 

**Title**: **Quality Assurance Audit for delivering cervical screening within a primary care practice or in non-primary care settings**

**Audit Period:**

[Specify the time frame]

**Objective:**

To assess and ensure the effective implementation of the *Cervical Screening Protocol* within [Practice/Clinic Name].

**Audit Coordinator:**

[Your Name and Position]

📝 **Explanatory Notes for Self-Audit on Cervical Screening Policy and Quality Assurance**🔍

The Commission on Patient Safety and Quality Assurance (2008, p. 152) defines clinical audit as ‘a clinically led, quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and to act to improve care when standards are not met.’

Since Part 11 of the Medical Practitioners Act 2007 came into effect in May 2011, it is now obligatory for every practicing GP to conduct at least one audit per year, in order to comply with the requirements of competence assurance set by the Medical Council.

The Clinical Audit of delivering cervical screening in a practice/clinic setting follows a cyclical process organised into five stages. When planning for this audit, careful consideration of the following stages is essential.



 **• Stage 1 Planning for audit**

 **• Stage 2 Standard/criteria selection**

**• Stage 3 Measuring performance**

**• Stage 4 Making improvements**

**• Stage 5 Sustaining improvements**

The Healthcare Audit Cycle (Health Service Executive, 2013) Source: HSE Quality and Patient Safety Division, 2013

The self-audit tool focuses on evaluating the processes within a General Practice/clinic setting. The aim is to ensure that your practice aligns with the established policy, procedure, protocol, and guidelines for Cervical Screening, assuring a high standard of quality.

This self-audit tool can be used to measure the performance of individual sample takers and the criteria will need to be adapted to measure individual sample takers since the audit is designed to assess the implementation of the *Cervical Screening Protocol* in practice

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🏥 **Stage 1: Planning for Audit**:

***Overview:***

The initial stage involves comprehensive planning to ensure a well-organised and effective audit of cervical screening practices in your healthcare setting (primary care or non-primary care setting).

📋 **Objectives**:

**Objective alignment:**

* + Align the objectives of the audit with the goals of the practice and the established protocol for cervical screening.

**Scope definition:**

* + Clearly define the scope of the audit, focusing on the broader processes within your practice/clinic that align with policy and *Standards for Quality Assurance in Cervical Screening Quality Assurance in Primary care and other cervical screening settings (2023)* or focusing on your individual practice as a sample taker.

🤝 **Audit process and roles**:

**Auditor selection:**

* + Designate auditors, which can include the Practice Manager/Administrator, Clinical Lead for sample taking or Clinically Responsible Doctor (CRD/Contract Holder). The criteria will need to be adapted to measure individual sample takers since the audit is designed to assess the implementation of the *Cervical Screening Protocol*.

**Role clarification**

* + Clarify the roles and responsibilities of each designated auditor to ensure efficient completion of the audit.

🌐**Criteria establishment**:

**Criteria identification:**

* + Begin by identifying the criterions relevant for your audit, see audit tool below.

**Flexibility consideration:**

* Emphasise the flexibility to choose specific criteria based on the priorities of your practice, allowing for a tailored and focused evaluation e.g., a sample taker might focus on their own practice and choose criteria 7-12.

📋 **Documentation and recordkeeping**:

* Emphasise the importance of preparing for documentation, guiding the recording of findings, corrective actions, and noting dates for re-audit.

📊 **Stage 2: Standard/Criteria Selection**

***Overview:***

The second stage involves selecting the standards and criteria against which the cervical screening practices will be audited, see table 1.

The Criteria in Table 1 align with the quality requirements and standards set out in the *Cervical Screening Protocol* underpinned by the “*Standards for Quality Assurance in Cervical Screening Quality Assurance in Primary Care and Other Cervical Screening Settings*” document which mirror the woman’s journey through the cervical screening process and address the essential aspects of the screening pathway from a quality perspective.

**Audit Criteria:**

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| **Table 1. The audit process is based on the Quality Assurance Criteria, each serving as a guideline to evaluate specific aspects of cervical screening practices**:* **Criteria 1:** Promoting awareness of cervical screening
* **Criteria 2:** Promoting uptake and participation
* **Criteria 3:** Qualifications and skills for cervical screening
* **Criteria 4:** Organisational requirements
* **Criteria 5:** Optimal environment
* **Criteria 6:** Appropriate equipment and materials
* **Criteria 7:** Pre-screening: preparation for the cervical screening test
* **Criteria 8:** Screening: undertaking the cervical screening test
* **Criteria 9:** Post-screening: after the cervical screening test
* **Criteria 10:** Management of cervical screening test results
* **Criteria 11:** Referral and follow-up
* **Criteria 12:** Failsafe follow-up of abnormal results
 |

This step ensures a focused evaluation aligned with the priorities of your practice.

Criteria Selection:

* You have the flexibility to choose specific criteria based on the priorities of your practice for example, **if auditing against your own cervical screening practice you may choose criteria 7-12**.
* The criteria are based on the Quality Assurance Criteria, each serving as a guideline to evaluate specific aspects of cervical screening practices.

📌 **Stage 3: Measuring Performance**

***Overview***

In the third stage, the focus shifts to measuring the performance of the selected criteria. This involves conducting a thorough evaluation of the chosen elements of clinical practice.

Clinical audit elements:

**Measurement:**

* + Specific elements of clinical practice are measured.

**Comparison:**

* + Results are compared with the *Cervical Screening protocol*

**Evaluation:**

* + Reflection on the outcome of the audit and, where indicated, consider appropriate quality improvements to change practice accordingly.

**Confirmation Methods:**

* The confirmation methods involve a combination of physical checks, record reviews, and staff interviews.
* Findings are documented, including any corrective actions taken, and the date is noted for re-audit.

🏥 **Stage 4: Making Improvements**

***Overview***

The fourth stage emphasises making improvements based on the findings from the performance measurement. This is a crucial step in enhancing the quality of cervical screening practices.

**Improvement process:**

* Corrective actions are taken based on audit findings.
* Changes are implemented to address areas where standards are not met in the C*ervical Screening Protocol.*

**Roles and Responsibilities:**

* The CRD, Clinical Lead in Cervical Screening, sample takers, or the Practice Manager/Admin team may play a role in implementing improvements.

🏆 **Stage 5: Sustaining Improvements**

***Overview:***

The final stage focuses on sustaining the improvements made during the audit process. This involves ongoing efforts to ensure continued compliance and high-quality cervical screening practices.

**Ongoing compliance:**

* Regular audits are essential for maintaining ongoing compliance.
* Continuous improvement is emphasised to ensure sustained high standards.

**Roles and responsibilities:**

* The CRD, Clinical Lead in Cervical Screening, sample takers, or the Practice Manager/Admin team may be involved in overseeing the sustainability of improvements.

Adopting this approach through all stages, your practice can continually ensure that it meets the quality standards set forth in the *Cervical Screening Protocol*.

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| **Criterion 1****This criterion can be assessed by the CRD/Practice Manager/sample taker** | **Promoting awareness of cervical screening** *Health professionals in primary care and other cervical screening settings have a pivotal role in identifying eligible women and encouraging them to participate in regular cervical screening. Staff must ensure that the information they give to women is accurate and in a format that is easily understood* | **Confirmation****Method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Promoting awareness of cervical screening | * Verify if the service has current CervicalCheck posters on display.
* Confirm the availability of current CervicalCheck information leaflets.
* Check if there is access to multilingual videos and resources on [www.CervicalCheck.ie](http://www.CervicalCheck.ie)
 | * Physically check the location for the presence of current CervicalCheck signage.
* Verify the availability of current/ CervicalCheck information leaflets in waiting areas or information racks
* Verify that staff are aware of the multilingual videos and resources on [www.CervicalCheck.ie](http://www.CervicalCheck.ie) and how to access them.
* Verify that staff are aware of how to order promotional materials/posters [Health Promotion website](https://www.healthpromotion.ie/)
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| Access and availability of learning and reference resources | * Confirm the presence or knowledge of how to access current versions of relevant learning and reference resources provided by CervicalCheck.
* Ensure the availability of the following resources:
* Quality Assurance in Primary Care chapter of the current Standards for Quality Assurance in Cervical Screening
* HPV Primary Screening: Eligibility Framework
* Cervical screening results and recommendations table
* Online CervicalCheck eLearning resources available through the www.nssresources.ie
* Information for women through the CervicalCheck website and promotional materials about cervical screening (including benefits and limitations, HPV, screening tests and results and colposcopy).
 | * Physically check if the current versions of learning and reference resources provided by CervicalCheck are available in the clinic or practice and staff are aware how to find them on [www.CervicalCheck.ie](http://www.CervicalCheck.ie)
* Ensure that all staff have an active account on NSSresources.ie
* Physically check if staff know how to order promotional material/leaflets
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| Understanding the benefits and limitations of cervical screening | * Assess whether all staff involved in cervical screening understand both the benefits and limitations of cervical screening.
* Ensure staff can apply this understanding when counselling women and promoting informed choice.
 | * Conduct interviews or surveys with staff involved in cervical screening to assess their understanding of the benefits and limitations.
* Check medical records of a minimum of 10 patients to ensure that informed consent was obtained.
* Review training records to ensure that staff have received appropriate education on cervical screening and all training is up to date.
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| Eligibility | * Verify that eligible women, including those not registered with the practice, are facilitated to have a free cervical screening test when due.
* Confirm that eligibility (which can be checked online [https://apps.cervicalcheck.ie/checkeligibility](https://apps.cervicalcheck.ie/health-professionals/professional-check-womans-eligibility.605.procheckeligibilityv2.html)) is confirmed for each woman before taking a screening test.
 | * Ensure that all staff including administrative staff are aware of the obligation to offer screening to any eligible person that requests it, even if they are not a registered patient of the practice.
* Confirm that admin staff check eligibility prior to making an appointment.
* Confirm with sample takers that eligibility checks are conducted for each woman before taking a screening test.
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| Understanding cervical screening programme operation | * Confirm that all practice and clinic staff (both clinical and administrative) involved in the cervical screening process are informed of programme policies and changes to practice.
* Ensure staff:
	+ Have completed the Clinical Update on [www.nssresources.ie](http://www.nssresources.ie) that is relevant to their role.
	+ Are subscribed to the CervicalCheck HPV newsletter.
	+ Are aware of ongoing educational resources such as the CervicalCheck lunch-and-learn webinars.
 | * Check training records to ensure that all staff (clinical and administrative) have completed a Clinical Update on nssresources.ie.
* Ask if staff have access to and have read the bimonthly CervicalCheck HPV newsletter.
* Confirm attendance records for CervicalCheck lunch-and-learn webinars.
* Ask sample takers if they are aware that first screening test of any woman will automatically register and unregistered woman.
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| **Criterion 2****This criterion can be assessed by the CRD/Practice Manager/sample taker** | **Promoting uptake and participation***The success of CervicalCheck depends on the uptake and ongoing participation of women from the target population. The potential percentage reduction in cumulative incidence of and mortality from cervical cancer can only be achieved if a high proportion of the target population attends for cervical screening. CervicalCheck aims to achieve at least 80% coverage of the target population.* | **Confirmation** **Method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Screening of eligible women | A cervical screening test is only required when a woman is due to have a test* Does your practice check eligibility (check website if letter not available)
* at time of booking appointment?
* and commencement of consultation?
* The free phone information line can be used as a step after checking eligibility on website if still unclear as to woman's eligibility, for example if woman attending colposcopy visibility of next screening test not available on website
 | * Ensure that your practice checks eligibility for cervical screening at the time of booking an appointment and commencement of consultation.
* Confirm that the eligibility check includes referring to the CervicalCheck website if the eligibility letter is not available.
* Record the CSPID number on screening form when eligibility is checked.
* If eligibility is not confirmed, document the reasons and any corrective actions taken.
* If the woman is confirmed as ineligible, document next steps taken (where consultation had commenced).
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| Promotion of Equitable coverage | Equitable coverage is an important factor in ensuring screening does not widen health inequalities.Are you aware of * hard-to-reach groups that may have difficulty accessing screening
* resources available to assist and support your practice
* the CervicalCheck Access Officer
 | * Survey or interview practice staff to determine their awareness of hard-to-reach groups that may face difficulties accessing screening.
* Confirm that staff are knowledgeable about resources available to assist and support the practice in reaching these groups.
* Verify that staff are aware of the CervicalCheck Access Officer and their role in promoting equitable coverage.
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| **Criterion 3****This criterion can be assessed by the CRD/Practice Manager/sample taker** | **Qualifications and skills for cervical screening** | **Confirmation method** | **Compliance****Yes****No****N/A** | **Action** | **Re-audit date** |
| Maintenance of professional registration of sample takers | * Are all sample takers qualified and registered?
* Is the doctor registered with the Irish Medical Council?
* Is the nurse registered on the General Nurse Division of the NMBI (Nursing and Midwifery Board of Ireland) Register (excluding any other nursing division)?
* Is the midwife registered on the Midwife Division of the NMBI Register?
 | * Verify the qualifications, ensuring all sample takers are registered with their regulatory bodies.
* Ensure that nurses/midwives are registered on the appropriate divisions.
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| Registration to provide cervical screening | * Are all the sample takers registered under the CRD or if more than one CRD, are all sample takers registered under each one?
* Are all the sample takers aware of the MCRN (Medical Council Registration Number) of each CRD?
* Do all sample takers understand the importance of selecting the correct CRD on the practice management system?
* Are sample takers and contracted doctors aware that CervicalCheck must be notified when professional registration of a doctor or nurse is ceased?
 | * Verify the registration status of all sample takers under the CRD or multiple CRDs.
* You can contact CervicalCheck Admin department at admin@cervicalcheck.ie to check all sample takers are correctly registered to all CRD’s.
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| Appropriate education and training |  Have all the sample takers in your practice: * completed an accredited evidence-based Cervical Screening Education Programme (contains both a theoretical and clinical component)
* undertaken a CervicalCheck Clinical update on nssresources.ie at least once in the preceding three years
 | * Validate completion of an accredited evidence-based Cervical Screening Education Programme by reviewing individual training records or certificates.
* Confirm that sample takers have undertaken the CervicalCheck Clinical update on nssresources.ie by reviewing training records or confirming participation in training sessions
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| **Criterion 4****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Organisational Requirements** | **Confirmation method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Confidentiality | * Do all healthcare professionals involved in screening maintain confidentiality in relation to each woman and her personal information throughout the cervical screening process?
 | * Conduct interviews or surveys with healthcare professionals involved in cervical screening to assess their understanding and commitment to maintaining strict confidentiality throughout the screening process.
* Review the practices’ policies and procedures related to confidentiality to ensure alignment with best practices and regulatory requirements.
* Check for any reported breaches or incidents related to confidentiality and assess how they were addressed.
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| Data Protection | * Is your Practice or Clinic's storage, access, and transfer of women’s personal and health information compliant with relevant national and European statutory requirements for data protection, including, but not limited to, GDPR?
 | * Review the policies and procedures related to the storage, access, disposal of and transfer of women's personal and health information in the practice or clinic.
* Assess whether there is documentation of adherence to relevant national and European statutory requirements, including GDPR, in the handling of personal information.
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| Practice Records | * Does your practice or clinic effectively manage and maintain accurate records related to cervical screening in a safe and secure environment?
* Are patients with similar demographics flagged on the practice management system?
* Are sample takers aware that women who previously held a PPSN ending with ‘W’ have been issued new PPSN numbers by DEASP and ensure that the new PPSN is used when completing the screening form?
 | * Review the record-keeping policies and procedures in place at the practice or clinic, specifically focusing on those related to cervical screening.
* Assess the security measures in place to ensure the safe and secure storage of records, including access controls and data encryption if applicable.
* As CC letters no longer display the PPS No., it is imperative that the patient’s current & where required former PPS no. are checked at the time of making the appointment and again at the time of the test.
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| **Criterion 5****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Optimal Environment***Cervical screening services must be provided in an environment that respects the privacy, dignity, and autonomy of women. Every effort must be made to ensure that the cervical screening environment is acceptable to the women who use them.* | **Confirmation Method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Privacy and Security | * Are all cervical screening tests undertaken in a private and secure setting with respect to the woman’s needs?
 | * Observe the screening rooms to ensure they provide a private and secure environment.
* Interview staff and patients to gather feedback on the perceived privacy and security of the screening setting.
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| Room Temperature | * Are all cervical screening tests undertaken in a comfortable environment where the room temperature is suitable for the woman’s comfort?
 | * Assess the screening environment for comfort, considering factors like seating, lighting, and room temperature.
* Gather feedback from patients regarding their comfort during the screening process.
* Check clinic records for any reported issues related to discomfort during screening.
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| Chaperone | * Is a chaperone available upon request?
 | * Confirm the availability of a chaperone.
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| Women with disabilities or additional needs | Does your Clinic or Practice facilitate eligible women with disabilities, considering:* the woman’s ability to give informed consent and ensuring benefits versus limitations have been considered
* adequate time and an environment that accommodates their requirements
* referral to colposcopy if unable to facilitate cervical screening locally due to lack of equipment/facilities
* Aware of the availability of an Access Officer in CervicalCheck.
 | * Assess the physical environment to ensure it accommodates individuals with various disabilities.
* Interview staff to confirm awareness of assisted decision-making legislation and protocols for facilitating women with disabilities.
* Review records to check if there's evidence of considerations regarding informed consent, adequate time, and appropriate referrals for women with disabilities.
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| **Criterion 6****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Appropriate Equipment and Materials***There must be advanced preparation of equipment and consumables for the screening test.*  | **Confirmation Method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Examination Couch | Does your Clinic or Practice have:* an examination couch with a disposable sheet/paper roll.
 | * Physically inspect the examination area to ensure the presence of an examination couch with a disposable sheet/paper roll.
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| Consumables – cervical screening test kits and speculae | Does your Clinic or Practice:* use a single-use disposable speculum and cervix brush for each test?
* have a range of speculum sizes available for use?
* operate a stock rotation system
* check the expiry dates on consumables in particular vials which display the expiry date in American date format (YYYY/MM/DD)
 | * Verify through observation and records that the clinic or practice consistently use single-use disposable speculums and cervix brushes.
* Confirm the availability of a range of speculum sizes by physically inspecting the stock.
* Interview staff to ensure they are aware of the variety of speculum sizes available.
* Physically inspect the stock of consumables to ensure a systematic stock rotation is in place with last in, first out.
* Physically inspect consumables to confirm that expiry dates are visibly checked and monitored.
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| Infection Control & Clinical waste | Does your Clinic or Practice:* have an infection control policy and procedure in place?
* dispose of speculums and cervix brushes in accordance with clinical waste procedures and hazardous waste regulations?
 | * Verify the existence of an infection control policy and procedure by reviewing clinic documents.
* Confirm through records and interview that disposal of speculums and cervix brushes aligns with clinical waste procedures and hazardous waste regulations.
* Review waste disposal records to ensure proper disposal practices are consistently followed.
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| **Criterion 7****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Pre-Screening Preparation for the screening test** *All aspects of the cervical screening process must be clearly explained to the woman* | **Confirmation Method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Communication with the women about cervical screening | * Does your practice order the Information Sheet from Screenlink?
* Does your practice/clinic ensure that all women are provided with a copy of the Information Sheet?
* Aspects of the cervical screening process to be communicated include:
	+ when cervical screening is appropriate and not appropriate
	+ the cervical screening test(s) including the underpinning reasons for Primary HPV testing and reflex cytology
	+ high-risk human papillomavirus (hrHPV) and its role in cervical cancer
	+ the importance of regular screening and following screening recommendations
	+ the opt-out process if a woman does not wish to participate in screening or if a woman cannot participate in cervical screening (e.g. post-pelvic radiotherapy)
	+ how the CervicalCheck programme stores and shares screening data
	+ the benefits and the limitations of HPV cervical screening
	+ when and how results will be received
	+ the likelihood and meaning of a normal result
	+ what it means if further tests are required
	+ if results are abnormal, the options available, including an assessment of the risks, limitations, side effects and benefits of each option
	+ Post total hysterectomy?
 | Document review * Examine a sample of woman’s records, focusing on a specific time period, to confirm that all aspects of the cervical screening process mentioned were documented.

*Interviews:** Conduct interviews with sample takers to assess their understanding and adherence to the cervical process.
* Gather feedback from women on their recall and understanding of information provided prior to and during the screening appointment.
* Evaluate if there is consistent communication prior to sample taking as per the C*ervical Screening Protocol* document.
* Use of consultation template in the Practice Management system may aid the consistency of the consultation process.
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| Informed Consent | * Does your practice/clinic ensure that all sample takers obtain informed consent from women each time they attend for a screening test, and this consent is not accepted from a third party unless there is specific legal basis to do so?
* Is information provided to every woman in a way that is understandable to her to ensure awareness of the transfer of information between service providers in the cervical screening pathway (screening and diagnostic laboratories, colposcopy clinics and the National Cancer Registry Ireland)?
 | * Review a sample of patient records to confirm that informed consent was obtained directly from the woman attending for the screening test.
* Check clinic policies to ensure they explicitly state that consent must be obtained directly from the woman.
* Interview sample takers to confirm that they explain the transfer of information between service providers during the screening pathway in a way that is easily comprehensible to women.
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| Completion of the CervicalCheck Cervical Screening form and sample vial | * Is the current revision of the CervicalCheck Cervical Screening form completed at the time of taking a cervical screening test in the presence of the woman, with the women verifying the accuracy and completeness of her details?
* Is a new medical record established if one does not already exist? (if woman is not a patient in the practice)
* Is particular care taken to ensure correct details are retrieved from practice management systems for sisters, twins, mothers and daughters, and women with the same or very similar demographics?
* Are women with similar demographics flagged on the practice management system to avoid demographic mix-ups or cases of mistaken identity?
 | * Verify the current version of the Cervical Screening form is uploaded on the IT software and ensure NMBI/MCRN identifiers of sample takers and CRDs are correctly populating.
* Check clinic records/documentation to ensure that samples were not returned due to the incorrect version of the form being used.
* Interview staff to verify their awareness of the consequences of using an incorrect version of the form, and the corrective actions taken.
* Verify through women’s records and documentation or interview that the current revision of the Cervical Screening form is completed in the presence of the woman.
* Interview sample takers and administrative staff to confirm their awareness of the need for particular care in retrieving women’s details with similar demographics.
* Review a sample of women’s records to ensure that correct details are consistently retrieved.
* Check if any call was received from the laboratory staff due to incorrect or inadequate details on a form.
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| Identification of the woman - mandatory fields to maintain a robust ‘chain of custody’Matching of sample vials with associated cervical screening formsQuality of data – completeness, accuracy, and legibility | * Does your Practice/Clinic ensure that all sample takers consistently record the current minimum demographic details of the woman at the time of the screening test?
* Are demographic details recorded in the presence of the woman to ensure accuracy and completeness?
* Are the mandatory demographic details recorded on both the Cervical Screening form and the sample vial?
* Is the chain of custody for the sample maintained by ensuring robust recording of demographic details on both the form and the vial?
* Do the mandatory demographic details on the form include forename, surname, address, date of birth, sample taker details, contract holder details (CRD), professional registration numbers, date of the last menstrual period, and sample site?
 | * Ensure consistent and accurate recording of the woman’s demographic details in screening test records, including forename, surname, address, and date of birth.
* Assess sample takers' understanding of the importance of complete and accurate demographic recording, including confirmation of recording details in the presence of the woman during the screening test.
* Assess sample takers knowledge of the implications and consequences of inconsistent information between the vial and the screening form.
* Review clinic policies to emphasize the importance of recording demographic details in the presence of the woman, physically inspect completed forms, and verify consistency between form and vial demographic details to maintain a robust chain of custody.
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| Unique identification of the women | Does your practice/clinic ensure that sample takers consistently document at least one unique identifier from the provided list on the Cervical Screening form for accurate matching to the woman’s record on the cervical screening register? | * Review a sample of women’s records to verify that at least one unique identifier, such as Personal Public Service (PPS) number, Cervical Screening Programme Identification number (CSP ID), DOB, Surname at birth, or Mother’s maiden name, is consistently recorded on the Cervical Screening form.
* Interview sample takers to assess their understanding of the importance of recording unique identifiers for accurate matching.
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| **Criterion 8****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Screening: Undertaking the cervical screening test***Effective sampling is an integral component of a quality screening programme.* | **Confirmation Methods** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Visualisation of the cervix | * Do sample takers consistently ensure the cervix is visualised, assessed, and effectively sampled during cervical screening, as indicated by ticking the cervix box on the Cervical Screening form?
* Is a screening test not taken if the cervix is not visualised during the screening process?
 | * Review a sample of completed Cervical Screening forms to verify that the cervix box is consistently ticked, indicating proper visualisation, assessment, and sampling.
* Interview sample takers to assess their understanding of the importance of visually assessing and effectively sampling the cervix and by submitting a sample the sample taker is consenting that the cervix was visualised and sampled correctly
* Interview sample takers to verify their adherence to the *Cervical Screening Protocol* and understand the steps taken if the cervix is not visualised.
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| Condition of sample | * Are samples ensured to be in optimal condition, with adequate solution, no contamination, and a sealed vial that is not broken, damaged, or leaking?
 | * Physically inspect a sample of vials to confirm the presence of adequate solution, absence of contamination, and intact sealing.
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| Relevant clinic details and findings | * Do sample takers consistently document relevant clinical details on the Cervical Screening form, including the use of OCP/hormones/HRT, presence of IUCD, post-menopausal status, post-coital bleeding, and hysterectomy details?
* Are women with unexplained abnormal vaginal bleeding appropriately referred to gynaecology services and not colposcopy?
* Are sample takers aware of special populations on the eligibility framework (post-transplant, etc…) and do they use the check boxes provided on the cervical screening form?
 | * Review a sample of completed Cervical Screening forms to verify that relevant clinical details are consistently documented, and the sample taker has not written further information on the form.
* Interview sample takers to assess their understanding of the importance of documenting these clinical details.
* Review clinic policies or procedures to ensure that unexplained abnormal vaginal bleeding is appropriately referred to gynaecology.
* Confirm the availability of ambulatory gynaecology clinics for managing these referrals.
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| **Criterion 9****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Post Screening: after the cervical screening test** | **Confirmation method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Women’s Medical Record | **Documentation accuracy:*** Are screening tests recorded in the correct woman's medical record?

**Record content:*** Does the medical record include the date of the screening test?
* Is the screening test result documented in the woman's medical record?
* Is there a process in place to identify results that are delayed or not received from the laboratory?

**Communication record:*** + Are there records of written or verbal communications related to the cervical screening test result in the woman's record?
 | **Review of Medical Records*** Examine a sample of medical records to verify that screening tests are correctly recorded under the corresponding woman's name.
* Check if new medical records are established for women who are not already patients in the practice.
* Randomly select a sample of medical records and confirm the presence of the date of the screening test
* Verify that the screening test result is documented in the selected medical records.
* Examine written communication logs or documentation systems to ensure records of written/verbal communications related to cervical screening test results are present in the woman's medical record.
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| Advising the women of the result process | **Communication of result availability:*** How is the information regarding the availability of screening test results communicated to the woman?
* Are women consistently informed about the expected timeframe for receiving their screening test results?

**Programme's communication commitment:*** Is the programme's commitment to making results available within four weeks clearly communicated to the woman?

**Counselling provision:*** Is there a process in place to identify situations where counselling for the woman about her screening test results and next steps is required?
* Are counselling services consistently provided to women when required, and is this documented in the records?
 | * Interview staff to confirm understanding of the process.
* Examine a sample of women's records to verify timely communication.
* Review documented criteria for identifying counselling needs.
* Interview staff on counselling processes.
* Analyse records for evidence of provided counselling.
* Ascertain that all staff are aware that a women must be facilitated with a face to face consultation to discuss results if requested
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| Sample Identification | Are sample vial labels consistently inclusive of the woman's forename, surname, and date of birth as required identifiers? | * Conduct a random sampling of labelled vials from recent screenings.
* Verify the presence of the woman's forename, surname, and date of birth on each sampled vial label.
* Cross-reference the information on the vial labels with the corresponding medical records to ensure consistency and accuracy.
* Cross reference the information on the cervical screening form and the vial label to ensure consistency and accuracy
* Interview personnel responsible for labelling to confirm adherence to the labelling protocol.
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| Dispatch of samples | * Were samples dispatched to the laboratory within 3 working days of the test?
* Is there a documented record of the dispatch date for each sample?
* Were all cervical screening forms fully completed and cross checked before dispatch, including necessary details?
* Can the practice provide evidence of completed checklists for sample dispatch?
* Is there a procedure to ensure each form matches a labelled vial accurately?
* Can the practice demonstrate proper labelling and attachment of vial labels to forms?
* Is there documented evidence of informed consent for each screening test?
* Were sample vials used within the acceptable timeframe, avoiding the last six weeks/42 days before expiry?
* Can the practice demonstrate a system for checking and validating vial expiry dates?
* Is there a documented procedure for handling sample vials approaching or reaching expiry?
* Are sample takers aware of the YYYY:MM:DD format for vial expiry dates?
 | Documented Dispatch Records (Practice log):Review dispatch records and verify the date of dispatch for a sample. Cross-reference with the test date to ensure it was within 3 working days.Examine the sample dispatch records to ensure there is a documented record for each sample indicating the dispatch date.Completed Screening Forms:* Inspect a sample of dispatched screening forms and verify if they are fully completed and include necessary details.
* Review the procedure documentation and observe a random batch of samples ready for dispatch to confirm that there is a process in place to ensure accurate matching of forms to labelled vials.
* Inspect a batch of samples ready to be dispatched and verify that vial labels are properly attached to the corresponding forms.
* Examine a sample of screening records and confirm the presence of documented evidence of informed consent for each screening test.
* Review records of vial usage and confirm that sample vials were used within the acceptable timeframe, avoiding the last six weeks before expiry.
* Evaluate the practice's documented system for checking and validating vial expiry dates. Cross-verify with a batch of samples ready to be dispatched.
* Review the documented procedure for handling sample vials approaching or reaching expiry. Confirm its existence and assess its effectiveness.
* Conduct a survey or interview with sample takers to confirm their awareness of the YY:MM:DD format for vial expiry dates.
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| Packaging of samples | * Are all vials and forms packaged in specific-purpose transport boxes supplied by CervicalCheck for secure transport to the laboratory?
* Is there a written record maintained by the practice indicating the date each sample was sent to the laboratory?
 | * Physically inspect a batch of samples ready to be dispatched to confirm that the specific-purpose transport boxes provided by CervicalCheck are used for transporting samples and that all vials and forms are securely packaged in transport boxes.
* Examine the practice's records to confirm the existence of a written record indicating the date each sample was sent to the laboratory.
* Interview relevant staff members to confirm the awareness and adherence to the practice of maintaining a written record for the dispatch date of samples.
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| **Criterion 10****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Management of cervical screening test results***The practice / clinic protocol must include clear directions on roles and responsibilities for obtaining results of screening tests and providing women with their results. All staff, including administrative staff, must be aware and informed of this protocol.* | **Confirmation method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Results Management | * Does the practice have a documented protocol for communicating abnormal cervical screening test results, and can evidence of this protocol be provided?
* Are women informed about the practice's communication protocol for screening test results during their cervical screening test consultation?
* How does the practice ensure its communication protocol aligns with and complements the official notification process by CervicalCheck?
* Is there a consistent and documented process for communicating screening test results within the established timeline, and can the practice provide evidence of this communication for sampled cases?
 | * Interview relevant staff members to ensure awareness and understanding of the communication protocol
* Conduct interviews with a sample of women who recently underwent cervical screening to verify if they were informed about the practice's communication protocol for screening test results during their consultation.
* Examine a representative sample of documented communications for screening test results to ensure adherence to the established timeline.
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| Receipt and checking of cervical screening test results | * Does the practice's results management protocol include provisions for identifying overdue results, such as those outstanding after four weeks, and does it outline appropriate steps for follow-up with the laboratory?
* Is there a systematic process in place to ensure that a result is received for each sample, and conversely, that every result is cross-checked against the original sample to confirm there is a result for each sample and a sample for each result?
 | * Examine the practice's results management protocol to confirm the inclusion of provisions for identifying overdue results, particularly those outstanding after four weeks, and review the steps outlined for appropriate follow-up with the laboratory.
* Interview relevant staff members involved in results management to ensure awareness and understanding of the protocol, especially the steps related to identifying and following up on overdue results.
* Conduct a sample audit by reviewing a representative set of results and corresponding samples to verify that there is a result for each sample and a sample for each result. Cross-reference with documentation and records
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| Matching cervical screening results to the correct woman’s record | * Are cervical screening test results consistently recorded in the correct woman's medical record, and is the woman's medical record promptly updated with the test result and corresponding management recommendation?
* For practices utilising electronic results, is there a robust process in place to ensure that electronic results, from Healthlink, are downloaded accurately into the correct patient file within the available 30-day period, considering the subsequent archiving of Healthlink electronic results?
 | * Examine a sample of cervical screening test results and corresponding medical records to ensure accurate and prompt recording.
* Interview staff to assess understanding and adherence to the protocol
* Audit the electronic results management system, focusing on the timely download of Healthlink results
* Confirm the existence of a documented procedure for archiving Healthlink results and assess staff awareness through interviews
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| Checking management recommendations | * Do sample takers consistently check management recommendations accompanying screening test results in relation to the woman's medical history and CervicalCheck screening history to ensure alignment and accuracy?
* How does the practice ensure that sample takers access the most current information and documentation related to screening test results and management recommendations during the review process?

**Communication and Query Resolution**:* Is there a documented process in place to ensure that sample takers contact the laboratory in case of queries or uncertainties regarding screening test results or management recommendations?
* How is the practice monitoring and verifying, that sample takers consistently follow the procedure to address queries by reaching out to the laboratory?
 | * Verify through records or system access logs that sample takers have the means to access the most current information and documentation related to screening test results and management recommendations.
* Inspect the practice's documentation and procedures to confirm the existence of a documented process that instructs sample takers to contact the laboratory in case of queries or uncertainties regarding screening test results or management recommendations.
* Conduct interviews with sample takers to ensure their awareness of the protocol for contacting the laboratory in case of queries and verify if they have done so when faced with uncertainties
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| Communicating results and outcomes to women | * Does the practice or clinic have a well-defined and effective communication protocol for conveying cervical screening test results to women, and are all staff members, including administrative staff, consistently informed and aware of this protocol?
* When a screening test result is abnormal, is the woman provided with comprehensive details of the result, and is she adequately advised about the subsequent steps in the management process
 | * Examine the practice's documentation to verify the existence of a well-defined communication protocol for conveying screening test results.
* Conduct interviews with a sample of staff members to assess their understanding of the communication protocol and ensure alignment with the documented procedures.
* Review a sample of cases where screening test results were abnormal to confirm that women were provided with comprehensive details of the results. Cross-reference with documentation to verify that advice about subsequent steps in the management process was adequately communicated
* Collect feedback from a sample of women who received abnormal results to understand their experience and assess whether they were appropriately informed and advised about the next steps in the process
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| **Criteria 11****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Referral and follow up** | **Confirmation method** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Follow-up of women | * Do sample takers consistently make reasonable efforts to follow up on screening test management recommendations, including ensuring that there are two recorded attempts to contact the woman, with at least one attempt in writing when over a screening test?
* Do sample takers consistently respond to follow-up letters (failsafe) issued by the programme when a recommended test or referral to colposcopy has not happened?
* Are sample takers aware that it is their responsibility to follow up where needed with women who are not patients of the practice who had their screening test at the practice
 | * Examine a sample of cases with screening test management recommendations. Verify the presence of records documenting two contact attempts, with at least one in writing.
* Conduct interviews with sample takers to understand their adherence to the protocol for follow-up. Confirm that documented records align with the actions taken by the sample takers.
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| Use of CervicalCheck colposcopy referral form | * Are sample takers consistently using the CervicalCheck Colposcopy Referral form when referring a woman to a CervicalCheck colposcopy service?
* Is there consistent adherence to the practice of including a copy of the complete screening test result report with the colposcopy referral form, and are completed referrals sent directly to the colposcopy service?
 | * Review a sample of colposcopy referrals made by the practice. Verify that the CervicalCheck Colposcopy Referral form is consistently used, especially when the screening test result carries a 'refer to colposcopy' recommendation.
* Conduct interviews with sample takers to understand their awareness of and adherence to the use of the CervicalCheck Colposcopy Referral form.
* Examine a sample of colposcopy referrals to ensure that each includes a copy of the complete screening test result report. Confirm that completed referrals are being sent directly to the colposcopy service.
* Interview relevant staff involved in the referral process to assess their understanding and compliance with the protocol for accompanying documentation and direct submission of colposcopy referrals.
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| Referral to Colposcopy | * Are women whose screening test result recommends referral to colposcopy consistently referred directly by the clinically responsible doctor to a colposcopy service within 10 working days of receiving the screening test result and recommendation?
* Are women counselled about the potential for longer waiting times if referred to a unit of their choice rather than attending the programme-nominated colposcopy unit?
* Is all necessary referral information about the woman, her screening test result, and relevant history consistently forwarded directly to the colposcopy service as per the protocol, and is the use of partially pre-filled colposcopy referral forms facilitated when applicable?
* When referral is made by email, do sample takers ensure that the email has been received by the colposcopy clinic?
* Do sample takers consistently follow-up with colposcopy clinics when an appointment is not received?

**Direct referrals for clinical indications:**Are sample takers aware that referral to colposcopy for clinical indications is outside the remit of the CervicalCheck programme, only those women who are suspicious for invasive cervical disease should be referred to colposcopy.Are sample takers aware that referral for any other clinical indications should be to gynaecology clinics or ambulatory gynaecology clinics.  | * Examine a sample of colposcopy referrals for women with a recommendation for referral. Verify that these referrals were made within the specified timeframe of 10 working days.
* Conduct interviews with clinically responsible doctors to access that they understand the processes and timeframes involved in referring women to colposcopy.
* Review a sample of colposcopy referral forms to ensure that all necessary information, including screening test results and relevant history, is consistently forwarded directly to the colposcopy service
* Assess the practice's procedures to confirm that partially pre-filled colposcopy referral forms are used as necessary, in accordance with the guidance.
* Review a sample of referrals for clinical indication to ensure it was directed appropriately to colposcopy or to the gynaecology clinics or ambulatory gynaecology clinics.
* Review any referrals in an identified timeframe for suspicion for invasive cervical disease to ensure a screening test was not taken inappropriately prior to the referral
* Interview sample takers to assess their understanding of the rational for not taking a screening test on a woman with suspicion for invasive cervical disease.
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| **Criterion 12****This criterion can be conducted by the CRD/Practice Manager/sample taker** | **Failsafe follow-up of abnormal results***Failsafe follow-up of abnormal results refers to the process that occurs when a recommended action for a woman following an abnormal screening test has not occurred or has not been notified to the programme within a defined period from the due date of the recommended action. The failsafe is added to the woman’s screening history. Recommended actions may be a repeat test or attendance at colposcopy following an abnormal screening test, or a test following a discharge from colposcopy.* | **Confirmation methods** | **Compliance****Yes****No** | **Action** | **Re-audit date** |
| Failsafe follow-up of abnormal results (information requests) | * Are all failsafes followed up when requested by CervicalCheck, ensuring that the woman has been contacted twice by phone (with recorded attempts) and once in writing?
* Are all failsafes responded to either online or by post to ensure that CervicalCheck has been updated regarding the women’s screening status.
 | * Review a sample of failsafes initiated by CervicalCheck to verify that the established follow-up process has been consistently applied.
* Confirm that there are recorded attempts of at least two phone contacts and one written communication with the woman.
* Conduct interviews with staff involved in failsafe procedures to assess their understanding and adherence to the follow-up protocol outlined by CervicalCheck
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| Continuity of care for women | Is there awareness among the practice staff that a woman must have a clinically responsible doctor assigned to her care, and in the event the assigned clinically responsible doctor leaves the service, the practice remains clinically responsible for women who had their most recent cervical screening tests with this practice until alternative arrangements are made, if necessary?  | * Interview staff members to assess their awareness of the requirement for women to have a clinically responsible doctor and the practice's responsibility in case the assigned doctor leaves.
* Review documentation, such as training records or communication materials, to confirm that information regarding the continuity of clinical responsibility in case of a doctor's departure is adequately communicated within the practice.
* Ensure that staff members understand the steps and protocols in place for maintaining clinical responsibility during transitions and until alternative arrangements are made, if necessary.
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**Acronyms**

CC CervicalCheck

**CRD** Clinically Responsible Doctor

**CSPID** Cervical Screening Programme Identifier

**CSR** Cervical Screening Register

**DEASP** Department of Employment Affairs and Social Protection

**DOB** Date of Birth

**GDPR** General Data Protection Regulation

**GP** General Practitioner

**hrHPV** High Risk Human Papillomavirus

**HRT** Hormone Replacement Therapy

**HSE** Health Service Executive

**IUCD** Intrauterine Contraceptive Device

**IMC** Irish Medical Council

**MCRN** Medical Council Registration Number

**NCRI** National Cancer Registry of Ireland

**NMBI** Nursing and Midwifery Board of Ireland

**OCP** Oral Contraceptive Pill

**PPSN** Personal Public Service Number