



CervicalCheck
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CervicalCheck Audit - May 4th 2018

We are writing to you as a partner body to update you on the evolving situation around the cervical screening programme and its recent audit process, and to ask for your support and that of your team in helping women to allay concerns caused by the way this issue has been communicated and how it may be resolved over the coming weeks.

It's very important that the health service works to protect women's health and continues to prevent cases of cervical cancer where possible. The HSE is aware that the failures in sharing information and communicating with women about this audit have created an understandable level of concern and distress among women in Ireland and is committed to improving the process around this to ensure women are informed when they are part of an audit process. We must begin the work to rebuild trust in this service.

The HSE and the CervicalCheck programme have reiterated our deepest apologies to women for any worry caused by this ongoing situation. We are keen to provide reassurance to women who may be affected, and to those involved in their care and from who they may seek advice and support. With this in mind, we have outlined below an overview of what has happened to date and advice for you and the women you come in contact with.

What do we know about what happened?

CervicalCheck carried out an audit of 1,482 previous cervical screening tests on women who were diagnosed with cervical cancer from 2008 to 2018. This audit was undertaken **after** the women were diagnosed and began in 2010.

Over 3 million cervical screening tests have been performed in Ireland since 2008, and over 50,000 cases of pre-cancer and over 1,200 cancers have been detected and treated following cervical screening. Approximately 3,000 women have been diagnosed with cervical cancer since 2008, and approximately half of these cases were notified by local colposcopy clinics to CervicalCheck. When CervicalCheck is notified that a woman has been diagnosed with cervical cancer, the women's previous screening history can be reviewed.

Of 1,482 women who were notified to CervicalCheck as being diagnosed with cervical cancer and whose cases were audited, it was found that in the cases of 209 women, on look-back, the screening test could have provided a different result and recommended earlier follow up.

Importantly, this audit was undertaken **after** the women were diagnosed. That is to say that the Cervical Screening Programme did not withhold information from any woman that delayed their diagnosis of cancer. Rather the audit process of their previous smears was undertaken as a response to them having been diagnosed and of this being notified to CervicalCheck.

It is clear that there has been a very serious breakdown in communicating to the women concerned that this audit was happening, and the outcomes of the audit. All those affected, who were not previously made aware of this, are now being contacted.

How has the HSE responded?

A HSE Serious Incident Management Team (SIMT) has been assigned to support the CervicalCheck and National Screening Service Team. We have been working to determine the details of what occurred and continue to do so as the situation evolves.

The HSE supports open disclosure and believes that 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 is now being established by HIQA, and will look at why this happened and what needs to be done to ensure that information is always shared with patients.

The HSE SIMT is also working with the National Cancer Registry to identify other women who have had cervical cancer during this time, and who may have been part of the cervical screening programme, and should be included in the audit of historical screening tests, and will review these if needed.

Why doesn't cervical screening find all cancers and pre-cancers?

Screening programmes are proven to be of great benefit in detecting early cervical disease in women and preventing cases of cervical cancer, but no screening programme is 100% effective. This is the case internationally and is factored into how screening programmes are designed. The limitations of cervical screening are outlined in the information provided to women when they are invited to take part in the programme.

Cervical screening tests are not diagnostic. Cervical screening tests are used to detect early signs of pre-cancer and cancer and this is outlined in the information provided to women as they progress through the programme

Cervical screening programmes by their nature, and like most clinical tests and processes, have a margin of error. In these types of 'eye to glass' testing of slides, a margin of human error is always expected.

The fact that no screening programme is 100% effective and is one of the reasons why we offer cervical screening tests every three years to women in Ireland. Routine screening i.e. attending for cervical screening test when called is the best way to remain vigilant and be assured about cervical health.

How reliable is CervicalCheck?

We know that cervical screening in Ireland is very reliable and effective. Over 3 million cervical screening tests have been performed in Ireland since 2008, and over 50,000 cases of pre-cancer and over 1,200 cancers have been detected and treated. All laboratories contracted by CervicalCheck have ISO accreditation, certified by the relevant national authorities.

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

- A result may be negative even though there are changes to the cells of the cervix (this is called a false negative). This is why it is important to have regular tests and to consult your doctor if you have any symptoms.
- A result may be positive even when there are no changes to the cells of the cervix (this is called a false positive). If your result is positive, you will be offered a more detailed investigation called a colposcopy. Some women may be treated for abnormalities that may have cleared up on their own

Why does CervicalCheck use laboratories outside of Ireland?

Cervical screening tests carried out by CervicalCheck are currently processed in three laboratories under contract: Quest Diagnostics Inc, Teterboro, New Jersey, USA; MedLab Pathology Ltd, Dublin; and Coombe Women and Infants University Hospital, Dublin. All these laboratories contracted by CervicalCheck have ISO accreditation, certified by the relevant national authorities.

These laboratories are contracted because there are not sufficient quality-assured laboratory services available in Ireland to meet the need of the screening programme. The HSE's SIMT is assured that these services are being provided to the required standard and should continue to be used to process CervicalCheck's screening tests.

Advice for a woman who has been diagnosed with cervical cancer

If a woman has been diagnosed with cervical cancer since 2008, she may have been included in this audit after their diagnosis. If she had cancer and has queries about her case, she should contact the CervicalCheck information phone line on 1800 45 45 55. Our team will be able to check the audit records and let her know if she was part of the CervicalCheck audit, or may be part of a further audit in future.

Why would a woman who has been diagnosed with cervical cancer not have been included in the audit?

Of the approximately 3,000 women diagnosed with cervical cancer over the ten year period since 2008, 1,482 of these cases were notified to CervicalCheck and included in this audit. The HSE SIMT is working with the National Cancer Registry to see if any other women who have had cervical cancer should be included in the audit of historical screening tests.

Advice for a woman who has had normal screening test results

The HSE Serious Incident Management Team has reviewed the overall screening process and how it is affected by this audit and along with our other clinical team members, are assured that women who have had normal screening results do not clinically require an urgent screening test.

However if a woman is concerned we advise her to review our updated information on www.cervicalcheck.ie and if they remain concerned, to consult with her GP or smearer, where she can decide to access a free screening test under the CervicalCheck programme.

What's the current situation with the CervicalCheck information line?

A large number of calls have been received by the CervicalCheck information line in recent days; many from people with normal screening test results. Call numbers are dropping today as the information being provided to women improves. Every effort is being made to ensure these calls are returned over the coming days and additional staff are helping to deal with the high volume of calls. Due to the number of calls received, we are prioritising those women who were part of the audit, and ensuring their calls are answered as a priority. Frequently asked questions and any further information for women with concerns are now available on www.cervicalcheck.ie and being updated with any new information as it arises.