Introduction and Background

The national cervical screening programme, CervicalCheck, has been in operation for approximately eight years. The principles of coverage, co-ordination and quality assurance underpin the programme, which aims to prevent cervical cancer through the detection and treatment of precancerous abnormalities. During the first seven years of operation, in excess of 41,000 high grade precancerous abnormalities and 1082 cancers were diagnosed. Currently coverage rates are 79.6%, which is almost at the target level of 80%.

The current screening test is cytology. All screening tests must reach a balance between sensitivity (ability to detect an underlying lesion) and specificity (the chance that a detected abnormality represents underlying disease). The relatively low sensitivity of cervical cytology (50-70%) means that programmes have to repeat the test at regular intervals, in order to ensure effectiveness. The limitations of screening are recognised; not all cancers can be prevented by screening.

There is merit in reviewing the screening history of women who develop cancer, to determine where improvements can be made. In common with other national cervical screening programmes, CervicalCheck established a clinical audit process in 2009, which examines the screening history of all notified cases of cervical cancer, diagnosed since the programme commenced in September 2008. It must be noted that not all cancers in the country are currently notified to the programme – The National Cancer Registry is the most suitable national data source for the total numbers of cervical cancers.

Audit Review Process

As part of the review, all notified cases have been categorised and classified, as outlined in the CervicalCheck publication “Clinical audit process for incident cases of invasive cervical cancer”. A programme review group, with the support of an independent pathologist carries out a review of the cases, focusing on one or more elements of the cervical screening pathway – programme operation, screening, cytopathology and HPV testing, colposcopy, or histopathology. In particular, all cases with prior cytolopathology or histopathology samples, undergo an internal review, with many then undergoing further external review.

Audit Review Outcome

By the end of June 2016, 1,214 cases of cancer were notified to the programme. Of these, 718 had a diagnosis of cervical cancer diagnosed on the basis of an abnormal cervical smear test. In 142 cases, no prior screening has been undertaken, while 16 other women had received a previous normal smear, but had been overdue a repeat test.

A screening history was present in 349 cases (29%). These were flagged for further review, of which 258 underwent a cytology review. In approximately 58% of these, the review interpretation differed from the original cytology interpretation. It is understood that post event Cytology reviews have an inherent bias, as it is obvious to the reviewer that there has been a cancer diagnosis. The outcome of the review is available for 203 of these cases. The appended guidance provides more information on the reasons for this difference, including potential bias.
Operational Improvements Made in Response

A number of operational improvements have been made to the programme, in response to clinical audit review findings, as follows;

- Introduction of HPV testing to improve the assessment of risk, for women with low grade abnormalities. Women who test positive for HPV infection are referred to colposcopy, without having to wait for a repeat smear test in six or twelve months
- Introduction of HPV testing post-treatment, to improve the assessment of risk for women who have been treated
- Improvements in the way the programme operates failsafe, to follow up women with abnormal results, who delay repeat testing
- Improvements in communication between colposcopy services and the programme when women are discharged from colposcopy
- Laboratories are required to make digital images of all cancer cases and to add these slides to the training materials for cytoscreeners.
- Improved monitoring of subsequent treatment and/or biopsy of women referred to colposcopy, following a high grade cytology abnormality. The programme will continue to ensure audit findings are acted upon, as part of the NSS approach to continuous quality improvement

Process for Communicating Review Outcomes

In February 2016, the programme commenced formally communicating cytology review outcomes to the consultant doctor looking after an individual woman diagnosed with cervical cancer. Previously, requests from women or doctors for review outcomes have been issued upon receipt and reviews of colposcopy have been issued to colposcopy services.

To date, a total of 203 letters have been issued to 29 consultant doctors for historical cases where cytology prior to diagnosis (one or more smear tests) was reviewed.

Reviews are in progress for more recently notified cases with the findings to be obtained and communicated in due course. As of September 2016, cytology reviews are likely to be undertaken (and outcomes communicated to consultant doctors) at the rate of between 4 and 6 per month.

Legal and Communications Context

Women diagnosed with cervical cancer

One legal proceeding has been taken by a woman, who has since passed away – the action is continued on her behalf. The HSE, represented by the State Claims Agency, has been indemnified by a laboratory in this particular case. In addition, four letters from legal representatives of women seeking copies of all medical records have been received. Two of these requests relate to women recently diagnosed, with the programme only having just initiated the cancer audit process in these cases. Two women have directly enquired informally about their diagnosis and have been informed of the cancer audit process and that any review findings will be communicated to their consultant doctors.
**Laboratories**

Contracted cytology laboratories raised initial concerns regarding the communication of cytology review findings. Legal correspondence was exchanged with one contracted organisation. Subsequent engagement with senior clinical, scientific and corporate personnel in laboratory organisations, has resulted in a shared understanding of the audit requirements.

**Consultant doctors and colposcopy services**

Several consultant doctors have engaged with NSS CervicalCheck on the next steps to be taken following communication of a (cytology) review outcome. A short explanatory document was developed to accompany letters issued to consultant doctors and can be found appended. In addition, administrative leads in programme colposcopy services have been advised of the process. NSS CervicalCheck is providing additional support to consultant doctors in relation to carrying out an assessing of open disclosure requirements and appropriate protocols. Engagement between CervicalCheck and the consultant doctors will constitute an ongoing process.

**Media and public**

Given the number of letters that has issued in recent months, it is possible that individual cases could appear in the public domain. This could happen for a past notified case, or for a newly diagnosed case going forward.

The Health and Wellbeing Communications and Press Office functions of the HSE have been briefed on the cervical cancer audit process and outcomes. The designated spokesperson for NSS CervicalCheck on matters related to the cervical cancer audit is Dr. Gráinne Flannelly, Clinical Director, CervicalCheck Programme.

**Summary**

The cervical cancer audit process is an integral part of the quality assurance of the CervicalCheck programme and contributes to ongoing improvement of programme implementation. The communication with stakeholders and patients is being appropriately managed at this time.

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