears within 10 years** (unless under cytological surveillance or follow-up: see footnote) ▪ Under cytological surveillance or follow-up (for any reason) ▪ Two previous mild or borderline smears within 10 years** 	<ul style="list-style-type: none"> ▪ Repeat in 6 mths ▪ Refer colp (8 wks) ▪ Refer colp (8 wks)
Moderate Dyskaryosis	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer colp (urgent 4 wks)
Severe Dyskaryosis	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer colp (urgent 4 wks)
Severe Dyskaryosis/ ?Invasive Carcinoma	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer colp (immediate 2 wks)
Glandular Neoplasia	<ul style="list-style-type: none"> ▪ In all cases 	<ul style="list-style-type: none"> ▪ Refer colp (immediate 2 wks)

* Cytologically inadequate smears only

** Ignore previous smears prior to colposcopy

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NB: when using the table to determine the appropriate management, it is important to read the whole of the relevant section (especially if the woman is already under cytological surveillance) to ensure that you are applying the correct previous history. CSW will, in all cases, issue a result with the recommended action on it to sample takers, and act on the recommended action

2R.32 SMEARS FROM WOMEN WITH SYMPTOMS

Cervical cytology is a screening test and should never be considered a diagnostic test. The taking of a cervical smear, as an investigation of symptomatic women, is never clinically justified.

Samples taken from women with clinical symptoms that are not due under current screening policy will, nonetheless, continue to be screened and reported by the laboratory in accordance with the relevant SOPP (4P.90). An appropriate disclaimer must accompany the cytology result; the disclaimer informs the woman's smear taker and GP that the cervical smear test is not appropriate for women with clinical symptoms and that her management must not be based on the result – it is expected that the woman will be treated for her clinical symptoms and managed accordingly or referred if appropriate to a gynaecologist

Further Guidance

FOR SPECIFIC GUIDANCE SEE 4P.81

2R.33 MANAGEMENT FOLLOWING DIAGNOSIS OF INVASIVE CERVICAL CANCER

Total Hysterectomy where Woman has Invasive Carcinoma of Cervix

- The woman is immediately ceased from the screening programme
- The woman will receive further follow-up determined by her gynaecologist or oncologist, which might include subsequent vault smears and/or colposcopy. It is the responsibility of the clinician to ensure that the woman is properly followed up; she will not be subject to further recall by CSW
- The smears will be examined at the laboratory but no management recommendations will be made

Total Hysterectomy for Carcinoma of Cervix also Treated by Radiotherapy/Chemotherapy

- The woman is immediately ceased from the screening programme
- The woman will receive further follow-up determined by her gynaecologist or oncologist, which might include colposcopy. It is the responsibility of the clinician to ensure that the woman is properly followed up; she will not be subject to further recall by CSW

Treatment for Carcinoma of the Cervix by Radiotherapy/Chemotherapy alone

- The woman is immediately ceased from the screening programme
- The woman will receive further follow-up determined by her gynaecologist or oncologist, which might include colposcopy. It is the responsibility of the clinician to ensure that the woman is properly followed up; she will not be subject to further recall by CSW

Treatment for Carcinoma of the Cervix by Trachelectomy (with or without radiotherapy/chemotherapy)

- The woman will receive further follow-up determined by her gynaecologist or oncologist, which might include subsequent cytology and/or colposcopy. It is the responsibility of the clinician to ensure that the woman is properly followed up and to request further recall by CSW if appropriate

The Guidelines for the management of women with invasive disease require that they are managed according to local guidelines and are seen initially by the consultant responsible for the care of the woman, or the lead colposcopist.

The regional gynaecological oncologist or cancer lead must be informed of the case to decide definitive management.

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The treatment of early invasive cervical cancer (FIGO stage Ia1, Ia2, Ib1, Ib2 and IIa) is outwith the responsibility of Cervical Screening Wales and consequently the outside the general scope of the colposcopy SOPPs. However, the following specific guidance applies.

If early invasive disease is detected, the lead colposcopist and the consultant responsible for the care of the woman should be informed as soon as possible.

Further Guidance

FOR SPECIFIC GUIDANCE SEE 5C.145

2R.36. DISCORDANT RESULTS AND INCIDENTS

Managing the Smear Taker Incident Process

2R.36.1 Staff Responsible

Managerial Responsibility
Regional Programme Co-ordinator
Cervical Cytology Manager

Operational Staff

Regional Nurse Co-ordinators

QA Adviser

All Wales Programme Manager
Regional Programme Coordinator
Dave Nuttall Scientific Advisor

2R.36.2 Quality Standard

A Smear Taker incident is said to have occurred when a woman's care has been compromised as a result of a smear taker error and the woman advised to have the test repeated

Incident Categories:

- Unprocessed samples
- Processed samples
- Processed Special Category

Unprocessed Samples

- Misidentification, which may involve more than one woman's details
- Unlabelled vials
- Illegible details, some labs may report this as unlabelled.

Processed Samples

- Leaked vial (less than 8ml of fluid left in vial) rendering samples with no abnormality as inadequate
- Smear taken too soon
 - Within 6 weeks of previous test
 - Less than 12 weeks post natal
 - Less than 12 weeks post miscarriage or termination of pregnancy
- Smear taker error
 - Endocervical brush used on its own
 - Brush head not in vial
 - Cervix not fully visualised ([written on HMR Form](#))
- Out of date vial
- Faulty vials

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Processed Samples Special Category

Incidents identified after smear test result sent:

- CSAD advised by the woman, smear taker or the service that the wrong woman has received a smear test result attributable to incorrect details being entered on the original smear test request form

2R.36.3 Method

Unprocessed - misidentification, which may involve more than one woman's details.

Actions:

- Sample(s) not processed but recorded in a separate booking in area on the Lab Management System (LIMS)
- No entry on Exeter
- No letter generated
- Details passed to Regional Nurse Co-ordinator (RNC) to activate the incident procedure

Unprocessed - Unlabelled/label illegible

The sample cannot be accepted because the vial is unlabelled/illegible but as the details of the woman are on the form the sample can be entered on the system:

Actions:

- Sample not processed
- Test entered on to Exeter
- Unprocessed letter sent to the woman
- Details passed to Regional Nurse Co-ordinator to activate the incident procedure

Processed samples

Sample is processed at the laboratory if there has been a sampling error/fault providing the identification of the woman is deemed correct the following actions are taken

Actions:

- Inadequate result is issued if the sample tested normal, as it cannot be ruled out that abnormal cells may not have been missed or lost
 - Note: if the sample tested abnormal the result may be issued. In these cases the incident process would not be instigated as the woman's care has not been compromised. RNC to contact the smear taker to meet any training needs

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- The woman is advised to have the test repeated but not within 6 weeks of the previous test
- Exeter result letter generated and the appropriate letter sent
- Details passed to Regional Nurse Co-ordinator to activate the incident procedure

Processed samples - Special Category

Incident identified after smear test result sent out to the woman

Actions:

Once notification has been received that a woman with a test recorded on Exeter did not have a smear taken the smear taker must be contacted to:

- Confirm in writing that the test on that date did not belong to the woman in question. This may either be confirmed on the incident form or by letter
- Once written confirmation has been received the smear test may be removed from the CSAD Exeter database system and the laboratory system
- A letter of apology is written to the woman as agreed locally.
- If the identity of the woman who had the smear taken is known to the smear taker appropriate steps under the incident procedure should be followed
- Regional Nurse Co-ordinator to activate the incident procedure

2R.36.4 Regional Nurse Co-ordinator Incident Procedure

The incident process commences as soon as notification is received from the laboratory or CSAD officers that a smear taker error constituting an incident has occurred.

RNC to contact the smear taker either personally or by standard letter to:-

- Investigate how the incident occurred
- Discuss measures to prevent it happening again
- Identify any training need
- Management of the woman
- Request the woman's notes to be flagged accordingly in the practice
- RNC to authorise the sending of an incident form to the smear taker. In exceptional circumstances, such as a faulty vial or leaked vial, where the incident could not be totally attributable to a smear taker error, the incident form may be completed by the reporter e.g. RNC
- RNC to monitor smear taker incident occurrence

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In the case of 'Misidentification' or 'Special Category' and the details of the woman/women who had the test performed is known to the smear taker, the smear taker is advised to:

- Inform the woman/women that the test needs to be repeated, but not within 6 weeks and confirm this in writing on the incident form
- Flag surgery records of the above information
- Provide CSW with written confirmation as to who the sample(s) belonged to together with full identification details of the woman/women involved

On receipt of written confirmation as to the identity of the woman/women involved the information is passed to CSAD staff to:

- Enter the details on the Exeter system
- Make a note on the screen that an incident is involved and document the incident number
- Send an unprocessed letter
- Alter management to immediate repeat
- File a screen dump of the entry on Exeter in the manual file together with any supporting information such as Laboratory Z form

Secretary or designated person to:

- Send an incident form and guide, on how to complete, with standard covering letter
- Register the incident on the Datix system
- On receipt of the incident form:
 - designated person adds form to Datix
 - RNC to complete and approve the incident
 - to verify that the woman is on the correct recall status on Exeter
- Incidents discussed at LEMG

Non return of completed incident form

After 2-4 weeks if not returned a 2nd incident form and letter to be sent to Smear Taker and Practice Manager/Clinical Lead

- If not returned within 8 weeks inform RNC
- If no response from the Smear Taker RNC to complete and submit incident form with all relevant details
- Covering letter and copy of completed incident form to smear taker/Practice Manager

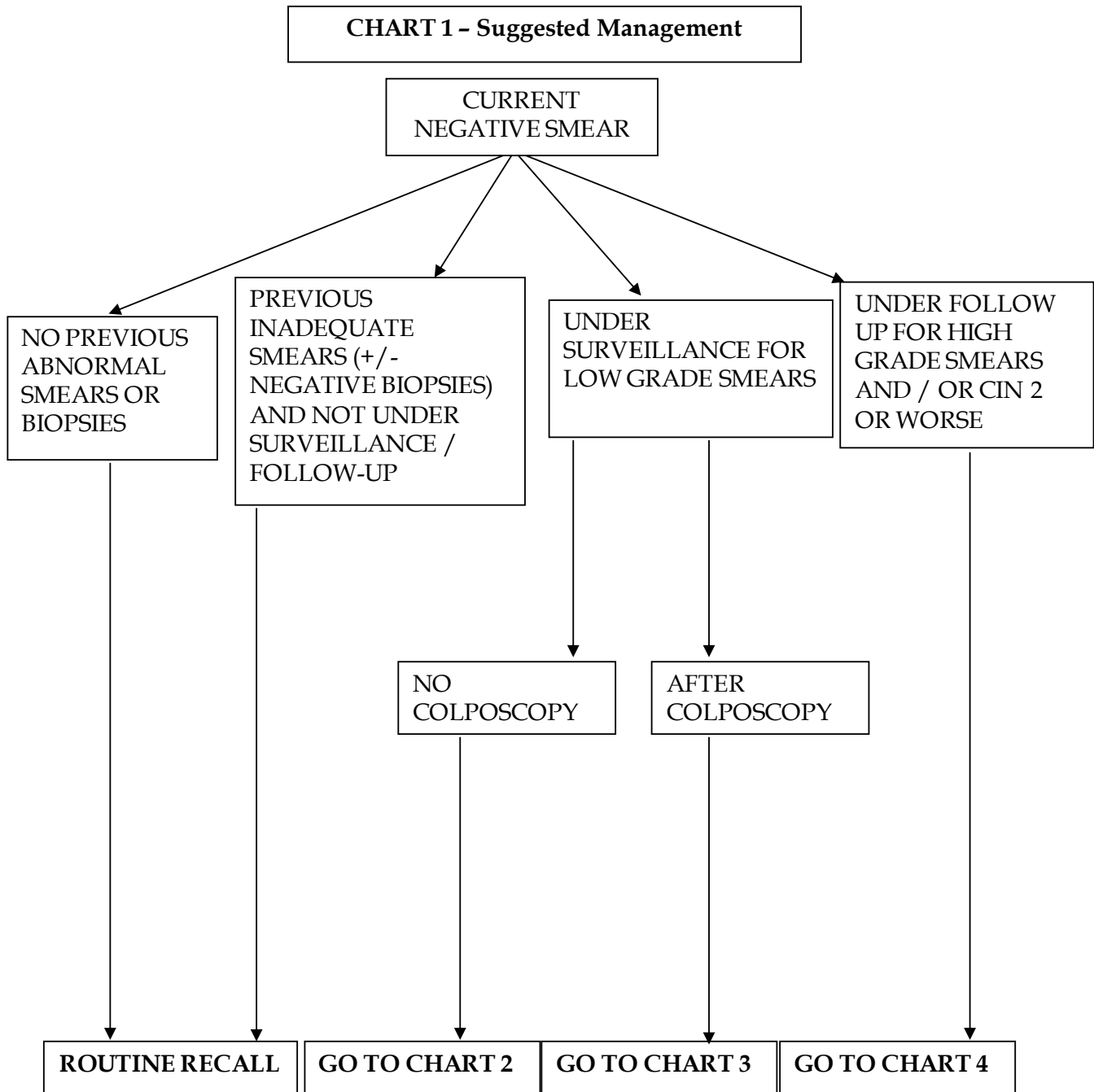
2R.36.5 Quality Measures

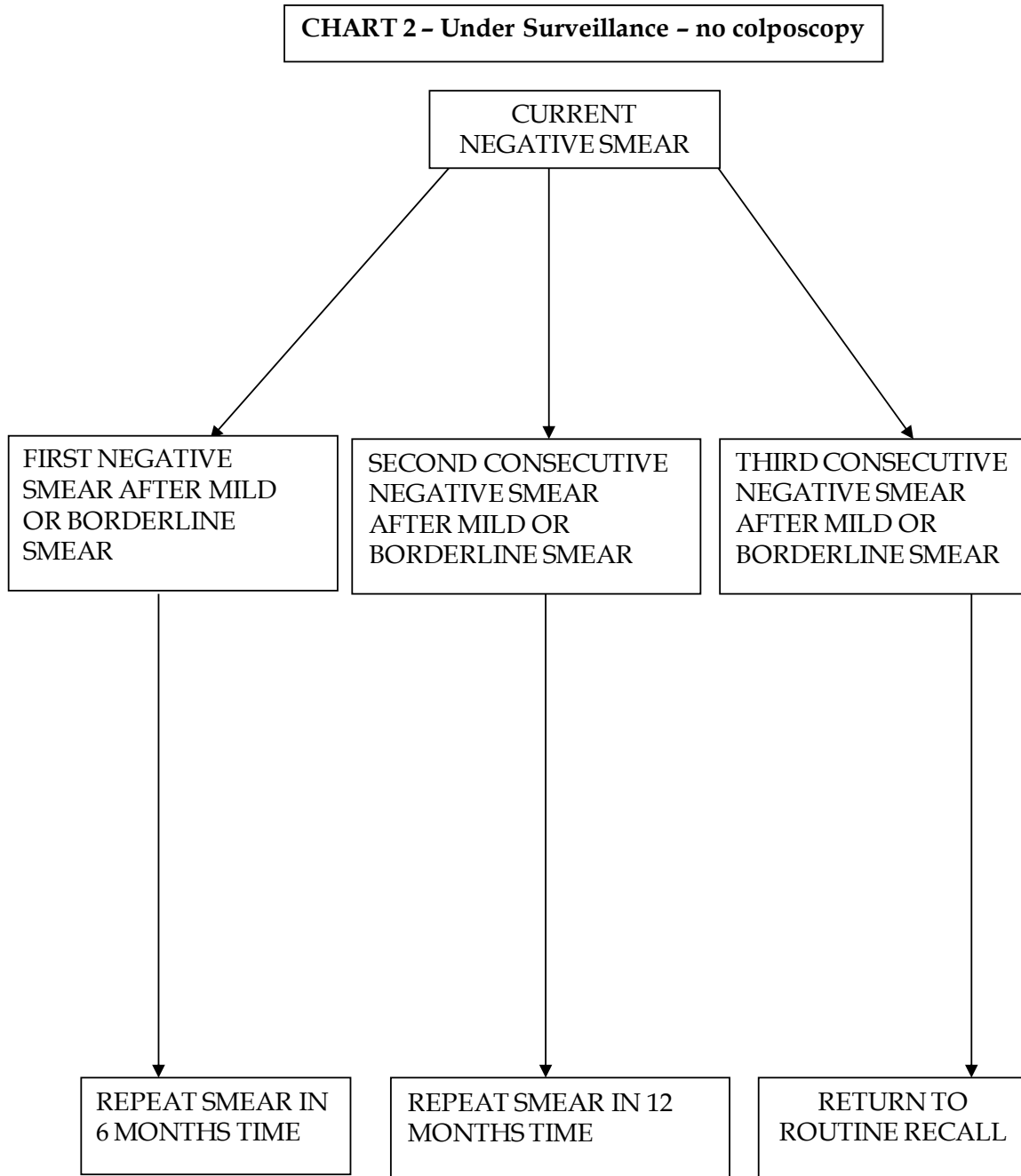
- Incident completed within 10 weeks
- All women involved in an incident have had a test repeated or have been returned to correct recall status

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Further Guidance

2R.40. ALGORITHMS





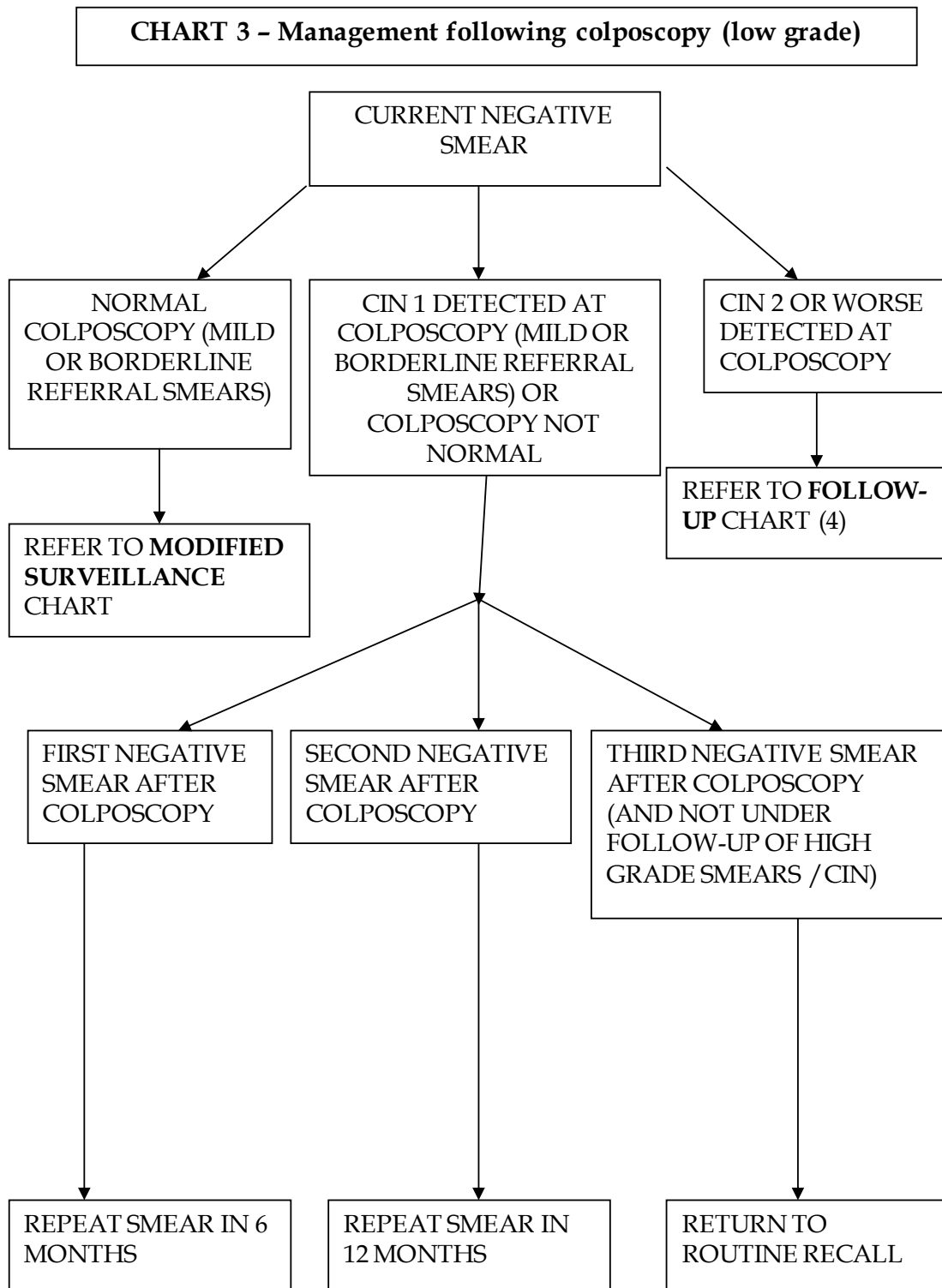
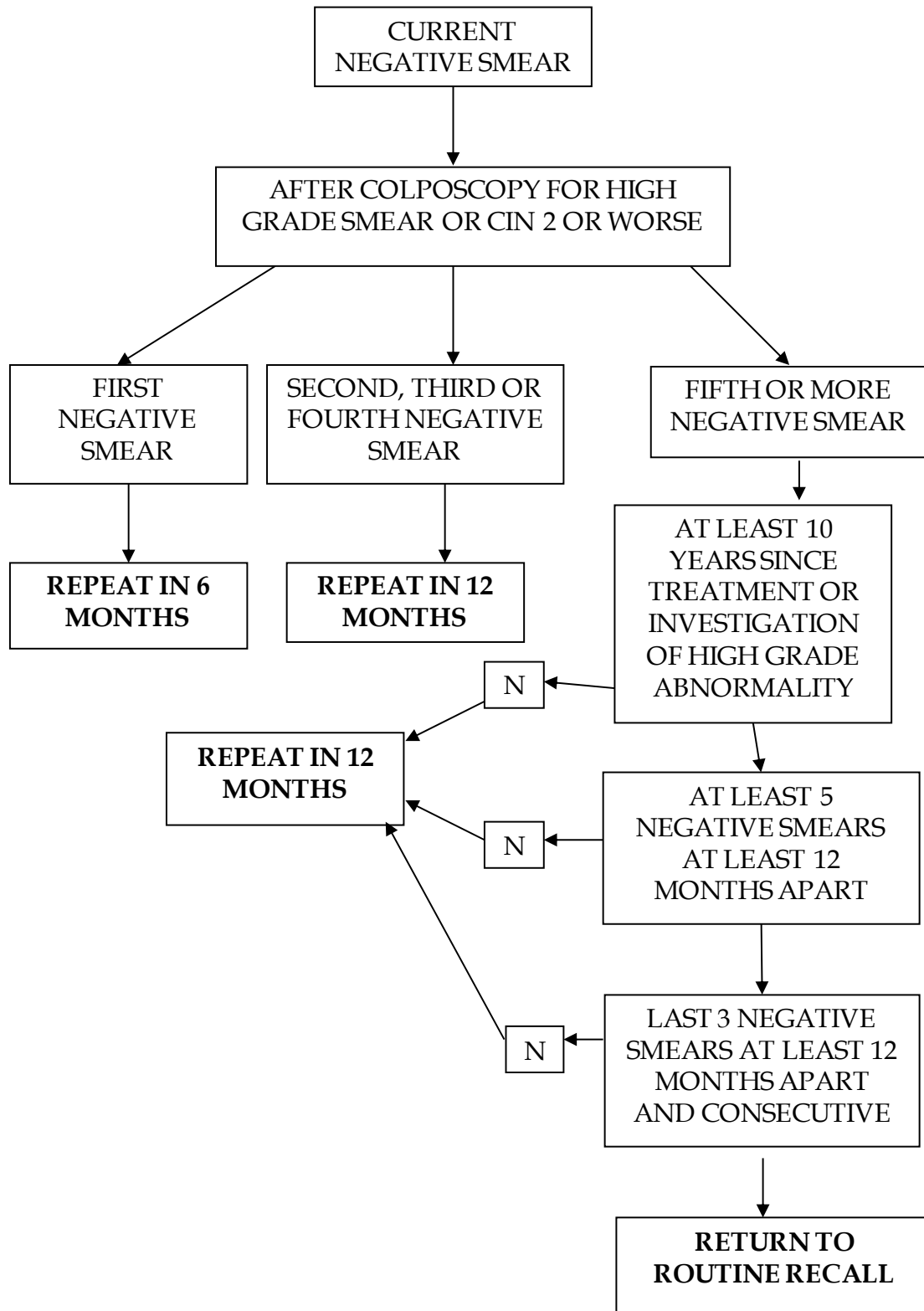
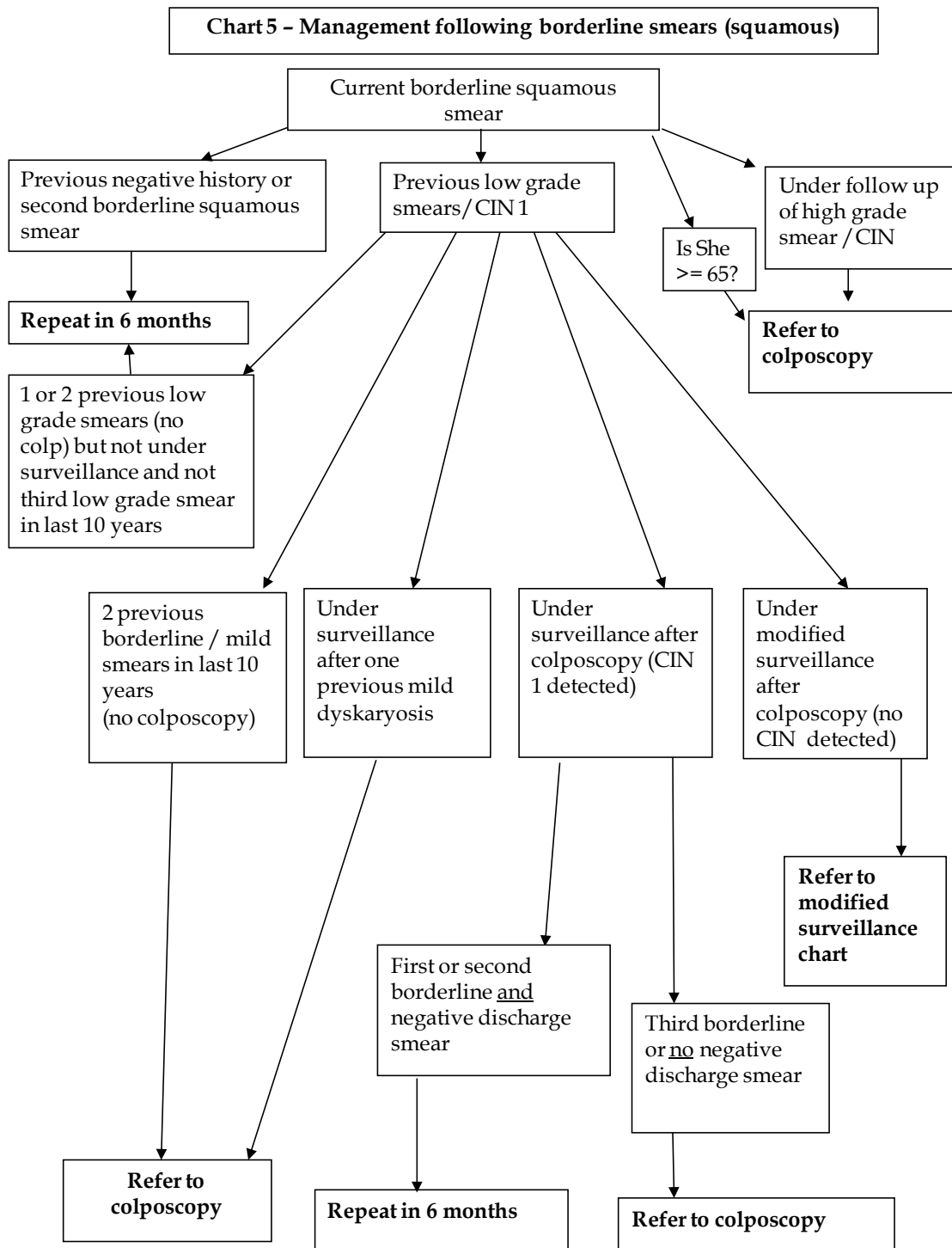


CHART 4 - Management following colposcopy (high grade)



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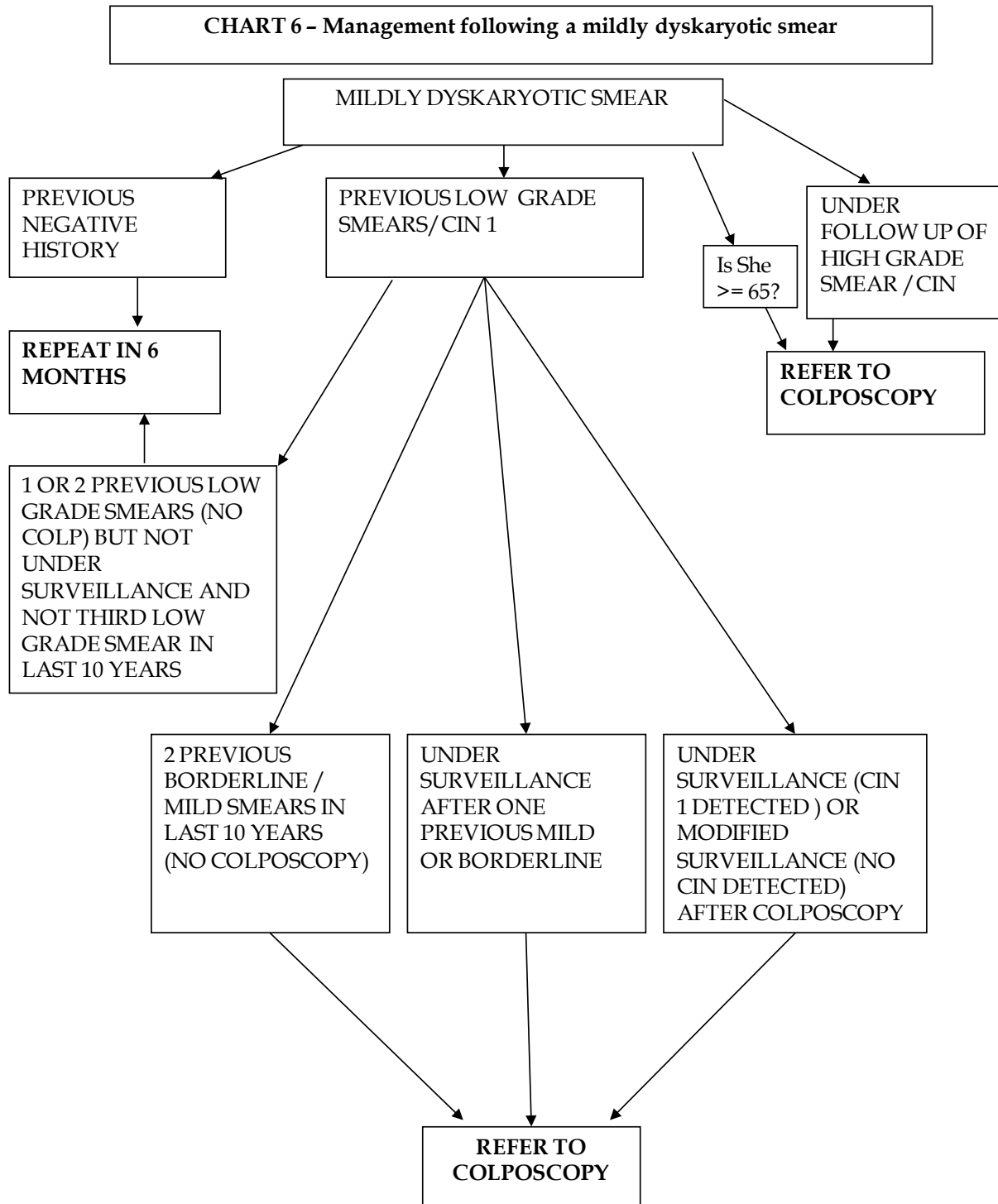
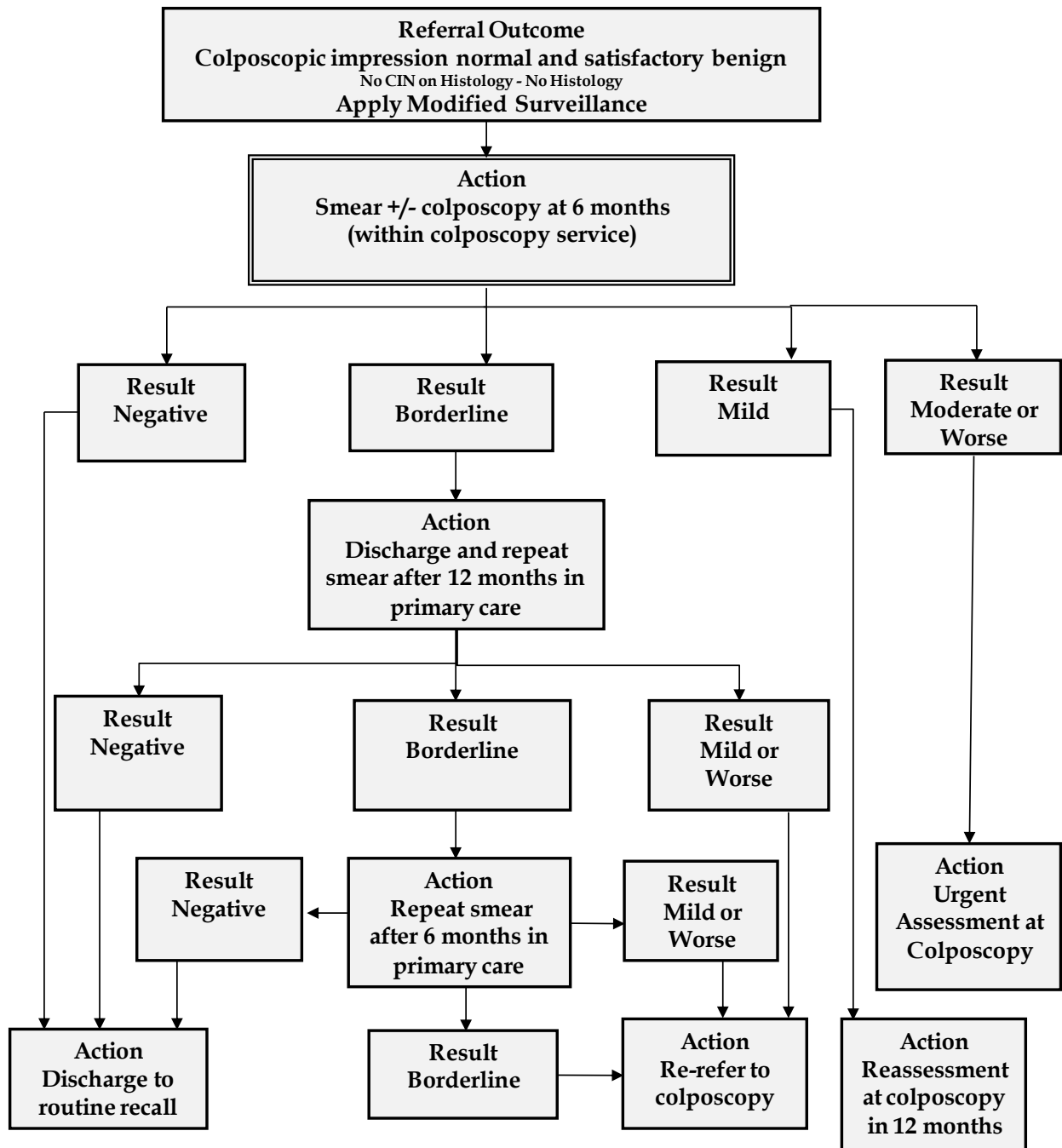
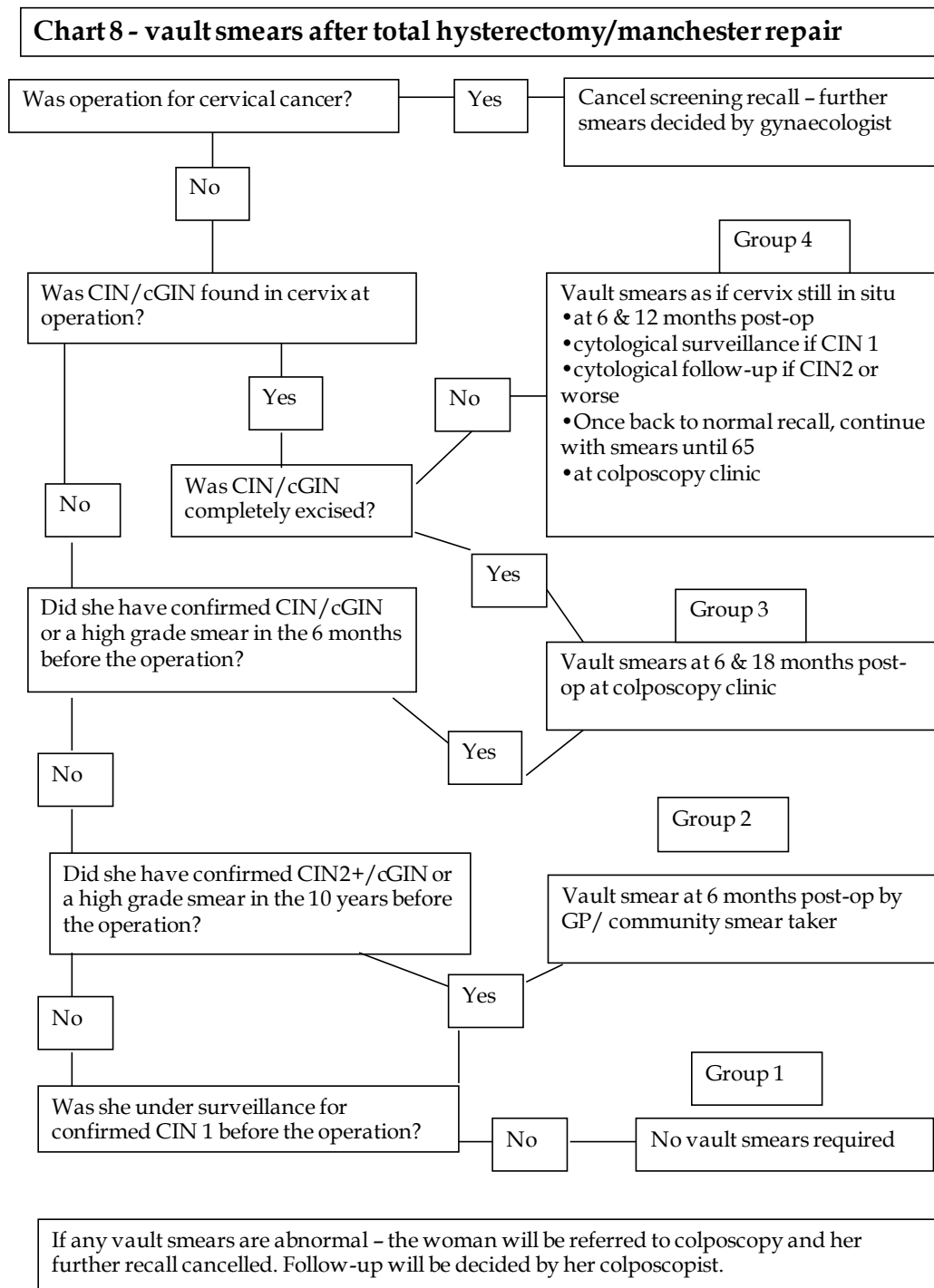


CHART 7 - modified cytological surveillance following referral for low grade cytology



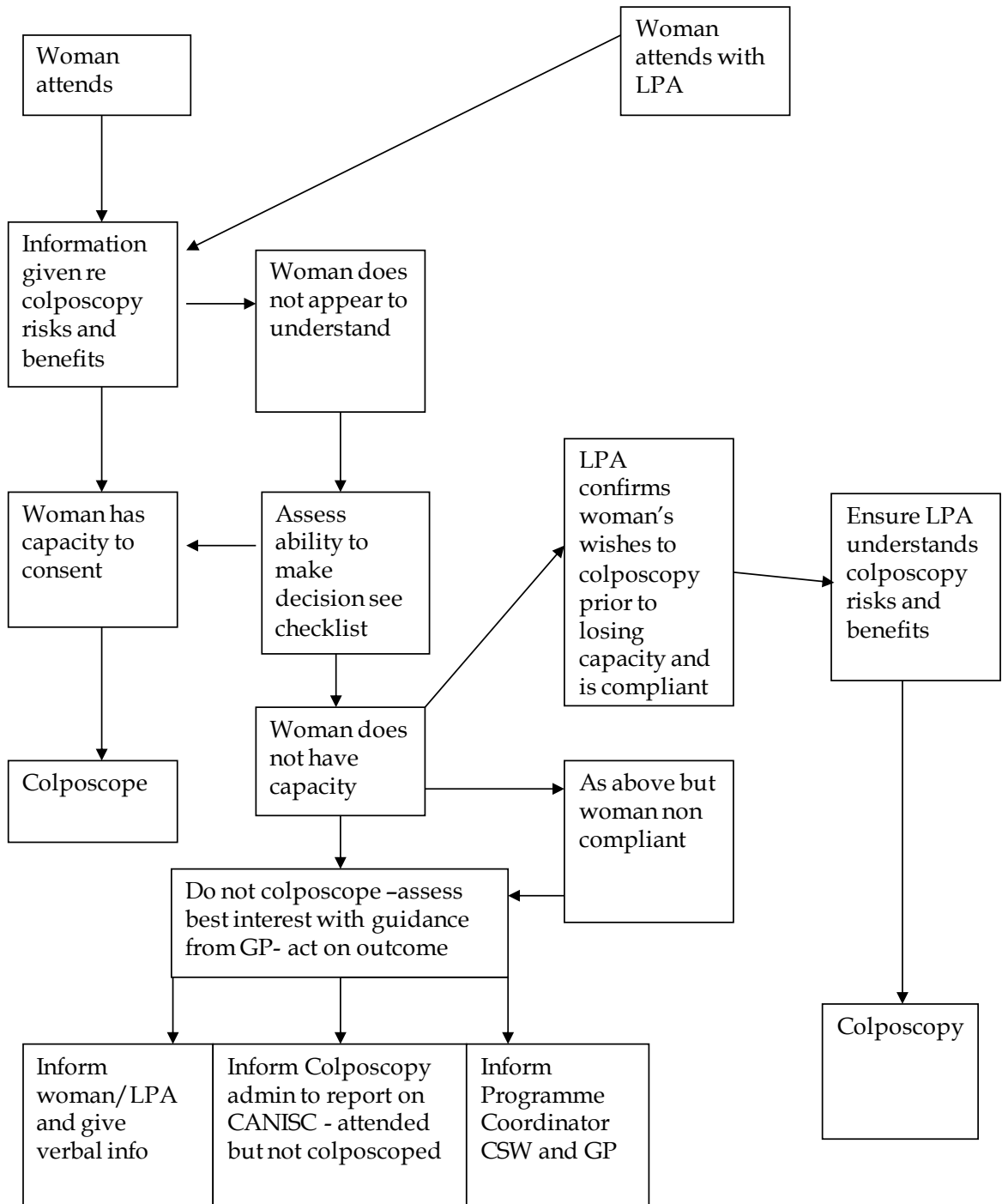
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N.B. This also applies to Manchester Repair unless there is concern about the completeness of excision of the cervix

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Chart 9 - Consent and Capacity Flow Chart



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Chart 10 - The uninterrupted path through ColpSafe

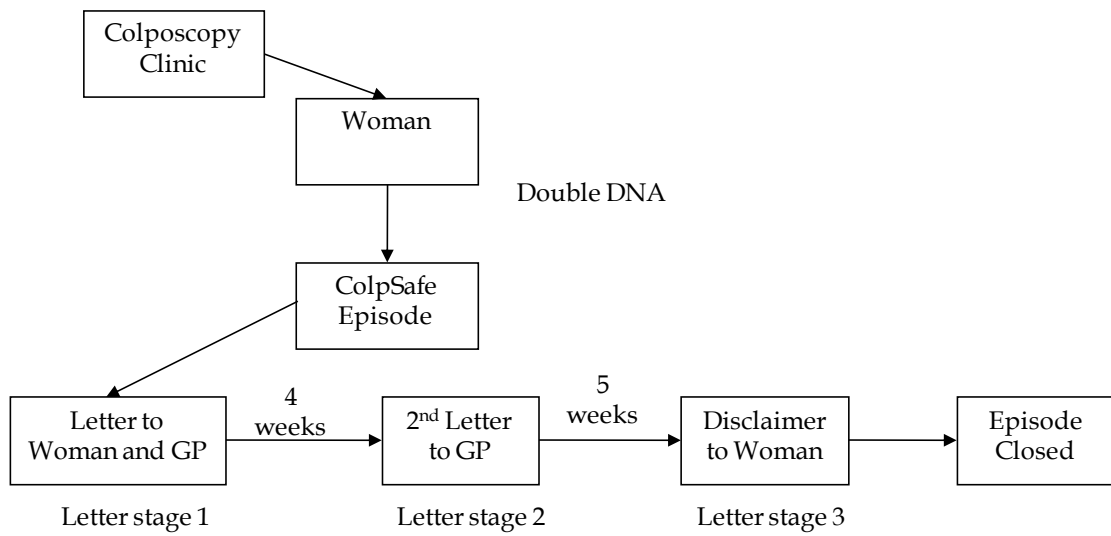


Chart 11 - What if the Woman wants another appointment?

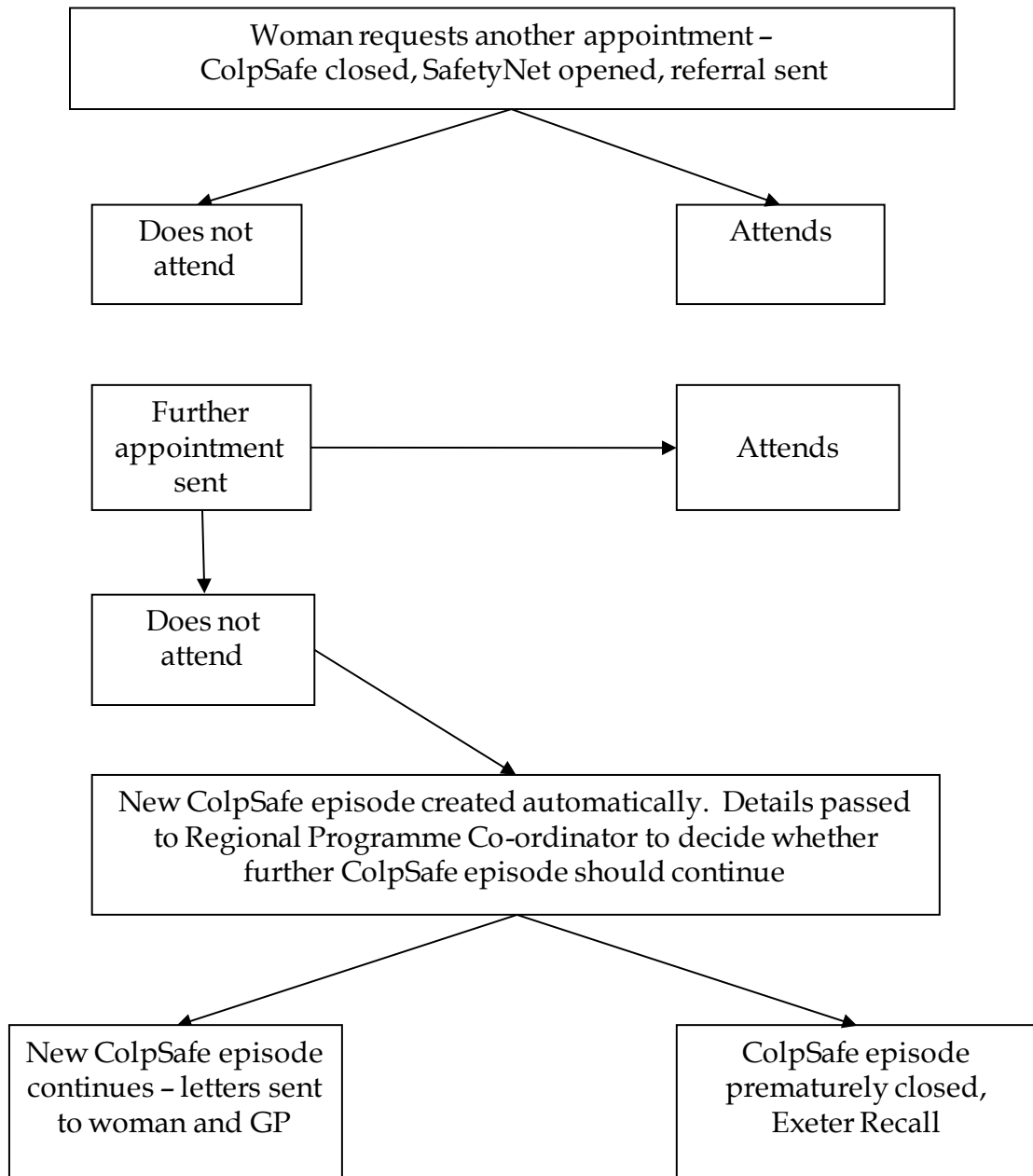
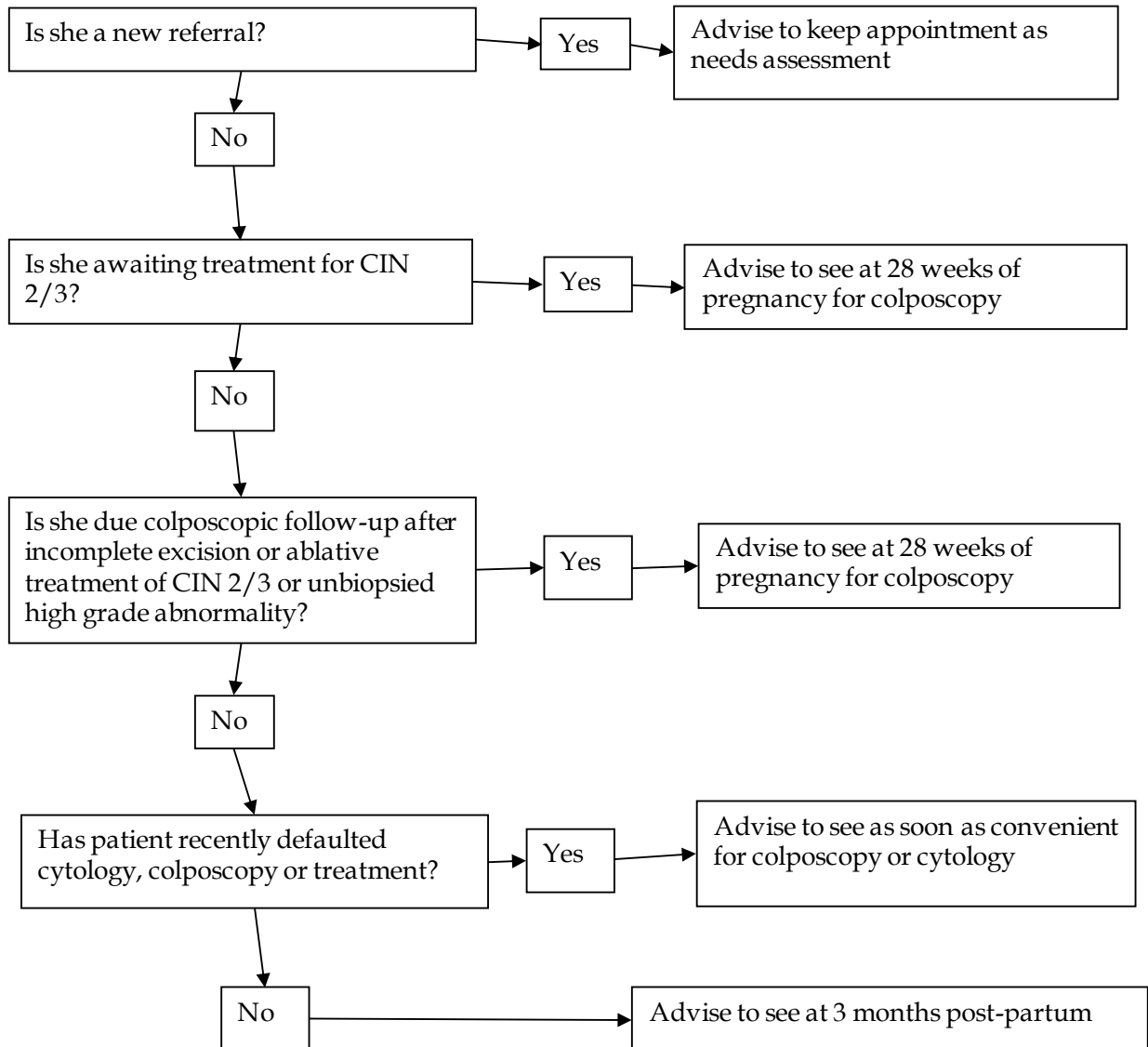


Chart 12 - colposcopy for pregnant women

This flowchart is designed to provide guidance when a woman who is due to be seen in the colposcopy clinic contacts the clinic to say that she is pregnant



2R. 50 GLOSSARY

Aceto-White Epithelium - AWE: if acetic acid is applied to the cervix any abnormal epithelium stains white. The colposcopic impression of these areas is used to determine presence and degree of abnormality

Cervical ectropion: also known as cervical eversion or ectopy - normal columnar epithelium is present on the ectocervix appearing as a bright red area on the ectocervix. A normal finding that does not require treatment if asymptomatic

Cervical Intra-epithelial Neoplasia - CIN: (see dysplasia) new cell growth occurring within the squamous epithelium of the cervix

CIN1 - changes confine to lower 1/3rd of squamous epithelium

CIN2 - changes confined to approximately lower 2/3rd of squamous epithelium

CIN3 - full thickness epithelial change

Cervical Glandular Intra-epithelial Neoplasia - CGIN: new cell growth occurring within the glandular epithelium of the cervix.

Colposcopy: examination of cervix and surrounding anatomy using magnification and illumination. Acetic acid and iodine are used to detect dysplasia and determine whether treatment needed, and if so what type

Condylomata acuminta: warts

Cryocautery/cryotherapy: a treatment method whereby a probe is placed on the cervix and allowed to freeze - mainly used for treatment of symptomatic cervical eversions and low grade CIN

Cold coagulation: a treatment method whereby a probe is placed on the cervix which is then heated to a high temperature - mainly used for treatment of cervical eversions, low grade CIN, and in certain cases high grade CIN

CSAD - Cervical Screening Administration Department: -runs the call and recall system for cervical screening for women resident in Wales. In addition, directly refers women with abnormal cytology to colposcopy clinics as well as managing a "fail-safe system" to ensure women are managed and followed up appropriately

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Dyskaryosis: distorted nucleus of cells

Mild dyskaryosis – minor nuclear abnormalities which may indicate presence of minor or low grade changes such as CIN1 or HPV infection

Moderate dyskaryosis – moderate nuclear abnormalities which may indicate presence of high grade disease such as CIN2

Severe dyskaryosis - more obvious nuclear abnormalities which may indicate high grade disease such as CIN3

NOTE – dyskaryosis is a possible indicator of disease, but whilst the categories mild, moderate and severe may indicate CIN1/HPV, CIN2 and CIN3 respectively, this is not necessarily the case (e.g. some studies have shown high grade disease associated with up to 1/3rd women with mild dyskaryosis)

Dysplasia: abnormal cell growth or development of cells (see CIN)

High grade dysplasia – also called high grade disease or high grade squamous intra-epithelial lesion (HSIL) – equivalent to CIN2 or CIN3

Low grade dysplasia – also called low grade disease or squamous intra-epithelial lesion (LSIL) – equivalent to CIN1 or viral change

Human Papilloma Virus – HPV: there are more than 100 different sub-types of this very common sexually transmitted virus. A small number of these subtypes (including types 16, 18 and some others) are linked with developing CIN and cervical cancers in some women, although the exact mechanism is unknown. Others such as HPV 6 and 11 are linked to warts. Majority of women now exposed to HPV – but majority will eradicate virus BEFORE it causes any problems by the body's own immune system.

Knife Cone Biopsy: excisional Treatment method for CIN whereby a cone-shaped piece of cervical tissue is removed using a scalpel, under general anaesthetic – now mainly carried out for areas suspicious of invasion, or deep endocervical lesions

Large Loop Excision of Transformation Zone – LLETZ: commonest treatment method for CIN using a small wire loop to excise the abnormal area. Also known as DLB, DLE, Loop excision

LASER – Light Amplification by Stimulated Emission of Radiation: a destructive method of treatment for CIN which uses laser light to vapourise abnormal tissue on the cervix

Metaplasia: the process by which columnar/glandular epithelium on the cervix is replaced by squamous epithelium (see transformation one)

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Nabothian follicles: blocked glands on the cervix appearing as small yellowish cysts to the naked eye

Polyp: benign overgrowth of epithelial tissue

Punch biopsy: small piece of tissue removed with a biopsy forceps and sent for histological examination

Squamo-columnar junction: line of demarcation between columnar and squamous epithelium (see TZ)

Transformation zone - TZ: the area of cervix where the columnar/glandular epithelium has converted to squamous epithelium by the process of metaplasia (see metaplasia). This is the area of the cervix most susceptible to dysplastic change which is why a smear must be taken from here

The Bethesda System (TBS) - The Bethesda System is an internationally recognised classification system for reporting cytological abnormalities. It is not used in the UK but is included here for reference

2R.60. APPENDIX 1 ~ ROUTINE MONITORING DATA

The following two headings list the information published in the Cervical Screening Wales - Colposcopy Reports issued periodically to the service. These items are based on data extracted from the CANISC-Cancer Information System Cymru for both Clinics (1) and Individual Colposcopists (2):

- **1 Colposcopy Clinic Data**
- 1 Total number of visits
- 1B Number of new patients seen
- 2 Reasons for referral of new cases
- 3 New referrals by cytology result
- 4 Type of visits - Total visits
- 4B Type of visits - New patients
- 5 Written or verbal consent recorded
- 5B Consent for imaging recorded
- 6 Women having colposcopic assessment prior to treatment of abnormal cytology
- 7 Colposcopist assessment compared with biopsy result; clinic total
- 7B Colposcopist assessment compared with biopsy result; by individual colposcopist
- 8 Biopsies taken by type
- 9 Treatment details
- 10 Anaesthetic details
- 11 Satisfactory/unsatisfactory colposcopy
- 12 Colposcopy where the whole lesion was seen
- 13 Attendance rates for first offered appointments to a new referral
- 14 Attendance rates for planned treatment appointments
- 15 Attendance rates for follow-up appointments
- 16 Women waiting less than 8 weeks from date of receipt of referral to date of colposcopy (excluding patient instigated delays)
- 17 Women with moderate or worse cervical samples waiting less than 4 weeks from
date of receipt of referral to date of colposcopy (excluding patient instigated delays)
- 18 Women with abnormal referral cytology assessed having a biopsy
- 19 Percentage of planned treatment biopsies having evidence of CIN on histology by biopsy type
- 20 Women referred with abnormal cytology having their histological diagnosis established prior to destructive therapy; by type of therapy

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- 20B All women referred having their histological diagnosis established prior to destructive therapy; by type of therapy
 - 21 Women treated by excisional biopsy at the first visit with evidence of CIN on histology
 - 22 Biopsies adequate for interpretation by biopsy type
 - 23 Complications at time of visit
 - 24 Cases admitted as in patients due to treatment complications
 - 25 Treated women attending post treatment follow up with cytology results within 8 to 12 months
 - 25B Treated women attending post treatment follow up with cytology results within 8 months; by result
 - 25C Treated women attending post treatment follow up with cytology results within 12 months; by result
 - 26 Confirmed histological treatment failures within 12 months of treatment
 - 26B Confirmed histological treatment failures within 12 months of treatment; by result
 - 27 Number of patients still under follow up 2 years after referral
 - 28 Compliance with standard regarding communication of results and management
 - 29 Compliance with standard regarding communication of results and management plans to General Practitioner/ referring clinician
-
- **2 Individual Colposcopist Data**
 - 1 Number of patients seen
 - 2 Reasons for referral of new cases
 - 3 New referrals by cytology result
 - 4 Type of visits - Total visits and New patients
 - 5 Written or verbal consent recorded
 - 5B Consent for imaging recorded
 - 6 Women having colposcopic assessment prior to treatment of abnormal cytology
 - 7 Colposcopist assessment compared with biopsy result; by individual colposcopist
 - 8 Biopsies taken by type
 - 9 Treatment details
 - 10 Anaesthetic details
 - 11 Satisfactory/unsatisfactory colposcopy
 - 12 Colposcopy where the whole lesion was seen
 - 13 Women with abnormal referral cytology assessed having a biopsy
 - 14 Percentage of planned treatment biopsies having evidence of CIN on histology by biopsy type

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- 15 Women referred with abnormal cytology having their histological diagnosis established prior to destructive therapy; by type of therapy
- 15B All women referred having their histological diagnosis established prior to destructive therapy; by type of therapy
- 16 Women treated by excisional biopsy at the first visit with evidence of CIN on histology
- 17 Biopsies adequate for interpretation by biopsy type
- 18 Complications at time of visit
- 19 Treated women attending post treatment follow up with cytology results within 8 to 12 months
- 19B Treated women attending post treatment follow up with cytology results within 8 months; by result
- 19C Treated women attending post treatment follow up with cytology results within 12 months; by result
- 20 Confirmed histological treatment failures within 12 months of treatment
- 20B Confirmed histological treatment failures within 12 months of treatment; by result
- 21 BSCCP Certification Statistics – provided as required

2R.70. APPENDIX 2 ~ KEY PUBLICATIONS - BIBLIOGRAPHY

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Colposcopy.

2R.100 APPENDIX 4 ~ REFERRAL PANEL

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