

CervicalCheck: Update for Health Professionals May 9 2018

The HSE and the CervicalCheck programme reiterate our deepest apologies to women for any worry caused by the cervical screening programme's recent audit process. The HSE is keen to provide reassurance to those who may be concerned following the significant media coverage in recent days. With this in mind the HSE is providing an overview of what has happened to date and advice for women below.

1.1 What has happened to date

Approximately 3,000 women have been diagnosed with cervical cancer since 2008. Approximately half of these cases were notified to CervicalCheck. The audit looked at the 1,482 cases which we were notified of. A clinical audit is used to test and assure the standard of work that is being done by a health service or facility.

The audit found that in the cases of 209 women, the smear test could have provided a different result or recommended earlier follow-up.

Importantly, this audit was undertaken after the women were diagnosed. CervicalCheck did not withhold information from any woman that delayed their cancer diagnosis. The audit of their previous smears was undertaken in response to CervicalCheck learning of their diagnosis.

A HSE Serious Incident Management Team (SIMT) has been working to respond to and clarify the details of what occurred, and this will continue as the situation evolves.

It is clear that there has been a very serious breakdown in communicating to the women concerned. They should have been told that this audit was happening and of the outcomes of the audit, but in many cases they were not. We are now doing this.

You can find out more information about the audit in this [statement](#).

1.2 Information and Support for Women

Women in Ireland have been understandably worried following the failures in communication about this audit. An information line was provided to women from April 28th, and women were offered the facility to receive a call-back from a member of our clinical staff.

The service provided on our information line and waiting times have improved steadily during the week, but our call team remains extremely busy, and our priority is women with specific clinical queries or a history of cervical cancer.

Calls are being returned to women following a careful exercise of checking records, checking data quality and assigning calls to health professionals. The call backs take a period of time as in those cases where the person has a history of referral for colposcopy treatment or a history of cancer, we are providing a clinical consultation with a clinical staff member with expertise in colposcopy or cancer treatment. To date, 3,649 calls have been returned to women. Calls were made throughout the past weekend and will continue through this week, with support with staff from health facilities around the country.

Key points:

- CervicalCheck apologises unreservedly to you for any concerns or distress encountered as a result of this incident.
- Since 2008 over 3 million tests that have been taken in CervicalCheck, 208 of these tests were found to be inaccurate in this current review.
- Like all screening tests, cervical screening cannot unfortunately prevent all cancers. While it can detect pre-cancerous changes, it cannot always detect these changes or the presence of cancer if it has already developed.
- The clinical advice is that women who have had normal test results in the past can continue to participate in the cervical screening programme according to their normal schedule. We are working to provide information to women across a range of channels to assist those whose query can be answered without the need for them to call the CervicalCheck information line.
- Regular cervical screening is still one of the best ways to prevent cervical cancer. To date, CervicalCheck has detected over 50,000 pre-cancerous changes in women, reducing their cancer risk by more than 90%.
- CervicalCheck ensures that the laboratory analysis of our screenings is of the highest possible standard. All our screening tests are analysed in laboratories in Ireland and the US which have reached the highest standards of accreditation by national authorities. The laboratories have robust quality assurance and two screeners examine every test.

1.3 Most frequently asked questions

1.4 About the Audit

CervicalCheck carried out an audit of women who had been diagnosed with cervical cancer over the last 10 years. The audit happened after their cancer was notified to CervicalCheck. Not all of these women were told about the audit or that, in some cases, the audit found their screening test could have provided a different result and recommended earlier follow-up.

Contact with women directly affected

Most women have at this stage been contacted and meetings either held or arranged to discuss the audit and the response.

Cases where the audit showed their test could have provided a different result:	209* women
Contact made to date	201 women / families

Women diagnosed with cancer but not notified to CervicalCheck

The HSE is working with the National Cancer Registry of Ireland (NCRI) and the Department of Health to identify any other women who had cervical cancer during this time, who may also have had a CervicalCheck test. Reconciliation of data on relevant cases is currently ongoing between CervicalCheck and NCRI.

1.5 I am concerned regarding my cervical screening results – what should I do?

Women who have had normal screening results do not need a repeat smear test. We have received a large number of calls from people with normal smear test results. We understand people are very worried and need reassurance.

The HSE Serious Incident Management Team has reviewed the overall screening process and how it is affected by this audit. Women who have had normal screening results do not clinically require an urgent smear test.

If you are still concerned you should visit your GP and discuss those concerns with them and you can request a repeat screening test free of charge if you or your GP remain concerned.

1.6 For women who have had their smear test in the last three months

The best advice is for you to continue with your cervical screening as scheduled.

You should wait three months before having another smear test. As your results were normal you do not urgently need a repeat but if you are still concerned or are experiencing any symptoms you should talk to your GP who can organise a repeat test for you. The screening and consultation will be free of charge.

1.7 Request for previous screening test to be reviewed/re-examined

We are recommending that you carry on with your next cervical screening as scheduled since your last smear test was normal.

If you are concerned or are experiencing any symptoms such as vaginal bleeding in between periods, abnormal discharge or pelvic pain you should visit your GP and you can request a repeat screening test. The screening and consultation will be free of charge.

Please note a gap of at least 3 months is necessary for a rescreen as there will not be enough cells to test.

1.8 Can you reassure me that the programme is safe?

We would again like to apologise for any concerns or distress encountered as a result of this issue.

There is no evidence to suggest the clinical elements of the screening programme are faulty. The quality of smear-taking by doctors and nurses is not in question. All of contracted laboratories which currently look for abnormalities in smears have passed all quality control tests and are operating to international standards.

Cervical screening is for women with no symptoms and in the vast majority of cases, results show no abnormalities. Every test is examined by two trained medical scientists in all of the labs that provide screening service to CervicalCheck

1.9 If asked where their test have been screened/sent to or will be sent to?

CervicalCheck currently uses three laboratories to analyse cervical screening tests. It used other laboratories in the past. All laboratories meet CervicalCheck's quality assurance guidelines and are certified by the relevant national authorities to an international standard. The laboratories have robust quality assurance and two screeners examine every test.

The laboratories currently used are

- Quest Diagnostics, Teterboro, New Jersey, USA;
- MedLab Pathology, Dublin;
- Coombe Women and Infant's Hospital, Dublin.

If the woman wants to know where her screening was carried out

This information is available on the cytology report.

1.10 Explanation of Screening - Limitations

The aim of cervical screening is to determine the presence or absence of pre-cervical cancerous changes. Like all screening programs, the results of cervical screening can never be 100% accurate. Cervical screening is not diagnostic and cannot always detect pre-cancerous changes. Despite its limitations, cervical screening is still one of the most effective ways to reduce your risk of developing cervical cancer.

To date, CervicalCheck has detected over 50,000 pre-cancerous changes in women, reducing their cancer risk by more than 90%.

1.11 Concerns from women currently in the care of Colposcopy.

The colposcopy clinics conform to a high set of standards, any queries regarding your specific case should be discussed with your colposcopy clinician.

1.12 What is a cervical screening test?

This is a screening test for well women and the vast majority of results show no abnormality. Screening tests are not diagnostic tests but can identify individuals who should have additional tests to determine the presence or absence of disease. Cervical screening does

not prevent all cases of cervical cancer. Cervical screening tests, like other screening tests, are not 100% accurate.

1.13 Women who have had a hysterectomy

If you have had a radical hysterectomy then there is no need for you to have a smear test. If however you have had a partial hysterectomy then you should participate in the CervicalCheck Programme. You can register online and if you are already registered you can also check the date of your next smear test online at cervicalcheck.ie.

Your doctor can advise you what type of hysterectomy you have had and whether you need to continue in the CervicalCheck programme.

If you have any concerns or you have signs or symptoms, such as irregular vaginal bleeding, abnormal vaginal discharge and pelvic pain you should discuss them with your GP.

1.14 Pregnancy and cervical screening

I am pregnant and have received a letter, what do I do?

If you are due your routine smear test and you are pregnant, then the smear test can be delayed until three months after you give birth. Simply call the CervicalCheck Freephone and indicate that you wish to defer your routine smear test.

I have had a baby; do I need a smear test?

You do not need a smear test after having a baby unless you are due to have a smear test.

My last result was not normal and now I am pregnant, what should I do?

A not normal result will not affect your pregnancy. If you have had a not normal result and a repeat smear test is due then you can discuss this with your doctor or nurse. If you have been recommended to attend colposcopy you should attend your appointment. You can discuss this with your doctor or nurse if more information is needed.

Can a smear test that is not normal affect my pregnancy?

A not normal smear test has no effect on pregnancy. Occasionally women may have slight bleeding after having a smear test in pregnancy, but a smear test will not increase the risk of miscarriage.

1.15 Open disclosure (sharing information)

The HSE supports open disclosure. Information should always be shared with patients relating to their care. It is not in keeping with our policy and is not acceptable to us, that this did not happen in many of these cases. An independent statutory review has now been

established. It will look at why this happened and what we need to do to ensure that it doesn't happen again.

1.16 Additional Smear

You can get an additional cervical screening consultation and smear test free of charge from your GP if you want one.

1.17 Can I get my result which was negative rechecked?

We are not recommending this. The reason is that while we're happy to stand over the lab process, and as is stated on all cervicalcheck information letters, results letters and information leaflets, no screening process is 100% accurate. The value of screening tests, which are not the same as diagnostic tests, is to regularly check for a very slow-growing disease, at planned intervals. Our advice, if people are concerned about their cervical health, after talking to their GP, is that they should book in for a free, new screening test.

1.18 What is the difference between HPV test and current cervical screening? When will it be introduced? Does it replace smear test?

Cervical smears examine a sample of the cells on the cervix under a microscope, by 2 different people, to check for any abnormalities that can be seen. Later in 2018, we are adding a new test, where we'll look at the cells as before, but also test for the presence of HPV virus in the sample. HPV is a sexually transmitted infection that is extremely common, and which causes about 70% of all cervical cancers. This new screening process will be the same for you – you will visit their smear-taker, and the sample will be collected in the same way, but the testing for HPV will offer an additional level of accuracy and reassurance.

1.19 Will the figures for the individual labs be published?

We have published data from the 3 labs we currently use on the HSE website (<https://www.hse.ie/eng/services/publications/cervical-check-daily-report-may-5.pdf>) and this indicates that these labs are performing as they should, compared to international norms, and to each other. The cervical screening programme is safe and effective, and we urge women, despite the poor communications process that has been seen during this audit, to remain within the programme, to continue attending for screening as per their normal schedule.