



CervicalCheck
King's Inn House,
Parnell St,
Dublin 1.

May 2nd 2018.

Dear Colleague,

We are writing today to all GPs and smertakers contracted to the National Cervical Screening Programme, with an update on the evolving situation around the cervical screening programme and its recent audit process. We would also specifically like to seek the support of you and your teams 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.

As we hope you are aware, the HSE and the CervicalCheck programme has reiterated its deepest apologies to women for any worry caused by this ongoing situation. The HSE is 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 both healthcare workers and women.

What has happened to date?

Over 3 million cervical screening tests have been performed in Ireland since 2008, and over 50,000 cases of pre-cancer and cancer have been detected and treated following cervical screening.

Approximately 3,000 women in Ireland 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. CervicalCheck carried out an audit of 1,482 previous cervical screening tests on women who were diagnosed with cervical cancer from 2008 to 2018. The audit began in 2010.

Of 1,482 women who were notified to CervicalCheck as being diagnosed with cervical cancer, it was found that in the cases of 208 women, on look-back, the screening test could have provided a different result or a warning of increased risk or evidence of developing cancer.

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.

HSE Response

A HSE Serious Incident Management Team (SIMT) has been assigned to support the CervicalCheck and National Screening Service Team, and the National Women and Infants' Health Programme, of which team I am a member, has been appointed as the lead governance for the programme as part of this assignment. We have been working to uncover the details of what occurred in recent days and will continue to do so as the situation evolves. At this point 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.

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.

Reliability of Cervical Screening in Ireland

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 tests are not diagnostic,

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.

Screening programmes are proven internationally to be of great benefit in detecting early cervical disease in women and preventing cases of cervical cancer. 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.

No screening programme is 100% effective - this is the case internationally and is factored into how screening programmes are designed. For example; it 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.

Women who have been diagnosed with cervical cancer

Approximately 3,000 women have been diagnosed with cervical cancer over the ten year period since 2008, and 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 and anyone affected by this will be also be contacted.

If you have a patient who has been diagnosed with cervical cancer since 2008, they may have been included in this audit after their diagnosis. If your patients who have had cancer have queries about their case, you can direct them to contact the CervicalCheck information phone line on 1800 45 45 55. Our team will be able to check the audit records and let your patient know if they were part of the CervicalCheck audit, or may be part of a further audit in future.

Women who have had normal screening test results

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 cancer have been detected and treated.

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.

Over 6,000 calls have been received by the CervicalCheck information line in recent days; many from people with normal screening test results. Every effort is being made to ensure these calls are returned in the coming days and additional staff are now in place in the helpline 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 cervicalcheck.ie and being updated with any new information as it arises.

New Screening Tests

The HSE Serious Incident Management Team has reviewed the overall screening process and how it is affected by this audit. We, 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.

In the first instance we are advising women to review our updated information, and if they remain concerned, make contact with their GP or smearer to discuss their case. If, following that consultation, the women, or you as their clinician, remain concerned, they can access a screening test under the CervicalCheck programme. It is the intention of the SIMT and the National Screening Service that GPs and smearers will be paid for these sessions through CervicalCheck, whether a screening test is performed or not. This is the subject of immediate discussions between the HSE and GP representatives. We will forward details of the mechanism for reimbursement in the coming days.

I hope this update has been useful to you, and I and our wider team are extremely appreciative of any support that you can offer women affected by this very regrettable situation.

With thanks and best regards,

Dr. Peter McKenna,

Clinical Director, National Women and Infants' Health Programme

Dr. Jerome Coffey,

Director, National Cancer Control Programme