Cervical Screening Programme
Quality Statement

England, 2018-19

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The United Kingdom Statistics Authority has designated these statistics as National Statistics, in accordance with the Statistics Registration Service Act 2007 and signifying compliance with the Code of Practice for Statistics.

Designation can be broadly interpreted to mean that the statistics:

• meet identified user needs;
• are well explained and readily accessible;
• are produced according to sound methods; and
• are managed impartially and objectively in the public interest.

Once statistics have been designated as National Statistics it is a statutory requirement that the Code of Practice shall continue to be observed.

Find out more about the Code of Practice for Statistics at: https://www.statisticsauthority.gov.uk/code-of-practice/

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

They are derived from information that is routinely collected by Public Health England (PHE) for the operation of the screening programme, including quality assurance and performance management purposes.

We would like to acknowledge the key contributions made by members in PHE Screening who provided a significant contribution to the collection and interpretation of data, as well as acting as subject matter experts informing the production of this report.
Introduction

This document is designed to accompany the main publication report, available on the publication homepage via the following link:

https://digital.nhs.uk/pubs/cervical1819

This document includes contextual information to aid understanding and presentation of the data including the methods used to compile the statistics and other background information readers may find useful.

Where Appendices are referred to in the this document, they are available in a separate document, also published on the main homepage.

The main report presents information about the NHS Cervical Screening Programme in England in 2018-19 as well as key statistics from the previous ten years.

It includes statistics on the call and recall programme for women aged 25-64 years, as well as statistics on screening samples examined by pathology laboratories and on referrals to colposcopy clinics.

The report focuses on England but also includes regional comparisons, local coverage statistics and coverage from other UK countries.

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

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Data sources

The statistics presented in this publication are derived from information that is routinely collected by PHE 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 is collected on the following NHS Digital Korner Collection (KC) returns:

- **KC53** – Information from the call and recall system, collected for all Upper Tier Local Authorities (LAs). (Data reported for 2018-19 is based on LA geography as at 1 April 2019, 151 LAs).
- **KC61** – Information on screening samples examined by pathology laboratories, collected from all 48 laboratories carrying out cervical cytology in 2018-19.
- **KC65** – Information on referrals to colposcopy, subsequent treatment and outcomes, collected from 193 clinics providing colposcopy services in 2018-19.

The full KC forms are available via the main publication page: https://digital.nhs.uk/pubs/cervical1819

In addition to the KC returns, the following data is also collected:

- **VSA15** – Data on time from screening to receipt of results, collected for all LAs. (Data reported for 2018-19 is based on LA geography as at 31 March 2019, 152 LAs).
- **PHOF** – Data on age appropriate coverage, collected for all LAs. (Data reported for 2018-19 is based on LA geography as at 1 April 2019).

NB. There was a change to the LA boundaries on 1 April 2019. Due to timing of data extracts, this is why the KC53 and PHOF are reported for the 151 LAs in existence as of 1 April 2019 and the VSA15 reported for the 152 LAs in existence in the prior year.

Further information on the underlying sources of information can be found in the separate Quality Statement and in NHS Digital’s List of Administrative Sources:


2. PHOF outcome figures may show small variances year-on-year as updates are made to historic figures after the data are published.

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Data sources

The data from each of the three KC returns are collected at the end of each financial year.

The KC53 data comes from the NHS Digital’s National Health Application and Infrastructure Services (NHAIS) system via Open Exeter from which aggregate LA level reports are produced.

The KC61 and KC65 data come to NHS Digital via the NHS Cervical Screening Programme’s Screening Quality Assurance Services (SQASs), which collect them from cytology laboratories and colposcopy clinics in each region.

The SQASs, which are part of PHE, 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.

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.
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\textsuperscript{4} 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 or percentages in some tables will not always equal 100%.

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

Relevance

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

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

An incident was identified with the Cervical Screening Programme prior to last year’s 2017-18 publication.

Between January and October 2018, approximately 43,220 invitation or reminder letters were not sent, equivalent to less than 1% of women invited in 2017-18 or 2018-19.

A further 4,508 test result letters were not sent, equivalent to less than 0.2% of test results in 2017-18 or 2018-19.

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.

Quality Assurance (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.

Further information is available here:

https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-11-15/HCWS1086/
Accuracy and reliability
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 condition5).

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.

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 all 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 not 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 generally no accepted or expected level of false negatives in the NHS Cervical Screening Programme.

5. Source: UK National Screening Committee: https://www.gov.uk/guidance/nhs-population-screening-explained

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Accuracy and reliability

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 Table 19a of the Data Tables.

Under the Human Papillomavirus (HPV) Triage and Test of Cure (TOC⁶) 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 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 F contains further information and data validation and data quality.

6. For more information on HPV triage and test of cure (TOC) see: https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management
Timeliness and punctuality

The cervical screening data is 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).

At the time of publication (21 November 2019), no amendments to any of the data used in this report have been received.

A list of cervical screening reports published by NHS Digital are available via the following link:


‘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.
Accessibility and clarity

Most data fields are published in the Data Tables which are available via the publication webpage:

http://digital.nhs.uk/pubs/cervical1819

The tables are also available as both Excel and CSV files.

Further analysis may be available on request, subject to resource limits and compliance with disclosure control requirements.

An interactive data dashboard is provided 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 25-64 years (for Local Authorities and Clinical Commissioning Groups (CCGs)) and statistics on the time it takes for screening results to be received (for Local Authorities).

Also includes data on:

- Turn-around times (time from sample to receipt of result)
- Time from sample to authorisation of reports by labs

The dashboard can be accessed directly here:

Coherence and compatibility

Time series
For key statistics, the report presents a 10 year time series. For all other statistics, figures for the current year are compared with the previous year.

The changes in policy described in the main report under ‘Changes to the report’ and in this document’s ‘Impact of NHS reorganisation’ section need to be considered when examining trend data.

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.

LA age-appropriate coverage statistics for previous years are published as part of the Public Health Outcomes Framework (PHOF) available at:
http://www.phoutcomes.info/

When comparing data at the link above with PHOF data published in this report, the differences between regional groupings of LAs should be considered (see next page).

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
The main report includes coverage comparisons with other UK countries which can be found in the table on page 12.

It should be noted that cervical screening programmes in different UK countries cover different age-groups and vary in the frequency of screening and how coverage is calculated.

Data for each country are available via the following links:

Northern Ireland
http://www.cancerscreening.hscni.net/statistics/wstats05.html#P-4_0

Scotland
http://www.isdscotland.org/Publications/index.asp

Wales
http://www.cervicalscreeningwales.wales.nhs.uk/statistical-reports
Coherence and compatibility

Local and regional comparisons

The statistics are presented at a national, regional and local level. Local level statistics are presented up Upper Tier Local Authority (LA), pathology laboratory and colposcopy clinic.

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

LAs are assigned to regions based on region of responsibility within the cervical screening programme during that reporting period. If the responsibility for that LA changes from one reporting period to the next, then the assignment of the LA to a region will also change.

This means that the regional groupings of some LAs for PHOF data in this report will differ from that in the PHOF fingertips tool (https://fingertips.phe.org.uk/profile/public-health-outcomes-framework)

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 separately) and the South (showing the South East and South West).

There have been some laboratory and colposcopy clinic changes (mergers and/or closures) during the 2018-19 collection year which will impact on the ability to compare data over time.

Full details of the LA regional changes are shown below.

<table>
<thead>
<tr>
<th>Upper Tier Local Authority</th>
<th>PHOF reported region (reported in fingertips tool)</th>
<th>Region of responsibility (reported in this publication)</th>
<th>Reporting period(s) change covers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milton Keynes</td>
<td>South East</td>
<td>East of England</td>
<td>2015-16 onwards</td>
</tr>
<tr>
<td>Hampshire</td>
<td>South East</td>
<td>South West</td>
<td>2015-16 onwards</td>
</tr>
<tr>
<td>Isle of Wight</td>
<td>South East</td>
<td>South West</td>
<td>2015-16 onwards</td>
</tr>
<tr>
<td>Oxfordshire</td>
<td>South East</td>
<td>South West</td>
<td>2015-16 onwards</td>
</tr>
<tr>
<td>Portsmouth</td>
<td>South East</td>
<td>South West</td>
<td>2015-16 onwards</td>
</tr>
<tr>
<td>Southampton</td>
<td>South East</td>
<td>South West</td>
<td>2015-16 onwards</td>
</tr>
</tbody>
</table>
Coherence and comparability
Changes in screening policy

Age and frequency changes to screening policy were introduced in 2003 based on new research evidence (Sasieni et al, 2003):

Target age group changes to 25-64

Prior to this, women aged 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.

Screening interval changed to be dependent on age

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.

Since 2004 women aged 25-49 are invited for screening every 3 years whereas those aged 50-64 are invited every 5 years.

Introduction of HPV\textsuperscript{7} testing

HPV testing as triage and test of cure (TOC)

A number of sentinel sites began HPV testing as triage for women with mild or borderline test results in early 2007.

Improving Outcomes: A Strategy for Cancer (Jan 2011)\textsuperscript{8} 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.

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.

Prior to the introduction of HPV testing as triage women with borderline or low-grade results were recalled for a repeat test in around six months and only referred if the abnormality persisted.

Coherence and comparability
Changes in screening policy

HPV testing as triage impact

The introduction of HPV testing as triage has been found to initially increase referrals to colposcopy (Moss et al, 2011). At first, the introduction of HPV testing as triage increased the numbers of referrals to colposcopy as referrals can be speeded up where women test positive for HPV.

HPV testing as triage 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 in six pathology laboratories (Bristol, Liverpool, London, Manchester, Norwich and Sheffield).

The pilot aimed 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”.

HPV primary screening differs from the usual process for examining cervical samples cytologically, instead the sample is first tested for HPV and where a sample tests positive for HPV a cytology screen is then performed. Therefore cytology acts as the triage.

Evidence suggests that testing for 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.

Coherence and comparability

Changes in screening policy

In HPV primary screening 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 result with a cytology negative result, will be recalled in 12 months for a further screen.

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. The UK National Screening Committee (UK NSC) has evaluated evidence and has recommended that in HPV screening intervals can be extended to five years for all age groups. The implementation of five year extended screening intervals is being planned however this will only be possible once there is full conversion to HPV primary screening.

HPV primary screening impact

Implementation of HPV primary screening across England has had an unintended impact on the cytology workforce and reduced cytology screening capacity.

This has led to an increase in the turnaround times of cervical screening samples since 2016-17. Further information on this issue can be found in Appendix J, of the Appendices document.
Coherence and comparability
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)\(^1\)11.

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 et al, 2004\(^1\)2) 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 changes in terminology are in the table below and full details are shown on the next page.

<table>
<thead>
<tr>
<th>Previous terminology (BSC 1986)</th>
<th>New terminology</th>
<th>Result code</th>
</tr>
</thead>
<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>3</td>
</tr>
<tr>
<td>Borderline changes with koilocytosis</td>
<td></td>
<td></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>


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Coherence and comparability
Changes in reporting and classification of cervical cytology

The changes, which were implemented from April 2013 are detailed in full below.

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 impacted 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.
Coherence and comparability
Changes in reporting and classification of cervical cytology

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 some time 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 these changes have been caveated appropriately.
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:

https://digital.nhs.uk/services/the-challenging-burden-service
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\(^\text{13}\).

An annual risk assessment is undertaken prior to publication which addresses any potential issues around disclosure.

The following disclosure rules 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\(^\text{14}\) (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 LAs (VSA15 data) or by 149 LAs (PHOF and KC53 data), two of which include another small LA.

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14. See Appendix E on Outcomes of Gynaecological Referrals for further information about cervical intra-epithelial neoplasia (CIN).