Joint Committee on Health

Meeting

Wednesday 16\textsuperscript{th} May 2018

Opening Statement

by

Mr John Connagahan

Interim Director General

Health Service Executive
Good morning Chairman and members of the Committee. Thank you for the invitation to attend the Committee meeting. I am joined today by my colleagues:

- Dr Stephanie O’Keeffe, National Director, Strategic Transformation and Planning
- Mr. Damien McCallion, National Director, National Screening Services
- Dr. Peter McKenna, Clinical Director, National Women and Infants Programme

Firstly I would like to acknowledge and apologise for the confusion and alarm which has been created in relation to the CervicalCheck Programme as a result of the failure to communicate with the women affected. This failure has ultimately impacted on every female in Ireland, their families, their spouses and their children. Irrespective of the original, well-intentioned undertaking by the CervicalCheck Programme to conduct an audit of invasive cervical cancers and communicate the results to the patients affected, the organisation (in that respect both CervicalCheck and the HSE) have failed by any measure.

I want to sincerely apologise on behalf of the HSE and CervicalCheck to the women and their families who have been directly affected by what has happened and to all the women of Ireland who have been understandably frightened and concerned by what they have read and heard. We must learn lessons from what has happened. I want to assure you and especially the women of Ireland that I am determined that we will take on board these lessons. Together with my colleagues we will work to bring about the changes with a view to ensuring that this does not happen again. The CervicalCheck Programme is vital to women’s health and we must clearly understand the mistakes that have been made and how we can learn from these and restore confidence in this life-saving public health programme.

In the short time that I have been interim Director General I have asked for a full record search and a full chronology of events to be compiled. That exercise is now underway. The HSE last week provided three separate briefing notes at short notice to the Public Accounts Committee and we have also submitted them to this Committee for information. Regrettably there was not sufficient opportunity at the PAC meeting last week to provide appropriate context and interpretation of the three briefing notes. I have brought colleagues to this Committee who will be prepared to answer any questions of detail on these notes. The full record search has allowed three further briefing-notes relating to the Audit process. These briefing notes are provided to the Committee here. It is fair to say that the language in all of the briefing notes is very functional and somewhat lacking in empathy for the women who were to be communicated to.
I have submitted an information note to the Committee regarding the briefings that were submitted to the PAC together with other information. In relation to the three specific briefings given to the PAC last week and which we have also copied to you, the context for the briefing given in March 2016 to the National Director Health and Wellbeing, HSE, the former Director General of the HSE, and to the Department of Health (the DoH Acutes Hospital Division and Office of the Chief Medical Officer) was to raise awareness of the audit process that CervicalCheck was engaged in and the initial outcomes and next steps of that process. The intent of the CervicalCheck Programme was that all treating clinicians would be given individual audit findings for their patients so that these could be in turn communicated to the women concerned, in line with guidelines at that time.

A key element within the March 2016 briefing was the assurance it gave that there was no systemic quality issues of concern with the programme. This is the most important element of an audit from a cancer prevention and effectiveness perspective, namely to provide assurance that there is nothing systematically happening in the screening programme and its operations that would lead to it operating outside of internationally acceptable quality parameters (e.g. European guidelines).

The process involved sending audit results to treating clinicians in order that these results could be communicated to the women concerned, in line with relevant guidelines. The CervicalCheck Programme had commenced sending letters to treating clinicians in February 2016. All individuals briefed expected that women affected would be receiving information from their treating clinicians on the result of the audit findings pertinent to their case.

The subject matter of the March 2016 briefing was to provide a snapshot of the process to date and to escalate a particular issue at hand. This issue concerned one laboratory (Quest Diagnostics) that challenged the CervicalCheck Programme communications process with treating clinicians and invoked a dispute resolution process, as provided for in their contract. CervicalCheck and the National Screening Service requested support to resolve it. I have been advised that this is why ‘pause all letters’ was listed as a next step in the briefing. It was imperative that CervicalCheck and the National Screening Service resolved this issue so as to ensure it had solid legal footing to continue with its work in sending audit findings to treating clinicians for onward disclosure to the women concerned, within the guidelines set out.
If CervicalCheck were to continue sending letters, without the assurance that it had legal cover to do so, it could have created subsequent legal issues for the operation of the CervicalCheck programme, in addition to potential risks for any women seeking redress where the laboratory could claim its legal rights/entitlements were infringed by the process. This is why the “await advice from solicitors” was one of the next steps in the briefing note from March 2016.

CervicalCheck were supported in resolving the dispute with Quest Diagnostics and the process of issuing letters to treating clinicians re-commenced in June 2016. During the time it took to resolve the dispute, CervicalCheck were preparing individual letters for each patient case history to send to treating clinicians. The March 2016 briefing note states that “There is now a batch/accumulation of clinical audit case reports that have been completed”. It was understood, by those that were briefed, that these case reports needed to be converted into individual letters in relation to each patient concerned. Correspondence demonstrates that this work was happening at this time and this correspondence will be made available to the scoping inquiry.

CervicalCheck explained in the briefings how the audit and communications process was complex, multi-layered and resource intensive. They made clear to those being briefed that each communication needed to be specific to the individual, checked and rechecked for accuracy relating to the specifics of each patient and the logistics of sending these communications needed to be carefully thought through so as to mitigate any risks relating to the manner, mode, content and logistics of the communication.

This is why ‘decide on the order and volume of dispatch to mitigate any potential risks’ is set out as a next step in the briefing note. It is important to note that CervicalCheck issued the majority of the correspondence concerned during July and August 2016 – approximately 200 letters according to the July 2016 briefing notes.

We need to be realistic in an assessment of the communication process. The CervicalCheck Programme did not escalate the issues that were subsequently encountered regarding the breakdown in the process of treating clinicians discussing audit findings with their patients. Indeed, it is not clear to me that the staff within the programme were aware of the scale of the difficulty in terms of the proportion of women who had not been communicated with. That is evident from additional briefing notes that I have released to JCH last night.
It is important that we look at some key facts. Most women’s smear test results are accurately reported. Every year some 270,000 smears are undertaken. For women who have received a normal result the chance of going on to have cervical cancer by their next smear test three years later is less than 1%. Since 2008, the CervicalCheck programme has provided some 3 million cervical screenings to over 1 million women. The programme has detected over 50,000 high grade pre-cancerous changes in women reducing their risk of cervical cancer by 90%. These were women without any symptoms who, without the screening programme would not have known that they had pre-cancerous changes. Latest figures show that the incidence of cancer in Ireland has reduced by 7% in the period 2010 to 2015. This means that fewer women have developed cancer and hundreds of lives have been saved.

The open disclosure policy of the HSE is there to provide an ethical framework for staff and social care services to fulfill their duty of care in relation to communicating with service users and their families. The original intention of that policy was to provide an ethical response and to promote a fair, open and just culture within healthcare organisations. However any policy which is not set in legislation requires to be closely monitored in terms of delivery and to have swift dispute resolution and escalation processes where professionals disagree on the correct course of action.

It is quite clear in hindsight that the necessary actions as outlined in the open disclosure policy were not taken in a timely and effective manner.

Can I take the opportunity to say a few words in defense of our national audit programme. The process of clinical audit is about measuring the quality of care against relevant standards and best professional practice. It encompasses the requirement to identify any factors causing sub-optimal delivery of care, either at an individual patient level or more widely, and allows the necessary remedial actions to be identified and taken.

In light of the controversy over the CervicalCheck audit we must ensure that healthcare professionals are not discouraged from taking part in clinical audit. Fostering an open culture which supports clinicians and encourages learning must be part of our ethos.

At this point it might be useful for me to say a few points about accountability. To me accountability is the obligation for an organisation or individual to account for its activities, accept responsibility for them, and to disclose the results in a transparent manner.
As Interim DG it might be useful to also outline how I see myself discharging my duties against the obligation to be accountable to the Minister and more generally.

First of all, as part of the Health Service Governance Act (2013) which established the Directorate as the Governing Body of the HSE, the Directorate is accountable to the Minister for the performance of its functions and those of the HSE. As the Interim DG I account to the Minister on behalf of the Directorate through the Secretary General of the DoH. It is important that we foster a culture of openness, transparency and both personal and organisational accountability; it is also essential that we keep the wishes and welfare of patients at the center of all that we do.

The process and procedures for how the CervicalCheck programme intended to communicate the results of the audit to patients was developed at that time with the best of intentions, with a view to ensuring that women would receive the results of the audit, consistent with policy and best practice as set out in the 2015 Open Disclosure National Policy, and informed by wider best practice for the disclosure of cancer screening audit results. The failure – our collective failure – was on ensuring effective follow through on these good intentions. While the results of the audit were communicated to the relevant clinicians, the arrangements thereafter appear to have broken down. The outcome was that a large proportion of women were not told about either the audit itself or the results for them as individuals. The impact of this failure has been profound both for every single woman affected and their families. It has also undoubtedly caused significant levels of fear and anxiety for the wider population of women living in Ireland. And it has sadly undermined public confidence in the CervicalCheck programme.

I would like to conclude my opening Statement with the following pledges:

1. We will move swiftly and with compassion to provide effective support packages to the women and families who require support. We will do that with the minimum of fuss and bureaucracy and with empathy.

2. We will fully openly and transparently co-operate with the Scally Inquiry, the International Expert Panel Review and any subsequent inquiries.
3. If there is a requirement to hold individuals to account on a personal basis we will do so. In that respect the Scally Inquiry and subsequent inquiries will be important for the independence of their views and to allow due process and fair procedures to be followed.

4. We will learn lessons from recent weeks not least the ability to say sorry. Patients need to know what happened, what can be done to deal with any harm and what will be done to prevent someone else being harmed.

Thank you.