Cervical Screening Programme
England, 2016-17

Quality Statement

Published 7 November 2017

This document is designed to accompany the main publication document and includes contextual information, the methods used to compile the statistics and other background information readers may find useful.
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This is a National Statistics publication

National Statistics status means that official statistics meet the highest standards of trustworthiness, quality and public value.

All official statistics should comply with all aspects of the Code of Practice for Official Statistics. They are awarded National Statistics status following an assessment by the Authority’s regulatory arm. The Authority considers whether the statistics meet the highest standards of Code compliance, including the value they add to public decisions and debate.

It is NHS Digital’s responsibility to maintain compliance with the standards expected of National Statistics. If we become concerned about whether these statistics are still meeting the appropriate standards, we will discuss any concerns with the Authority promptly. National Statistics status can be removed at any point when the highest standards are not maintained, and reinstated when standards are restored.


This report may be of interest to members of the public, policy officials and other stakeholders to make local and national comparisons and to monitor the quality and effectiveness of services.
Introduction

This report presents information about the NHS Cervical Screening Programme in England in 2016-17 as well as key statistics from the previous ten years. It includes statistics on the call and recall programme for women aged 25 to 64 years, as well as statistics on screening samples examined by pathology laboratories and on referrals to colposcopy clinics.

The publication includes analysis and commentary, a set of data tables, an interactive data dashboard and a number of appendices. The report focuses on England but also includes regional comparisons, local coverage statistics and coverage from other UK countries.

The statistics in this report are used to inform policy and to monitor the quality and effectiveness of screening services.

Where appendices are referred to in this Quality Statement, they can be found in a separate document available through the following link:

http://digital.nhs.uk/pubs/cervical1617

1.1 Data Sources

The statistics are derived from information that is routinely collected by the NHS Cancer Screening Programmes (NHSCSP) for the operation of the screening programme, including quality assurance and performance management purposes. They are presented by Upper Tier Local Authority (LA), region, pathology laboratory and colposcopy clinic.

Information on the NHS Cervical Screening Programme is collected on the following Korner Collection (KC) returns:

- **KC53** – information from the call and recall system, collected on all 152 Upper Tier Local Authorities operating in 2016-17.
- **KC61** – information on screening samples examined by pathology laboratories, collected from all 51 laboratories carrying out cervical cytology in 2016-17.
- **KC65** – information on referrals to colposcopy, subsequent treatment and outcome, collected from 195 clinics/trusts providing colposcopy services. In some instances, smaller clinics have included their data in the main hospital return. The KC65 return was first collected in 2000-01.

The full KC forms are available through the following link:

http://digital.nhs.uk/pubs/cervical1617

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1 Data is available on NHS Digital’s website from 2004-05 onwards on the following link: https://digital.nhs.uk/search?q=cervical+screening+programme&s=

In addition to the above returns, data on age-appropriate coverage and on time from screening to receipt of results is obtained from monthly reports produced by the Open Exeter system\(^2\).

- VSA15 – data on time from screening to receipt of results, collected on all 152 Upper Tier Local Authorities operating in 2016-17.
- PHOF\(^3\) – data on age-appropriate coverage\(^4\), collected on all 152 Upper Tier Local Authorities operating in 2016-17.

The NHS Data Model and Dictionary Service contains more information on the KC53, KC61 and KC65 returns including guidance on content, completion and definitions. Links to the returns are given below:

**KC53**


**KC61**


**KC65**


Further information on the underlying sources of information can be found in the NHS Digital’s List of Administrative Sources, available through the following link:


The data from each of the three KC returns are collected at the end of each financial year. The KC61 and KC65 data come to NHS Digital via the NHS Cervical Screening Programme regional Screening Quality Assurance Services (SQASs), which collect them from cytology laboratories and colposcopy clinics in their regions. The KC53 data comes from the NHS Digital’s NHAIS\(^5\) (Exeter) system from which aggregate LA level reports are produced.

The SQASs, which are part of Public Health England, are responsible for quality assuring the screening programme including the KC53, KC61 and KC65 returns before final submission. Data are quality assured by the SQASs on an annual basis. Aggregated data are provided to NHS Digital in a defined format.

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\(^2\) NHS Digital ‘Exeter’ system (NHAIS), Cancer Screening Statistics.

\(^3\) PHOF outcome figures may show small variances year-on-year as updates are made to historic figures after the data are published


\(^5\) National Health Application & Infrastructure Services (NHAIS).
Further validation and quality assurance checks are carried out on both the KC and Open Exeter datasets by NHS Digital as part of the publication process. Appendix I contains more information on the data validation process.

Regional QA Managers at the SQASs are asked to check some of the tables produced for publication by NHS Digital as part of the validation process.

1.2 Methods used to compile the statistics

NHS Digital validates and analyses the KC53, KC61, KC65 data and data from Open Exeter using automated processes developed in SAS\(^6\) as well as spreadsheets (Microsoft Excel).

Most of the figures presented in the report and tables are in the form of simple counts and percentages (rounded to one or two decimal places). Due to rounding, the sum of percentages in some tables will not equal 100%.

Definitions and formulae detailing how the statistics in the report are calculated are given in Appendix B.

1.3 Relevance

Appendix F gives details of who uses the statistics in this publication and what they use them for.

1.4 Accuracy and Reliability

These are established collections based on complete data (i.e. not a sample). For 2016-17, submissions have been made for all LA’s and all pathology laboratories. All colposcopy clinics submitted data for 2016-17.

False positive and false negative screening results

Users of these statistics should be aware that screening is not 100% accurate and that in any screening programme, there will be some false positive results (samples wrongly reported as having the condition) and some false negative results (samples wrongly reported as not having the condition).

False Positives

Some people with a positive screening test result do not actually have the condition being screened for. These people are said to have a ‘false-positive’ result\(^7\).

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\(^6\) Statistical Analysis System (SAS) is an integrated system of software products which enables functions such as data management, statistical analysis and quality improvement.

\(^7\) Source: UK National Screening Committee: [https://www.gov.uk/guidance/nhs-population-screening-explained](https://www.gov.uk/guidance/nhs-population-screening-explained)
In cervical screening, false positive results are suggested when an apparent abnormality is detected at screening but no evidence of disease can be found at subsequent investigations. This may occur if normal cells are mistaken for abnormal cells at initial screening or if minor cell abnormalities were detected at screening that cleared up on their own. Given that minor cell abnormalities can clear up on their own, it is not possible to estimate what proportion of cervical screening results are false positives.

False Negatives

Some people with a negative screening test result do actually have the condition being screened for. These people are said to have a ‘false-negative’ result.

In cervical screening, early cell changes that may lead to cancer may not always be detected. Abnormal cells on a slide may not be recognised because:

- sometimes they do not look much different from normal cells;
- there may be very few abnormal cells on the slide; or
- the person reading the slide may miss the abnormality (this happens occasionally, no matter how experienced the reader is).

It is also possible that an area of abnormality was present on the cervix but this area was not included in the sample taken and therefore no abnormality could be identified by the laboratory.

There is no generally accepted or expected level of false negatives in the NHS Cervical Screening Programme.

Users may be interested in a recent audit report published by the NHS Cancer Screening Programmes which includes an examination of false negatives in relation to diagnoses of invasive cervical cancer.

Referral Value

Referral value (RV) is the number of women referred to colposcopy (excluding inadequate referrals) per detection of one CIN2 or worse lesion, and is reported in section 3.4 of the main report and in Table 19 of the Data Tables. Under the Human Papillomavirus (HPV) Triage and Test of Cure (TOC) protocol there can be some scenarios where women with negative cytology are tested for HPV. Women who test positive for HPV are referred to colposcopy.

Changes are required to the KC61 central data return to enable this to be recorded on parts C1 and C2 but until these changes are made these women are not included in the calculation of RV. It is not known whether women with negative cytology but who test positive for HPV are more or less likely to have

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8 Source: UK National Screening Committee: [https://www.gov.uk/guidance/nhs-population-screening-explained](https://www.gov.uk/guidance/nhs-population-screening-explained)
CIN2 or worse than other women referred to colposcopy and so the impact of the exclusion of this group of women from the RV is not known.

Appendix H contains further information on data validation and data quality.

1.5 Timeliness and Punctuality

The cervical screening data are made available as soon as possible after they have been compiled and validated (usually the November following the end of the financial year to which the data relate).

The statistics published in this report reflect data submitted as of 30th September 2017. At the time of publication (7th November 2017), no amendments to these data had been received.

During December 2016 Queen Elizabeth Hospital (part of Gateshead Health NHS Foundation Trust) resubmitted some data for the 2015-16 reporting year. These figures have not been updated in the 2015-16 publication but are updated where referenced within the 2016-17 publication materials. As a result users may notice slight changes to previously published figures though the effects of these changes are negligible when considering outcomes, particularly at a national level.

A copy of last year’s report can be found at:

http://digital.nhs.uk/pubs/cervical1516

‘Age appropriate’ data listed within the publication materials are sourced from the Public Health Outcomes Framework (PHOF) hosted by Open Exeter. On occasion, these data are updated retrospectively after they have been published. Data are always published correct at the time of release but are not updated retrospectively to account for these revisions. As a result users may notice slight changes to previously published figures.

1.6 Accessibility and Clarity

Most data fields are published in the Data Tables as part of this main report which is available on the publication webpage:

http://digital.nhs.uk/pubs/cervical1617

The tables are also available as Excel files and as CSV files which are also accessible through the webpage. Further analysis may be available on request, subject to resource limits and compliance with disclosure control requirements.

We have also made an interactive data dashboard available for the first time as part of the data resources for this publication. The dashboard has been developed in software called Microsoft Power BI and is designed to make data more meaningful by allowing local, regional and national comparisons over time. This includes coverage statistics for women aged 25 to 64 years presented by Upper Tier Local Authority (LA), and for the first time by Clinical Commissioning Group (CCG)
Printed copies of this report are available on request. For further information contact: enquiries@nhsdigital.nhs.uk or telephone 0300 303 5678.

1.7 Coherence and Comparability
The Screening and Immunisations team at NHS Digital maintain awareness of changes that may affect the data through regular meetings/communication with the NHS Cancer Screening Programmes (operated within Public Health England (PHE)) and the Department of Health.

Time series
For key statistics, the report presents 10 year time series, enabling comparison with ten years ago where possible. For all other statistics, figures for the current year are compared with the previous year. The key statistics in this report are coverage, numbers invited for screening, numbers tested and percentage of inadequate tests.

The changes in policy described in the main report under section 1.2 on (Changes to the Report) and below in ‘Impact of NHS Reorganisation’ need to be considered when examining trend data.

Local and regional comparisons
The statistics are presented at a national, regional and local level. Local level statistics are presented by Upper Tier Local Authority (LA), region (see ‘Impact of NHS Reorganisation’ below), pathology laboratory and colposcopy clinic.

At a regional level, LA (KC53 and VSA15) data are aggregated up to eight reporting regions with sub-regional breakdowns for the South (showing the South East and South West).

Data from pathology laboratories (KC61) and colposcopy clinics (KC65) are aggregated up to seven reporting regions with sub-regional breakdowns for North East Yorkshire and the Humber (showing the North East and Yorkshire and the Humber) and the South (showing the South East and South West).

There have been a number of laboratory mergers during the 2016-17 collection year which will impact on the ability to compare laboratory data over time. Where laboratories have merged during the first half of the collection year, activity which took place under the old laboratory is reported separately unless the laboratory was unable to do this.

Impact of NHS Re-organisation
The statistics presented in this publication are presented by Upper Tier Local Authority (LA) rather than PCO, in line with the new responsibilities of LAs for public health. LA data was published in this report for the first time in 2013-14. Local Authority age-appropriate coverage statistics for previous years are published as part of the Public Health Outcomes Framework (PHOF) and available at: http://www.phoutcomes.info/

Data presented by LA are based on the resident population (i.e. women who live within the geographical boundary of the LA).
Comparisons with other countries

This report includes coverage comparisons with other UK countries which can be found in Table D of the main report.

Changes in Screening Policy

Age and Frequency Changes

Age and frequency changes to screening policy were introduced in 2003 based on new research evidence (Sasieni et al, 2003). Prior to this, women aged 20-64 were included in the screening programme. Beginning in 2004 women received their first invitation shortly before their twenty-fifth birthday. Since December 2012, women have been invited six months before their twenty-fifth birthday so that they can decide to be screened by their twenty-fifth birthday.

Prior to 2004, national policy was to invite women for screening at intervals of not more than 5 years and therefore there was some variation in local practice. This also changed in 2004 based on the Sasieni et al paper so that women aged 25-49 were invited for screening every 3 years whereas those aged 50-64 were invited every 5 years.

The above changes in policy need to be considered when analysing trend data. NHS Digital maintains awareness of changes that may impact on the data through regular meetings and communication with the NHS Cervical Screening Programme at Public Health England and the Department of Health.

HPV testing as triage and test of cure

Improving Outcomes: A Strategy for Cancer (Jan 2011) announced the roll out of HPV testing across England as triage for women with borderline or low-grade cervical screening test results and as a test of cure (TOC) for women previously treated for cervical abnormalities.

Prior to the introduction of HPV testing as triage (and where it had not been fully rolled out in 2015-16), women with borderline or low-grade results were recalled for a repeat test in around six months and only referred if the abnormality persisted. With the introduction of HPV testing as triage, referrals to colposcopy are speeded up where required and avoided where HPV is not found.

HPV testing can also be used to test whether women who have had cervical abnormalities treated have been cured. Further information is available from: https://www.gov.uk/guidance/cervical-screening-programme-overview

A number of sentinel sites began HPV testing as triage for women with mild or borderline test results in early 2007. Roll out to all areas began towards the end of March 2012. Laboratories implemented a phased roll out for the implementation of HPV testing for triage and TOC over a two year period to 31 March 2014, and the policy became routine from 1 April 2014.

The introduction of HPV testing has been found to initially increase referrals to colposcopy (Moss\textsuperscript{11} et al, 2011). At first, the introduction of HPV testing should increase the numbers of referrals to colposcopy as referrals can be speeded up where women test positive for HPV. HPV testing also increases the numbers of women who are returned to routine recall status and thereby decreases the numbers of women on early repeat recall due to abnormality. Early repeat recall due to abnormality requires one or more further tests, typically around six months of the previous test, before the woman can be returned to routine recall. An evaluation of HPV triage at six sentinel sites suggested that it would “…allow approximately a third of all borderline and mildly dyskaryotic women to be returned immediately to routine recall…” (Moss et al, 2011, p 8).

**HPV Primary Screening**

The NHS Cervical Screening Programme began an HPV primary screening pilot in May 2013. HPV primary screening differs from the usual process for examining cervical samples as instead of the sample being examined under a microscope by a cytologist for any signs of abnormality, it is first tested for HPV. If the sample is found to be HPV negative, the woman is returned to routine recall and invited for screening again in three or five years’ time depending on her age. If the sample is HPV positive, a slide is prepared from the same sample and is then examined by the cytologist for any abnormal cells. Women who have a HPV positive with a cytology negative result, will be recalled in 12 months for a further screen.

Evidence suggests that testing for the Human Papilloma Virus (HPV) first is more sensitive at detecting abnormalities. HPV primary screening may therefore be a better way of identifying women at risk of developing cervical cancer. The pilot aims to:

“……establish whether using HPV testing as the primary screen for cervical disease results in better outcomes for women, while minimising over-treatment and anxiety, and whether it is practical to roll out nationally”\textsuperscript{12}.

A negative HPV result will achieve a longer protection than the current cytology method of examining cervical samples. In future women who test negative for HPV may not need to attend screening as frequently, and modelling is underway to predict optimal recall frequency.

HPV primary screening is being piloted in six pathology laboratories (Bristol, Liverpool, London, Manchester, Norwich and Sheffield) As this is a pilot currently only a small population of women in these pilot areas will be offered this type of screening.

In January 2016 the UK National Screening Committee recommended that HPV Primary Screening should be adopted by the screening programme. This


\textsuperscript{12} UK National Screening Committee briefing on the meeting of 25 April 2012. See: \url{http://webarchive.nationalarchives.gov.uk/20150408175925/http://www.screening.nhs.uk/cms.php?folder=3456}
was followed by a further announcement in July 2016 by the Public Health Minister Jane Ellison that HPV primary screening will be implemented into the English cervical screening programme. This will be a significant change to the programme and implementation is planned for completion by 2019.


**Changes in reporting and classification of cervical cytology**

In January 2013 the NHS Cancer Screening Programmes published the third edition of ‘Achievable standards, Benchmarks for reporting, and Criteria for evaluating cervical cytopathology’ (ABC3)\(^{13}\). This outlined a new classification for abnormal cervical cytology, as agreed by the NHSCSP and the British Association for Cytopathology.

Historically, the UK has used the British Society for Clinical Cytology (1986) classification to report cervical cytology. Elsewhere, other classifications are used, notably the Bethesda Classification (Solomon\(^{14}\) et al, 2004) which was introduced in the US in 1991. The new classification adopted by the NHSCSP narrows the gaps between the two systems and makes it easier to make international comparisons.

The new classification for abnormal cervical cytology:

- divides the category ‘borderline change’ into ‘squamous’ and ‘endocervical’ categories.
- divides dyskaryosis into ‘low-grade’ and ‘high-grade’ categories
- divides glandular neoplasia into ‘endocervical’ and ‘non-cervical’ categories

Table 1 summarises the changes in terminology which are also used in this report.

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Table 1: Summary of changes to terminology

<table>
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<th></th>
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<tbody>
<tr>
<td>Borderline change</td>
<td>Borderline change in squamous cells</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Borderline change in endocervical cells</td>
<td>9</td>
</tr>
<tr>
<td>Mild dyskaryosis</td>
<td>Low-grade dyskaryosis</td>
<td></td>
</tr>
<tr>
<td>Borderline change with koilocytosis</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Moderate dyskaryosis</td>
<td>High-grade dyskaryosis (moderate)</td>
<td>7</td>
</tr>
<tr>
<td>Severe dyskaryosis</td>
<td>High-grade dyskaryosis (severe)</td>
<td>4</td>
</tr>
<tr>
<td>Severe dyskaryosis / ?Invasive</td>
<td>High-grade dyskaryosis/?invasive squamous carcinoma</td>
<td>5</td>
</tr>
<tr>
<td>?Glandular neoplasia</td>
<td>?Glandular neoplasia of endocervical type</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>?Glandular neoplasia (non-cervical)</td>
<td>0</td>
</tr>
</tbody>
</table>

The changes, which were implemented from April 2013, included the following changes to the classification of cervical cytology samples which will impact on the statistics reported in this publication:

1. Prior to April 2013, many samples showing koilocytotic change (which occurs as a result of HPV infection) would have been recorded as borderline change with koilocytosis and recorded as result code ‘8’. From April 2013 all such cases should have been classified as low grade dyskaryosis (mild dyskaryosis under the old terminology), result code ‘3’. Although the precise impact of this change is not known, a significant proportion of what used to be classified as borderline change should therefore be classified as low grade dyskaryosis.

2. Samples which might previously have been classified as ‘borderline – high-grade dyskaryosis not excluded’, and recorded as result code ‘8’, may have been recorded as high-grade dyskaryosis (moderate), result code ‘7’, or ‘borderline - not otherwise specified’, result code 8, from April 2013. Again, the impact of this change is not known but is expected to be less than for samples showing koilocytotic change.

3. The division of ?glandular neoplasia into two categories impacts on a number of tables in the report. ?glandular neoplasia (non-cervical) was previously included in tables showing test results of ?glandular neoplasia. These test results are now given result code ‘0’ and shown in the Data Tables as negative test results as they are not cervical abnormalities. The number of test results showing ?glandular neoplasia is relatively small and so the impact of this change on that group is substantial. The addition of ?glandular neoplasia (non-cervical) to the negative result category has minimal impact as this group makes up the majority of sample test results. Positive predictive value (PPV) and Referral Value (RV) calculations no longer include ?glandular neoplasia (non-cervical) test results/referrals.
Changes to the KC forms are required before the borderline change in squamous cells and endocervical cells can be distinguished in the reported statistics. Discussions between NHS Digital and the Cervical Screening Programme within PHE suggest any revisions to reflect terminology changes are likely to take at least another two years to implement. In the meantime these two categories are reported together as borderline change.

Tests showing ?glandular neoplasia (non-cervical) have been recorded on the KC forms as negative from April 2013 onwards as they are non-cervical abnormalities and therefore are dealt with outside of the cervical screening programme.

?invasive squamous carcinoma is referred to as ?invasive carcinoma in the tables and commentary for ease of reporting.

Tables in this publication affected by the changes above have been caveated appropriately.

1.8 Performance Cost and Respondent Burden

The publication is based on information that has been routinely collected by the NHS Cervical Screening Programme for a number of years as part of the operation and performance management of the cervical screening programme.

All data collections used in this publication are subject to the Burden Advice and Assessment Service (BAAS) procedure (previously known as Review of Central Returns (ROCR)) and licensed by BAAS. This is to ensure that data collections do not duplicate other collections, minimise the cost to all parties and have a specific use for the data collected. Information on BAAS can be found at: http://content.digital.nhs.uk/baas

1.9 Confidentiality, Transparency and Security

The standard NHS Digital security and confidentiality policies have been applied in the production of these statistics. The data are received in aggregate form from the Open Exeter Team (KC53) and SQASs (KC61/KC65) via the secure NHSmail system. An annual risk assessment is undertaken prior to publication which addresses any potential issues around disclosure. The following disclosure controls have been applied to this publication:

In Table 26b the actual number of biopsies by organisation has been suppressed, leaving totals by region available. The percentage showing CIN (cervical intra-epithelial neoplasia) or worse has been banded to 2.5% increments.

The eligible populations in two LAs are relatively small and in these instances their data have been combined and reported under other LAs. Data for the Isles of Scilly are reported under Cornwall and City of London data are reported under Hackney. Statistics in this report are therefore presented by 150 Upper Tier Local Authorities, two of which include another small LA.

See https://digital.nhs.uk/nhsmail/secure-email-standard for more information.

See Appendix E on Outcomes of Gynaecological Referrals for further information about cervical intra-epithelial neoplasia (CIN).
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www.digital.nhs.uk
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enquiries@nhsdigital.nhs.uk

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