Standards for

Quality Assurance in Cervical Screening

Standards for Quality Assurance in Colposcopy

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

Standards for Quality Assurance in Colposcopy

Introduction

Colposcopy services play a key role in the success of any cervical screening programme by ensuring optimal management of women with detected screening test abnormalities. In particular, colposcopy services must ensure accurate diagnosis and effective treatment. Quality assurance for colposcopy services is therefore essential. Interventions must reduce the risk of cancer in these women while minimising the risk of any significant physical and psychosocial impact. The quality of any colposcopy service is reliant on the skill and judgement of the individual practitioners as well as adequately resourced, well organised administration.

This chapter provides requirements and standards for the provision of quality assured colposcopy services. It is based on the model of care agreed between the National Health Service Cervical Screening Programme, British Society for Colposcopy and Cervical Pathology (BSCCP) and the Royal College of Obstetricians and Gynecologists (RCOG).

This edition of requirements and standards for colposcopy services operating within the CervicalCheck programme have been based on the following references:

- The second edition of the NSS 'Guidelines for quality assurance in cervical screening.[1]
- European guidelines for quality assurance in cervical cancer screening.[2]
- The evolution of standards and guidelines in response to technological developments and research outcomes in other cervical screening programmes including Public Health England[3] Cervical Screening Wales[4] and National Cervical Screening Program Guidelines Australia[5]
- The CervicalCheck colposcopy algorithms.[6,7,8,9,10]
- The activity and performance of colposcopy services collated since the commencement of CervicalCheck.

Please note, throughout this document, where we refer to 'women', we mean women and anyone with a cervix.

Tools for monitoring compliance with the requirements and standards include:

- Service standard operating procedures/process guidelines documented and in place.
- Service record of failsafe management.
- Local register of BSCCP certified colposcopists and trainers including BSCCP identities updated six monthly.
- Training logs.
- Attendance records list of women discussed and minutes of multi-disciplinary team (MDT) meetings (excluding confidential women's information which can be retained in the woman's records.
- Audit of waiting times/clinic schedules.
- Colposcopy monthly returns and extracts of colposcopy information.

- Analysis of data provided to the Cervical Screening Register (CSR) by screening labaratory, colposcopy and histopathology services providers.
- Quality assurance visits.

Note: Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards. Quality standards are those with a measurable level of performance and associated target for achievement. Where no target is provided these are considered quality requirements that the service provider must fulfil. These requirements are identified with a “must” or “will” statement.

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

Quality requirements are stated as a description. There is no target associated with a requirement as service providers must fulfil the requirement.

Quality standards are stated as a description of an activity with a measurable level of performance, with an associated target for achievement. The standards are designed to be measurable i.e. quantitative with criteria that are valid, reliable and feasible.

[Note: Document will be reviewed every 3 years or as significant clinical evidence emerges]

4.1 Clinic organisation

QR4.01

Quality requirement

Access area

The colposcopy service should be provided in a dedicated outpatient facility, with a dedicated reception area and a dedicated waiting area for people. There must be clear signage from the hospital entrance to the colposcopy clinic.

QR4.02

Quality requirement

Administrative area

There must be dedicated office space to house the administrative support for the colposcopy service ensuring compliance with hospital health and safety guidelines.

There must be space for secure storage of the colposcopy clinical records of all current colposcopy women within this administrative area. There must be a provision to enter data into the colposcopy computerised management system.

QR4.03

Quality requirement

Clinical area

There must be a dedicated area for history taking and consultation which should ensure the privacy of the woman. There must be provision to enter the history onto the IT system in this clinical space. There must be adjacent toilet facilities for the woman. A separate recovery room/area must be available. There must be a private changing area.

QR4.04

Quality requirement

Equipment

There must be an examination couch capable of postural adjustment. There must be at least one working colposcope which must be maintained in accordance with the hospital guidelines on the maintenance of medical equipment. The colposcope must be linked to a camera to enable image capture. A monitor must be available to allow the woman to view the procedure. Images must be captured using the colposcopy management software.

Resuscitation equipment must be available at the colposcopy clinic. Clinical and nursing staff must be trained in the use of the resuscitation equipment.

A panic button must be accessible within the clinical room which provides communication with staff outside the clinical room. There must be a computer connected to the hospital network in the clinical room to facilitate data entry of clinical information.

4.2 Governance

QR4.05 **Quality requirement**	**Governance** The service must have regular (at least quarterly) operational meetings between nursing, hospital administration/managers and colposcopists. Management reports including numbers attending, waiting times and default rates must be reviewed at these operational meetings and appropriate corrective actions taken. The service must have MDT meetings at least every two months to enable efficient decision making and timely discussion of challenging cases. Colposcopy clinics must be scheduled in sessions of a notional half day to include administration time to accommodate appointment slots of 20 minutes (30 minutes if a trainee is present) per room to maximise throughput while minimising waiting times at the colposcopy service.

4.3 Quality assurance and continuous improvement

QR4.06 **Quality requirement**	**Standard Operating Procedures** The colposcopy service must have clinical and administration guidelines and procedures which have been agreed by both the colposcopy team and the hospital administration.
QR4.07 **Quality Requirement**	**CervicalCheck reports** A complete and accurate report containing prescribed quality metrics shall be provided at regular intervals to CervicalCheck. Information is submitted to CervicalCheck on a monthly and quarterly basis.
QR4.08 **Quality requirement**	**Quality metrics improvement** Colposcopy services will undertake appropriate and timely measures to address performance issues that impact upon quality metrics and cause values outside of national norms.
QR4.09 **Quality requirement**	**Quality assurance visits** Colposcopy services shall accommodate on-site visits by CervicalCheck-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.

QR4.10 **Quality Requirement**	**Quality Improvement and Audit** To ensure continued high standards within colposcopy it is essential that each clinic undertakes a program of quality improvement. This is underpinned by audit of practice and it is expected that each clinic will carry out at least one organisational audit and one clinical audit per year. A summary of each audit should be forwarded to CervicalCheck and will be held as a repository which other clinics may access for examples of good practice. This is the responsibility of the lead colposcopist.

Audit of invasive cervical cancers

To be updated when an implementation plan for the recommendations of the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population is agreed.

4.4 Clinic staffing

QR4.11 **Quality requirement**	Colposcopists must be trained and certified by a recognised body such as BSCCP and must appear as such on the list of certified colposcopists of the certification body Having a dedicated, specialist team in the colposcopy unit provides continuity of care and allows women to develop confidence in individual members of staff. This in turn helps reduce anxiety and improves both attendance and satisfaction with the service. The extended role of the nurse colposcopist is of particular benefit here. Women undergoing colposcopy should be supported by a registered nurse. A support person trained in colposcopy is needed to assist in making the necessary preparations for cervical sampling, biopsies and treatment, and to support the colposcopist directly during the examination. All colposcopists (doctors and nurses) working in a clinic must receive the same level of nursing staff support. All clinic staff must be familiar with the treatment method(s) used.
QR4.12 **Quality Requirement**	There must be adequate dedicated nursing staff available to the service as agreed in the memorandum of understanding for each service. A clinical nursing care assistant must be available to facilitate cleaning and enhance the turnaround time between women at the colposcopy clinic. There must be a separate nurse-led HR-HPV cervical screening clinic.

QR4.13

Quality Requirement

The colposcopy service requires adequate clerical and secretarial support to ensure timely communication with women and their GPs. In addition, administrative support is needed to ensure efficient data collection, effective communication with other agencies, and effective and timely failsafe activities.

There must be enough dedicated administrative support available as agreed in the memorandum of understanding to provide administrative support to the service.

Staffing for the service should ensure that there is appropriately trained cover available for planned absences and there is no over-reliance of the service on single individuals.

QR4.14

Quality Requirement

Lead Colposcopist

Each organisation providing a colposcopy service must have a lead colposcopist who holds overall accountability, whose role is reflected in their job description and who has suitable time allocated in their job plan. Time allocation needs to be assessed in terms of the scope and complexity of the services provided. The lead colposcopist must hold regular team meetings; ensure that good practice is followed, that protocols are developed and observed, and that the quality requirements outlined in this document are met. They must also ensure that the service collects accurate and valid data by which to measure its performance. This will ensure that the requisite information is available to enable the completion of all required and mandated returns and audits. A deputy must be nominated to provide cover.

QR4.15

Quality Requirement

Lead Nurse

Each organisation providing a colposcopy service must have a named lead colposcopy nurse, whose role is reflected in their job description and who has suitable time allocated in their job plan. The lead nurse takes day to day responsibility for running the colposcopy service and will be actively involved in colposcopy clinics. A deputy must be nominated to provide cover.

4.5 Information technology and data quality

QR4.16

Quality requirement

Infrastructure

A computerised colposcopy management system must be installed at the colposcopy clinic. This system must be networked in an accessible form from all areas in use by the team. The colposcopy management system must be interfaced with the hospital patient administrative system and the hospital appointments system.

Adequate numbers of concurrent user licenses should be available to enable efficient data entry by all necessary staff.

QR4.17

Quality requirement

Training in colposcopy systems

Training in the use of the colposcopy management system is mandatory for new staff and must be documented. This is the responsibility of the lead clinician. For new releases all staff must receive appropriate training and this is the responsibility of the developers.

QR4.18

Quality requirement

Utilisation

The colposcopy service must generate appointment letters from the colposcopy management system. The IT system must be used for specimen management using a defined report that lists specimens taken at each clinical session. The IT system must be used to store image and video data. The IT system must be used to enter the results of any tests. The IT system must be used to enter follow-up and management plans. The IT system must be used to generate result and management plan letters to referrer GP and the woman. The IT system must be used to check failsafe processes. The IT system must generate quarterly mandatory audit returns.

QR4.19

Quality requirement

Information transfer to CervicalCheck

All updates to records of women who have consented to transfer of personal data to CervicalCheck must be transmitted to the CSR on a daily basis.

QR4.20

Quality requirement

Error files

Error files that are returned from the CervicalCheck CSR must be checked on a regular basis. All error records sent by the CSR must be actioned in a timely fashion and corrected updates resent to the CSR.

QR4.21

Quality requirement

Management of specimens

There must be a defined process for checking all specimens to ensure that all are correctly dispatched to the laboratory in a timely fashion (within 72 hours).

QR4.22 **Quality requirement**	**Management of test results** There must be a defined process for tracking all test results to ensure that all are received by the colposcopy service and entered on the colposcopy IT system. There must be a defined process for the review of the result in conjunction with the medical record to decide the most appropriate course of action based on the results. The defined process for review of results must include a method of fast tracking results suggestive of invasive cancer.
QR4.23 **Quality requirement**	**Audit and systems review** Each colposcopy unit must have a defined process whereby computerised failsafe checking procedures are performed monthly. Each colposcopy team, on a quarterly basis must meet and review this process, in conjunction with the previous 3 months failsafe reports.
QR4.24 **Quality Requirement**	**Confirmation of demographic details** Woman's demographic details must be confirmed and updated at each attendance and women are reminded to inform the clinic of change of address whilst attending. Mandatory fields must be completed. Demographics to be confirmed forename, surname, date of birth, address, Surname at birth, mother's maiden name, PPS number, Colposcopy Reference Number and telephone number.

4.6 Communication

QR4.25 **Quality requirement**	**Provision of information** All women must be sent a personalised invitation with clinic-specific information on colposcopy in advance of appointments. this must include directions to the clinic.
QR4.26 **Quality requirement**	**Communication of results to the woman and to the referring doctor (negative and abnormal)** There must be a defined process to ensure that all test results and management plans are communicated to both the woman and the referring doctor.

Standard 4-1	**Communication of results and management plans** Information on results of investigations must be issued to the woman and to the referring doctor in a timely manner.	**Target** Minimum 90% within 6 weeks of the woman's attendance.

QR4.27 **Quality requirement**	**Follow-up** There must be a defined process for ensuring that all women attending colposcopy have a management plan which includes recommendations for appropriate follow-up with advice on where and when subsequent screening tests should be performed. This must be communicated to the woman and referring clinician. Updates to CervicalCheck should be sent electronically.

4.7 Appointments management

QR4.28 **Quality requirement**	**Management of new referrals** There must be a defined process for the management of new referrals. There must be a defined process for informing women of the appointment by letter from the colposcopy management system. Services must use the facilitated referral process and inform the programme via a "red flag alert" if it is unable to process appointments within these timeframes.

Standard 4-2	**Management of waiting times for new referrals to colposcopy**	**Target**
	Women referred to colposcopy should be offered a timely appointment following receipt of referral.	Minimum 90%
	Women with a clinical suspicion of invasive cancer or a screening test suggestive of invasive cancer	Within 2 weeks.
	Women with a screening test suggestive of high grade disease (HSIL/ASCH) or any glandular abnormality (including Atypical Glandular cells – AGC)	Within 4 weeks.
	All other women	Within 8 weeks.

Standard 4-3	**Management of women who default**	**Target**
	The percentage of women who do not attend and who do not notify the colposcopy service should be maintained at a low level to maximise the efficiency of the colposcopy service and to avoid the loss of women to follow-up.	Maximum 10%
	There should be a local policy for contacting and dealing with defaulting women.	

QR4.29 **Quality Requirement**	**Number of appointments defaulted prior to discharge** Following a number of attempts to contact the woman and GP (including by telephone), and except in exceptional circumstances no more than two appointments must be offered before discharging due to DNA.

4.8 Clinical requirements and standards in colposcopy

Please refer to appendices 1, 2, 3, 4 & 5 for algorithms outlining required management strategies for women attending colposcopy. Transfer of care recommendations must be selected based on these algorithms.

4.9 Diagnosis and management

Standard 4-4	**Satisfactory biopsies** Biopsy specimens should be suitable for histological diagnosis	**Target** Minimum 90%
QR4.30 **Quality Requirement**	**Reason biopsy not performed** Reasons for not performing a biopsy in the presence of an abnormal TZ at the first visit e.g. pregnancy should be recorded.	

4.9.1 Low grade CIN

Standard 4-5	**Low grade referral & normal colposcopy** At first Visit if the TZ is Type 1 or 2 and normal i.e. there is no evidence of CIN either visually or on biopsy (if performed), then the woman should be invited for screening in primary care in 3 years[3] (regardless of age).	**Target** Minimum 95%
Standard 4-6	**Low grade referral and CIN 1** If the colposcopy is abnormal a biopsy should be performed. If diagnosis is CIN 1 or less, then the woman should be invited for screening in primary care in twelve month's time. Treatment should only be offered in special circumstances (woman's choice, previous treatment)	**Target** Minimum 90%
Standard 4-7	**Women who present HR-HPV positive with low grade cytological abnormality** Women who on subsequent testing become HR-HPV negative should return to routine screening (3 years).	**Target** Minimum 90%

4.9.2 High grade CIN

Standard 4-8	**Colposcopic detection of high grade** Compliance between colposcopic impression of high grade disease and histologically proven high grade CIN.	**Target** Minimum 65%
QR4.31 **Quality Requirement**	**High grade cytology and normal colposcopy** Women who present with a high grade cytological abnormality and who have no colposcopic abnormality identified on a fully visible TZ including biopsy and examination of the vagina must have the screening test reviewed by the Cytopathologist at an MDT meeting. Further management is based on MDT decision.	
Standard 4-9	**Biopsy of Type 3 TZ** Where a lesion extends into the endocervical canal and the upper limit is not clearly seen (Type 3 TZ) and the cytological report suggests a high grade lesion, an excisional biopsy should be considered in preference to a punch biopsy.	**Target** Minimum 95%
Standard 4-10	**High grade cytology and low grade CIN** Women referred with high grade cytology and who have CIN 1 or less diagnosed on a biopsy should be managed by a senior colposcopist. If excision is not performed the case should be discussed at MDT. Further management is based on MDT decision.	**Target** Minimum 95%
Standard 4-11	**Women who present with high grade cytological abnormality** If the colposcopy suggests low grade disease and treatment is not performed, multiple biopsies should be taken where possible.	**Target** Minimum 95%
Standard 4-12	**High grade disease** Women with CIN 3 confirmed on a diagnostic biopsy should have a treatment performed. Pregnancy is an exception and is discussed under management of complex cases (Section 4.13.4). Note: Treatment of CIN 2 may be recommended but conservative management is acceptable where deemed appropriate by the colposcopist, See section 4.9.3 for conservative management of CIN 2.	**Target** Minimum 95%

4.9.3 Conservative management of CIN 2

Conservative Management of CIN 2

Previous guidance has recommended treatment of CIN 2. However International evidence is growing that many CIN 2 lesions regress spontaneously and conservative management of CIN 2 is a safe option in certain circumstances.[11, 12] BSCCP guidelines recommend that women who have not completed childbearing may be considered for conservative management.

Conservative management of CIN 2 may be recommended in the following circumstances, please refer to algorithm 5:

- Care is supervised by an experienced colposcopist
- Multiple biopsies are taken to confirm the diagnosis
- Colposcopy examination is satisfactory (TZ Type 1 or 2) and has excluded CIN 3, glandular abnormality and an invasive lesion
- Treatment must be performed if the lesion progresses to CIN 3
- CIN 2 lesion occupies no more than 2 quadrants of the transformation zone
- Woman agrees to regular follow-up by the colposcopy team as outlined in algorithm 5 and understands that resolution may take 24 months
- Woman has the option to request treatment of CIN 2 at any stage
- The case is discussed at a multi-disciplinary meeting if there is discrepancy or need for review of laboratory findings the senior colposcopist may decide that MDT discussion is not essential in all cases
- Woman has no history of previous treatment.

QR4.32 **Quality Requirement**	Treatment must be offered if CIN 2 has not resolved in 24 months.
QR4.33 **Quality Requirement**	If CIN 2 regresses the woman must have 2 negative hrHPV tests at 12 month intervals before returning to routine screening in the community. These may be performed in colposcopy or primary care at the discretion of the colposcopist.
QR4.34 **Quality Requirement**	Regular audit of the process and outcomes of conservative management of CIN 2 must be performed. This guideline will be reviewed as further evidence emerges.

4.10 Treatment

Choice of treatment:

There is no one technique considered superior for treating and eradicating CIN.

Ablative treatment is only suitable when:

- The entire TZ is visualised
- There is no evidence of either glandular or invasive disease
- There is no significant discrepancy between the cytology and the biopsy – see standard 4-10 high grade cytology and low grade CIN
- There has not been a previous treatment.
- There is no gland crypt involvement on punch biopsy.

Standard 4-13	**Biopsy before ablative treatment** Women should have a biopsy performed before ablative or destructive treatment and the result should be available before the treatment is carried out. This biopsy should have been performed within the preceding 6 months and the colposcopic impression should be consistent with the biopsy result.	**Target** Minimum 95%
Standard 4-14	**High grade cytology and unsatisfactory colposcopy** Women who present with a high grade cytological abnormality and who have an unsatisfactory colposcopy (Type 3 TZ) should have an excisional treatment performed. If excisional treatment is thought to be inappropriate, then discussion at MDT meeting is required.	**Target** Minimum 90%
Standard 4-15	**Select and treat – high grade** Histology must show evidence of CIN in the majority of select and treat cases. Excisional treatment at the first visit to colposcopy can be offered for women who present with a high grade cytological abnormality and who have suspected high grade disease at colposcopy ('select and treat').These women should be sent information before their visit that includes the possibility of treatment being offered. Full explanation and consent for treatment must be sought before commencing the examination if treatment is likely to be offered.	**Target** Minimum 90%

Standard 4-16	**Select and treat low grade**	**Target**
	Treatment at the first visit to colposcopy should not routinely be performed on women who present with low grade cytological changes (even if there is a colposcopic suspicion of high grade disease) except in special circumstances.	Maximum 10%
QR4.35 **Quality requirement**	**Pre-treatment information** All women who require treatment must be provided with sufficient information including potential complications and their written or verbal consent recorded.	
QR4.36 **Quality Requirement**	Women who require treatment must have a prior colposcopic assessment and all treatments must be recorded.	
Standard 4-17	**Outpatient treatment**	**Target**
	The majority of women should have treatment performed as an outpatient under local anesthesia as deemed appropriate.	Minimum 90%
Standard 4-18	**Excision – removal of the specimen**	**Target**
	The specimen should usually be excised as a single specimen to maximise the interpretation of margins.	Minimum 80%
Standard 4-19	**Excision depth**	**Target**
	The goal of excision is to remove all the abnormal epithelium in accordance with the type of transformation zone	
	Type 1 cervical transformation zone For treating ectocervical lesions, excisional techniques should remove tissue to a depth of more than 7mm and <10mm in women of reproductive age	Minimum 95%
	Type 2 cervical transformation zone Depending on the position of the SCJ in the endocervical canal excisional techniques should remove tissue to a depth of more than 7mm and maximum depth of 15mm	Minimum 95%
	Type 3 cervical transformation zone The colposcopist should aim to remove the entire transformation zone.	Minimum 95%

Standard 4-20	**Results of all excisions** Women treated by excisional techniques should have at least CIN 1 on histology.	**Target** Minimum 85%

QR4.37

Quality Requirement

Management of incomplete margins

High grade CIN extending to the deep lateral or endocervical margins of excision (or uncertain margin status) results in a higher incidence of recurrence but does not justify routine repeat excision if:

- there is no evidence of glandular abnormality
- there is no evidence of invasive disease
- the woman is under 50 years of age
- clinical discretion and discussion at MDT should be considered if clinical concern.

Women over the age of 50 years who have high grade at the endocervical margin must have a repeat treatment performed to obtain clear margins if satisfactory screening samples and colposcopy cannot be guaranteed.

QR4.38

Quality Requirement

Low grade result on LLETZ for suspected high grade

Women treated by excision for suspected high grade disease (CIN 2/3) and who have no significant abnormality on histology must be discussed at the colposcopy MDT meeting before repeat colposcopy including examination of the vagina and consideration of a repeat excision Further management is based on MDT decision.

4.11 Follow-up after treatment of CIN

Standard 4-21	**HR-HPV test of cure** Follow-up HR-HPV test with reflex cytology if positive HR-HPV should be performed 6-9 months after treatment.	**Target** Minimum 95%
QR4.39 **Quality Requirement**	**Positive HR-HPV after treatment** Women who test positive for HR-HPV at 6-9 months after treatment must have colposcopy regardless of cytology result within 3 months.	
Standard 4-22	**HR-HPV negative after treatment** Women who test negative for HR-HPV 6-9 months post treatment for CIN should be invited for screening in primary care in 3 years (regardless of age).	**Target** Minimum 95%
Standard 4-23	**Follow-up after hysterectomy** Women who test negative for HR-HPV 6-9 months after a hysterectomy showing completely excised CIN can be discharged (no further screening) from the cervical screening programme. If HR-HPV positive, colposcopy should be performed within 3-6 months & further screening determined according to findings.	**Target** Minimum 95%
QR4.40 **Quality Requirement**	**Follow-up after hysterectomy** Follow-up after a hysterectomy showing incompletely excised CIN should include annual vault screening for 10 years and if no abnormal results then the woman may exit the screening programme. Annual screening may occur in primary care but in cases where there is clinical concern, the follow up of the woman may remain under the care of the colposcopy clinic.	
QR4.41 **Quality Requirement**	**Follow-up after trachelectomy** Women who have radical trachelectomy as part of conservative management of cervical cancer must remain under the care and guidance of their treating gynaecologist or gynaecological oncologist. Owing to the limited information on outcome. However, all cases must be subject to local audit. Cervicalcheck will process HPV screening tests on request but clinical decision making is at the discretion of the treating gynaecologist.	

4.12 Management of CGIN and SMILE

QR4.42

Quality Requirement

Women with biopsy proven CGIN or SMILE must be managed according to the same clinical pathway as high grade cytological abnormalities except for the quality requirements and standards stated below. Women referred with cytology showing atypical glandular cells and who have a normal colposcopy must be followed up by the colposcopy team in 6-12 months for further screening.

When treating CGIN or SMILE excisional techniques must be used and must consider the anatomical site of the squamo-colmunar junction (SCJ) to ensure complete excision of the lesion. In younger women or women who wish to conserve their fertility, who have colposcopically visible squamocolumnar junction (SCJ), a cylindrically shaped excisional biopsy including the whole transformation zone (TZ) at least 10mm proximal to the SCJ is appropriate. A cylindrically shaped sample can be achieved with a loop or straight wire. Discussion at MDT is not essential if the colposcopist is satisfied that the above criteria have been met, the excision margins are clear of disease and there are no complicating factors.[11, 12]

In post-menopausal women or where the SCJ is not visible the excision should include all of the TZ and approximately 2.0-2.5cm of the endocervical canal. Following treatment of CGIN or SMILE women must have test of cure HPV test after 6-9 months and a further HPV test 12 months after that.

If excision has been complete and the second HPV test is negative and there have been no cytological or colposcopic abnormalities detected post treatment, then the woman should be invited for screening in primary care in 12 months. These women should have annual screening for 10 years.

Women who have incomplete excision of a primary lesion or where there is doubt about the excision margin must be discussed at MDT and offered further treatment (repeat excision or hysterectomy).

Women who have disease identified at repeat excision should remain under the follow up of colposcopy for 10 years.

If on re-excision there is no residual disease, women may be managed as per complete excision above.

Simple hysterectomy may be considered if:

- fertility is not required
- there are positive margins after an adequate excisional procedure
- treatment by excision is followed by further high grade cytological abnormality
- the woman is unwilling to undergo conservative management
- adequate screening follow up has not been possible, for example because of cervical stenosis
- the woman has other clinical indications for the procedure.

Women who have had a hysterectomy with complete excision of their lesion should have follow up screening 6 and 18 months under the care of colposcopy and if they are HPV negative on both occasions they can be discharged from screening.

Women with incomplete excision must remain under the continued care of colposcopy.

4.13 Management of complex cases

4.13.1 Immunosuppression

Immunosuppressed women

Women with renal failure requiring dialysis and women taking maintenance immunosuppression medication after organ transplantation, including bone marrow transplants should have annual cervical screening in accordance with the national guidelines. Any positive HPV screening result should be referred to colposcopy regardless of cytology. Immune status should be considered when developing treatment plans with a lower threshold for treatment.

Other women who are immunosuppressed

In line with BSCCP guidelines and CervicalCheck standards there is no indication for increased surveillance for women receiving:

- cytotoxic chemotherapy for non-genital cancers
- oestrogen antagonists such as tamoxifen
- alemtuzumab
- cytotoxic drugs for rheumatological disorders or biologic agents for other disorders.

These women should have cervical screening according to the national guidelines for the general population.

QR4.43

Quality Requirement

Women who are human immunodeficiency virus (HIV) positive

All women newly diagnosed with HIV should have cervical screening performed by, or in conjunction with, the medical team managing the HIV infection. Annual screening must be performed and any HPV positive screening result should be referred to colposcopy regardless of cytology. Women with HIV infection are eligible for programme screening from the time of their HIV diagnosis until age of 65.

Despite the higher cervical treatment failure rate, high grade CIN must be managed according to national guidelines. Lesions less severe than CIN 2 should generally not be treated as these are likely to represent persistent HR-HPV infection of the cervix which responds poorly to treatment and may clear spontaneously. Regular surveillance will detect progression.

In line with BSCCP guidelines CervicalCheck recommends close co-operation between colposcopists and medical teams managing women with HIV to ensure that women are not over treated if there is a possibility of enhancing immunocompetence (for example by raising CD4 counts following compliance with antiretroviral therapy).

Women with HIV infection who do not require further review by the colposcopy team should be invited for annual screening in primary care.

4.13.2 Multifocal Disease

Women with multifocal disease

The screening and management of multifocal disease is a complex area of assessment and management. These women must be managed in a center with demonstrable skill and expertise, and sufficient access to womens numbers to maintain that expertise.

These women should be assessed by symptom enquiry, cervical screening sample (within the context of the cervical screening programme), colposcopy, vulvoscopy, and biopsy where indicated. Severity and activity of multifocal disease will inform visit intervals.

4.13.3 DES

Women who have been exposed to diethylstilbestrol (DES)

Women exposed to DES in utero are at increased risk of clear cell cancer of the vagina. These women should have a colposcopy assessment in a specialist setting. Arrangements should be made for the follow up of those individuals who have the stigmata of DES exposure. This is usually via annual colposcopy. Requesting cytology if individuals are HR-HPV negative will require local service agreements. Management of any abnormal cytology in the absence of a positive HPV is outside the programme. Women who do not have stigmata of DES do not require more intensive screening and should be managed within the normal screening programme.

Daughters of those exposed to DES in utero are not at any increased risk of cervical or vaginal cancer and require routine screening only.

DES exposure is rare in Ireland and generally all women are managed in a single specialised clinic by suitably experienced clinicians. CervicalCheck recognises the DES clinic at the National Maternity Hospital, Dublin as the appropriate location for the care of this group of women.

4.13.4 Pregnancy

QR4.44 **Quality Requirement**	**Pregnant woman** The focus of colposcopy is to out rule invasive cervical cancer and to provide reassurance for the woman that her pregnancy will not be affected by an abnormal screening test result. Colposcopy should be performed by a senior colposcopist because the pregnant cervix is difficult to assess due to increased vascularity, and viscid mucous discharge.
QR4.45 **Quality Requirement**	**Colposcopy in pregnancy** Women who are newly referred and pregnant must have colposcopy performed using the same criteria as for women who are not pregnant.

QR4.46 **Quality Requirement**	**Defer biopsy and treatment** Biopsy and treatment is usually deferred until the postpartum period except where there is a suspicion of invasive disease. If excision is performed during pregnancy postpartum colposcopy is necessary. Excision biopsy during pregnancy is not considered therapeutic.
QR4.47 **Quality Requirement**	**LSIL in pregnancy** If low grade CIN is suspected at colposcopy a repeat colposcopy appointment must be made three months post-delivery.
QR4.48 **Quality Requirement**	**Repeat colposcopy** If high grade CIN is suspected the colposcopy must be repeated at the end of the second trimester as well as post-delivery. It must be done no less than 6 weeks and preferably 3-4 months after delivery.
QR4.49 **Quality Requirement**	**Suspect invasion** If there is a suspicion of invasive disease a biopsy must be performed. This biopsy must be a small loop biopsy and not a punch biopsy.
QR4.50 **Quality Requirement**	**Women who become pregnant whilst attending colposcopy** Women who have been attending colposcopy with low grade changes or those who have been treated for CIN and are due a cervical screening test in pregnancy can have it postponed until 3-4 months postnatal at the discretion of the colposcopist. Test of cure for glandular abnormality or CIN 2/3 with incomplete margins should be performed during the second trimester.
QR4.51 **Quality Requirement**	**Post colposcopy advice to pregnant women** Women who have a colposcopy in pregnancy should be told to expect some light spotting for up to 48 hours afterwards.

4.14 Menopause and contraception

Menopause and use of hormone replacement therapy (HRT)

Postmenopausal women

The incidence of HR HPV positivity and abnormal cytology is low in postmenopausal women with previous normal results. The use of systemic HRT is not known to alter the risk of cervical disease. Colposcopic examination and adequacy can be improved by the use of topical HRT.

QR4.52

Quality Requirement

Postmenopausal bleeding

All unexplained post-menopausal bleeding should be urgently referred to a gynaecologist for appropriate investigation.

Contraception

QR4.53

Quality Requirement

Women with abnormal cervical screening results

Women with abnormal cervical screening results should not be advised to change from the oral contraceptive pill (OCP) if it is a successful method of contraception for them. An abnormal result should not influence the choice of contraception.

QR4.54

Quality Requirement

Women with an intra-uterine system (IUS)/IUCD

Women with an IUS must be given clear information on the clinic's management policy about whether their IUS will be removed or not. If there is a need to remove the IUS, inform the woman prior to treatment and give appropriate advice about the need for additional contraception. And if they have to schedule their treatment to coincide with the first half of their menstrual cycle. It is not necessary to remove an IUS to perform local treatment.

There is no evidence an IUS has any effect on hrHPV persistence or progression.

4.15 Multi-disciplinary team meetings

QR4.55

Quality requirement

Participation in MDT meetings

Multidisciplinary Team Meetings

The primary function of these meetings is to discuss the management of women with discordant cytological, colposcopic and histological findings and other issues **can** include:

- Atypical glandular cells, HPV+ with no abnormality on colposcopy and/or histology
- all cases of invasive cervical cancer
- If CIN 2 and considering conservative management where there is a clinical concern regarding proposed care pathway or discordance of results.

There must be facilities for colposcopy, histology and cytology to add to the list any case where they have concerns they wish to discuss

Slides and images may be presented, but is not mandatory. Cytology and histology must be reviewed prior to the meeting and the conclusions from the reviews must be presented and minuted (see below).

MDT membership should include:

All practicing colposcopists, cytopathologist representative, histopathologist representative, virologist as required, administrative support. Trainees and students should attend. A quorum of at least one colposcopist, one cytopathologist and one histopathologist should be present (in person or by audio/video link) at each meeting. There should be administrative and IT support to facilitate the smooth running of the meeting.

An attendance log must be kept.

Meetings must occur at least every two months (more frequently for larger units).

Each colposcopy service must nominate a MDT meeting coordinator who is responsible for scheduling meetings, defining the specific cases to be discussed and requesting the necessary materials for discussion. It is recommended that a schedule of meetings be organised and distributed quarterly in advance for scheduling purposes. The CervicalCheck Colposcopy coordinator must have a copy of this schedule for information purposes.

A list of women to be discussed must be circulated in advance to allow time for case preparation and there must be a facility made available for all MDT members to add cases to be discussed. A minimum of 10 working days' notice must be provided to allow for review and preparation of cases for discussion. For security purposes any files containing women's confidential details should be password encrypted prior to e-mail distribution

Minutes must be kept and clinical decisions/management plans recorded in the woman's records, also the electronic colposcopy record system. Outcomes must be recorded on the screening and colposcopy computer system or other systems. The supervising colposcopist must be informed of decisions/management plans as should primary care referrer and woman.

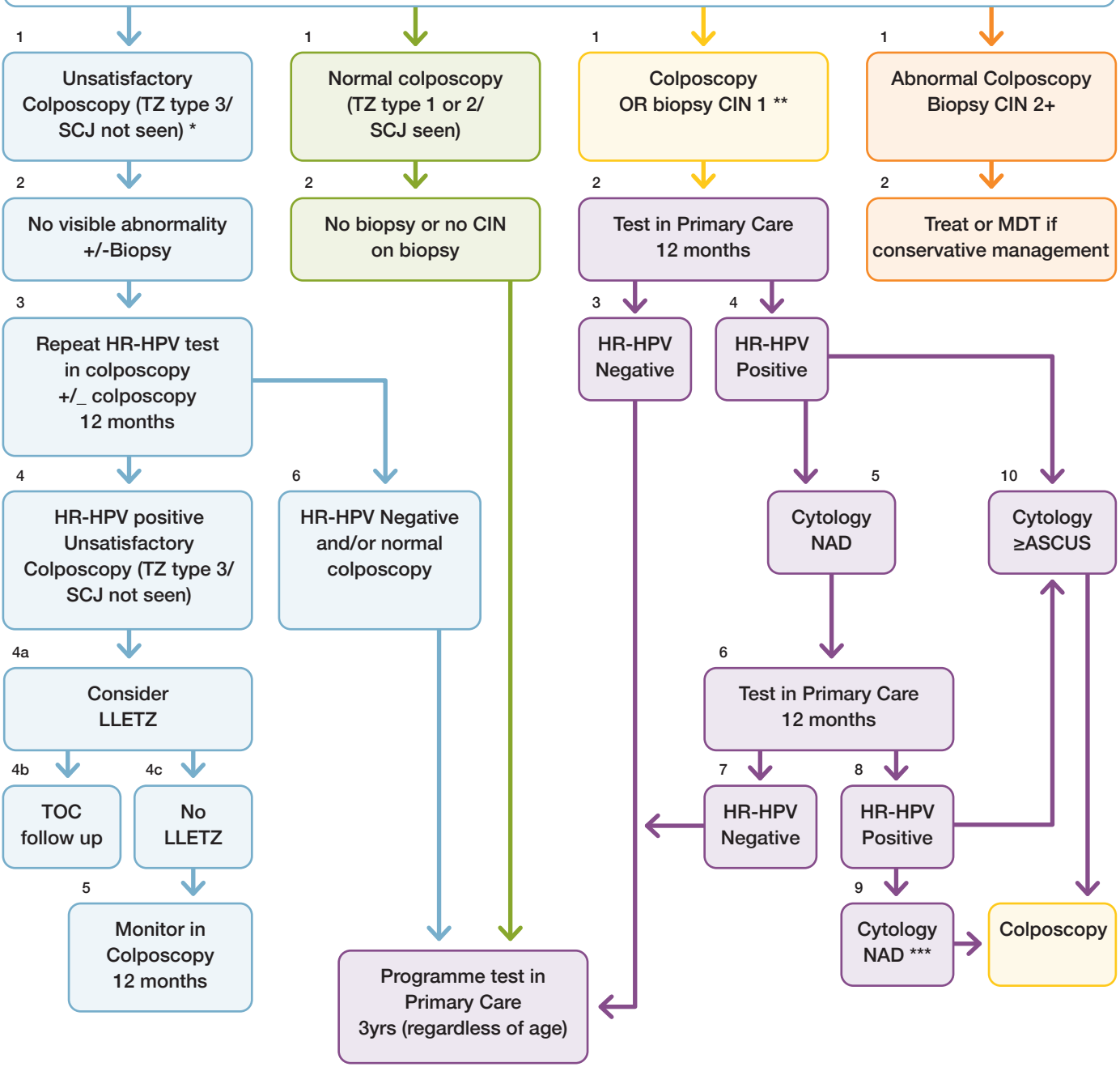
An annual management meeting of MDT members must take place to monitor the function of the MDT and its meetings. An attendance register and minutes must be recorded and regular audit is recommended.

References

1. Guidelines for Quality Assurance in Cervical Screening, CervicalCheck NCSS/PUB/Q-1 Rev 2 ISBN 978-1-907487-13-2.
2. Arbyn M., Antilla A., Jordan J., Ronco G., Schenck U., Segan N., Wiener H.G., Herbert A., Daniel J., von Karsa L. (2008) European guidelines for quality assurance in cervical cancer screening [2nd Edition]. International Agency for Cancer Research and EU, Health & Consumer protection Directorate-General.
3. https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management/2-providing-a-quality-colposcopy-clinic
4. Cervical Screening Wales 2R.40 Algorithms for HPV Primary Screening.
5. Australian National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. https://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening
6. CS/PUB/ CLP-15: Colposcopy Algorithm 1 Management of people with HR-HPV Positive & Normal or Low Grade Abnormal Cytology)
7. CS/PUB/CLP-16: Colposcopy Algorithm 2 Management of people with HR-HPV Positive and High Grade Abnormal Cytology or any Glandular Abnormality (including AGC).
8. CS/PUB/CLP-17: Colposcopy Algorithm 3 Colposcopy Management of People for Test of Cure Following Treatment of CIN.
9. CS/PUB/CLP-18: Colposcopy Algorithm 4 Colposcopy Management of People for Test of Cure Following Complete Excision of CGIN / SMILE.
10. CS/PUB/CLP-19: Colposcopy Algorithm 5: Conservative management of histologically confirmed CIN 2
11. Tainio Karoliina, Athanasiou Antonios, Tikkinen Kari A O, Aaltonen Riikka, Cárdenas Jovita, Hernándes et al. Clinical course of untreated cervical intraepithelial neoplasia grade 2 under active surveillance: systematic review and meta-analysis *BMJ* 2018; 360 :k499
12. Skorstengaard M, Lynge E, Suhr J, Napolitano G. Conservative management of women with cervical intraepithelial neoplasia grade 2 in Denmark: a cohort study. BJOG. 2020 May;127(6):729-736. doi: 10.1111/1471-0528.16081. Epub 2020 Jan 22. PMID: 31880054; PMCID: PMC7383715.

Appendix 1: Colposcopy Algorithm 1

Management of people with HR-HPV positive & normal or low grade abnormal cytology



* Consider treatment if previous history of CIN

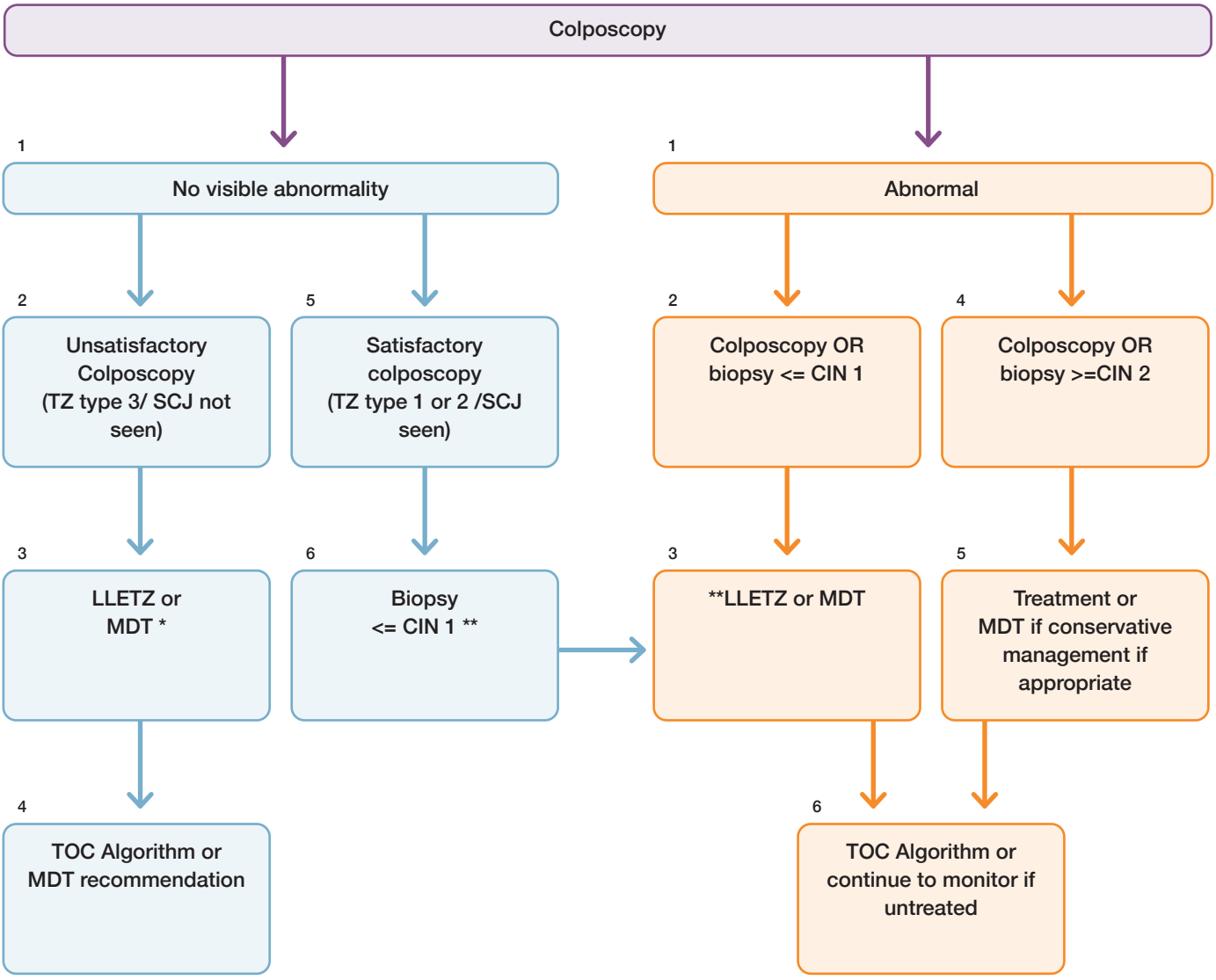
** Treatment may be considered in special circumstances
- Woman's choice
- Woman's age > 40
- Risk of non attendance

*** To be reviewed by colposcopy working group as evidence emerges

CS/PUB/CLP-15 Rev 2

Appendix 2: Colposcopy Algorithm 2

Management of people with HR-HPV positive and high grade abnormal cytology or any glandular abnormality (including Atypical Glandular Cells)



* use clinical judgement: e.g. in cases of young person with AGC (8a) –conservative management may be appropriate

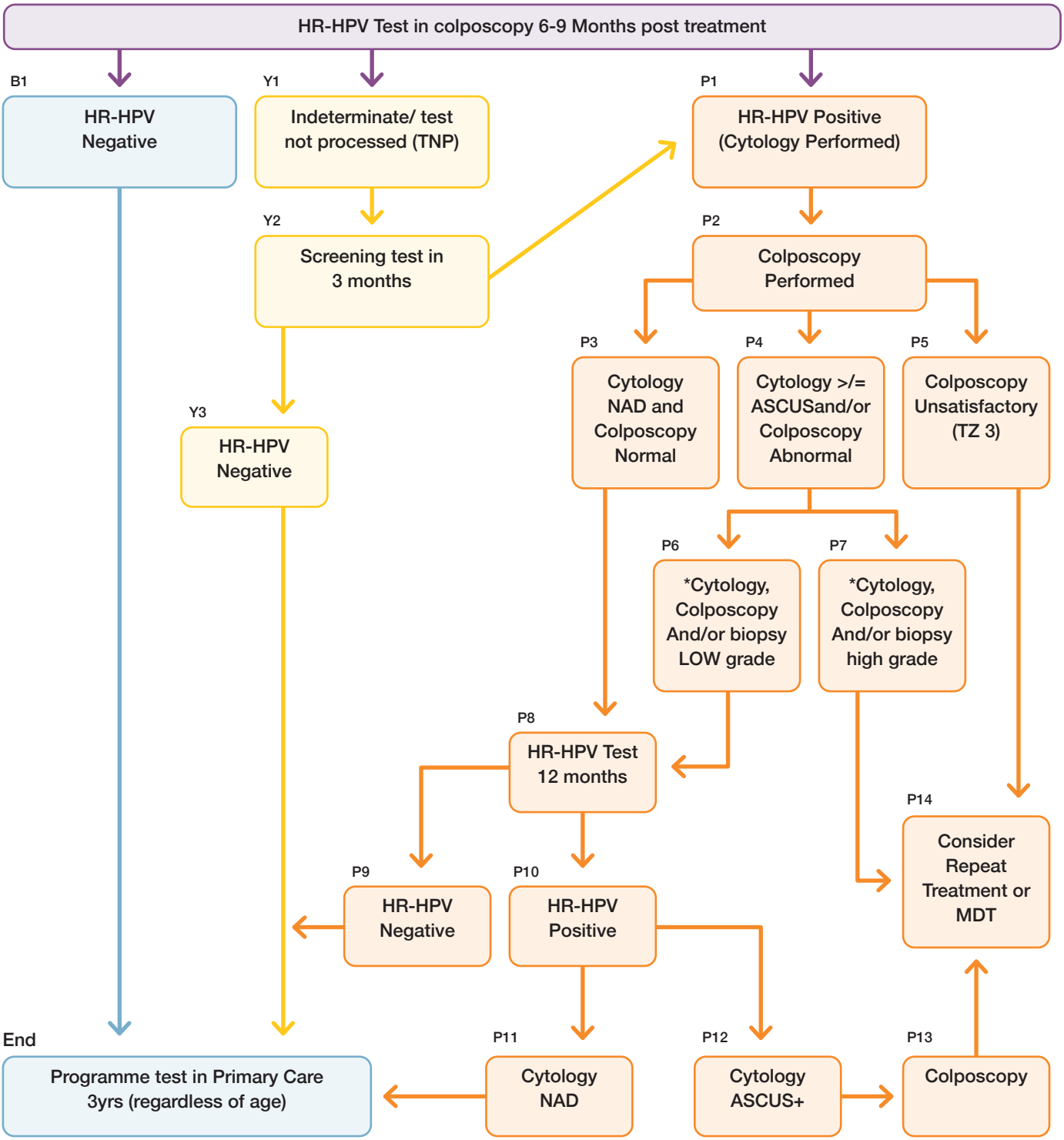
** if no biopsy taken the reason should be recorded e.g. pregnancy, patient declined etc. Pregnant woman with no suspicion of invasion should be reviewed at end of 2nd trimester and 3 months postnatal

Note: If colposcopy is low grade and no treatment is performed multiple biopsies should be taken where possible

CS-PUB-CLP-16 Rev 2

Appendix 3: Colposcopy Algorithm 3

Colposcopy Management of people for Test of Cure following treatment of CIN

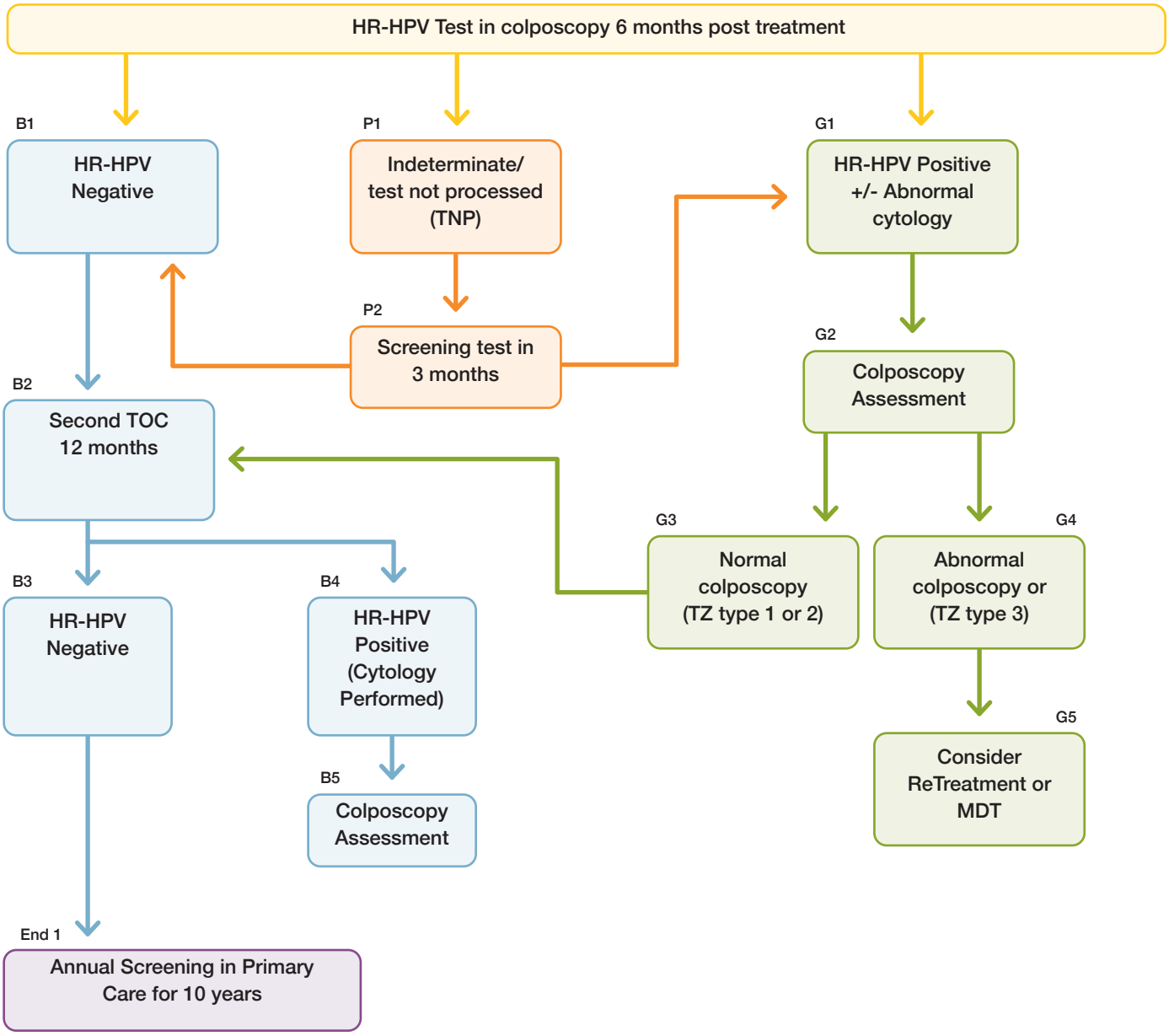


* Use clinical judgement, LLETZ may be performed if appropriate

CS-PUB-CLP-17 Rev2

Appendix 4: Colposcopy Algorithm 4

Colposcopy Management of people for Test of Cure following complete excision of CGIN/SMILE

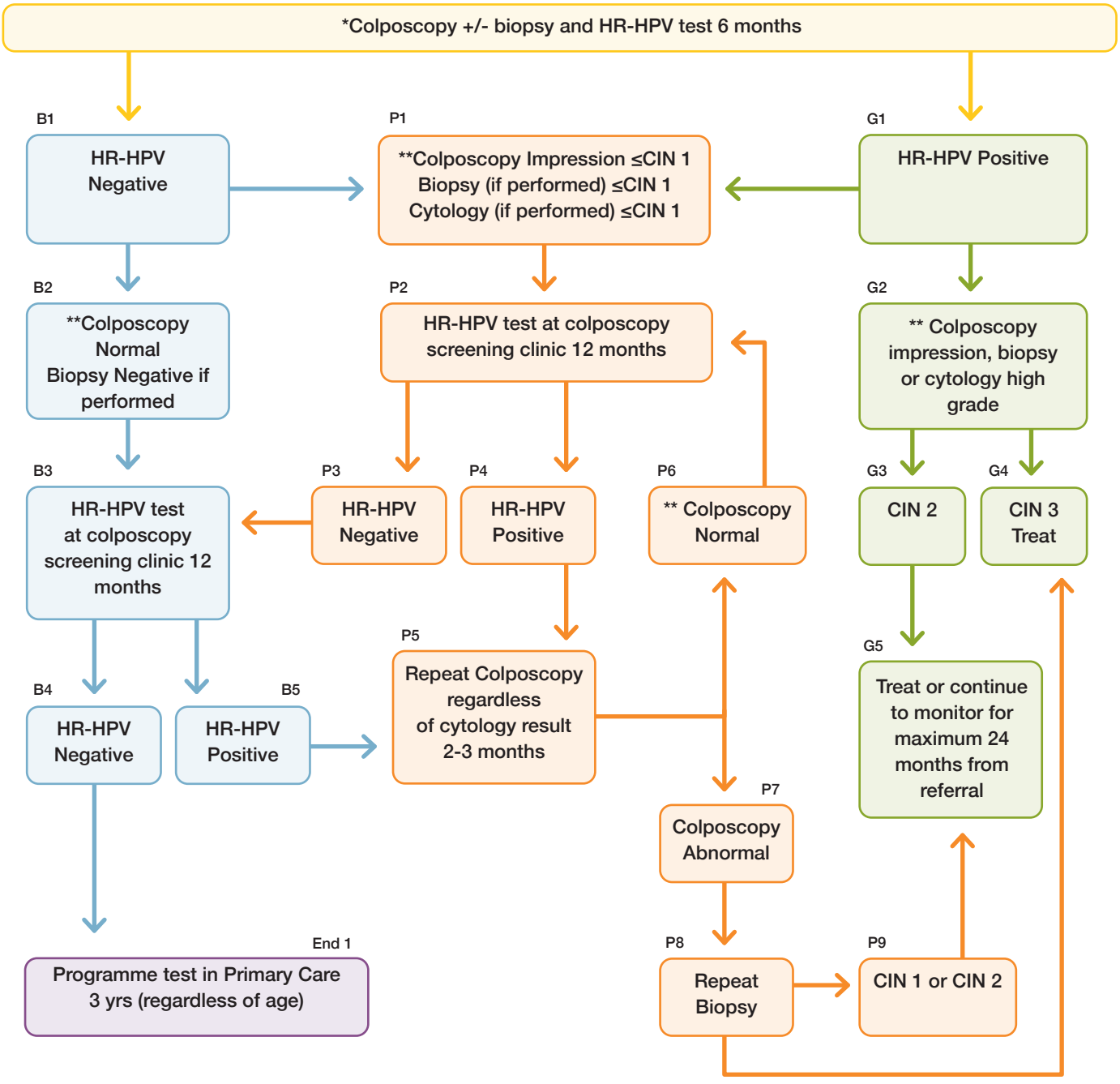


* If Retreatment management is based on the histology result. If MDT management is based on MDT decision

CS-PUB-CLP-18 Rev 2

Appendix 5: Colposcopy Algorithm 5

Conservative Management of histologically confirmed CIN 2



* Woman may have a consultation in 3 months if considered necessary to discuss options

** Colposcopy must be satisfactory, TZ type 1 or type 2. Excisional biopsy must be performed if TZ type 3.

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