

CervicalCheck Steering Committee

Weekly report to the Minister

8 March 2019

1. Update on support package

The provision of supports to women and families is continuing. In addition, measures have been put in place to ensure that retrospective costs are reimbursed, while an automatic review system is in place to simplify and streamline the claims process to ensure prompt payment of all items covered by the Government decision. To date, approximately €1.29m has been reimbursed in respect of various health and social care costs, approximately €955,000 of which relates to retrospective payments. There will also be additional costs associated with the medical cards that have been issued and the meeting of certain drug costs.

The HSE has completed an exercise on the data held on the 221 affected women. This is to ensure the National Screening Service has the most up to date information, which will be used to help with planning support needs for patients, for example. The report was shared with the 221+ Patient Support Group and has now been published on the CervicalCheck website.

2. Release of records

The HSE remains focused on responding to all requests for records as soon as possible. To aid this process external legal advisors are liaising with women and their solicitors on the release of slides. The protocol in place ensures the integrity and traceability of slides being transferred; solicitors are required to provide specific information about their chosen laboratory before slides can be released; this ensures the integrity of the slide is protected and all slides can be traced when they leave their current location. The HSE has reported that the average time to deliver slides to independent experts is 27 days.

The HSE has reported that 112 slides have been provided out of a total of 121. There are 9 outstanding requests. A total of 546 records have been provided, from 549 requests to date.

3. Independent Expert Panel Review

The protocol for the International Clinical Expert Review led by the Royal College of Obstetricians and Gynaecologists (RCOG) has been published on the Department of Health website.

The HSE project team is holding daily meetings and teleconferences to progress the project. As of Friday 15 February, 1,702 have been invited to participate in the review, including next-of-kin of women who have, sadly, died. Letters have issued providing information in relation to consent and the consent form for participation in the review, and 1,075 (63%) women have consented to take part. The final closing date for consents to be received was Friday 15 February. The Expert Review Panel has been provided with colposcopy and other data from CervicalCheck in respect of women who have consented to participate, and the transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review is ongoing. The most recent position, as of 1 March, is that approximately 656 slides have transferred. All slides from the Coombe have now been transferred with the exception of 1 late consent recently received, with transfer from the other labs continuing in batches. The HSE reports it is continuing to work closely with labs to facilitate and track the transfer. The HSE RCOG Support Team is holding weekly briefings with HSE Acute Operations to support the review, and the Information Line remains in service and integrated with the larger helpline, with a low level of calls being received.

4. Expiration of Tests - HPV Testing Outside Recommended Timeframe

In November 2018, the HSE became aware of an issue with Quest Laboratories in relation to the usage, outside the manufacturers' recommended timeframe, of a number of tests used for secondary HPV testing. Letters have now issued to all women affected. Retests arising from this issue will be prioritised for testing and the HSE has agreed with Quest to a four week turnaround time for these results.

The HSE has advised that clinical research shows that HPV tests remain effective even when they are performed outside the recommended timeframe and that there is little risk of inaccuracy due to the issue that Quest have identified.

5. Smear taking activity and laboratory capacity

The total number of additional GP consultations was around 111,000. The estimated number of early repeat smear tests which took place between May 1st and December 31st is approximately 57,810, or just over half the number of consultations.

The average processing time for smear tests is currently 27 weeks. The HSE has continued to focus on actively identifying solutions to the lengthening of smear test turnaround times. It is working with existing private providers, other private providers and public service providers in other countries to identify lab capacity. The HSE has indicated that this work is nearing completion, and that a report will shortly be provided to the Department for consideration. The HSE has advised that it has agreed with laboratories to prioritise those slides which originate from women who attended colposcopy as this cohort of women is considered to have the highest clinical risk. In addition, the HSE has agreed with the laboratory with the largest backlog that they carry out a HPV test on smear test samples, prior to cytology, as a means of prioritising slides appropriately.

6. Introduction of HPV as the primary method of testing

A pre-tender market engagement seminar has taken place, and feedback is completed. This, together with laboratory capacity planning, will inform the laboratory configuration strategy. A Periodic Indicative Notice has been published in the OJEU, putting the market on notice of the intention to procure a suitably qualified laboratory provider to provide HPV primary screening and secondary screening by way of liquid based cytology. A contract notice is due to issue in March to commence the procurement process.

ICT development and testing continues, along with work on resources for healthcare practitioners. Colposcopy capacity planning is underway by the National Women and Infants Health Programme, which is required to support the introduction of the HPV test. Six site visits have taken place as part of this work, which includes reviewing current operational pressures for all units as well as the impact of the introduction of primary HPV testing and the RCOG review, and the HSE has advised it is intended to have all site visits complete by early March.

7. Colposcopy waiting times

The most recently reported data is November 2018. 93% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 90% of women with low grade abnormalities were seen within 8 weeks of referral (against target of 90%). Currently, time taken in a clinical setting is reported to be considerably longer to facilitate answering questions and putting women at ease, and efforts to manage any impact on waiting times include extra clinical sessions and a focus on waiting list management through appropriate categorisation of referrals.