Standards for

Quality Assurance in Cervical Screening

Standards for Quality Assurance in Colposcopy – Interim Document

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

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4.1 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 Gynaecologists (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 NCSS '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] and Cervical Screening Wales.[4]
- The supplementary document – Organisational and Clinical Guidance for Colposcopy Services.[5]
- The CervicalCheck colposcopy algorithms.[6,7,8,9]
- 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[10], minutes of multi-disciplinary team (MDT) meetings.[11]
- 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 cytopathology, colposcopy and histopathology services providers.
- Quality assurance visits.

4.2 Organisational requirements and standards in colposcopy

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.

4.2.1 Facilities

QR225. 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 should be clear signage from the hospital entrance to the colposcopy clinic.
QR226. Quality requirement	**Clinical area** There should be a dedicated area for history taking and consultation which should ensure the privacy of the woman. There should be provision to enter the history onto the IT system in this clinical space. There should be adjacent toilet facilities for the woman. A separate recovery room/area should be available. There should be a private changing area.
QR227. Quality requirement	**Equipment** There should be an examination couch capable of postural adjustment. There should be at least one working colposcope which should be maintained in accordance with the hospital guidelines on the maintenance of medical equipment. The colposcope should be linked to a camera to enable image capture. A monitor should be available to allow the woman to view the procedure. Images should be captured using the colposcopy management software. Resuscitation equipment should be available at the colposcopy clinic. Clinical and nursing staff should be trained in the use of the resuscitation equipment. A panic button should be accessible within the clinical room which provides communication with staff outside the clinical room. There should be a computer connected to the hospital network in the clinical room to facilitate data entry of clinical information.

QR228. Quality requirement	**Administrative area** There should be dedicated office space to house the administrative support for the colposcopy service ensuring compliance with hospital health and safety guidelines. There should be space for secure storage of the colposcopy clinical records of all current colposcopy patients within this administrative area. There should be a provision to enter data into the colposcopy computerised management system from this administrative space. Computer and printer hardware as well as dedicated telephone and fax facilities should be available in this administrative space.

4.2.2 Governance

QR229. Quality requirement	**Governance** The service should have regular (at least quarterly) operational meetings between nursing, hospital administration/managers and colposcopists. Management reports including numbers attending, waiting times and default rates should be reviewed at these operational meetings and appropriate corrective actions taken. The service should have MDT meetings on at least a monthly basis to enable efficient decision making and timely discussion of challenging cases. Colposcopy clinics should be scheduled in sessions of 3 hours 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.

4.2.3 Staff

QR230. Quality requirement	**Staff** Colposcopy should be delivered by a defined team including medical, nursing and administrative staff. Colposcopists should be trained and certified by a recognised certification and recertification body such as the BSCCP and should appear as such on the list of certified colposcopists of the certification body. A local register of certified colposcopists and trainers should be maintained at each service and updated on a six monthly basis.
QR231. Quality requirement	**Lead colposcopist** There should be a lead colposcopist with a sessional commitment of one session per week to oversee continuous quality improvement and to troubleshoot any clinical or administration issues. There should be adequate dedicated nursing staff available to the service as agreed in the memorandum of understanding for each service. A clinical nursing care assistant should be available to facilitate cleaning and enhance the turnaround time between patients at the colposcopy clinic. There should be enough dedicated administrative support available as agreed in the memorandum of understanding to provide administrative support to the service. There should be a separate nurse-led HR-HPV cervical screening clinic for the follow-up of both treated and untreated patients.

4.2.4 Information technology

QR232. Quality requirement	**Infrastructure** A computerised colposcopy management system should be installed at the colposcopy clinic. This system should be networked in an accessible form from all areas in use by the team. The colposcopy management system should be interfaced with the hospital patient administrative system and the hospital appointments system. Adequate numbers of concurrent user licences should be available to enable efficient data entry by all necessary staff.
QR233. Quality requirement	**Training** Training in the use of the colposcopy management system should be available.
QR234. Quality requirement	**Utilisation** The colposcopy service should generate appointment letters from the colposcopy management system. The IT system should be used for specimen management using a defined report that lists specimens taken at each clinical session. The IT system should be used to store image and video data. The IT system should be used to enter the results of any tests. The IT system should be used to enter follow-up and management plans. The IT system should be used to generate result and management plan letters to both GPs and the patient. The IT system should be used to check failsafe processes. The IT system should generate quarterly mandatory audit returns.
QR235. Quality requirement	**Update records to CervicalCheck** All updates to records of women consented to participate in CervicalCheck should be transmitted to the CSR on a daily basis. Controls should be in place to ensure that mandatory fields cannot be overwritten in the colposcopy computer systems. All mandatory fields must be complete to allow the transfer of files and updates to the CSR.
QR236. Quality requirement	**Error files** Error files that are returned from the CervicalCheck CSR should be checked on a regular basis using the broker log. All error files sent by the CSR should be actioned in a timely fashion and corrected updates resent to the CSR.

4.2.5 Systems management

QR237. Quality requirement	**Management of new referrals** There should be a defined process for the management of new referrals. There should be a defined process for informing women of the appointment by letter from the colposcopy management system. Services should use the facilitated referral process and inform the programme via a "red flag alert" if it is unable to process appointments within these timeframes and needs the programme to redirect new referrals to other services.	
Standard 4-1	**Waiting times**	**Target**
	Women referred to colposcopy should be offered a timely appointment following receipt of referral.	> 90%
	• Women with a clinical suspicion of invasive cancer or adenocarcinoma in situ	within 2 weeks.
	• Women with a screening test suggestive of CIN2 or CIN3 (HSIL) or glandular abnormality	within 4 weeks.
	• All other women	within 8 weeks.

4.2.6 Management of women who default

Standard 4-2	**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. There should be a local policy for contacting and dealing with defaulting women.	< 10%
QR238. Quality requirement	**Management of specimens** There should be a defined process for tracking all specimens to ensure that all are correctly delivered to the laboratory in a timely fashion (within one week).	
QR239. Quality requirement	**Management of test results** There should be a defined process for tracking all test results to ensure that all are received by the colposcopy service. There should 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 should include a method of fast tracking results suggestive of invasive cancer.	

QR240. Quality requirement	**Provision of information** All women should be sent clinic-specific information on colposcopy in advance of appointments. Clinics which operate a 'select and treat' policy should send appropriate information regarding treatment to the patient in advance of the appointment.	
Standard 4-3	**Information to women** Women should be sent a personalised invitation to colposcopy in advance of attendance, this should include directions to the clinic.	**Target** > 90% within 2 weeks of receipt of the referral
QR241. Quality requirement	**Communication of results to the woman and to the referring doctor (negative and abnormal)** There should be a defined process to ensure that all test results and management plans are communicated to both the woman and the referring doctor. Copies should be sent to CervicalCheck.	
Standard 4-4	**Communication of results and management plans** Information on results of investigations should be communicated to the woman and to the referring doctor in a timely manner.	**Target** > 90% within 4 weeks of the woman's attendance
QR242. Quality requirement	**Audit and systems review** There should be a defined process whereby computerised failsafe checking procedures are performed on a monthly basis at least. The colposcopy team should meet to review quality assurance processes and identify any opportunities for improvement on at least a quarterly basis. The colposcopy statistical returns should be generated on a quarterly basis and reviewed by the team.	
QR243. Quality requirement	**Documentation** The colposcopy service should have clinical and administration guidelines and procedures which have been agreed by both the colposcopy team and the hospital administration.	
QR244. Quality requirement	**Follow-up** There should be a defined process for ensuring that all patients 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 should be communicated to the woman, referring clinican and CervicalCheck.	

4.2.7 Data quality

QR245. Quality requirement

Data capture – demographics

Every woman's record sent to the CSR must contain the following demographic details to allow the CervicalCheck programme to uniquely identify and accurately match the woman on the CSR.

- Minimum Demographics: Every woman's record sent to the CSR must contain at a minimum, the forename, surname, date of birth and address to uniquely identify the woman.
- Additional Demographics: In addition to the minimum demographics each record should include as many of the following elements where available: surname at birth, mother's maiden name, PPS number, CSPID, Colposcopy Reference Number and telephone number.

QR246. Quality requirement

Confirmation of demographic details

Woman's demographic details should be confirmed at each attendance and patients reminded to inform the clinic of change of address whilst attending. The computer record should be updated to reflect same.

QR247. Quality requirement

Notification of colposcopy procedures/outcomes to CSR

Every colposcopy update sent to the CSR should contain the following information:

a) For those who fail to attend the colposcopy appointment, the appointment status must be updated with one of the following scenarios:
   - Cancelled
   - DNA (Did Not Attend).

b) For those who do attend the colposcopy appointment, all of the following should be updated:
   - Appointment Status
   - Procedure
   - Examiner Identification
   - Outcome.

QR248. Quality requirement

Cervical screening test - data recording

When carrying out screening tests in colposcopy the Cervical Screening Form[12] should record sufficient, accurate details to enable accurate matching of the woman with her records on the CSR.

4.3 Clinical requirements and standards in colposcopy

4.3.1 Diagnosis

Standard 4-5	**Positive predictive value**	**Target**
	Compliance between colposcopic impression of high grade disease and histologically proven high grade CIN.	> 65%
Standard 4-6a	**Biopsy**	**Target**
	A biopsy should be performed in the presence of an abnormal Transformation Zone (TZ).	> 90%
Standard 4-6b	**Biopsy**	**Target**
	Reasons for not performing a biopsy in the presence of an abnormal TZ at the first visit e.g. pregnancy should be recorded.	> 95%
Standard 4-6c	**Biopsy**	**Target**
	Women should have a biopsy performed before ablative or destructive treatment and the result should be available before the treatment is carried out.	> 95%
Standard 4-6d	**Biopsy**	**Target**
	Where a lesion extends into the endocervical canal and the upper limit is not seen (Type 3 TZ), an excisional biopsy should be performed in preference to a punch biopsy.	> 95%
Standard 4-6e	**Biopsy**	**Target**
	Biopsy specimens should be suitable for histological diagnosis.	> 95%

4.3.2 Treatment

Standard 4-7a	**When to treat** Women with high grade CIN (CIN 2/3) or AIS confirmed on a diagnostic biopsy should have a treatment performed. Exceptions would include pregnancy. If conservative management for a high grade lesion is being considered this should be discussed at MDT meeting.	**Target** > 90%
Standard 4-7b	**When to treat** Women who present with a high grade cytological abnormality and who have no colposcopic abnormality identified on a fully visible TZ including examination of the vagina should have the screening test reviewed by the cytopathologist at a MDT meeting and if high grade changes are confirmed an excisional treatment should be performed.	**Target** > 90%
Standard 4-7c	**When to treat** Women who present with a high grade cytological abnormality and who have an unsatisfactory colposcopy (Type 3 TZ) should have an excisional treatment performed.	**Target** > 90%
Standard 4-7d	**When to treat** Women referred with high grade cytology and who have CIN1 or less diagnosed on a diagnostic biopsy should be managed carefully and should be treated if there is a subsequent cytological abnormality (LSIL at least) or remain HR-HPV positive at 12 months. Where serious disparity between colposcopy and cytology exists and treatment is not otherwise indicated then the case should be discussed at the MDT meeting.	**Target** > 95%
Standard 4-8a	**When to treat** Treatment at the first visit to colposcopy should be considered 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 have appropriate pre-visit information regarding the possibility of treatment.	**Target** > 80%
Standard 4-8b	**When to treat** 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.	**Target** < 10%

QR249. Quality requirement	**Pre-treatment** All women who require treatment must be informed about the procedure and their written or verbal consent recorded. Women who require treatment must have a prior colposcopic assessment and all treatments must be recorded. Treatments must be performed in suitably staffed and equipped clinics.	**Target** 100%
Standard 4-9	The majority of women should have treatment performed as an outpatient under local anaesthesia.	**Target** ≥ 90%

Choice of treatment: Ablative treatment is only suitable when:

- The entire TZ is visualised
- There is no evidence of either glandular or invasive disease
- There is no discrepancy between the cytology and the biopsy
- There has not been a previous treatment.

Standard 4-10a	**Excision – removal of the specimen** The specimen should usually be excised as a single specimen to maximise the interpretation of margins.	**Target** > 90%
Standard 4-10b	**Excision – removal of the specimen** Excision of ectocervical specimens should aim for a thickness of at least 7mm and not greater than 12mm thickness to overcome the potential for residual disease in the crypts.	**Target** > 95%
Standard 4-11a	**Results** Women treated by excisional technique at first visit should have CIN on histology.	**Target** > 90%
Standard 4-11b	**Results** Women treated by excisional techniques should have CIN on histology.	**Target** > 85%

Standard 4-12a	**Repeat excision** Women over the age of 50 years who have CIN3 at the endocervical margin and all women with AIS at a margin should have a repeat excision performed to obtain clear margins if satisfactory cytology and colposcopy cannot be guaranteed.	**Target** > 90%
Standard 4-12b	**Repeat excision** Women treated by excision for suspected high grade disease (CIN 2/3 or AIS) and who have no significant abnormality on histology should be discussed at the colposcopy MDT meeting before repeat colposcopy including examination of the vagina and consideration of a repeat excision.	**Target** > 90%

4.3.3 Follow-up after treatment

Standard 4-13a	**Follow-up after treatment** Follow-up after a hysterectomy showing completely excised CIN should include 2 negative HR-HPV tests at 6 and 18 months after surgery before discharge from CervicalCheck. Reflex cytology will be performed if HR-HPV positive and colposcopy should also be performed if HR-HPV positive.	**Target** > 95%
Standard 4-13b	**Follow-up after treatment** Follow-up after a hysterectomy showing incompletely excised CIN should continue as if the cervix were still in situ.	**Target** > 95%
Standard 4-13c	**Follow-up after treatment** Follow up HR-HPV test with reflex cytology if positive HR-HPV should be performed 6-9 months after treatment.	**Target** > 90%
Standard 4-13d	**Follow-up after treatment** The diagnosis of residual or recurrent CIN within 24 months of treatment should be very low.	**Target** < 5%
Standard 4-13e	**Follow-up after treatment** The results of the HPV test +/- cytology should facilitate discharge of the woman to routine screening (3 years) in the majority of cases.	**Target** >60%
Standard 4-13f	**Follow-up after treatment** Follow-up testing should take place between 6 and 9 months following treatment.	**Target** > 90%

Standard 4-13g	**Follow-up after treatment** Follow-up after a hysterectomy showing incompletely excised CIN should continue as if the cervix were still in situ.	**Target** > 95%
Standard 4-14a	**Follow-up after treatment** Women who test positive for HR-HPV at 6 months after treatment will have cytology performed and should have colposcopy.	**Target** > 95%
Standard 4-14b	**Follow-up after treatment** Women who test negative for HR-HPV 6 months post treatment for CIN should return to routine screening (3 years).	**Target** > 95%

4.3.4 Follow-up of women who have not been treated

Standard 4-15	**Women who present with high grade cytological abnormality** If the colposcopy suggests low grade disease and conservative management is preferred, multiple biopsies should be performed.	**Target** > 95%
Standard 4-16a	**Women who present HR-HPV positive with low grade cytological abnormality** If the colposcopy is satisfactory and normal i.e. there is no evidence of CIN either visually or on biopsy, then the woman can return to routine screening (3 years).	**Target** > 95%
Standard 4-16b	**Women who present HR-HPV positive with low grade cytological abnormality** If the colposcopy is abnormal a biopsy should be performed. If diagnosis is CIN 1 or less a HPV test should be repeated in twelve months, except in special circumstances (patient choice, risk of default).	**Target** > 90%
Standard 4-16c	**Women who present HR-HPV positive with low grade cytological abnormality** If persistently HR-HPV positive at 12 months and cytology remains abnormal, a repeat colposcopy with possible treatment should be performed. If cytology is negative repeat HPV test in 12 months.	**Target** > 90%

Standard 4-16d	**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** > 90%
Standard 4-17a	**Pregnant women** Women who are pregnant should have a colposcopy performed, using the same criteria as for women who are not pregnant.	**Target** > 95%
Standard 4-17b	**Pregnant women** Biopsy and treatment is usually deferred until the postpartum period except where there is a suspicion of invasive disease.	**Target** > 80%
Standard 4-17c	**Pregnant women** If low grade CIN is suspected at colposcopy a repeat colposcopy appointment should be made three months post delivery.	**Target** > 95%
Standard 4-17d	**Pregnant women** If high grade CIN is suspected the colposcopy should be repeated at the end of the second trimester as well as three months post delivery.	**Target** > 95%
Standard 4-17e	**Pregnant women** If there is a suspicion of invasive disease a biopsy must be performed. This biopsy should be a wedge or small loop biopsy and not a punch biopsy.	**Target** 100%

4.3.5 Discharges from colposcopy

QR250. Quality requirement	**Discharge recommendations** Discharge recommendations should be selected based on CervicalCheck colposcopy algorithms. For non standard cases, the number of annual screening tests required post colposcopy before discharge to routine screening is determined by the treating clinician and will be followed by the programme.
QR251. Quality requirement	**Discharge correspondence** A process should exist to ensure that the discharge recommendation (post colposcopy screening requirements) sent to the CSR reflects the discharge recommendation on the discharge letter to the referring doctor.
QR252. Quality requirement	**Communication to referring doctor** All communication from the colposcopy service in relation to diagnosis/treatment and discharge of a woman must be sent to the referring GP or referring Clinic (WWC/FPC/Gynaecology/STI) and electronically to CervicalCheck.

This is required so that the CervicalCheck programme office can ensure which doctor to send a failsafe letter to in the event of non compliance. A copy of the correspondence should only be sent to the woman's own GP (if they are not the referring doctor) at her request.

4.3.6 Multi-disciplinary team meetings

QR253. Quality requirement	**Participation in MDT meetings** All of the colposcopists should be invited to monthly MDT team meetings organised by the service and should attend a minimum of 50 per cent. Histopathology and cytopathology representation is essential.
QR254. Quality requirement	**Protocol for MDT meetings** Participation, including a signed record of personnel attending and operational decisions, shall be recorded. Participants must be subject to national legislation relating to confidentiality, professional registration and data security of personal health information. The outcome of the discussions and any management plans should be inputted into the patient medical record. The protocol should be consistent with the provisions of Guidance for MDT meetings for colposcopy services.[11]

4.3.7 Audit of invasive cervical cancers

To be updated once the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population publishes its report and recommendations.

4.3.8 Quality assurance and continuous improvement

Standard 4-18	**Quality metrics** 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
QR255. 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.	
QR256. Quality requirement	**Quality assurance visits** Colposcopy services shall accommodate on-site visits[13] by CervicalCheck-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.	

4.4 References

1. Guidelines for Quality Assurance in Cervical Screening, CervicalCheck NCSS/PUB/Q-1 Rev 2 ISBN 978-1-907487-13-2.
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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. CervicalCheck Organisational and Clinical Guidance for Quality Assured Colposcopy Services (CS/PUB/CLP-7).
6. Colposcopy Algorithm 1 HR-HPV Positive & Normal or Low Grade Abnormal Cytology)CS/PUB/CLP-15).
7. Colposcopy Algorithm 2 HR-HPV Positive and High Grade Abnormal Cytology or any Glandular Abnormality (CS/PUB/CLP-16).
8. Colposcopy Algorithm 3 Colposcopy Management of People for Test of Cure Following Treatment of CIN (CS/PUB/CLP-17).
9. Colpooscopy Algorithm 4 Colposcopy Management of People for Test of Cure Following Complete Excision of CGIN / SMILE (CS/PUB/CLP-18).
10. Colposcopy Service CPC/MDT Meeting Attendance Log (CS/F/CLP-7).
11. CervicalCheck Guidance for CPC/MDT Meetings for Colposcopy Services (CS/PUB/CLP-2).
12. CervicalCheck Cervical Screening Form (CS/F/LAB-2).
13. National Cancer Screening Service Colposcopy Service Quality Systematic Review – Visit Checklist (CS/F/CLP-8).