



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.25

Cervical Screening

November 2013

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Public health functions to be exercised by NHS England

Service specification No.25

Cervical Screening

Prepared by –

Cancer Screening, Early Diagnosis and Skin Cancer Prevention Team

Department of Health

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Service specification No.25

This is a service specification within Part C of the agreement 'Public health functions to be exercised by NHS England' dated November 2013 (the '2014-15 agreement').

The 2014-15 agreement is made between the Secretary of State for Health and NHS England under section 7A of the National Health Service Act 2006 ('the 2006 Act') as amended by the Health and Social Care Act 2012.

This service specification is to be applied by NHS England in accordance with the 2014-15 agreement. An update to this service specification may take effect as a variation made under section 7A of the 2006 Act. Guidance agreed under paragraph A38 of the 2014-15 agreement may inform the application of the provisions of this service specification.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2014-15 agreement including all service specifications within Part C is available at www.gov.uk (search for 'commissioning public health').

1. Background and introduction

Purpose of the cervical screening specification

- 1.1. The purpose of this specification is to ensure that there is a consistent and equitable approach to the provision and monitoring of cervical screening across England.
- 1.2. This document is designed to outline the service and quality indicators expected by NHS England to ensure that a high standard of service is provided to NHS England's responsible population. It therefore sets out the specific policies, recommendations, and standards that NHS England expects services to meet.
- 1.3. The specification outlines the arrangements for commissioning the cervical screening programme, to include:
 - Call/recall
 - Cervical cytology services (including HPV testing)
 - Cervical histology services
 - Colposcopy services.
- 1.4. This service specification applies to all organisations providing the above services as part of the delivery of the NHS Cervical Screening Programme. The service provided by such organisations must be consistent with national guidance (including NHSCSP best practice guidance and *ad hoc* communications). Detailed documentation is available at www.cancerscreening.nhs.uk and www.csp.nhs.uk.
- 1.5. In this document, the 'provider', when an acute Trust, is always the lead Trust. Other services, for example colposcopy, may be subcontracted to other Trusts by the lead Trust.
- 1.6. The specification operates up to and including the point of diagnosis of cervical cancer. Subsequent staging, investigations, management and treatment are outside of the scope of this document.
- 1.7. The service specification is not designed to replicate, duplicate, or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008, or the work undertaken by the Care Quality Commission. In the event of new guidance emerging, the specification will be reviewed and amended with as much rapidity as possible, but where necessary, both NHS England and service providers should work proactively to agree speedy variations of contract ahead of the production of a revised specification.
- 1.8. This service specification needs to be read in conjunction with the current NHSCSP guidance and recommendations. These can be found on the cancer screening programmes website: www.cancerscreening.nhs.uk

Aims, objectives and health outcomes

Aims

- 1.9. The aim of the NHS Cervical Screening Programme is to reduce the incidence of, and mortality from, cervical cancer by delivering a systematic, quality assured population-based screening programme for eligible women.
- 1.10. This will be achieved across the whole programme by delivering evidence-based, interventions that:
- identify the eligible population and ensure efficient delivery with maximum coverage
 - are safe, effective, of a high quality, equitable, externally and independently monitored, and quality assured
 - lead to earlier detection of cervical abnormalities, appropriate subsequent treatment of cervical intraepithelial neoplasia (CIN), and improved outcomes
 - are delivered in suitably equipped accommodation, and supported by suitably trained, competent, and qualified, clinical and non-clinical staff who, where relevant, participate in recognized ongoing CME, CPD, and EQA schemes
 - meet all published national standards
 - have audit embedded in the service.
- 1.11. All elements of the programme must operate strictly within existing published national guidance, including any updated or new documentation. Colposcopy clinics and sampling both need to be provided close to the individual, but cytology and HPV testing can both be centralised.

Objectives

Activities prior to screening

- 1.12. In accordance with good management practice and experience, in order to ensure appropriate and efficient use of NHS resources, the programme as a whole should¹:
- identify and invite eligible women for screening at appropriate intervals
 - provide the invited population with the information required, in the form in which it is required, so that women are able to make an informed choice about whether or not to participate
 - ensure that GPs are informed of the final outcomes of screening invitations for each of their patients
 - optimise attendance among informed/willing individuals

- maximise accessibility of the service for all groups in the community.

Primary Screening

1.13. The programme as a whole should:

- provide women who attend for cervical screening with a high quality, effective, and woman-centred service
- carry out cervical screening in a way that minimises the possible adverse aspects (e.g. discomfort, anxiety) and that maximises the benefits (i.e. detecting abnormalities at an early stage)
- optimise attendance rates and maximise accessibility of the service for all groups in the community
- use only equipment and technology that meets NHSCSP standards
- allow women to opt out of the service, on a single occasion or permanently
- provide adequate numbers of appropriately trained, qualified, and competent staff to carry out high-quality screening and laboratory work
- ensure that at least 98% of women receive results within two weeks of attendance for screening.

Assessment, diagnosis, referral, follow-up

1.14. The programme as a whole should:

- undertake assessment and diagnosis of individuals with abnormal primary screening results in appropriately staffed and equipped settings, at levels expected within the NHSCSP, and to the standards expected within the NHSCSP
- provide those attending follow-up appointments with clear information about the assessment process
- ensure that assessment results are communicated clearly, accurately, and promptly
- notify GPs of the outcome of further examinations
- diagnose and, where appropriate, treat cervical intraepithelial neoplasia (CIN)
- refer women with cervical cancer for treatment by appropriately trained and qualified specialists
- maintain surveillance of women treated for CIN until they can be returned to routine screening according to Programme protocols.

Standards

1.15. The programme as a whole should:

- minimise the incidence of invasive cancer of the cervix
- maintain minimum standards of screening, whilst aiming for achievable standards (see Appendix 1)

- participate in both approved national routine audits and *ad hoc* audits to evaluate overall programme performance.

Administration, failsafe

1.16. The programme as a whole should:

- make the best use of screening resources for the benefit of the whole population.
- minimise non-attendance at screening/clinics
- ensure effective and timely communication with individuals being invited, screened, assessed, or treated, and also with clinical multi-disciplinary, teams local screening centres, NHS England, Quality Assurance (QA) teams within Public Health England, the national office team within Public Health England, and the Health and Social Care Information Centre
- work to develop a seamless, integrated care pathway
- build robust failsafe measures into all key stages of that pathway
- deal with complaints in accordance with relevant protocols
- use the programme's IT systems to capture key screening data/outcomes promptly and accurately, supporting local and national QA and cancer registration processes and programme evaluation
- comply fully with NHS Cancer Screening Programmes/NHS information governance requirements relating to the confidentiality and disclosure of person identifiable information and system/information security.

Audit and QA

1.17. The provider, subcontractor providers, and the quality assurance team within Public Health England should work collaboratively to:

- regularly audit and evaluate the service to ensure that it is delivered in a safe, effective, timely, equitable, and ethical way, in accordance with national policy, standards and guidelines, internal and external QA arrangements, and risk assessments
- monitor, collect, and report statistical data and other relevant information to relevant bodies, use it to promote continuous improvement in service performance and outcomes, give formal feedback to NHS England and the population served by the programme, and provide key information and models of good practice/ innovation/ achievement to those working in the area of cervical screening
- participate willingly in multidisciplinary QA visits organised by the QA team within PHE.

1.18. The provider will maintain a high quality service at all times, to include:

- collection and circulation of routine activity data, outcome data, and statistics, and use of these to monitor the service against the published standards of the NHSCSP, thereby assisting NHS England, public health screening staff, and QA team within PHE
- production of an annual report on cervical screening activities
- contributing towards the local public health cervical screening annual report
- attendance of lead staff from each discipline (and provision of relevant data) at quarterly multi-agency cervical screening co-ordinating groups
- documentation and implementation of comprehensive internal QA processes
- full participation in external QA activities, including audits, investigation of incidents in the programme, external quality assessment schemes and QA visits by the QA team within Public Health England; this includes responsibility for taking action on recommendations made at QA visits.

Information Technology

1.19. The call and recall service must:

- maintain electronic links with GP surgeries and laboratories
- check that staff in GP practices and community clinics record all necessary data promptly and accurately via the NHAIS/Open Exeter system
- check that laboratories and colposcopy services capture key screening data/outcomes promptly and accurately in clinical systems, supporting local and national QA, cancer registration processes, and programme evaluation
- comply fully with local NHSCSP and NHS information governance requirements relating to the confidentiality and disclosure of person identifiable information and system/information security.

Accreditation, training, guidance, research

1.20. GP practices and community clinics should:

- ensure that all staff who undertake sample taking have appropriate initial training and achieve and maintain the necessary competencies. This must include regular updates on policy and technology.

1.21. The provider should:

- Maintain electronic links with call/recall services
- ensure that staff in provider Trusts are appropriately trained and supported by national continuing professional development and skills frameworks, enabling them to develop their skills, competencies, and potential. Only approved/accredited training courses should be used
- contribute to nationally-approved research into the screening and diagnosis of cervical cancer, to inform screening practice and policy

- ensure that all pathology laboratories dealing with screening programmes are formally accredited by UKAS or equivalent
- ensure pathologists reporting material comply with RCPATH/ NHSCSP reporting guidelines
- ensure that all staff who sign out cervical samples as either negative or abnormal report sufficient numbers of samples (defined in NHSCSP guidance) and participate routinely in the appropriate EQA schemes.

Safety and Safeguarding

1.22. The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract.

Common Health Outcomes

1.23. The programme as a whole aims to:

- reduce the incidence of and mortality from cervical cancer
- refer women promptly to treatment services
- ensure equity of access to cervical screening across all groups in society
- minimise the adverse, physical/psychological /clinical aspects of screening e.g. anxiety, unnecessary investigation.

Common Programme Aims

1.24. The programme as a whole aims to:

- detect cervical abnormalities which, left untreated, could develop into cancer
- treat cervical intraepithelial neoplasia (CIN) where appropriate
- meet all published national standards
- deliver a safe, effective, equitable, high quality, externally monitored and assured service
- make effective and efficient use of resources for the benefit of the whole population
- deliver a service supported by a suitably competent and trained clinical/non-clinical workforce, within suitably equipped accommodation
- refer women promptly to treatment services
- ensure equity of access across all groups in society
- minimise adverse physical/psychological/clinical aspects of screening (e.g. anxiety, unnecessary investigations)
- encourage early presentation to primary care of symptoms which may develop between screening episodes
- underpin services by a solid audit and research base

- meet local population needs.

1.25. Part 1 of the Public Health Outcomes Framework for England, 2013-2016 states that the NHS will aim to deliver improvements against cancer screening coverage in domain 2 and improve mortality rates from cancer in domain 4.

2. Scope of the screening programme

Description of the screening programme

- 2.1. Individual clinical areas discussed in this section can be included or excluded according to the local situation. For example, the information on laboratory services can be ignored if only colposcopy services are required.
- 2.2. This service specification is for the provision of cervical screening services to include:
 - Call/recall services
 - Cervical cytology services, including HPV testing
 - Cervical histology services
 - Colposcopy services.
- 2.3. Participation in screening and cervical sample taking is an additional service within the General Medical Services (GMS) contract.

Activities Prior to Screening

- 2.4. The call and recall service should:
 - invite eligible women for screening six months before their 25th birthday, then at three-yearly intervals between the ages of 25 and 49 years. Thereafter, between the ages of 50 and 64, women should be invited at five-yearly intervals
 - invite to screening any women aged 65 or over who had an abnormal result from any one of her last three tests.
 - keep supporting documentary evidence for an indefinite time period for any woman who is ceased from the programme
 - follow national guidance on the routine ceasing of women
 - cooperate with and/or carry out annual audits of ceased women.
 - send results of primary screening to the woman within two weeks of her attendance at an appointment with a sample taker

Primary Screening

- 2.5. In accordance with agreed professional best practice and guidance shown in Appendix 3, GP practices must:
 - verify the appropriateness for the screening of women on call/recall lists
 - ensure that women who are not on NHS lists have access to screening, and that local arrangements are made to cover residential institutions, including prisons.
 - ensure that all equipment used complies with national equipment standards

- ensure that staff working in the programme are trained to meet the required standards of competence and are actively involved in continuing personal and professional development.

2.6. The cytopathology laboratory will, as a minimum:

- accept samples from eligible women according to NHSCSP protocols
- communicate any issues with samples received to the appropriate parties as indicated in the relevant guidance/advice
- receive, book in, process, and examine/report cervical cytology samples, and provide clinical reports of these tests in line with NHSCSP guidance
- send results securely to the sample taker and the relevant GP (if different)
- send results securely to the appropriate call/recall register and ensure that suitable systems are in place to verify that all tests are reported and safely transmitted according to NHSCSP standards
- deal promptly with telephone and email queries in relation to cervical screening activities
- make sample results available at colposcopy
- make cytology slide(s) and/or result available to the histopathologist
- manage a safe and robust direct referral system for women where cytology results indicate that referral for colposcopy is required, according to NHSCSP guidance
- contribute to multi-disciplinary (MDTM) case discussions and to mismatch meetings designed to audit cytology/histology/colposcopy findings to agreed local protocols. These meetings must meet the requirements outlined in relevant NHSCSP publications
- produce quarterly activity reports, as determined locally, for both QA teams within PHE and NHS England, who will discuss these at local multi-agency cervical screening coordinating groups
- produce a validated mandatory annual return (KC61) for each laboratory and provide this to the QA teams within PHE and NHS England, by the specified deadline
- work with NHS England's Local Area Team to maintain a sample taker register, as determined locally, and provide comprehensive feedback both by individual sample taker and by general practice/clinic on reporting profiles, workload, and error rates (for example incomplete patient identity details), as agreed with NHS England
- provide feedback to trainee sample takers where required locally
- ensure that the performance of all staff involved in reporting cervical cytology tests is monitored according to NHSCSP and relevant professional society guidance.

- Take appropriate action where performance is outside national standards/guidelines
- provide a comprehensive failsafe system as defined by NHSCSP guidance
- comply with NHSCSP guidance and with local QA processes and audit requests from the QA team within Public Health England
- undertake regular audits on cervical screening activities, including the review of cytology tests on samples taken from women subsequently diagnosed with cervical cancer, in line with NHSCSP guidance
- maintain comprehensive quality management and quality control systems, including internal and external QA and processes (which includes participation in mandatory NHSCSP EQA schemes). All such activities should be documented in protocols and procedures that comply with NHSCSP guidance.
- undertake HPV triage and test of cure on appropriate samples, as defined by the NHSCSP, in accordance with the NHSCSP's HR-HPV triage and test of cure protocol.
- In the event that HPV testing is undertaken outside the cervical cytology service, identify a senior individual (ie clinical or scientific lead in the laboratory) as the lead for the HPV testing service. This individual is expected to participate fully in provider-based multi-disciplinary management meetings and, as determined locally, multi-agency cervical screening meetings.

Assessment, diagnosis, referral, follow-up

- 2.7. In accordance with NHSCSP standards and protocols, the organisations within the NHSCSP should undertake to meet the following criteria.
- 2.8. The GP practice will:
- counsel women before the screening test, and also after, where the result is abnormal and this is requested by the woman
 - ensure that follow-up/ treatment/ referral is recommended and initiated, and verify direct referral.
- 2.9. The colposcopy service will, as a minimum:
- provide services in line with all NHSCSP and British Society of Colposcopy and Cervical Pathology (BSCCP) standards and guidance, including accreditation of colposcopists
 - appropriately and efficiently manage women referred via direct referral, GP referrals, and tertiary referral within, or between, providers
 - ensure women are fully informed and counselled before an appointment

- manage/ treat precursor lesions and early stage 1A cancers according to protocol and retrieve excised tissue for histological evaluation (most commonly, during a separate appointment from that in which initial assessment was conducted)
- ensure that all clinical, operational, and administrative activities are documented in up-to-date service guidelines, and that usual practice avoids unnecessary attendance
- ensure that women are provided with the necessary information and advice in advance of their colposcopy appointment, including information relating to see-and-treat (when appropriate). All information given to individuals should conform with NHSCSP standards
- ensure that the colposcopist to whom the woman is referred takes responsibility for her management, including arranging further follow-up (either in the colposcopy or gynaecology clinic), and informs the GP (or responsible clinician) of the outcome of the examination, including any investigation performed, and the due date of subsequent colposcopic examination. When the woman is discharged back to primary care the colposcopist is responsible for informing call/recall, the laboratory, and the GP of the final diagnosis and the recall interval to the woman's next cervical cytological sample. Any failsafe process can then be closed.
- systematically send reminders to women who do not attend their appointments. In the case of follow-up appointments after treatment, this may include immediate discharge to the GP, as indicated in local protocols
- have a failsafe system in place, consistent with guidance from the national office of the Cancer Screening Programmes within Public Health England
- where a hysterectomy is undertaken, take responsibility for ensuring that the GP is informed of the type of operation, whether it included total removal of the cervix, and the results of any histology conducted. This will enable the GP to provide advice in relation to future screening for women who undergo such procedures
- meet the NHSCSP standards for attendance by colposcopists at multi-disciplinary case discussions/ mismatch meetings to audit cytology, histology, and colposcopy findings to the agreed local protocol. These meetings should meet the requirements outlined in relevant publications from the national office of the Cancer Screening Programmes within Public Health England
- carry out an agreed annual colposcopy audit programme and take the necessary action where performance is outside national standards
- produce validated quarterly KC65 reports for each clinic to the QA team within Public Health England and NHS England, within a maximum of six weeks after the end of each quarter. An overall annual KC65 return for each clinic should be supplied on request

- carry out people satisfaction surveys at least annually and collaborate with any surveys run by the QA team within Public Health England as required. The findings of such surveys should be used to improve the service
- undertake colposcopy and associated activities within accommodation that meets NHSCSP standards, using equipment that meets NHSCSP standards
- maintain a suitable IT system to enable an accurate electronic record to be made of all activity carried out within the colposcopy service, including colposcopy carried out under general anaesthetic. The IT system should support the audit process.
- ensure that staff working in the programme are trained to meet the required standards of competence and are actively involved in continuing personal and professional development.

2.10. The histology laboratory will, as a minimum:

- be accredited by UKAS, and provide a comprehensive histology service to support the cytology and colposcopy services
- process and report diagnostic and treatment specimens taken by the colposcopy service (including those taken under general anaesthetic) in a timely manner to allow colposcopy to meet reporting time standards for biopsy results
- send results securely to the originating clinician and to the cytology laboratory, where these are located in a different healthcare organisation
- provide histology results to cytology
- participate fully in the cancer registration process for both CIN3/ CGIN and cervical cancer results
- contribute fully to multi-disciplinary case discussions/ mismatch meetings to audit cytology, histology, and colposcopy findings to the agreed local protocol. These meetings must meet the requirements of the relevant NHSCSP publications
- undertake internal and external quality control measures and regular audits, in accordance with published standards. Take appropriate action where performance is outside national standards/guidelines
- participate in relevant EQA schemes, where available
- audit all cases where invasive cervical cancer is found in women within the programme run by the laboratory, in line with NHSCSP guidance
- comply with NHSCSP/Royal College of Pathologists histopathology reporting guidelines.

2.11. Where colposcopy services are located on more than one site, there must be consistency of procedures and protocols, accommodation, equipment, and IT, including robust policies for onward referral. In this situation, the lead colposcopist and lead colposcopy nurse will be responsible, as appropriate to their roles, for colposcopy activities occurring on all sites.

Standards

- 2.12. In accordance with best practice and national guidance shown in Appendix 3 the NHSCSP should:
- ensure that all staff working in the NHSCSP are familiar with relevant clinical, programme and QA guidelines
 - ensure that all staff maintain minimum standards, adhere to NHSCSP guidance and recommendations, and conduct internal audit and external QA monitoring
 - take prompt action where standards are lower than expected to identify the causes and improve the service
 - agree early warning systems and triggers with the local QA team within Public Health England
 - manage serious failures to provide services to the level specified in the NHSCSP QA guidelines according to NHSCSP protocols (see *Guidelines for Managing Incidents in the NHS Cervical Screening Programme*, 2nd edition, December 2010)
 - ensure that all programmes have a multi-disciplinary QA Visit at least once every three years
 - use nationally developed and agreed letters and leaflets.

Administration, audit, QA, failsafe, IT

- 2.13. The various elements of the service have the following responsibilities:

Call/recall

- 2.14. The call/ recall database used by the NHSCSP is the National Health Application Infrastructure Services (NHAIS) system, often referred to as the Exeter system. The Exeter system is a population database, with details of all eligible women registered with GPs in England. The system is used to:
- invite eligible women at the appropriate intervals
 - manage receipt and accurate recording of test results
 - ensure that women and GPs are promptly notified of test results
 - handle the results/screening histories of women moving in or out of the area and those screened outside of the NHSCSP
 - set the next test due date
 - facilitate failsafe, e.g. by running regular searches to ensure that no individual is missed
 - ensure that women who transfer between databases have their screening histories available and screening intervals maintained
 - report coverage on KC53.

- record the HPV vaccination status for girls

2.15. The GP should:

- ensure that they and their staff are adequately trained for the clinical practice they undertake
- be able to demonstrate training and competence for all staff taking samples, including understanding of up to date programme policies
- record all cervical tests and ensure sample taker access to all previous test results
- ensure that all women are appropriately informed of their test result in writing
- comply fully and promptly with non-responder and failsafe procedures
- provide specified data for national and local audits and other agreed purposes
- audit the data of all individuals taking cervical samples individually and for the practice as a whole on a quarterly basis

2.16. The cytology laboratory should:

- contribute effectively to MDT/audit meetings
- produce periodic and suitably detailed activity reports and returns as required for NHSCSP QA processes and national/regional audit.

2.17. The histopathology laboratory should:

- send results to the clinician and cytology laboratory as appropriate
- record and report on rejected and inadequate samples.

2.18. Each colposcopy service should:

- identify a lead colposcopist to oversee continuity of management/follow-up, and notification of outcome/ discharge/ next text due date
- manage external relationships
- organise failsafe arrangements to cover key stages of the process, including non attendance.

Accreditation, training, guidance, research

2.19. The programme as a whole should:

- ensure that all screening service staff regularly participate in QA activities (including 3-yearly QA visits, the EQA scheme (pathologists and technical staff), and that all professionals meet CPD/CME requirements

- invite eligible women to participate in appropriate clinical trials or studies.

Failsafe arrangements

- 2.20. QA within the screening pathway is managed by the inclusion of failsafe processes. Failsafes are a back-up mechanism, designed to ensure that, where something goes wrong, processes are in place to identify what is going wrong and what actions are necessary to ensure a safe outcome.
- 2.21. The provider is expected to:
- include appropriate failsafe mechanisms across the whole screening pathway for women who participate. Details of appropriate procedures are embedded in the guidance and recommendations on the NHSCSP website and may need development in some areas
 - review and risk assess local screening pathways in the light of guidance offered by QA processes or the National Office of the Cancer Screening Programmes
 - work with NHS England and QA Teams to develop, implement, and maintain appropriate risk reduction measures
 - ensure that mechanisms are in place to audit implementation of risk reduction measures regularly and report incidents should these occur
 - ensure that appropriate links are made with internal provider governance arrangements, such as risk registers
 - ensure routine staff training and ongoing development takes place
 - maintain a record of tests taken
 - check that results are received from the lab for every sample
 - ensure women whose samples they report will be notified of results (either via the practice, or call & recall)
 - ensure women whose samples are taken in genitourinary medicine clinics or colposcopy clinics obtain their results in writing
 - act on non-responder notifications (screening, and colposcopy appointments)
 - ensure required colposcopy referrals are made
 - respond to failsafe enquiries from laboratories/report critical incidents to NHS England.

Roles and accountabilities

- 2.22. The lead provider has lead responsibility across the entire care pathway. This begins with correctly inviting the woman to be screened and concludes with either onward referral for cancer treatment, return to routine recall, or correct ceasing from the NHSCSP.

- 2.23. The lead provider must create clear lines of accountability and responsibility for all cervical screening services carried out under this agreement. This includes identification of individuals to undertake the following roles, as defined by NHSCSP guidance, supplemented as appropriate by best practice guidance from QA teams within Public Health England:
- a hospital-based cervical screening programme co-ordinator (HBPC) with delegated responsibility from the chief executive for the quality of the cervical screening activities carried out by the provider. This role may be combined with that of pathway manager.
 - a lead cytopathologist
 - a lead histopathologist
 - a named laboratory lead (usually a senior biomedical scientist)
 - a lead colposcopist
 - a lead colposcopy nurse
 - a pathway manager.
- 2.24. Key staff should be formally appointed, should have sufficient designated sessions, and should be able to access sufficient administrative support in order to fulfil their roles. Where possible, deputies for key roles should be identified to provide cover in the event of absence.
- 2.25. The HBPC should maintain a close working relationship between all parts of the provider's cervical screening activities, and with NHS England and stakeholders. Where the provider undertakes cytology which results in colposcopy referrals to another Trust, the HBPC at the provider should ensure close working relationships with neighbouring HBPCs are maintained.
- 2.26. Regular multi-disciplinary cervical screening management meetings should take place within the provider, convened on a quarterly basis, to discuss performance and any issues arising with cervical screening services. Where appropriate, these should include representatives from subcontracted Trusts. Appropriate Trust systems should be in place to enable a six-monthly report from the HBPC to be discussed at a formal clinical governance committee within the provider's institution, thereby enabling escalation of key issues to the chief executive as required.
- 2.27. The provider will convene regular multi-disciplinary clinical case discussion meetings as outlined in NHSCSP guidance, and/or will ensure that provider staff attend and support (i.e. through sample review) meetings convened by other providers e.g. where colposcopy is carried out by other Trusts, to which the provider directs referrals. The provider will ensure that all staff involved in cervical screening activities are kept informed of programme performance and issues.
- 2.28. The NHSCSP is dependent on systematic, specified relationships between stakeholders, including relationships with treatment services, the laboratory, external

diagnostic services, Primary Care representatives, etc. The lead provider will be expected to identify a pathway manager to take the lead and ensure that inter-organisational systems are in place to maintain the quality of the whole screening pathway. This will include, but is not limited to:

- providing coordinated screening across organisations, so that all parties are clear about their roles and responsibilities at every stage of the screening pathway, and particularly where responsibility is transferred from one party to another
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway
- contributing to any initiatives led by NHS England or public health screening teams to develop the screening pathway in line with the NHSCSP expectations
- maintaining robust electronic links with IT systems and relevant organisations across the screening pathway
- agreeing links with primary care, and with secondary and/or tertiary care.

The role of pathway manager may be combined with that of the hospital-based programme co-ordinator.

Commissioning arrangements

2.29. Cervical screening services will be commissioned by NHS England alongside specialised commissioning of cancer services where appropriate. Minimum data requirements for NHS England are shown in Appendix 2.

Links with the National Programme and 'Do once and share'

2.30. Certain functions of English national screening programmes are managed from PHE by the national office of the NHS Cancer Screening Programmes. National guidance documents can be accessed via the NHSCSP websites.

3. Delivery of the screening programme

Service model summary

- 3.1. Providers should provide cervical screening services to the standard outlined in national standards, to all eligible women within the population defined by NHS England. This specification operates up to the point of diagnosis of cervical cancer; subsequent management and treatment is outside its scope.
- 3.2. If the optimal deliverable benefits from a screening programme are to be achieved, there must be seamless links between 'screening responsibility' and 'treatment responsibility', so that women at the end of the screening process are referred to treatment services if necessary.
- 3.3. All elements of the screening pathway must be delivered by appropriate staff, to national standards and guidelines.

Population coverage

- 3.4. NHS England and the service provider will work together to:
 - ensure that up-to-date population registers and lists of GP registered populations are maintained and cleaned to guarantee accuracy and completeness
 - optimise coverage and uptake across their catchment area
 - co-operate with regular analysis of coverage to identify groups of women who either access screening at lower levels, or do not access services at all

Programme Coordination

- 3.5. The lead provider or subcontracted provider will be responsible for ensuring that the part of the programme that they deliver is coordinated. Where collaboration is necessary, one part of the programme should interface seamlessly with others, particularly in the areas of timeliness and data sharing. This will ensure that the aims and objectives of the NHSCSP are met and an integrated service offered to women.

Clinical and corporate governance

- 3.6. The provider will:
 - ensure that staff co-operate with, and are represented on, the local screening oversight arrangements/ structures. This might include the local office of NHS England and local authority Health and Wellbeing Boards
 - identify responsibility for the screening programme at Trust Director level, or a named individual with delegated responsibility from the Trust Director
 - ensure that there is appropriate internal clinical oversight of the programme's management and internal governance

- regularly monitor and audit the screening programme as part of organisation's clinical governance arrangements, thus assuring the organisation's board of the quality and integrity of the service
- comply with the NHSCSP guidance on managing serious incidents and potential incidents
- put appropriate and timely arrangements in place for referral into treatment services (these should meet the programme standards)
- provide evidence of clinical governance and effectiveness arrangements on request
- produce an annual report of screening services, which is signed off by the provider's board
- have a sound governance framework in place covering the following areas:
 - information governance/ records management
 - equality and diversity, as defined by the Equality Act 2010
 - user involvement, experience, and complaints
 - failsafe procedures
 - communications
 - ongoing risk management
 - health and safety
 - insurance and liability.
 - Compliance with the NHS CSP Confidentiality and Disclosure Policy

Definition, identification, and invitation of cohort/eligibility

- 3.7. The target population to whom screening is to be offered comprises all women in the eligible age group who are registered on specified NHAIS systems with specified GPs, or who are resident in the specified area and not registered with the NHS but entitled to NHS care.
- 3.8. The target age group is currently:
- Age 25: first invitation (in practice, invitations to first screen are issued at 24.5 years)
 - Ages 25 – 49: 3 yearly screening
 - Ages 50 – 64: 5 yearly screening
 - Ages 65+: screening of those who have not been screened since age 50, or those who have not yet met the criteria to be ceased from the programme.
- 3.9. The provider must cooperate with efforts to optimise screening participation amongst vulnerable and hard-to-reach groups within the eligible population.

Location(s) of programme delivery

- 3.10. The providers of both initial screening and subsequent colposcopy must ensure that these elements of the programme take place in suitable and appropriate locations, which should take account of the public transport links and car parking facilities.
- 3.11. The lead provider will ensure accessible service provision for all referred women, while ensuring that all locations fully comply with the standards and guidelines referenced in this service specification. All services (cytology, histology, colposcopy) must be provided in locations that enable a full service to be delivered and that are compliant with the requirements of this service specification.

Days/hours of operation

The days and hours of operation of both primary screening appointments and colposcopy clinics will be locally determined and appropriate for the local populations. Easy access to initial screening appointments and timely further examination is essential, and this is a key criterion of quality for the entire screening pathway. The provider should therefore be able to demonstrate efficient and effective use of resources.

Working across interfaces

- 3.12. The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway. Accurate and timely communication and handover across these interfaces are necessary to reduce the potential for errors and ensure a seamless pathway for service users. The provider will
 - Ensure that there are clear, named lines of clinical responsibility at all times, and particularly where there is handover of care.
 - State these lines of clinical responsibility in an operational policy within the programme.
- 3.13. The provider will ensure that appropriate systems are in place to support an interagency approach to the quality of the interface between these services. This will include, but is not limited to:
 - taking the lead role in oversight of the entire screening pathway
 - agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
 - providing strong clinical leadership and clear lines of accountability.
 - developing joint audit and monitoring processes
 - working to agreed NHSCSP standards and policies
 - agreeing jointly, between all agencies, the failsafe mechanisms that are required to ensure safe and timely processes across the whole screening pathway

- meeting the screening programme standards set by the national office of the NHS Cancer Screening Programmes within Public Health England

3.14. The lead provider must ensure that procedures at interfaces follow these guidelines:

- letters should be sent to women, inviting them for screening at appropriate intervals
- a failsafe system should ensure laboratory receipt of correctly identified samples
- the laboratory service should provide results to the screening MDT
- the laboratory service should provide results to the call/recall system
- MDT outcomes should be accurately recorded on the cervical screening IT system.
- GPs should be informed of screening outcomes
- Symptomatic services should inform screening about interval cancers.

3.15. To ensure that the service delivered forms part of a high quality cervical screening programme for the local population, the provider will

- work collaboratively with other services to deliver services to national standards,
- ensure appropriate failsafe systems are in place between the different organisations involved in the provision of cervical screening
- where necessary, refer women on to appropriate services outside screening e.g. for cancer treatment.

Information on test/screening programme

The provider will ensure that

- at relevant points throughout the screening pathway, women are provided with appropriate information on cervical screening.
- a trained interpreter is available during appointments for women whose functional language is not English, along with appropriate written information
- provide appropriate support for women with physical disabilities
- ensure that women with learning disabilities are provided with support to enable them to understand all processes and results

Testing (laboratory service, performance of tests by individuals)

3.16. Laboratories are expected to follow the policy guidance and standards laid out in standard operating protocols. Laboratories must be accredited by UKAS and must process at least 35,000 cervical cytology samples from GP and community clinics each year. The evidence for this is set out in the NHSCSP advice to the NHS on achieving 14 day turnaround times to screening results.

- 3.17. Laboratories are also required to provide routine data to NHS England in a timely manner and using an agreed format. This includes but is not limited to:
- data on samples analysed both number and results
 - notification of positive results
 - notification of outcome data where possible.

Results reporting and recording

- 3.18. The laboratory will
- send results to relevant parties within the screening programme, including GPs, ideally using electronic means. Data should be presented with the nationally approved format and codes and follow NHS reporting formats and rules.
 - Ensure that the result of the cervical screening test is reported to the woman within 2 weeks of her attendance for screening.

Providing results

- 3.19. Laboratories must notify women of the result of the screening process by letter. Their GPs must also be informed. This must happen within 2 weeks of the screening test being taken.

Transfer of, and discharge from, care obligations

- 3.20. The screening programme covers the period from identification of the eligible population to diagnosis. On diagnosis, women will be transferred efficiently to treatment services. Any post-treatment follow-up will be the responsibility of the treatment services.
- 3.21. Women who have had cervical abnormalities treated will be followed up in accordance with current NHSCSP protocols.
- 3.22. This specification does not include the following activities, or any work or cost associated with them:
- Follow-up and management after a diagnosis of cancer
- 3.23. Women under the age of 24.5 are not eligible for cervical screening. They will be automatically invited as they approach their 25th birthday. In addition, women are normally excluded from the routine programme when they:
- will be aged 65 or over at the date of their next test, and meet the criteria for automatic ceasing
 - have been ceased from the programme at their own request
 - have no cervix, either because of a congenital absence, or because they have undergone a procedure remove the cervix completely

- have had radiotherapy for cervical cancer, so that it is not possible to make an accurate cytological report.
- 3.24. Women who are not registered on any NHAIS system do not receive automatic invitations, but may be registered if a sample is received (e.g. from a community outreach clinic). These samples should be reported if the woman is eligible for NHS care. If women aged 65 and over who have never attended for a test request screening, their samples should be reported.
- 3.25. See Clause 54 of *The Standard Terms and Conditions for Acute Hospitals* (Gateway Reference 15458) for the contractual requirements for equity of access, equality, and the avoidance of discrimination.

Staffing

- 3.26. The provider will ensure that there are adequate numbers of trained, qualified, and competent staff in place to deliver a high-quality cervical screening programme, in line with best practice guidelines and NHSCSP national policy.
- 3.27. Qualifications will be specific to the groups of staff delivering the service across the care pathway. However, all staff must demonstrate competence in their area (this is linked to training).
- 3.28. The provider will have in place a workforce plan designed to maintain a sustainable programme, especially where an increase in the eligible population is predicted (generally this is the case until 2027) and/or where there are difficulties in the recruitment of appropriately qualified healthcare staff.
- 3.29. All professionals involved in the NHSCSP screening programme are required to keep up-to-date with nationally approved training programmes and CPD/CME etc. and should participate in educational schemes such as histopathology EQA as appropriate.

User involvement

- 3.30. In accordance with good practice, to gain feedback on services provided, and to have public involvement on service provision, the provider will collect the views of service users, which will often be via surveys or questionnaires. It is expected that such surveys will take place on a regular (rather than ad hoc) basis and that the results will be made available to NHS England. The provider will :
- demonstrate that they have collected (or have plans in place to collect) the views of service users, in respect of the services they provide
 - demonstrate how those views will influence service delivery for the purposes of raising quality
 - show that all women are given information about how to provide feedback about the services they receive, including the complaints procedure.

Premises and equipment

3.31. The provider will ensure that:

- suitable premises and equipment are provided for the screening programme
- appropriate policies are in place for equipment calibration, maintenance, and replacement
- the IT systems are able to support the programme and to supply data for the purpose of national standards and KPIs
- the IT systems are able to perform failsafe checks
- there are appropriate and secure premises on which screening can safely take place.
- only technologies and protocols that have been evaluated and recommended by the national office of the Cancer Screening Programmes within PHE are used in the programme, and that the manner of their use accords with national guidelines. The provider must make all staff aware that unorthodox use of approved technologies or used of unapproved technologies is prohibited within the NHS Cervical Screening Programme, except as part of a formal national pilot, or a properly constituted and approved research project. The definition of 'technology' here is an inclusive one.

Key Performance Indicators

3.32. The provider will adhere to the requirements specified in Appendix 1.

Data collection and monitoring

3.33. The provider will

- ensure that services provide routine data to NHS England, PHE, and other official requesting bodies in a timely manner.
- contribute to national data collection exercises where required
- provide annual data, measuring performance against both standards and the Key Performance Indicators (the latter are shown in Appendix 1).

Data reporting

3.34. The provider will

- Ensure that data is reported to NHS England and QA teams within Public Health England on a quarterly and annual basis. Appendix 3 shows routine data requirements

3.35. Consolidated annual reports activity and coverage are published at a national level and detail local activity.

4. Service standards, risks and Quality Assurance

Key criteria and standards

- 4.1. Providers must meet at least the minimum and achievable NHSCSP standards found in Appendix 1, as well as adhering to specific professional standards, which can be found in the guidance provided on the NHSCSP website.
- 4.2. The national office of the NHSCSP within PHE supports health professionals in their endeavor to meet these standards and deliver a high quality cervical screening programme. A number of resources to support health professionals are therefore also available on the NHSCSP's website.

Risk assessment of the screening pathway

- 4.3. Providers
 - must have in place an internal QA process that assures NHS England and the quality assurance team within PHE of their ability to manage the risks of running a screening programme.
 - may use the Failures Modes and Effects Analysis (FMEA) method, which is recommended by the NHS National Patient Safety Agency's risk assessment programme. Risks should be defined in the standard NHS format (where likelihood and severity are multiplied to give a RAG score).
 - must maintain a register of risks, working with NHS England and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and ensuring that these points are reviewed in contracting and peer review processes.
 - identify and agree with NHS England on a quarterly basis high-scoring risks, and plans put in place to mitigate these.

Quality assurance

- 4.4. The provider will:
 - meet national programme standards
 - participate fully in national QA processes and respond in a timely manner to recommendations made
 - ensure that data on participation from external QA programmes are available to QA teams within Public Health England, the national office team within Public Health England, and NHS England

- collect and submit minimum datasets as required, to assure NHS England and the Quality Assurance Team in PHE of the safety and quality of the services provided
- participate in the 3-yearly QA visit process and provide data for these visits in a timely fashion
- review, categorise, and record all invasive cervical cancers in a timely manner and inform the quality assurance team within Public Health England as required

Serious incidents

- 4.5. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care. Inappropriate actions within one area, or communication failures between providers, can result in serious untoward incidents.
- 4.6. A screening incident is any unintended or unexpected incident(s) that could have or did lead to harm to one or more persons who are eligible for NHS screening, or to staff working in the screening programme.
- 4.7. A screening incident can affect populations as well as individuals, and be the result of an actual or possible failure in the screening pathway or of a problem at the interface between screening and the next stage of care.
- 4.8. Although the level of risk to an individual in an incident may be low, because of the large numbers of people offered screening, this may equate to a high corporate risk. It is important to ensure that there is a proportionate response based on an accurate investigation and assessment of the risk of harm.
- 4.9. Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as actual serious incidents.
- 4.10. Whether a “serious incident” should be declared is a matter of professional judgement on a case by case basis. It should be a joint decision by the key stakeholders informed by protocol and advice from experts and quality assurance teams.
- 4.11. In distinguishing between a screening incident and a serious screening incident, consideration should be given to whether individuals, the public or staff would suffer avoidable severe (i.e. permanent) harm or death if the problem is unresolved.
- 4.12. The provider will:
- comply with screening incident handling guidance developed by the national office of the Cancer Screening Programmes/ UK National Screening Committee including joint guidance developed with the UK National Screening Committee
 - provide all reasonable assistance to NHS England and the cancer screening quality assurance team within Public Health England in investigating and handling an incident
 - regularly review their processes and procedures against NHSBSP programme standards to reduce the likelihood of incidents occurring

Continual service improvement

4.13. The provider will

- in the event that national recommendations and core and/or developmental standards are not currently fully implemented, use service plans to indicate the changes and improvements that will be made over the course of the contract period
- develop a CSIP (Continual Service Improvement Plan) on the basis of the findings of the KPIs and the results of internal and external quality assurance checks. The CSIP will respond to any performance issues highlighted by NHS England, paying due regard to concerns raised via service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with NHS England
- construct, maintain, and test emergency preparedness and develop a business continuity plan. The plan must ensure that there is no diminution in the level of service provided. Any sub-contracting of services within this specification is subject to agreement by NHS England and the QA team within PHE in advance, will comply with NHSCSP guidance and standards, and will be documented in a service level agreement between the parties, which covers (at a minimum) accountabilities, responsibilities, quality, and performance standards.

5. Costs

- 5.1. Funding for the pilots of HPV Testing as Primary Screening will be provided centrally by PHE.

6. Teaching and research activities

- 6.1. Any research activities undertaken by the provider must have the appropriate approvals and the national office should be informed.

Appendix 1: Standards

Minimum Key Performance Indicators (KPIs) are nationally defined; NHS England may add further KPIs as required. KPIs will be reviewed annually to ensure they reflect the requirements of the screening programme. Performance reports may be required quarterly or annually as determined locally and may be available at different population levels eg GP practice, Local Area Team. As a minimum:

Cytology

- Laboratory workload >35,000 cytology samples per year from GP and community clinics
- Low grade reporting rate within national standards (ranges published each year by the Health and Social Care Information Centre)
- High grade reporting rate within national standards (ranges published each year by the Health and Social Care Information Centre)
- Positive predictive value within national standards (ranges published each year by the Health and Social Care Information Centre)
- Laboratory specimen turnaround time such that the 14 day standard covering time from taking the screening sample to delivery of result letter to the woman is met
- Laboratory sensitivity for all abnormalities (>90%)
- Laboratory sensitivity for high grade abnormalities (>95%).

Histology

- Specimen turnaround time such that the standard covering time from biopsy taken to issuing of result letter is met

Colposcopy

- Waiting times to 1st appointment - all referrals (99% within 6 weeks)
- Waiting time to definitive treatment for women who do not have cancer – 18 weeks
- >90% of women should receive definitive treatment for high-grade CIN within 4 weeks of the colposcopy clinic, after receipt of a diagnostic biopsy report
- Patient attendance at clinic – $\leq 15\%$ DNA rate at first and subsequent appointments

A full list of standards required to be met are documented in NHSCSP guidance.

Appendix 2: Minimum monitoring dataset

OBJECTIVE	STANDARD	CURRENT ACCEPTABLE VALUE
1. To minimise the incidence of invasive cancer of the cervix	Screen eligible women aged 25-49 every three years, and women aged 50-64.5 every five years	≥80% coverage of women in eligible population
	Audit screening history for all women with cervical cancer	100% of cases.
2. To ensure high-quality sampling of cervical tissue	Ensure that all sample takers have completed appropriate training courses in liquid-based cytology, as outlined in NHSCSP guidance	100% of sample takers
3. To ensure accuracy of cytology reporting	a. Laboratory workload should be within national standards	> 35,000 cytology samples p.a.
	b. Primary screener workload should be within national standards	>3,000 samples p.a. (7,500 per WTE maximum)
	c. Individual medical staff workload should be within national standards	> 750 samples p.a.
	d. PPV and RV should be within national standards	Methodology defined within ABC3. Figures given in annual <i>Cervical Screening Programme</i> statistical bulletin
4. To ensure accuracy of colposcopy testing and biopsy examination	Colposcopist's workload should be within national standards	>50 new patients per year

5. To reduce test waiting times along the whole pathway, and to reduce and non-attendance	a. Proportion of women who are offered a colposcopy appointment 2 weeks after referral due to cytological report of possible invasion	≥ 90 %
	b. Proportion of women who are offered a colposcopy appointment 2 weeks after referral due to cytological report of high-grade dyskaryosis (severe) or worse	>90 %
	c. Proportion of women who are offered a colposcopy appointment 4 weeks after referral due to cytological report of high-grade dyskaryosis (moderate)	> 90 %
	d. Proportion of women who are offered a colposcopy appointment 6 weeks after referral due to a positive HPV test and cytological report of low-grade or borderline dyskaryosis,	> 90 %
	e. Proportion of women failing to attend for first or subsequent colposcopy appointment	≤15%
6. To ensure that discrepancies between cytology and histology are investigated, and to encourage continuing professional development	MDTs to be held.	Once per month (best practice)
	Colposcopists to attend.	Once every two months (minimum standard)
		Register should be kept, and should show at least 50%

attendance by colposcopists.

7. To ensure that women receive accurate results, in a timely manner

Proportion of women to receive cytology results within 2 weeks from date of primary screen

≥98%

Proportion of women to receive colposcopy/biopsy results within 4 weeks from date of test

≥90% (100% within 8 weeks)

8. To ensure an safe, effective, high quality, equitable, externally and independently monitored, and quality assured screening service

All NHSCSP mandatory guidance followed.

Appendix 3: NHSCSP guidance not otherwise specified

Achievable standards, benchmarks for reporting and criteria for evaluating cervical cytopathology. NHSCSP Publications No 1, May 2000 (revision forthcoming)

Histopathology Reporting in Cervical Screening. NHSCSP Publications No 10, April 1999 (revision forthcoming)

Interim Guidelines for Managing Incidents in the NHS Cervical Screening Programme (second edition). NHSCSP Publications No 11, December 2010.

Laboratory organisation: a guide for laboratories participating in the NHS Cervical Screening Programme. NHSCSP Publications No 14, January 2003.

External Quality Assessment Scheme for Gynaecological Cytopathology v4. NHSCSP Publications No 15, May 2011

Ergonomic working standards for personnel engaged in the preparation, scanning and reporting of cervical screening slides. NHSCSP Publications No 17, September 2003
Cervical Screening Call and Recall: Guide to Administrative Good Practice. NHSCSP Publications No 18, February 2004

External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology, Protocol and Standard Operating Procedures. NHSCSP Publications No 19, April 2004

Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme. NHSCSP Publications No 20, May 2010 (revision forthcoming)

Guidelines on Failsafe Actions for the Follow-up of Cervical Cytology Reports. NHSCSP Publications No 21, December 2004

Improving the Quality of Written Information Sent to Women about Cervical Screening: Evidence-based Criteria for the Content of Letters and Leaflets. NHSCSP Publications No 26, December 2006.

Improving the Quality of Written Information Sent to Women about Cervical Screening: Guidelines on the Content of Letters and Leaflets. NHSCSP Publications No 27, December 2006

Guidelines for quality assurance visits in the Cervical Screening Programme. NHSCSP Publications No 30, October 2008

Impact of Cervical Screening on Young Women: A Critical Review of the Literature 2002-2009. NHSCSP Publications No 31, January 2010.

Requirements for Training in Cervical Cytopathology. NHSCSP, November 2009 (intranet-only)

Ceasing Women in the NHS Cervical Screening Programme. NHSCSP Good Practice Guide No. 1, February 2004.

Interim Good practice guidance for cervical sample takers. NHSCSP Publications: Good Practice Guide No 2, July 2011

HPV Triage and Test of Cure Implementation Guide. NHSCSP Good Practice Guide No 3, January 2012 (intranet only)

Quality Assurance for HPV Testing within the NHS Cervical Screening Programme. NHSCSP, January 2012

HPV Information Pack (containing implementation sheet, presentation, protocol chart, leaflets). NHSCSP, July 2011

Interim Implementation of “No Further Review”(NFR) using the BD FocalPoint™ Slide Profiler Guidance for the NHS Cervical Screening Programme. NHSCSP, Dec 2011

DH Advice to the NHS on achieving 14 day turnaround times
