Belfast Health and Social Care Trust
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FOI/28226

13 December 2022

Primary Cervical Cancer Audit Belfast HSC Trust

Explanatory notes on cervical screening and case review

In any screening test, there is always a trade-off between sensitivity and specificity. The aim of the NHS Cervical Screening Programme (NHSCSP) is to reduce the number of people who develop cervical cancer and the number of people who die from it. Cervical screening is not a diagnostic test for cancer.

It is estimated that cervical screening prevents about 75% of invasive cervical cancers by detecting and treating cervical abnormalities that, if left, would place patients at high risk of developing invasive cervical cancer.

It is important that the screened population has realistic expectations surrounding the screening programme, so that individuals can make an informed choice about participation.

There are limitations of cervical screening:

- Cervical screening will not prevent all cases of cervical cancer.
- Some women will still develop cervical cancer despite regular screening.
- Screening will not detect every abnormal cell change.
- Some abnormal cell changes may be missed.

Some reasons why abnormal cell changes may be missed:

- Few abnormal cells may be present in the sample.
- Abnormal cells can look like normal cells.
- The person reading the sample may miss the abnormality (this happens occasionally, no matter how experienced the reader is).

If a woman develops invasive cervical cancer, an audit is undertaken to review their screening pathway. The purpose of the audit is to monitor the overall effectiveness, to highlight areas where improvements can be made.

During the review process, it is impossible to reproduce the original screening conditions. During the process, as it is known that the person was diagnosed with cancer since being screened, vigilance is heightened and the threshold for reporting an abnormality is reduced.

Finding an unreported abnormality on review does not necessarily mean that the abnormality would be an expected finding under the initial conditions. Hindsight with new knowledge has a significant impact on the interpretation of images.

Like many other screening programmes, the outcome is somewhat subjective, based on interpretation of visual findings with no firm boundary between normal and abnormal. This may result in debate between experts as to the appropriate classification of the sample or the interpretation of the findings.

This table defines the outcome categories for invasive cancer audit reviews

Audit Outcome Category* for Invasive Cervical Cancer (*added to the NI process 2019)	**Description**
Category 1: Satisfactory review	No untoward findings.
Category 2: Satisfactory review with learning points	False negative cases – "minor process or management shortcomings, but considered to be within the limitations of the screening programme"
Category 3: Unsatisfactory review	False negative cases – "significant process or management shortcomings that constitute a patient safety incident".

Source: Public Health Agency (2019). Northern Ireland Screening Programme; Protocol for the Audit of Invasive Cervical Cancers

This background context should be read in conjunction with the specific responses to the questions below.

Where numbers in individual cells are 1-4, in line with Trust policy, it is given as <5, to reduce any risk of identification of individual patients.

Use of < 5 (less than five): We are unable to provide an exact figure - exempt from release under Section 40(2) of the Freedom of Information Act - as this could make patients personally identifiable. Disclosure would constitute a breach of the principles of the General Data Protection Regulation 2018.

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Between 2008 and 2021 for each Health Trust to detail for each year the following:

Pre-2014, audit review activity was intermittent. Audit outcomes at this time were recorded in paper form and submitted to the Quality Assurance Reference Centre (QARC) at the Public Health Agency (PHA), now called the Young Persons and Adult Screening Team (YPAST). Records of paper-based returns are not currently available in Belfast Health and Social Care Trust (BHSCT), and thus only information relating to 2014 onwards is available.

BHSCT also provides a cervical cytology laboratory service to the South Eastern Health and Social Care Trust (SEHSCT); information relating to SEHSCT is not provided here but can be provided by SEHSCT.

a) The number of women diagnosed in BHSCT with cervical cancer.

The table below illustrates numbers of patients with a primary cervical cancer diagnosis, yearly from 2014.

Year	Number of women diagnosed with cervical cancer
2014	25
2015	30
2016	26
2017	22
2018	25
2019	17
2020	22
2021	25
TOTAL	**192**

b) The number of women who had a retrospective audit review of their screening history.

Year	Number of women who had a retrospective audit review of their screening history
2014	25
2015	30
2016	26
2017	22
2018	25
2019	17
2020	22
2021	25
TOTAL	**192**

c) The number of women who had previous screening tests or smear tests reviewed as part of this audit.

Review of previous screening tests is not possible where there was no screening history within the previous 10 years.

Year	Number of women who had screening test reviewed
2014	5
2015	19
2016	19
2017	16
2018	20
2019	14
2020	17
2021	14
TOTAL	**124**

d) The number of women who were told this review was taking place.

Following issue of the Northern Ireland Cervical Screening Programme (NICSP) Framework document in 2019 (V1.0), the following number of patients have so far been informed of the review by BHSCT Colposcopy Service.

Year	Number of women informed of review
2019	<5
2020	11
2021	10
TOTAL	**<26**

e) The number of women who were offered disclosure of these audit reviews.

2019 onward only - the audit of invasive cancer is now fully underway, including offering disclosure of the outcome of the review to all women who have been informed of the audit.

Year	Number of women informed of review
2019	<5
2020	11
2021	10
TOTAL	**< 26**

f) The number of women who received disclosure of their audit review.

Fewer than 5 women so far have received disclosure of the outcome of their review in 2019; none in 2020 or 2021.

g) The number of audit reviews that showed a discordance between a screening test and the audit review.

PHA YPAST policy regarding disclosure and categories of discordance was issued in February 2019 and the outcome of audit review based on categories agreed at Multi-Disciplinary Meeting (MDM) have been supplied since that time (see table page 2 for definition of categories).

Year	Total discordance
2014	<5
2015	11
2016	8
2017	<5
2018	8

Year	Category 2 (within screening programme limitations)	Category 3 (unsatisfactory)
2019	5	<5
2020	<5	0
2021	6	0

h) The number of discordant cases identified in the audit review in which the screener who was carrying out the screening test was not meeting the acceptable benchmark standard of 95%.

The standard of 95% referred to in this query is assumed to refer to the 95% sensitivity for detecting high grade cervical cytology as per cervical screening guidance standards.

For the Category 3 discordant cases originally reported from 2019 to 2021, all screeners met the 95% sensitivity standard for detecting high-grade abnormalities at the time the samples were reported. (Figures are not currently available for screener performance prior to 2019.)

The performance of individual cervical screeners and pathologists is retrospectively reviewed by the laboratory and quality assured through YPAST, Public Health Agency. This data is then quality assured by YPAST, who undertake an annual NICSP Laboratory Quality Assurance data visit.

i) What actions were taken for any discordant cases in which the screener carrying out the screening test was not meeting the acceptable benchmark standard of 95% - was there a recall of patients involved or affected?

This is not applicable - see answer to question (h) above.

j) Considering all of the above questions was the Department of Health and the Public Health Agency kept regularly briefed on what was happening within each Trust. What written evidence is there of those briefings.

Quarterly Learning / Untoward Events Returns are submitted by the Trust to Public Health Agency YPAST.

YPAST undertake an annual NICSP Laboratory Quality Assurance data visit during which they undertake a retrospective Annual Laboratory Quality Assurance Data Review, and a one yearly and four yearly Quality Assurance Visit to the Laboratory and the Colposcopy service respectively.

Full details of this will be held with PHA YPAST.

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Appendix.1.

Overall table of BHSCT audit results

Year of Diagnosis	No. of Patients with 1º Cx Ca	No. of retrospective audits performed		No of audits involving review of screening tests (% of all cervical cancers diagnosed)		All discordant outcomes (% of all cervical cancers diagnosed)		
2014	25	25	100%	5	20%	<5	<20%	
2015	30	30	100%	19	63%	11	27%	
2016	26	26	100%	19	73%	8	31%	
2017	22	22	100%	16	73%	<5	< 23%	
2018	25	25	100%	20	80%	8	32%	

Year of Diagnosis	No. of Patients with 1º Cx Ca	No. of retrospective audits performed		No of audits involving review of screening tests (% of all cervical cancers diagnosed)		Cat 2 discordance		Cat 3 discordance	
2019	17	17	100%	14	82%	6	35%	<5	<29%
2020	22	22	100%	17	77%	<5	<23%	0	0%
2021	25	25	100%	14	56%	6	24%	0	0%