

Opening Statement

Secretary General, Department of Health

Joint Oireachtas Committee on Health, 13 February 2018

Chairman, Committee members

I would like to thank the Committee for the opportunity to meet this morning. I am joined by my colleagues Mr Greg Dempsey, Deputy Secretary, Governance and Performance Unit; Ms Tracey Conroy, Assistant Secretary, Acute Hospitals Policy; and Ms Celeste O’Callaghan, Principal Officer, Acute Hospitals Policy.

The issues relating to non-disclosure of the results of the retrospective CervicalCheck audit emerged in late April 2018.

Since that time there has been considerable focus within the Department of Health and the HSE on the management and oversight of related operational challenges and strategic priorities, and on the implementation of key Government decisions in relation to CervicalCheck.

Primary and social care supports

Resulting from the Government’s desire to assist women and families affected by a lack of disclosure, Government decided in May to provide a comprehensive package of health and social care supports for the cohort of 221 women and families for whom the audit carried out by CervicalCheck found discordance with the original reading of their slide or slides. The HSE now has an established and stable process in place to ensure that these supports are being provided, through designated Liaison Officers.

In making its decision, Government also decided that this comprehensive package of supports would be provided to any other woman for whom the Independent Clinical Expert Review being carried out by the Royal College of Obstetricians and Gynaecologists identified

discordance with her original smear test reading. In its invitation, the Committee has referenced women not included in the 221 and I trust that clarifies the position in that regard.

The HSE has recently completed a validation report on the status of the 221 group which has been shared with women and families within the group. It is intended that this report will assist in ensuring appropriate supports are provided to these women and families.

Implementation of Recommendations of the Scoping Inquiry

Also in May, Government decided to establish a Scoping Inquiry, led by Dr Gabriel Scally., Dr Scally's report sets out the impact of non-disclosure on the women and families affected by it, as well as providing useful clarity on the limitations of screening and audit, and the impact of non-disclosure on the women and families affected by it. He set out 50 recommendations aimed at addressing the shortcomings which he identified across a range of areas in screening.

In December, following Government approval, an implementation plan for all of the recommendations of the Scoping Inquiry was published on the website of the Department of Health. Some of the key elements include:

- continuation of the current dedicated team within CervicalCheck to ensure access to medical records and slides
- the inclusion of patient advocates on the HSE Board
- establishment of a National Screening Committee
- actions to address recommendations on laboratory services and on procurement
- the need for mandatory disclosure, which is addressed within the forthcoming Patient Safety Bill
- establishment of an Independent Patient Safety Council, which will as its first action undertake a review of open disclosure policies
- a number of actions to be led by the National Cancer Registry addressing data sharing, data definitions and collection of patient level details as between it and the NSS as well as governance
- establishment of an Expert Group within the HSE to review clinical audit processes across all cancer screening programmes; patient advocates will be included in this process

Independent Clinical Expert Review

I have referred earlier to the Independent Clinical Expert Review which is being led by the Royal College of Obstetricians and Gynaecologists following a Government decision on 8 May 2018. Expertise for this Review is also being sourced through the British Society for Colposcopy and Cervical Pathology. The Review includes women who were part of the CervicalCheck audit and women who were not. Specifically, the scope of the review includes cases of invasive cervical cancer in Ireland since CervicalCheck was established, or around 3,000 cases, up to May 2018.

This 3,000 cases includes the 1,482 cases which were notified to CervicalCheck since 2008. These women's screening histories were audited by CervicalCheck once it had been notified of their cancer diagnosis, and through that process the 221 were identified for whom there was discordance with their original results.

In addition to the cases notified to CervicalCheck, a further approximately 1600 cases were not notified to, and therefore not audited by, CervicalCheck. Some of these women had been screened prior to diagnosis.

The Independent Clinical Expert Review encompasses those women within the overall group of 3,000 approximately who were screened by the programme prior to diagnosis, or approximately 1,700 women who are currently contactable and comprehended by the Review following a detailed validation process.

Where the expert panel's opinion of cytology results differs to the original results provided by CervicalCheck, the panel will endeavour to determine, wherever possible, any failures to prevent cancer or to intervene at an earlier stage and will prepare individual reports for those affected, setting out the facts and their expert and independent assessment of those facts. The review will also produce an aggregated report which will be provided to the Minister and which is to include recommendations where appropriate, with the aim of improving care for women.

A consent process has been undertaken over the past number of months, following an extensive process of validation of data. The HSE has advised that more than 1,070 women have now consented to take part in the review. This is approximately 63% which is a welcome level of uptake and will facilitate the production of a robust aggregated report.

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 to the Review laboratory has begun. The Royal College has indicated a timeframe of at least six months to complete the review.

Independent Statutory Tribunal

The Government agreed on the 18th of December to establish an independent statutory tribunal, chaired by Ms Justice Mary Irvine. Primary legislation will be required to establish the tribunal. Judge Meenan provided Government with detailed recommendations on the establishment of the Tribunal. The Department of Health has been working intensively on the drafting of a General Scheme. The required legislation is legally novel, in providing for the determination of liability outside a traditional court setting. It is expected that the General Scheme will be submitted to Government very shortly for approval to draft the Bill. This Bill is a Government priority and is therefore included in the Spring Legislative Programme.

The Department is also working on the operational elements on the Tribunal's establishment, including securing premises.

Separately, the Minister also confirmed in December that, in advance of the establishment of the Tribunal, he would examine the early establishment of a non-statutory scheme to provide ex-gratia payments for the women who were affected by the non-disclosure of results of the retrospective audit. The development of this draft scheme is in progress in the Department, in advance of going to Government.

The Department is aware that these are issues to which a very high priority is attached by the women and families involved.

In conclusion

In his Final Report, Dr Scally emphasised that continuation of cervical screening was of crucial importance. His report affirmed that the lifetime risk of a woman in Ireland getting cervical cancer was 1 in 135 in 2015, compared with 1 in 96 in 2007, representing a substantial improvement since the programme commenced. The HSE undertook detailed negotiations in the latter half of 2018 to extend the contracts of existing laboratory service providers in order to ensure continuation of screening.

Dr Scally also stated in his report that improved screening uptake, the new HPV testing regime, and the extension of the HPV vaccine to boys, together create a realistic prospect of the virtual elimination of cervical cancer in Ireland in the coming decades. These are a key focus for the Department and the HSE in 2019. In parallel, and interlinked with these priorities, the management of current capacity issues remains a priority.

Thank you.