Information Note for Joint Committee on Health re the Briefing notes submitted to PAC last Thursday

The HSE submitted a cover memo and three briefing notes to the PAC last Thursday. Please find attached the 3 briefing notes referred to and below an information note providing the context for those 3 briefing notes. While the three briefing notes in March, and July were sent to the Director General, there are an additional three briefing notes in the system that were not seen by the Director General and which are now attached.

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 (Acutes Hospital Division and Office of the Chief Medical Officer) was to raise awareness of the process that CervicalCheck was engaged in. 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 communicated to the women concerned, in line with guidelines at that time.

Each of the three briefing notes concerned either came with or followed from a verbal briefing on the work of the CervicalCheck Programme and the process it had commenced. This 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 people receiving these briefings, both verbally and paper based, were aware that population-based screening programmes, like CervicalCheck, will not prevent all cases of cervical cancer and the test is not 100% accurate (false negatives/false positives) and that while the CervicalCheck programme is demonstrating that it is effective at reducing the incidence of cervical cancer in the population and identifying cancer at an earlier stage for women, it does not work for all women and some women will continue to get cancer, even though they have attended a screening programme. The most important element of an audit from a cancer prevention and effectiveness perspective, is 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 CervicalCheck Programme gave assurance that there was no systemic quality issues of concern in their March 2016 briefing.

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 the 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.

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 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 in their briefings explained 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.

The context for all of these briefing’s to the National Director Health and Wellbeing, the former Director General and to the Department of Health (Acutes Hospital Division and office of the Chief Medical Officer) was CervicalCheck’s work and process to communicate audit findings to women via their treating clinicians and in line with practice in other jurisdictions regarding disclosure of audit results in cancer screening. Verbal briefings during this time, given by CervicalCheck/NSS, supported by various pieces of correspondence confirm the intent of CervicalCheck to let women know of their case findings via their treating clinician. The March 2016 briefing details a case, confidentially, where the Clinical Director of the CervicalCheck Programme was personally meeting a lady diagnosed with Cervical Cancer, to discuss her case and audit findings with her. All of this information and correspondence will be made available to the Scoping Enquiry to independently assess this.

Correspondence and briefings would suggest that the expectation of the Programme, the NSS, (and consequently of those briefed), was that women would receive information relating to the audit findings from their clinicians. The expectation of the Programme was that women would be taking legal advice and there existed the potential that the details of these legal cases would be in the media. The briefing in March 2016 makes clear that CervicalCheck was preparing for this media coverage - in advance of this media - and the potential for negative publicity that could have led to the undermining of a population screening programme whose primary purpose is saving lives (within the limits of the science available). Such steps are both appropriate and necessary. It is critical to understand that CervicalCheck assured those who were being briefed that the audit process found “no systematic quality problem of concern”. This is set out in the March 2016 briefing note. As CervicalCheck was undertaking this work and communicating with treating clinicians in the expectation that these clinicians would be talking to their patients about the results of the audit, and if they had not been planning to be in a position to respond to questions from the public and from media they would have been failing in their duty to patients.

This is why ‘continue to prepare for reactive communications response for a media headline that ‘screening did not diagnose my cancer”’ is set out as a next step in the briefing note. For a population cervical cancer screening programme to be successful at reducing the incidence of the disease it is imperative that uptake levels reach the target required.
Therefore, any media coverage questioning the effectiveness or robustness of the screening programme (where there is no evidence) would need to be carefully avoided in order to ensure the CervicalCheck Programme continues to save lives.

Neither the CervicalCheck Programme nor the NSS escalated the issues they subsequently encountered regarding the breakdown in the process of treating clinicians discussing audit findings with their patients. While CervicalCheck and the NSS were dealing with these issues as they arose, the problems were not reported through the NSS governance line, to the National Director Health and Wellbeing. Consequently, neither the former Director General nor the Department of Health were briefed by the National Director Health and Wellbeing on these issues. Management updates from the NSS indicated that the audit process was continuing as planned and that the audit findings were making improvements to the programme.

Clearly in hindsight, different actions could have been taken and there is a need for us to ensure we learn and respond fully from what has happened on foot of this audit process and the levels of distress that it has caused to women, their families and the public.

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