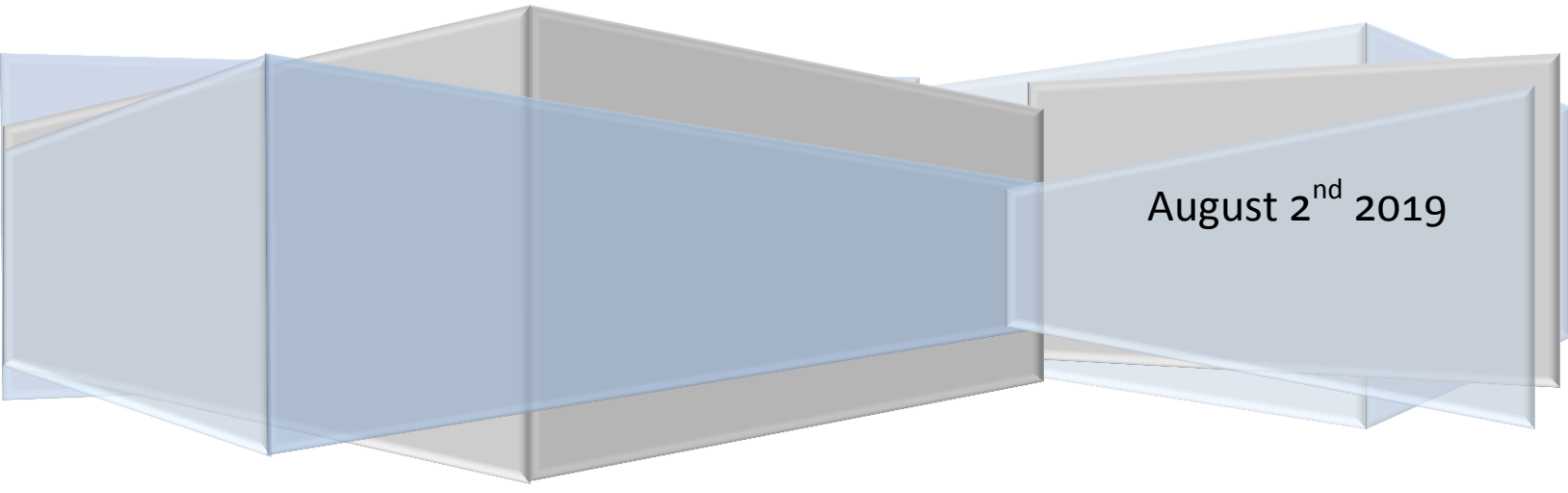
Independent Rapid Review of Specific Issues in the CervicalCheck Screening Programme

PROFESSOR BRIAN MACCRAITH



August 2nd 2019

Contents

1. Introduction

Beginning on April 3rd, 2019, a woman, known as Sharon, sent a series of emails to the Department of Health (DoH) outlining her concerns regarding a significant delay in receiving results back from a smear test (taken on December 3rd 2018). Prior to this representation, Sharon had been in contact with CervicalCheck (CC) and, in her emails to the DoH, expressed her dissatisfaction with the response received, including the lack of clarity regarding the status of her results.

As with other queries received regarding delays the DoH responded to Sharon on a number of occasions including by explaining the general situation regarding turnaround times for test results. On June 7th, in light of her further inquiries and the fact that she had not yet received her results as might have been anticipated at the stage based upon expected turnaround times, the DoH contacted the HSE's National Screening Service (NSS) requesting individual patient level information to assist with their response to her.

On June 25th, the NSS wrote to the DoH with information for a response to the representation made by Sharon. The letter stated that Sharon's test had been processed, and reported on June 17th, but that "due to an IT issue in the laboratory", Sharon was "not issued with a result letter from CervicalCheck", although they did understand that her GP had received her result. The letter went on to state that they were "addressing this issue with the laboratory in question and are writing to all the women who have been affected".

Later on the same date (June 25th), the DoH contacted NSS by email, seeking clarification on the issue, its impact, if any, and how it had been resolved. The NSS provided a report on the matter to the DoH on July 10th).

The report confirmed that the tests in question were HPV tests undertaken by a quality-assured Quest Diagnostics (QD) laboratory at Chantilly, Virginia, which the NSS agreed (in November 2018) could provide additional capacity for HPV testing in order "to assist Quest Diagnostics in processing an unprecedented increase in tests, caused by high demand for cervical screening in 2018, due to women's understandable concerns during this period". The report stated that the Chantilly laboratory was also used to re-test HPV (using a HPV DNA test) on a number of cervical screening samples on which HPV testing had been carried out initially outside of the manufacturer's recommended timeframe of 30 days (the 'Expiration issue').

The NSS report stated that the IT system used in Chantilly "required updates to ensure that it could generate result files that were compatible with CervicalCheck's Cervical Screening Register (CSR) and thus ensure notifications were issued to GPs and results letters were issued to women". The HSE became aware of the extent of this IT issue in June 2019, following their

investigations in response to queries arising from the representations made by Sharon to the DoH.

In their July 10th report to the DoH, the NSS stated that IT updates had taken longer than anticipated to implement and outlined the following related impacts:

- Results letters were not issued to approximately 800 women (number identified at that time)
- A number (unspecified) of GPs did not receive hard-copy reports of results that the HSE had understood (from QD) to have been sent to the GPs. The HSE had already written to women to contact their respective GPs to receive these results.

As a result of these issues emerging (followed by media coverage, beginning on RTE's Six One News on July 11th), and particularly the concerns relating to how these matters were communicated to the women concerned, the CEO of the HSE Mr. Paul Reid announced on Monday, July 15th that he was commissioning an immediate and independent rapid review of the incident, to determine the facts that led to this situation and to identify how the communication of screening results to women and their GPs was planned and managed.

The Terms of Reference (ToR) for the Review are as follows:

1. To determine the complete chronology of events from the time the IT issues first emerged up to the public reporting of these issues on July 11th 2019.
2. To establish the agreed process for the communication of results to women and their GPs, how this was planned and managed and how this process worked in practice.
3. To determine the adequacy of the response put in place once these issues emerged and to determine where and what the learning is for the management and communication processes within and from the Screening Programmes.
4. To determine if the relevant procedures as set out in the HSE's Incident Management Framework and Integrated Risk Management policy were followed and implemented.
5. To examine the appropriateness of the escalation and if, how and when the communication of the incident within the HSE's governance structures and between the HSE and the Department of Health, and the relevant CervicalCheck committee structures was managed.
6. To provide a report to the HSE's CEO setting out the facts relating to the incident and to make recommendations for any appropriate further actions and future learning.

I was pleased to accept the invitation of Mr Reid to conduct the review on an independent basis. The date for submission of the report to the Mr Reid was identified as Friday August 2nd, 2019.

Professor Brian MacCraith,
President, Dublin City University

2. Context

The CervicalCheck (CC) programme, which is part of the National Screening Service of the HSE, provides cervical screening tests (previously known as smear tests) to women between the ages of 25 and 60 in order to provide, where appropriate, interventions that can reduce the risk of developing cervical cancer.

Guided by the Terms of Reference outlined in Chapter 1, this Review addresses concerns arising from HPV DNA Testing of CC samples at a Quest Diagnostics (QD) Laboratory located in Chantilly, Virginia, USA.

The specific decision to begin using that laboratory derives from a range of developments during 2018 and the pertaining circumstances in late 2018:

- The public concern arising from the CC Audit in April 2018
- The announcement (April 28th 2018) by the Minister for Health that for any women who had a CC smear test and where her GP felt she should have a further test as part of her reassurance, the facility of a free smear test would be provided
- The additional workload arising from increased uptake of screening by women called in the normal course of the programme.

Two other related developments in this period are:

- The announcement (May 8th 2018) by the Minister for Health on behalf of the Government that they were commissioning Dr Gabriel Scally to carry out an independent Scoping Inquiry into the issues that came to light in April 2018.
- Around 1,075 women, who were screened and who later developed cervical cancer, consented to be part of the Independent Clinical Expert Review led by the Royal College of Obstetrics and Gynaecology (RCOG). The RCOG review is ongoing currently.

In 2018, around 370,000 women presented to the CC programme, an increase from 280,000 in 2017. This >30% increase created significant challenges for testing laboratories with a consequent impact on 'turnaround time' (TAT) and the creation of a backlog of samples. In normal circumstances, the target TAT from the receipt of a sample for testing is about 4 weeks. Currently, over half of samples received into the CC programme are being processed within 7 weeks, although it can take up to 33 weeks for the report to be provided.

At a time when there was a clear need to identify increased capacity to deal with increased demand in the screening programme: one of the laboratories contracted by the programme did not renew its contract with CC. With limited capacity in the Coombe Women and Infants University Hospital Laboratory at the time, protracted negotiations with the one remaining laboratory provider (QD) became a major focus. An extension to the contract with QD, which

was due to expire in October 2018, was signed in November 2018 and a second extension was signed on June 7th 2019 after intensive negotiations involving senior CC and NSS personnel.

In November 2018, CC agreed with QD to use an additional, quality-assured QD in Chantilly, Virginia to process cervical screening tests. The decision was made in order to address the substantial increase in tests caused by the high demand for cervical screening in 2018 (for the reasons outlined above). In November 2018, QD advised CC of a problem (the Expiration issue) related to expiration of samples for HPV testing at its Teterboro facility. The HPV test used at the QD Teterboro laboratory is an RNA test, which needed to be completed within the manufacturer's room temperature stability period of 30 days from the sample collection date. The HPV test used at the QD Chantilly laboratory, on the other hand, is a DNA test which has a sample expiration window of up to 6 months, depending on sample treatment. This meant that the QD Chantilly laboratory could also be used to retest samples from the Teterboro laboratory (thereby 'rescuing' expired samples) or to test 'backlog' samples that were close to expiry.

Further information on HPV testing and its significance is provided in Appendix 1.

3. High-level Chronology

November 2018 – July 2019

NOVEMBER 2018

November 5th 2018

Quest Diagnostics (QD) Teterboro laboratory determine that a number of samples for HPV RNA testing were performed beyond the manufacturer's recommended room temperature stability period of 30 days.

November 20th 2018

QD undertake to identify how many samples could be rescued using DNA testing and to identify the samples that tested positive and to determine where women are in their screening pathway.

November 28th 2018

QD identify that they have approximately 700 samples in Teterboro that can still be tested for HPV DNA in their Chantilly laboratory. ('Rescue samples')

At final analysis there were 871 such unique samples.

November 30th 2018

CervicalCheck (CC) grants permission for QD to use their Chantilly laboratory for HPV DNA testing. The granting letter stipulated that a condition of this granting was that the HPV DNA results from the Chantilly laboratory "can be transmitted back to CC using the existing electronic methodology".

DECEMBER 2018

December 13th 2018

NSS establish a Serious Incident Management Team (SIMT) to address the Expiration issue.

December 17th 2018

The Expiration issue notifies formally to the National Patient Safety Office, DoH via the Patient Safety Protocol.

December 14th 2018

The first HPV DNA testing is conducted at the Chantilly laboratory.

December 18th 2018

QD disclose to CC that the HPV expiration issue goes back to 2015. The analysis conducted by QD shows that the total number of samples impacted 2015-18 is 11,577.

December 21st 2018

CC categorise the 11,577 samples to identify what action is required for the women impacted by the sample expiration problem.

JANUARY 2019

January 10th 2019

QD write to National Screening Service (NSS) outlining the problems with RNA testing that led to the Chantilly DNA solution and the revised process to address these.

January 11th 2019

Initial engagement between CC and QD on the issue of transferring results electronically onto the Cervical Screening Register (CSR).

January 24th 2019

RTE report that the HSE has confirmed that up to 6,000 women will likely be called for a repeat smear test following the identification of an issue with HPV tests.

January 24th 2019

CC Clinical Director writes to all GPs [**LETTER GP1**] informing them of the Expiration issue that has arisen in relation to a number of HPV tests carried out on samples between 2015 and 2018 and that up to 6,000 women will likely be called for a repeat smear test.

January 31st 2019

CC Clinical Director and NSS Director of Public Health write to all GPs [**LETTER GP2**] enclosing a copy of the letter of the January 24th. In this letter they reiterate the advice previously provided and advise GPs of the actions taken and required.

January 31st 2019

SIMT discusses IT issue for first time and possible solutions to this.

January 31st 2019

The CC Clinical Director and NSS Director of Public Health writes to categories of women affected by the Expiration issue.

FEBRUARY 2019

February 4th & 8th 2019

CC Clinical Director and NSS Director of Public Health writes to further categories of women affected by the Expiration issue.

February 8th 2019

QD indicates that they have a difficulty in transferring the results of DNA tests from Chantilly to Teterboro laboratory so that they can 'come over the CSR' and that a manual process may be required.

February 13th 2019

It is agreed that a manual workaround will be used by QD so that the "Category D" (rescue sample) results can be entered onto the CSR (Cervical Screening Register) so that a result letter can issue. The risk for error arising from manual approach is flagged in SIMT minutes.

February 13th 2019

CC Clinical Director and NSS Director of Public Health issue a letter to relevant GPs [**LETTER GP3**] in relation to women whose rescue sample on retesting changed status from negative to positive on re-testing. It attaches detail of the relevant patient their test result. The attached result report also indicates that GPs would also receive results from programme laboratory through the usual channels.

MARCH 2019

March 26th 2019

NSS sought an update from QD regarding results transfer to NSS and are informed that the QD e-Labs team are working on a solution and that manual generation of files is required until a solution was found.

APRIL 2019

April 3rd 2019

First email representation from patient Sharon to DoH.

April 15th 2019

Serious Incident Management Team (SIMT) stepped down and remaining actions are transferred to operational management for completion.

April 16th 2019

CC Clinical Director (newly appointed) sends a briefing letter to all GPs [**LETTER GP4**] with update on broad range of issues relating to the National Cervical Screening Programme. The ICT systems are referenced as being a source of delays. The letter also notes that paper results are being issued to healthcare professionals and that results letters are not being issued to women.

JUNE 2019

June 18th 2019

CC emails QD to express concern regarding significant feedback from practices in relation to not receiving results from Chantilly. CC express concern that all reports, once authorised, are issuing to practices in a timely fashion.

June 25th 2019

Letter is sent from NSS to DoH providing response to queries included in Sharon representation. This is the first association of Sharon's delayed results with an IT issue.

Email from DOH to NSS requests clarification on the statement in NSS letter that NSS were writing to 'all women who have been affected'.

JULY 2019

July 1st 2019

QD advises CC that they have issued the results of Category D women to GPs. CC issues a letter [**LETTER D1**] to these women and advises them that their results are with their GPs and asks them to contact their GP to discuss the result and any steps that they might need to take.

July 4th 2019

Feedback and some social media comments indicate that women have received letters (Letter D1) to contact GPs for results but results have not reached GPs.

Week of July 8th

NSS learns that QD has failed to send the test results to the GPs of around 800 women in Category D.

July 10th 2019

NSS report to DoH in response to their query of June 25th reveals that approximately 800 women 'were not issued with results letter'. The Minister for Health subsequently received a brief from the DoH later that day on the NSS report.

July 13th 2019

The CEO of the HSE emails all members of the HSE Board to advise them of the issue. Within this email, the CEO indicates that he had contacted the Chairman of the Board on July 11th to apprise him the issue.

July 15th 2019

NSS establishes a Serious Incident Management Team (SIMT) to address Non-issuing of Reports.

Rapid Review (the outcome of which is this report) is announced.

July 16th 2019

QD confirms to NSS that 'in or about April 2019', a single data file containing the results for Category D women was not sent to Quest's Dublin facility (which prints and issues the results to GPs) due to 'human error'.

July 26th 2019

The issue is notified formally to the National Patient Safety Office, DoH via the Patient Safety Protocol.

The issue is notified formally to the Head of Healthcare Regulation, Health Information and Quality Authority (HIQA).

4. Sequence of Events November 2018 – July 2019

4.1 Addition of Chantilly laboratory

In 2018, around 370,000 women presented to the CervicalCheck (CC) programme, a significant increase from 280,000 in 2017. This >30% increase created significant challenges for testing laboratories with consequent impact on 'turnaround time' (TAT) and the creation of a backlog of samples.

The target turn-around-time (TAT) for testing and issuing of reports to GPs is normally 2-4 weeks. During 2018 this turnaround time rose to as high as 33 weeks in some cases. This increased workload, which includes repeat as well as routine smear tests, led to the development of a backlog. Although it is reducing, there is currently at the time of writing a backlog of approximately 33,750 slides.

In an effort to manage this backlog, CC reached an agreement with Quest Diagnostics (QD) in November 2018 to use its additional quality-assured laboratory in Chantilly to process cervical tests. The decision to use Chantilly was made primarily to assist in reducing the backlog. Prior to giving permission to QD to use the Chantilly laboratory, CC sought a number of assurances in relation to the stability period of samples, the contractual arrangements and the ability of Quest to use existing electronic methodology to transmit the test results.

In November 2018, QD advised CC of a problem (the Expiration issue) related to expiration of samples for HPV testing at its Teterboro facility. The HPV test used at the QD Teterboro laboratory is an RNA test, which needs to be completed within the manufacturer's room temperature stability period of 30 days from the sample collection date. When a full retrospective analysis was carried out, it turned out that 11,763 samples were tested outside the recommended stability period (further details on those samples are provided in the following Section 4.2). The HPV test used at the QD Chantilly laboratory, on the other hand, is a DNA test which has a sample expiration window of up to 6 months, depending on sample treatment. This meant that the QD Chantilly laboratory could also be used to retest some samples from the Teterboro laboratory (thereby 'rescuing' expired samples) or to test 'backlog' samples that were close to expiry for RNA testing, thereby avoiding, in both circumstances, the need for women to undergo a repeat smear.

4.2 Cervical Test Samples at Chantilly Laboratory

As indicated in the previous section, 11,763 sample tests were identified as having been affected by the expiration issue. In order to ensure that all women, whose samples were affected, were managed in a clinically appropriate way, a series of decisions was taken to triage them. The

decisions taken, together with the number of women/samples associated with each decision, are shown in Figure 1 below.

For example, the number of samples, for which sufficient material was still available to conduct a HPV DNA test (so called 'rescue samples') was 856. Use of the HPV DNA test on the 'rescued' samples would avoid the need to ask the women who had originally provided these samples to attend for a retest. Upon further examination, 60 of the 856 samples were deemed unsuitable for retesting, e.g. 47 had been rendered unusable following treatment with acetic acid, a substance that is sometimes required in preparing slide samples. This left 796 of the original 856 'rescue' samples. During the sample verification process, a further 77 samples were added to the 'rescue' group, resulting in a total of 873 for this group.

Between December 2018 and July 22nd 2019, a total of 4,088 CC samples were sent to the Chantilly Laboratory for HPV DNA tests. The breakdown of these samples is shown in Figure 2.

- 3,215 were 'backlog samples', deemed 'at risk' of expiring before they could be tested using the HPV RNA test
- 873 were the 'rescue samples', whose origin was described above

When re-tested using the HPV DNA test, 55 of the 'rescue samples' yielded a positive result despite the fact that the original HPV RNA test was negative. This phenomenon is well understood (arising from the differential specificity of DNA and RNA tests for HPV), and unsurprising. As will be seen in later sections, the GPs of the women who provided these samples were communicated with quickly.

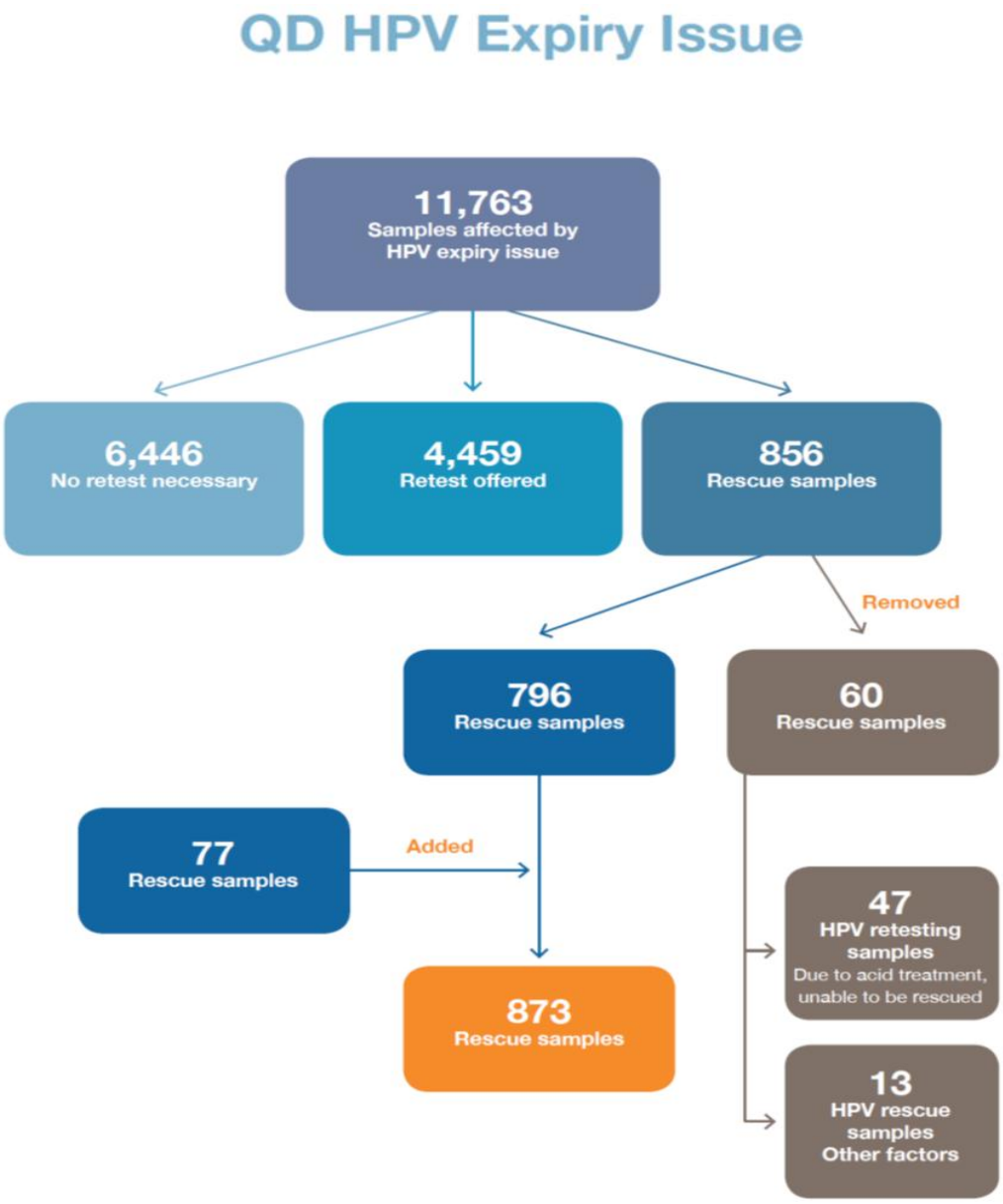


Figure 1- Quest Diagnostic HPV Expiry Issue

Figures based on current understanding 22/07/2019

QD Chantilly Samples

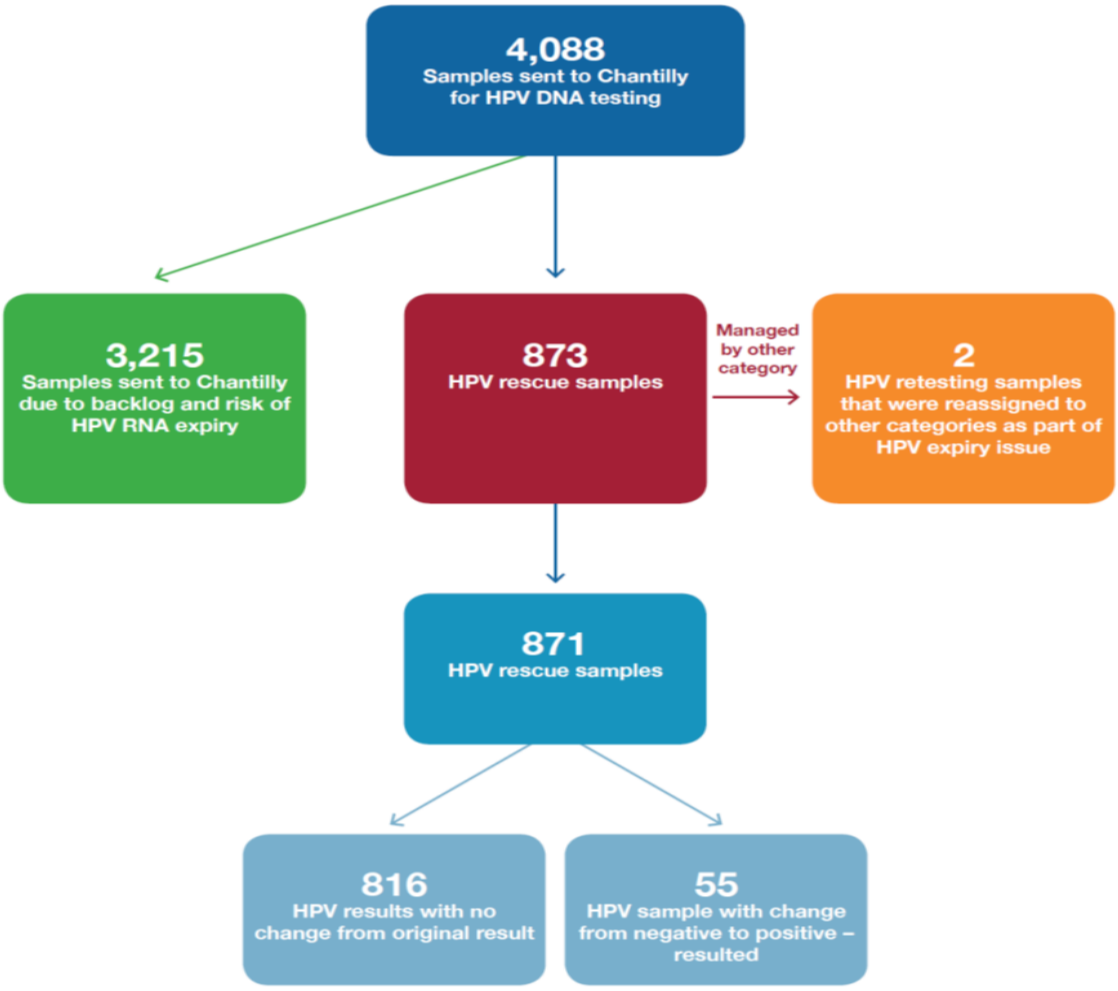


Figure 2 – QD Chantilly IT issue

Figures based on current understanding 22/07/2019

4.3 Standard Process for Report Generation

Approximately 90% of all cervical test samples from Ireland are processed by QD in their US laboratories, the primary site (hub) being in Teterboro, New Jersey.

Cervical samples are sent from GP surgeries, clinics and colposcopy units to the QD sample reception and dispatch centre in Dublin. Here, samples arrive and are received, noting any issues with the samples and request forms. If any issues are evident, the sample reception team contacts the sender directly; any queries that cannot be resolved directly are escalated to the CC programme office in Limerick.

Once accepted for testing, samples are accessioned on the QD LIMS (Laboratory Information Management System) and assigned bar-coded accession numbers and patient identifiable information via a 2D barcode. Samples are then transported to QD Teterboro, usually via DHL air freight. On receipt in Teterboro, the samples are processed to create stained slides for cytology. The barcode on the sample is scanned and each corresponding slide is permanently etched with that sample's unique accession number and patient demographic information.

Figure 3 outlines overleaf all steps in the process flow from the woman's smear-taking process in Ireland through to the generation of Result Reports for GPs and Result Letters to women in Ireland. This process is well established for the Teterboro Laboratory. It is worth noting that there is a number of points along the process flow where information is conveyed to or from NSS electronically.

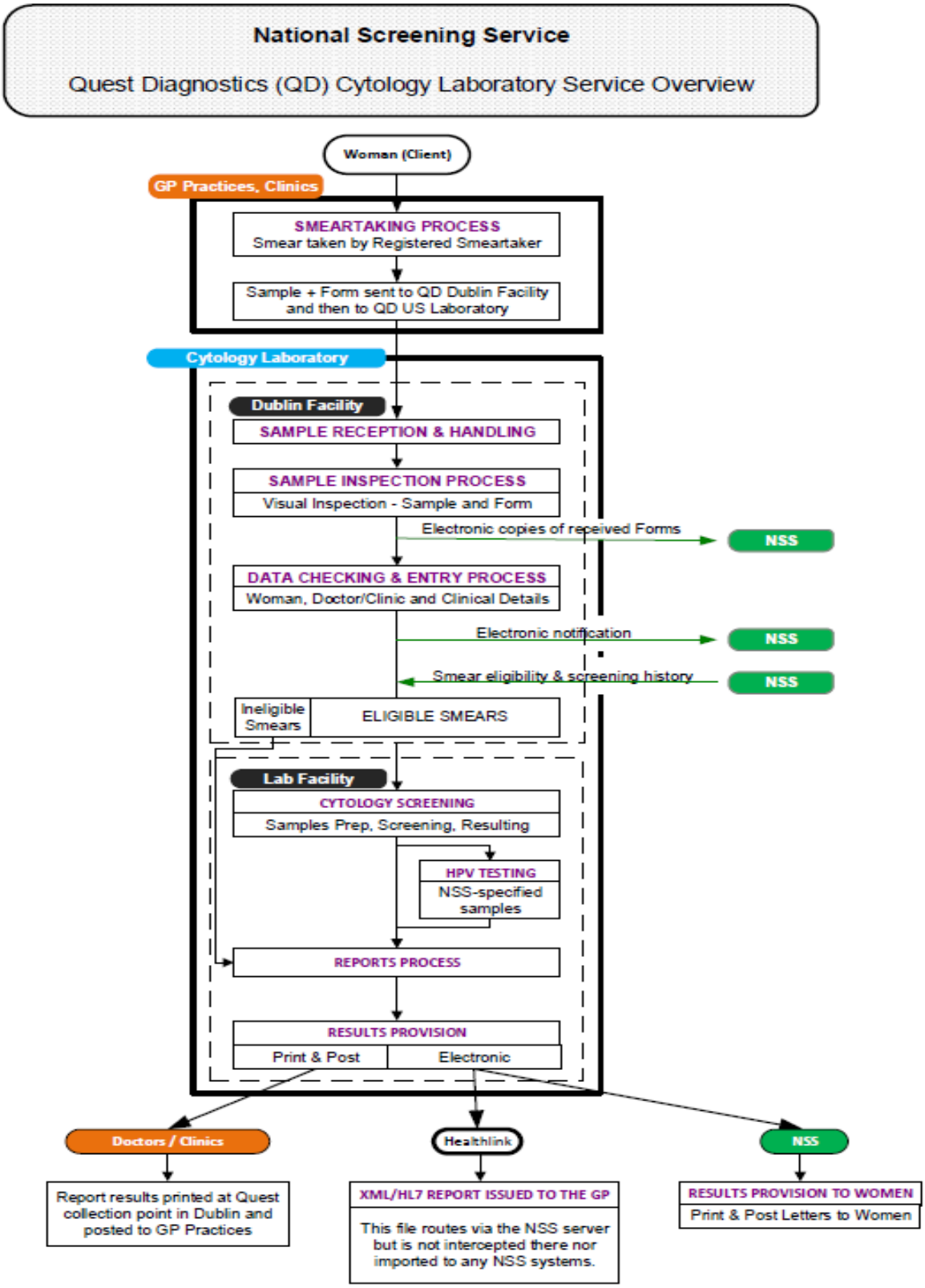

National Screening Service
Quest Diagnostics (QD) Cytology Laboratory Service Overview
Woman (Client)
GP Practices, Clinics
SMEARTAKING PROCESS
Smear taken by Registered Smeartaker
Sample + Form sent to QD Dublin Facility and then to QD US Laboratory
Cytology Laboratory
Dublin Facility
SAMPLE RECEPTION & HANDLING
SAMPLE INSPECTION PROCESS
Visual Inspection - Sample and Form
Electronic copies of received Forms
NSS
DATA CHECKING & ENTRY PROCESS
Woman, Doctor/Clinic and Clinical Details
Electronic notification
NSS
Smear eligibility & screening history
NSS
Ineligible Smears
ELIGIBLE SMEARS
Lab Facility
CYTOLOGY SCREENING
Samples Prep, Screening, Resulting
HPV TESTING
NSS-specified samples
REPORTS PROCESS
RESULTS PROVISION
Print & Post
Electronic
Doctors / Clinics
Healthlink
NSS
Report results printed at Quest collection point in Dublin and posted to GP Practices
XML/HL7 REPORT ISSUED TO THE GP
This file routes via the NSS server but is not intercepted there nor imported to any NSS systems.
RESULTS PROVISION TO WOMEN
Print & Post Letters to Women

Figure 3 – Quest Diagnostics (QD) Cytology Laboratory Service Overview

The Results Provision element of Figure 3 is particularly relevant to this review. In the case of the Teterboro Laboratory, an electronic interface exists that enables results from the QD LIMS to be passed onto the QD Reporting System (QDRS) for transfer onto the National Screening Service (NSS) Cervical Screening Register (CSR) system. This enables three outputs to be generated, two from QD and one from NSS:

1. Hard copy Result Report that is printed at a dedicated printer at the QD sample reception centre in Dublin and distributed to those GPs who opt to receive hard copy reports.
2. Electronic Results Report that is routed via the NSS server (but not imported into any NSS system) and issued to GPs who opt to receive electronic reports.
3. Letters to Women that are printed and posted at the CC programme office in Limerick.

4.4 IT Issues and their Impact

NSS made a decision to send samples ('rescue samples' and 'backlog samples') to the QD Chantilly Laboratory for the purposes of carrying out HPV DNA tests for the reasons outlined earlier in Section 4.1.

The initial focus at Chantilly was on developing a working process for HPV DNA tests on the 871 'rescue samples', i.e. those samples that had previously undergone HPV RNA (and Pap Cytology) testing at Teterboro but had been outside the manufacturer's recommended room-temperature stability period of 30 days (for RNA) at the time of measurement.

It became clear quickly that there were IT compatibility issues to be addressed between the Chantilly and Teterboro laboratories and with the NSS system.

Due to data-file incompatibility issues, the QD LIMS and the NSS CSR could 'not handle' the HPV DNA results generated at Chantilly and, consequently, the HPV DNA results did not pass onto the QD Reporting System (QDRS) for transfer onto the NSS CSR (as happens routinely for results generated solely at Teterboro – as illustrated in Section 4.3). Specifically, the challenges related primarily to sending results data in the correct format from Chantilly to Teterboro.

When this IT interface issue was addressed initially (January 2019), an automated solution was developed but was found to be ineffective. In February 2019, a manual process was proposed and explored. This required a range of 'manual workarounds' involving transfer of files (in various formats) from Chantilly to Teterboro and from Teterboro onto the NSS CSR system. This approach encountered a number of technical hurdles and delays, including difficulties associated with 'amending verbiage' linked with the data, as specified by the NSS.

On April 26th, the HPV DNA results for the rescue samples (797 at that stage) were released onto the QD LIMS system. Following this release, and reflecting the dependence on human intervention in the process, there was (according to QD) "an interdepartmental communication

breakdown and the completed results for each of the 797 Dual HPV RNA / DNA Cases ('rescue samples') were never re-queued for printing to the Ireland Special Task printer". QD has acknowledged this "human error", which resulted in women, on foot of receiving letters from CC to act accordingly, visiting their GPs to find that they had not received their respective results.

In June 2019, QD received an inquiry from the NSS asking for a report on the status of the 'rescue sample' cases. The full LIMS query identified an additional 76 Rescue Samples, bringing the total number to 873 (797 + 76). The original LIMS analysis performed in January 2019 identified 797 Rescue Samples. An additional 76 Rescue Sample tests were performed subsequent to that analysis. On July 30th, the reporting status (according to QD) of the 873 Rescue Samples was as follows:

- 797 Reports were reconciled and re-queued for printing to the dedicated Ireland Special Task Printer on July 11th, 2019.
- 71 Reports were reconciled and re-queued for printing to the dedicated Ireland Special Task Printer on July 18th, 2019.
- 5 Reports required further investigation.

Between December 2018 and July 22nd, 2019, 4,088 (including the 873 above) HPV DNA tests were performed on samples where HPV RNA tests were unsuitable due to exceptions to the manufacturer's recommended stability requirements. Many of these tests experienced significant delays, thereby giving rise to queries and concerns from GPs and women. Of the 4,088 tests, 2861 experienced delays in reporting results greater than 14 days. The source of the delays is essentially the same as outlined above for the 'rescue samples' – the absence of appropriate IT interfaces that would enable automated generation of reports (and letters) without human intervention.

A status update on the Chantilly IT issue was provided to me on August 2nd. With respect to the 3215 'backlog samples', I have been assured that the issuing of result letters to these women by the fully operational automated system will commence from Tuesday August 6th.

5. Sharon's Story

As the person whose representations to the Minister for Health, the DoH and National Screening Service (NSS), over an extended period, triggered the disclosure of information that culminated in this review, it is appropriate that a summary of Sharon's story over the past 8 months be included here. Moreover, some of Sharon's experiences highlight issues in the Cervical Screening system that inform some of the recommendations presented at the end of this report. The facts presented in this Chapter reflect Sharon's personal recollection of events and are presented in summary form.

Having been diagnosed with pre-cancer cells 10 years ago, Sharon has been attending for annual screening since then, and had been used to receiving a letter from CervicalCheck (CC) with the results of her cervical smear within about 6 weeks from the date on which the sample was taken. On December 3rd 2018, Sharon had a smear taken. As she had not received a letter from CC within the normal 4-6 week window, Sharon followed up with her GP to check if he had received the test report and was advised by him that the current waiting time for smear test results was up to 14 weeks 'due to issues over the past year'.

On March 26th, Sharon called the CC helpline to enquire about her test and was advised that her results were not available. Her query was escalated to a CC doctor, who called Sharon on April 3rd, but he was unable to tell her where her results were.

On the same day (March 26th), Sharon's sample was transferred from the Quest Diagnostics (QD) Teterboro laboratory to the QD Chantilly laboratory. The reason for the transfer was to avoid the expiration of her sample by availing of the longer stability period associated with HPV DNA testing (available at Chantilly), and to ensure that Sharon would not be requested to repeat the smear test. The test was carried out in the Chantilly laboratory on March 27th but the test result report (that is sent to GPs) was not created at this time.

On April 3rd, 17 weeks after Sharon had her smear taken, she emailed info@health.gov.ie outlining the delay in getting results back from her smear test. She went on to state that her GP had called QD and was advised that there was currently a '20 week window for negative results and up to 27-30 weeks for positive' results to be issued. In her email, Sharon also referred to her March 26th phone call to CC and the follow-on phone call from their doctor on April 3rd and that he apologised but wasn't able to say where her own tests results were. In the email she expressed her dissatisfaction and indicated her intention to bring her 'concerns to the media'.

Later that day Sharon received an email from the Private Secretary of the Minister for Health, acknowledging her email and advising that the issues raised would be examined and that she would receive a reply shortly.

When she had not received a reply within 11 days, she emailed the Minister's Office on April 14th and again on April 28th. She conveyed her frustration about the absence of the expected reply from the exchange on April 3rd and also indicated that her almost 5 month wait for her results was' totally unacceptable'.

On April 30th, Sharon received an email response from the Minister's Private Secretary. The response includes the following: "The Minister acknowledges there has been an increase in the time taken to receive cervical smear test results, and would like to apologise for any distress this has caused you and assure you that this is a priority concern for his Department and the Health Service Executive (HSE)."

The email outlined the reasons for the delay and the actions being taken by the HSE to address the capacity of laboratories to deal with these delays. The email also states that the 'HSE has advised that the natural history of cervical cancer indicates that the disease would normally develop over a period of 10 to 15 years. The HSE has advised that in this context, a delay in the return of cervical screening results, whilst undesirable, is not necessarily dangerous and poses a very low risk.'

The official outlined that the reduction of the backlog is a priority for the Minister and the HSE. However, the official stated, it is clear that it will take some time to resolve. The official emphasised that "smear tests are a screening test and not a diagnostic one" and advised consultation with a GP to address any concerns that Sharon might have.

On May 9th, Sharon emailed the Minister's Office again expressing her dissatisfaction with the response of April 30th, with particular reference to its 'insensitivity' regarding her condition. Sharon contacted the DoH again on May 16th and June 4th seeking a response to the Department's email of April 30th and expressing her growing frustration with the time delay in obtaining her results.

On June 5th, in a phone call to the DoH, Sharon was advised to contact CC directly. Sharon called CC Customer Services and was advised that the wait time for her results is 33 weeks. Sharon requested that her case be escalated.

On June 6th, Sharon received an email from the Minister's Private Secretary in which the official acknowledged the call that Sharon had with a DoH colleague the previous day. The official requested her personal details by return so that the DoH could engage directly with the NSS on her behalf.

Sharon emailed the DoH official that day, thanking the official for the reply and advising that she had contacted CC immediately after her call to the DoH the previous day. She felt the person she had spoken with in CC 'didn't care' and said she couldn't help her and that the delays were now up to 33 weeks. She again asked if someone 'who knows about her results' could contact her.

On June 7th, the DoH made contact by email with CC attaching the representations received from Sharon. The email requested CC to investigate 'these matters' and provide the DoH with an update to allow the DoH to issue a response to Sharon.

Using the personal details provided by Sharon to the DoH on June 7th, CC contacted QD to request an update report on Sharon.

On June 17th, Sharon's sample was resulted and the report was sent to her GP. On June 25th, CC confirmed to the DoH that Sharon's test was processed and that the result was with her GP on June 17th. They confirmed that, 'due to an IT issue', Sharon had not received a letter from CC, which would have been the normal process. The letter stated that CC was addressing the issue with the laboratory in question and that they were writing to 'all women who have been affected'. As explained earlier in this report, the follow up queries to that issue revealed the unsent results for approximately 800 women and the fact that results letters were not being sent to women in the normal manner. That information ultimately triggered the establishment of this review. It turned out that Sharon was not part of the cohort of 800 women; hers was one of the samples sent to Chantilly to avoid the expiry problem described earlier.

On June 26th, the CC doctor called Sharon with her results, to advise her of the IT issue and to inform her that her results were with her GP. When Sharon asked why she had not received the standard CC letter, she was told that there was an 'IT issue'. On June 27th, Sharon received a phone call from her GP, who subsequently shared with her a copy of her Laboratory report. Sharon texted the CC doctor asking him to escalate the issue as her GP had no idea that letters 'were not being sent to women'.

During the following two weeks, the DoH continued to follow up with CC in relation to this query and were advised that CC were preparing a report for submission to them.

On July 8th, Sharon phoned the DoH and raised a number of issues with the official whom she spoke with, including the delay in receiving her results, the non-issuing of letters to women, and the 'rude' encounter with a staff member on the CC help-line. The DoH official confirmed that the Department was still awaiting a report from the HSE arising from Sharon's queries. The DoH official committed they would follow up and phone Sharon with an update on Tuesday July 9th.

That afternoon the DoH sought urgent follow up from CC on the report requested, particularly in terms of impact, and the resolution of the issue. The DoH official asked for the report to be prioritised as a matter of urgency.

Later on July 8th, Sharon emailed Fergal Bowers, RTE news correspondent, to advise him of the issues she had raised with the DoH.

On July 9th, CC emailed the DoH to advise that the report was awaiting sign off by the NSS Head of Screening. The DoH responded requesting a copy of the report as they wished to call Sharon later that day.

Strongly disputed versions of developments between July 9th and July 10th were provided to me (by Sharon and the relevant DoH official). I make no judgement on the veracity of either. Sharon's version is provided here and the version of the DoH official is provided in a separate section at the end of this chapter.

According to Sharon, at approximately 5.30pm on July 9th, she received a phone call from a DoH official who confirmed to her that "the HSE report was back today and is on the Department Head's desk awaiting sign-off". Sharon then asked the official if the Minister (for Health) was aware of the content of the report, to which, according to Sharon, the official replied: "Yes, he's fully briefed on that." In the same call, the DoH official also asked if they could share details of the report when signed off and agreed to talk again by the end of the week (July 12th). Sharon is still awaiting a reply from the DoH regarding her last email.

On the morning of July 10th, Fergal Bowers made enquiries to CC and the DoH in relation to both the IT issue and the delayed results.

On July 10th, at 12:54, CC sent a briefing document ('the report') to the DoH, as had been requested.

On the evening of July 10th, Sharon received a phone call from the CC doctor to ask if she was ok and to advise that he was going on holiday. With that in mind, he gave her the personal e-mail of the NSS Head of Screening so that she could use this if she had any issues while he was away.

On July 11th, the story broke on RTE News at 6pm.

On July 26th, Sharon received a letter from CC. The letter did not note any abnormalities and recommended a 3-year recall and annual check-ups.

In conclusion, when I asked Sharon to summarise the overall situation, she replied as follows:

"There is an absence of customer service from CervicalCheck. If I had been treated with respect, this may not have evolved like this. And also, if the DoH had responded to my email of April 3rd, things would have been discovered earlier".

Response from DoH Officials

Sharon's account of the 5:30pm phone call on July 9th is disputed strongly by the DoH official involved. The DoH official advised me that "It is likely that I told her about the current status of the report and that it was with the Head of the NSS (National Screening Service) for sign off".

This latter statement regarding the sign-off is backed up by email evidence from the HSE at 9.17am on July 9th which stated that the report was currently with the Head of Screening in the NSS for sign-off. The DoH has also provided an electronic summary of the July 9th conversation which states that Sharon was informed that a report was awaited from the HSE on the detail of the issues raised and that the official would continue to follow up with them. In my conversation with another DoH official, she commented on the above: "No report from the HSE would ever go to the Department Head for sign off. In any event, we don't use that terminology".

Regarding the portion of the conversation about the engagement of the Minister of Health, the DoH official remembers it like this: Sharon asked whether the Minister gets involved in CervicalCheck issues, delays etc. and whether he cares. I responded: "All issues relating to CervicalCheck are a priority for the Minister. He receives detailed reports and frequent briefings on issues related to CervicalCheck". Documents provided by the DoH clearly show that the briefing on the report was not submitted to the Minister until July 10th.

6. Analysis and Conclusions

6.1 Communications with Women and GPs

The decision to proceed with the addition of a new Laboratory into the CervicalCheck (CC) programme, however well motivated, without first testing and validating that it could be seamlessly integrated into well-established operating processes led to a number of significant impacts on the primary stakeholders of the programme:

- Significant delays in issuing Results Reports (see, for example, the case of Sharon in Chapter 5)
- The non-issuing of results letters to women (the exception is the 55 women in the 'rescue sample' group; these letters were issued manually)
- The non-issuing of approximately 800 Results Reports to GPs through human error (this error was corrected subsequently)
- Potential confusion with GPs regarding their responsibility in contacting their patients

Communications with Women and GPs are treated separately below.

(a) Communications with Women

In the normal course of events, when a woman's cervical screening test is processed, she receives a Results Letter from the CC programme. Depending on the result of the test, this letter either outlines that no abnormalities have been found and recommends further routine screening or it advises the woman to contact her GP for results. This standard process became a casualty of the IT issues associated with the Chantilly Laboratory.

The decision not to issue letters to women via manual intervention, lay in the fact that there was a broad range of possible letter types (across the 'rescue' and 'backlog' samples) that could issue to women. The letter type was dependent on the outcome of a woman's test results. Therefore, the only way to match the test results to the correct letter category was by use of a manual workaround. There was an added risk that the wrong letter type might be sent to women, e.g. telling a woman that no further action was required when she may have needed referral for further treatment. On the basis of assessment of risk, it was therefore decided not to send the letters to women. While this may have been a good decision from a risk perspective, this decision was not communicated to women who were still expecting to receive such letters.

The full range of letters sent by CC to women over the period covered by this review is shown in Table 1 below.

Table 1: Letters issued by CervicalCheck to women

Letters issued by CervicalCheck to Women	
Letter Date	**Code**
31 January 2019	Letter A
31 January 2019	Letter B1
31 January 2019	Letter B2
31 January 2019	Letter C
31 January 2019	Cp Letter
4 February 2019	Letter A (additional)
4 February 2019	Letter B2 (additional)
4 February 2019	Letter C (additional)
4 February 2019	Letter D
8 February 2019	Letter E
8 February 2019	Letter F
1 July 2019	Letter D1

Copies of these letters can be found in Appendix 2.

Between January 31st and February 8th (inclusive), the CC Clinical Director and National Screening Service (NSS) Director of Public Health wrote to categories of women affected by the Expiration issue, explaining, for each category, the next steps to take, if any. Examples of the information and guidance given can be seen by browsing the letters in Appendix 2. The category labels used in Table 1 are explained in detail in Appendix 3. For example, Category D represents women whose samples became the 'rescue samples'. CC focused on this cohort in the first instance as they had 'no visibility of numbers coming through in other categories'.

It is worth noting that, when tested using the HPV DNA test in Chantilly, 55 samples in Category D that had previously yielded a negative result now produced a positive result. CC wrote to the relevant GPs/smear-takers on Feb 13th (see Table 2 below) and a manually-created notification outlining the change of result was issued by QD directly to the GPs/smear-takers. CC has established that all such women have been referred onwards to Colposcopy clinics, as appropriate. On July 1st, a letter was issued to all women in Category D to inform them that the respective GP/smear-taker had received the results of the re-test and to contact their doctor / nurse.

Apart from the Category D cases (871) outlined above, it is important to highlight that **no communication** was issued by CC to women from February 8th until the end of July 2019. 4088 samples were sent to Chantilly for HPV DNA testing from December 2018 to July 22nd 2019.

(b) Communications with GPs

The full range of letters sent by CC to GPs over the period covered by this review is shown in Table 2 below.

Table 2: Letters issued by CC to GPs

Letters issued by CervicalCheck to GPs	
Doc No.	**Letter Date**
GP 1	24 January 2019
GP 2	31 January 2019
GP 3	13 February 2019
GP 4	16 April 2019

Copies of these letters can be found in Appendix 4 and their general content is summarised below.

GP1: January 24th 2019

CC Clinical Director wrote to all GPs informing them of the Expiration issue that had arisen in relation to a number of HPV tests carried out on samples between 2015 and 2018 and that up to 6,000 women would likely be called for a repeat smear test.

GP2: January 31st 2019

CC Clinical Director and NSS Director of Public Health wrote to all GPs enclosing a copy of the letter of January 24th. In this letter they reiterate the advice previously provided and advise GPs of the actions taken and required.

GP3: February 13th 2019

CC Clinical Director and NSS Director of Public Health wrote to relevant GPs in relation to women whose rescue sample changed status from negative to positive on re-testing. It attached details of the relevant patient test result (manually generated).

GP4: April 16th 2019

CC Clinical Director (newly appointed) sent a briefing letter to all GPs with an update on a broad range of issues relating to the National Cervical Screening Programme. The ICT systems are referenced as being a source of delays. The letter also highlights that paper results are being issued to healthcare professionals and that results letters are not being issued to women.

The GP4 letter is significant for the following reason. In the body of a 4-page overview letter covering 13 topics, topic #9 addressed the ongoing IT issues and this section is reproduced below:

> ***9. ICT issues***
>
> *In order to facilitate HPV DNA testing, another Quest Diagnostics facility in the USA is being used, however we are experiencing some ICT issues that has resulted in the laboratory being unable to send electronic results to the cervical screening register. As an interim measure, paper results are issued to healthcare professionals. Result letters are not being issued to women, nor is the facilitated referral form issuing for refer to colposcopy recommendation. A copy of this referral form is available on the CervicalCheck website: www.hse.ie/cervicalcheck/colposcopyreferralform/*
>
> *Please print a copy from the website, complete and refer to as usual to colposcopy without delay.*

While there is a responsibility on all professionals to read communications carefully, one has to question the wisdom of including such a key piece of information (of importance to both women and GPs) in a manner such as this where it might be easy to miss. It is clear from Sharon's story (Chapter 5), for example, that her GP was unaware of this information.

So, although GPs were notified of this change from normal practice arising from the Chantilly IT issues, it may still have resulted in negative impact if GPs did not take particular notice of that section in the GP4 letter. In cases, as GPs normally expect contact from the woman, there is a risk that a GP might not contact the woman with her result. In such cases, women may not have been made aware of their negative results.

Finally, to deal with the issue of delays, CC has informed me that, of the 4088 HPV DNA tests processed at Chantilly between December 2018 and July 22nd 2019, 3215 experienced delays in issuing reports of six weeks or more.

6.2 Risk and Incident Management

The HSE's **Integrated Risk Management Policy** requires services to proactively identify risks that threaten the achievement of objectives and to put in place actions to reduce these to an acceptable level. The HSE's **Incident Management Framework** (IMF) provides an overarching approach for the management of incidents, which are events that have happened and caused, or could have caused, harm.

When Quest Diagnostics (QD) was given approval to conduct HPV DNA testing at its Chantilly Laboratory, it was specified by CC that permission would be granted on the basis that the

samples were within the 6 month stability period for DNA testing, the Chantilly Laboratory would meet the tenets of the current contract, and that the HPV DNA results "can be transmitted back to CC using the existing electronic methodology".

As the electronic transmission of results was critical to the automated process, it was essential that this was in place, hence its inclusion in the granting conditions. The electronic transmission of results does not appear to have been verified by CC in advance of commencement of testing and delivery of samples to Chantilly. From a risk management perspective, there was no evidence of assurance being provided for such a critical process. In any event, it should have been verified in advance by testing. Without such testing, the risk of failure of report generation and letter generation was not identified at this time.

When it was identified that Result Reports were not being issued on an automated basis, a risk analysis should have been conducted. The outcome of the impact analysis is likely to have identified the impact of this risk, if it materialised, as major[1]. The basis for this impact assessment lay in the critical nature of the automated process for the issuing of Result Reports and Result Letters. The automation of this process (as is well established in Teterboro) was essential for the issuing of Result Reports to GPs and the issuing of Result Letters to women. The absence of an automated process therefore threatened the continuity of the business of CC.

The seriousness of this risk appears not to have been fully appreciated by senior managers in the NSS and consequently a formal risk assessment was not carried out.

When the IT incompatibility problems became apparent, the solution that was chosen at this time relied on putting in place a manual workaround as an interim measure while work continued on the development of the required interface. This was proposed on February 13th. This manual workaround would allow the issuing of Result Reports to GPs but not the issuing of Result Letters to women. There is no evidence that alternative strategies, up to and including the pausing of the cervical screening programme, were actively considered before opting for the manual workaround. The availability of a formal risk assessment would have assisted decision making.

From a risk perspective, manual workarounds are highly error prone and this was flagged in the SIMT (Expiration Issue) on February 13th. Manual workarounds should only be used as a short term solution and require very careful monitoring from a quality assurance perspective to avoid errors occurring. From an IT perspective, the average development and testing time for interfaces of this type should have been identified and agreed. This work has taken 8 months to date. If the expected development, testing and validation time had been estimated even reasonably accurately, the decision to use a manual workaround for such a long period of time is likely to have been questioned, given that the risk of an error occurring would increase with time (as

[1] Sustained loss of a service which has serious impact on the delivery of service user care or service, resulting in major contingency plans being involved (Ref. HSE Impact Table)

happened ultimately with the non-issuing of approximately 800 GP Reports through 'human error').

Having taken this decision, it was agreed to issue results to GPs only. The decision not to issue letters to women lay in the fact that there was a broad range of possible letter types that could issue to women. The letter type was dependent on the outcome of a woman's test results. Therefore, the only way to match the test results to the correct letter category was by use of another manual workaround. There was an added risk that the wrong letter type might be sent to women, e.g. telling a woman that no further action was required when she may have needed referral for further treatment. It was therefore decided that it was too risky to send the letters to women and a decision was taken not to do so. While this seems like a good decision from a risk perspective, this was not communicated to women who were still expecting to receive such letters (this issue is dealt with in more detail in section 6.1).

The SIMT (Expiration Issue) was stepped down on April 15th and remaining actions were transferred to operational management for completion. The stepping down of the SIMT which included the IT issues in its agenda, at this time shows that there was not a full appreciation of the potential risk associated with the manual workarounds. The NSS Risk Register was also reviewed and, to date, no risk relating to this issue has appeared on the register.

The impact of risk became apparent to CC towards the middle of June when it was identified in CC that there was significant concern conveyed from GP practices in relation to not receiving results from Chantilly. What was previously a risk (the potential for something to happen) had become an incident at this point (something that has actually happened). As the impact of this incident at this point was some disruption in service with an unacceptable impact on service user care, this incident should have been reported and categorised as Category 2 incident (moderate), for example. There is no evidence that this incident was reported on NIMS (the National Incident Management System), which is a requirement of the IMF. In response to the concerns raised from GP practices, CC contacted QD to enquire about the reason for this delay. In the week of July 8th, it became apparent that approximately 800 results had not issued to GPs. This information should have led to a re-categorisation of the incident from a Category 2 to a Category 1 incident (serious). The IMF requires Category 1 incidents to be notified to the Senior Accountable Officer within 24 hours, who in turn is required to establish a SIMT within 5 working days of that notification. The Deputy Programme Manager, who was the Senior Accountable Officer, was notified at this time and the SIMT was established on July 15th 2019 by the NSS. There is no evidence that this second incident was reported on NIMS (the National Incident Management System)

The role of the SIMT is to gain assurance in relation to the immediate actions taken in relation to the incident, the provision of support to anyone affected, to minimise the risk of harm to others and to plan actions required on foot of the incident. The draft minutes of the first SIMT (Non-

issuing of reports) meeting held on July 15th 2019 does not indicate a full appreciation of these issues.

6.3 Awareness of Problem

Analysis of the risk situation in the Chantilly context points to two key issues that were milestones along the path to system failure:

- IT issues were delaying the issuing of Results Reports to GPs, and
- 'manual workarounds' were being used to generate result reports.

As part of this review, both issues were considered in terms of the 'earliest awareness' along the chain of command from within CervicalCheck to the HSE CEO and from the HSE CEO to the Minister for Health.

The full analysis of 'earliest awareness' for both issues is shown in Table 3.

Table 3: Awareness that IT issues were delaying the issuing of results

Awareness that IT issues were delaying the issuing of results			
Person	**Nature of Information**	**Means**	**Earliest Date**
Minister for Health	On March 29th 2019, in the HSE's weekly briefing[1] to the Minster in relation the HPV expiration issue, there is evidence that the HSE had informed the Minister that there was "an initial delay in the establishment of the ICT system for dealing with these requests [for results] and that "there was a delay of 4-6 weeks for the issuing of results." [1] This Ministerial Briefing is sent each week from the DG/CEO to the Department of Health.	Ministerial Briefing	March 29th 2019
Secretary General DoH	On March 29th 2019, in the HSE's weekly briefing to the Minster in relation the HPV expiration issue, there is evidence that the HSE had informed the Minister that there was "an initial delay in the establishment of the ICT system for dealing with these requests [for results] and that "there was a delay of 4-6 weeks for the issuing of results."	Ministerial Briefing	March 29th 2019
HSE Director General (Acting)	On March 29th 2019, in the HSE's weekly briefing to the Minster in relation the HPV expiration issue, there is evidence that the HSE had informed the Minister that there was "an initial delay in the establishment of the ICT system for dealing with these requests [for results] and that "there was a delay of 4-6 weeks for the issuing of results." This means that the Acting DG was aware of the IT issue during the week of March 25th 2019	Ministerial Briefing	Week of March 25th – 29th 2019
National Director NSS	After each SIMT (Expiration) meeting it was the practice to email the minutes of the meeting to the members of the SIMT and copy a number of people. February 14th 2019 the ND NSS was copied on the minutes of the SIMT (Expiration) meeting of 14th February. Evidence of direct knowledge	SIMT Expiration Meeting Minutes	February 14th 2019

	The IT issue was again raised at a meeting on 01/03/2019 with Quest and NSS (Damien Mc Callion/Prof John O Leary/Dave Nuttal/Maeve Waldron/Sean Bresnan/ Grainne Gleeson in attendance) in relation to increasing Quest share of Ire workload: "MW & BD: prior to any go live it is essential that IT issues are addressed for current laboratories (Chantilly) and in place and tested for any additional laboratories, needs to be included in proposal docs".		March 1st 2019
Head of Screening, NSS	Minutes of the SIMT (Expiration) meeting January 31st 2019, make reference to 'it still is an ops challenge to manage the receipt of HPV only at this point. (from an ICT perspective)' (C022) Minutes of the SIMT (Expiration) meeting February 13th 2019, note that 'The approx...800 retests for this group will be manually changed by Joe in QD (timing: asap/ starting today), Risk for error flagged during the SIMT [Expiration] here as this is being done manually.' This is the first time that there is evidence that the SIMT (Expiration) were aware that the impact of the IT issue was resulting in difficulty in issuing results automatically and a manual workaround was required. This demonstrates that there was an awareness of the existence of an IT issue in January 2019	SIMT Expiration Meetings	31st January 2019 13th February 2019
CervicalCheck Programme Manager, NSS	In the email exchange between Quest and a senior member of CervicalCheck on the January 14th 2019 there is evidence that Quest are querying if CC can see result files for a number of accessions [unique patient numbers] that they have transmitted to CC. It is confirmed that these results are not available on the register. When asked more specifically about which of two interfaces CC were using to view the results, a staff member in Quest, who is copied on the email confirms that NSS does not use the second of these interfaces.	Email exchange between Quest and CervicalCheck	January 14th - 31st 2019

Table 4: Awareness that 'Manual Workarounds' were being used to generate result reports

Awareness that 'Manual Workarounds' were being used to generate result reports			
Person	**Nature of Information**	**Means**	**Earliest Date**
Minister for Health	As the briefing cited below was part of the daily briefing that the Minister receives, it can be deduced that the first knowledge the Minister had of this issue was on July 10th 2019.	Daily Briefing Minister's office to the Minster for Health	July 10th 2019
Secretary General DoH	A briefing to the Minister, prepared on July 10th 2019 by the Minister's Office, evidences that the Secretary General reviewed this document prior to the document being submitted to the Minister. The document referenced the report of July 10th 2019 received from the NSS by the Acute Hospitals Division of the DoH. This briefing contained the following sentence 'As these [the reports] could not be completed in time, letters were to issue manually. It appears this did not happen, or that letters issued to GPs but not to women.'	Daily Briefing Minister's office to the Minster for Health	July 10th 2019
Acute Hospitals Policy Unit DoH	To assist the DoH in responding to a representation made by Sharon to the DoH, CervicalCheck sent a letter to the DoH on June 25th. This letter made reference to CervicalCheck 'writing to all who have been affected' by an IT issue in a laboratory resulting in the delay in Sharon being issued her result letter. As a consequence, the DoH requested CervicalCheck to prepare a report for them on the matter. This report, received by the DoH on July 10th, stated: "…that while the IT issue has been on-going, the Chantilly laboratory has been issuing report of results to GPs manually, in hard copy format, in order to provide women with results." This was the first time DoH was aware of the manual issuing of result reports.	Letter CC to DoH	July 10th 2019
Chair of Board of HSE	No knowledge that manual workarounds were being used to generate results reports up to July 11th.	N/A	N/A
HSE Chief Executive Officer	No knowledge that manual workarounds were being used to generate results reports up to July 11th.	N/A	N/A

HSE Acting Director General	No evidence could be identified to demonstrate that the Former DG was aware of the use of manual workarounds.	N/A	N/A
National Director NSS	The minutes of the SIMT (Expiration) meeting February 13th 2019 show that the Interim National Director of the NSS was present at this meeting.	Minutes of the SIMT (Expiration) meeting 13th February 2019	February 13th 2019
Head of Screening, NSS	After each SIMT (Expiration) meeting it was the practice to email the minutes of the meeting to the members of the SIMT and copy a number of people. Though the Interim Head of Screening was a member of the SIMT (Expiration), she is noted as having sent her apologies on this day. It was practice to send the minutes of the meeting to all members. These minutes were copied to her the following day. This demonstrates that the Head of Screening was made aware of the existence of the use of a manual workaround to deal with the issuing of results.	Email to members of the SIMT sent 14th February 2019 @09:26	February 14th 2019
CervicalCheck Programme Manager, NSS	The minutes of the SIMT (Expiration) meeting February 13th 2019 state under Item 3 **3. IT Issue** a. The approx. 800 retests for this group will be manually changed by Joe in QD (timing: asap/ starting today), Risk for error flagged during the SIMT here as this is being done manually. The CervicalCheck Programme Manager is listed as attending on the minutes of this meeting.	Minutes of the SIMT (Expiration) meeting February 13th 2019	February 13th 2019

In relation to IT problems delaying the issuing of results, this was first identified on January 14th 2019 when CC identified that there was a problem with the IT interfaces between the QD and CC. This was known to both the Head of Screening and the National Director NSS by February 14th 2019. In an effort to ensure that the development time for the IT interface would not affect the issuing of results, it was decided to put in place a manual workaround. The use of manual workarounds and the risk that was identified in relation to their use (referred to in Section 6.2) should have triggered an immediate escalation to the HSE's Director General and if deemed necessary, onwards to the Department of Health and the Minister.

As Table 4 shows, there is no evidence of escalation of the manual workaround issues to the DG/CEO of the HSE.

6.4 Clinical Implications of HPV Testing of CervicalCheck samples at Quest Diagnostics Laboratory, Chantilly*

The primary emphasis of any cervical screening programme is clearly to reduce the incidence and mortality related to cervical cancer. However, any population-based screening programme also has an ethical obligation to minimise over-investigation and unnecessary treatment. In the context of this particular episode, HPV testing was used to triage low-grade cytological abnormalities identified on smear tests. HPV can be detected using DNA or RNA tests, which have different levels of sensitivity; hence it is predictable that two different tests would produce some discordant results. Overall the clinical risk associated with these discordant results is likely to have been extremely low.

HPV triage was introduced in an attempt to reduce over-investigation and over-treatment of low-grade abnormalities which are highly likely to regress spontaneously over time and have an extremely low risk of progressing to cervical cancer, particularly in women partaking in a national screening programme. Women with HPV-negative, low-grade abnormalities return to routine screening, while those with HPV-positive abnormality are referred to colposcopy. These would be considered low-risk referrals compared to women with a high-grade cytological abnormality, which are currently not subjected to HPV testing, and require urgent colposcopy appointment.

The delays in reporting HPV tests will obviously have delayed referral to colposcopy of women with HPV-positive, low grade abnormalities. However the overall clinical risk in this cohort is low compared to the delays in identifying high-grade abnormalities caused by the backlog of smear tests generated over the last year.

Notwithstanding the obvious issues surrounding delayed communication of results, there are unlikely to have been any clinical consequences for women with discordant HPV DNA and RNA results. To provide a complete assessment of the clinical risk to which these women were exposed, it would be necessary to perform an audit of their findings at colposcopy. This would not be considered necessary in the vast majority of international screening programs, where audits are focused on high grade abnormalities and interval cancers. This episode does highlight that even automated assays such as HPV DNA and RNA testing will not be 100% effective and will have inherent false negative and false positive rates, which are lower than cervical cytology alone.

*This commentary was provided by:

Donal Brennan
UCD Professor of Gynaecological Oncology
Mater Hospital

7. Major Findings and General Observations

7.1 Major Findings

A. In the period from December 2018 to July 22, 2019, 4088 CervicalCheck samples were sent to the Quest Diagnostics (QD) Chantilly Laboratory for HPV DNA testing. These comprised 873 'rescue samples' (thereby avoiding women having to take a repeat test) and 3215 backlog samples and those risking expiry for HPV RNA testing. A key feature across almost all samples was the delayed reporting of results.

B. The addition of the QD Chantilly Laboratory as a CervicalCheck (CC) Test facility took place without proper operational due diligence, risk assessment of the downstream implementation and, therefore, risk mitigation. However well motivated, and although taken in the context of a major backlog of samples, the decision to proceed with Chantilly without first testing and validating that it could be seamlessly integrated into well-established operating processes led to system failure with consequent impact on women and GPs. The early introduction of 'manual workarounds' should have triggered serious concerns, proactive risk management and escalation. There was a gross underestimation of the scale and implications of the problem.

C. When a system that is designed to be fully automated relies on a range of manual interventions over an extended period of time, system failure is almost inevitable. The primary casualty here was communications with the primary stakeholders (women and GPs), with the breakdown in automated Results Report generation for GPs and automated Results Letter generation for women. While manual intervention for generating Results Reports worked for most of the time, there was a significant failure when a batch of approximately 800 results reports was not transmitted for printing and delivery in Ireland, due to human error.

D. Throughout this review there was a constant theme of women frustrated by poor service and lack of information, their information! This was most evident in the decision not to communicate with women, whose samples were in Chantilly, about the IT problems and its implications for a full six months in 2019. Moreover, my engagement with this review caused me to discover multiple examples of women (in person, via social media, Parliamentary Questions etc.) frustrated not only by delays in receiving their results but more so by the lack of any clarifying or contextual information. Sharon's story in this report exemplifies such experiences.

E. Within CC, there are too few people managing too many significant projects simultaneously: e.g. high-risk contract negotiations (especially in the context of a single out-sourced laboratory carrying out 90% of Ireland's cervical screening tests),

preparations for the roll-out of HPV Primary Screening, the RCOG process, the Expiry problem and backlog reduction. Senior staff in the National Screening Service (NSS) and CC have essentially been dealing with rolling crises over the period encompassed by this review. It is very difficult, if not impossible, to effect operational best practice in that context, especially when human resources are very stretched and below optimal capacity.

7.2 General Observations

A. There is an absence of clear lines of authority and clarity of role responsibilities within CC.
B. The almost total reliance on a single, outsourced, international supplier of laboratory services for CC is a source of significant fragility for the programme.
C. At all times throughout this review, I encountered highly engaged and committed CC staff who were most helpful and provided any information or clarification that I required.
D. The culture of engagement between patient representatives and the Department of Health is not positive.

8. Recommendations

1. The HSE needs to move quickly to ensure that CervicalCheck (CC) becomes a well-structured, strongly-led organisation with good management practice and an active culture of risk management.

2. A strengthened CC needs to adopt a **'Women First'** approach as a matter of priority. This initiative will have a primary focus on the continuous flow of information to women, customer relationship management and trust-building measures. The feasibility of sample tracking at every stage of the process from woman to result should be pursued actively. Human resource needs to be dedicated solely to this 'Women First' approach.

3. The HSE needs to ensure that QD delivers on its commitment to appoint a 'Dedicated Project Manager' for Ireland. A matching Programme Manager at CC needs to be appointed as a matter of urgency. (This position is currently vacant).

4. All recruitment for a strengthened CC needs to be given the highest priority and facilitated with an accelerated process.

5. In order to ensure the efficient implementation of these recommendations, it would be prudent to integrate them into the remit of the existing Oversight Group for Scally Report Implementation.

6. Although the clinical risk is deemed to be low for the patients in the cohort covered by this review (see section 6.4), for complete assurance more detailed evaluation of the referred history and subsequent findings should be carried out for this cohort.

7. The HSE, with the support of Government, needs to accelerate progress towards the establishment of a National Laboratory for Cervical Testing, encompassing state of the art informatics, analytics and sample / result tracking. This will remove Ireland's current high risk dependence on a single outsourced supplier.

8. The issue of recognising the important role of patient representatives should be addressed with a view to placing it on a more stable footing and enhancing relationships with all relevant elements of the healthcare system.

9. The HSE should appoint an International Advisory Group for CC to ensure that it is adopting and implementing best international practice

Appendix 1

Information on HPV Testing

Information on HPV Testing

What is a HPV test?

Active HPV infection is a risk factor for cervical cancer. A high percentage of the population will come into contact with HPV virus during their lifetime. For most people, as with other viral infections, their immune system will clear it and they will have no consequence from it. However, the presence of the HPV virus over a number of years can cause cell changes on the cervix which can, over a number of years, if untreated, lead to the development of cervical cancer.

HPV testing detects genetic fragments from the HPV virus. For DNA HPV tests it is the DNA material and for RNA HPV tests it is the RNA. Genetic material can be present for a while after an infection has resolved. The DNA tests can pick up evidence of active or resolved infection, whereas RNA picks up active infection only. Therefore, DNA has more positive tests than RNA but some of those positive tests are for resolved infections that do not affect a woman's risk of developing cancer.

About the use of Human PapillomaVirus (HPV) testing in CervicalCheck

Approximately 15 in every 1,000 of all tests processed by CervicalCheck every year present changes in the cells of the cervix. These range from low to higher grade changes. HPV testing has been a part of CervicalCheck protocols since 2015 for smears showing low-grade abnormalities. The HPV allow risk stratification of the sample and allows a more tailored recommendation. Negative smears do not require HPV. The protocol for anything more serious than 'low-grade' is referral to colposcopy so HPV testing does not change the decision making on the screening sample.

Appendix 2

Letters sent by CervicalCheck to women

Letter A – Issued January 31st 2019

31 January 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck screening test (smear test) which you had on the above date(s).

The results of your test were that low-grade (minor) changes were found in the cells of your cervix.

When these changes are found, the lab also tests the smear test sample for the human papillomavirus (HPV). HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life. HPV infections usually clear without treatment. Some types of HPV can cause changes to develop in the cells of the cervix. The result of your HPV test recommended that you be referred to colposcopy for further investigation.

It is recommended that HPV testing is carried out within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe.

We are confident that the test result is accurate. The recommendation you were given to attend colposcopy was correct and we are satisfied that the advice and care you were given at the time was correct.

You do not need to take any further action.

Keeping you informed

You do not need to do anything in relation to this test. We are writing to you to ensure that you are fully aware of this issue which has come to our attention with one of the labs that we use.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

We would like to offer you our sincere apologies for what has happened and for any concern this may cause you. We assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely

Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Letter B1 – Issued January 31st 2019

31 January 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck screening test (smear test) which you had on the above date(s). The result of this test was that low-grade (minor) changes were found in the cells of your cervix. Low-grade changes are quite common and most will clear up on their own.

When these changes are found, the lab also tests the smear test sample for the human papillomavirus (HPV). HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life. HPV infections usually clear without treatment. Some types of HPV can cause changes to develop in the cells of the cervix. Your test showed that HPV was not detected. The result of your HPV test in addition to the detection of low grade changes recommended that you be invited for routine screening.

It is recommended that HPV testing is carried out within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe.

We would like to reassure you that your HPV test result is almost certainly accurate but as a precaution, we recommend that you have a repeat screening test.

What should you do next?

Please contact your GP or smear taker as soon as is convenient and make an appointment for a free screening test. We have written to your GP/smear taker to inform them that this has happened. We have provided them with information to assist with questions you may have. You can also find more information at www.hse.ie/cervicalcheck

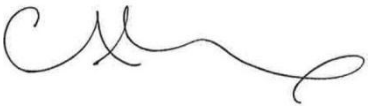
Please take this letter and the attached yellow insert with you to your appointment. This will help us to make sure that your test is processed as a priority. We expect to issue your results as a matter of priority after your GP or smear taker sends the sample.

Please note that a repeat smear test can only be carried out three months after your last smear test.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

We would like to offer you our sincere apologies for what has happened and for any inconvenience that this may cause for you. I assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely



Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Priority Sample

Cytology & HPV

Please include this insert with the cervical screening form and sample when dispatching to the laboratory to ensure priority processing

Re: **Name:** [Title] [Forename] [Surname] **CSP ID:** [CSPID] **Category:** [Category]
Address: [Address 1], [Address 2], [Address 3], [Address 4], [Address 5]

Dear Doctor

Quest Diagnostics has advised us of an issue in relation to a number of HPV reflex tests that were carried out outside of the manufacturer's recommended timeframe of 30 days.

It is important to highlight that there is no issue with the processing of the cytology slides. A number of HPV tests carried out on smear test samples, which reported low-grade abnormalities at cytology during the period 2015 to 2018, were done so outside of the manufacturer's guidelines.

Our clinical management team is assured that these HPV tests are likely to remain effective outside the manufacturer's recommended timeframe and that the risk of erroneous results is low. However, as a precaution and to ensure patients' management recommendations remain appropriate, we will be inviting some women to attend for a repeat smear test.

We have written to all women affected to inform them of this issue.

The above named patient has been offered an opportunity to attend for a repeat cytology and HPV test. This test should be taken in the usual way and **dispatched within 5 days of test date**, as per CervicalCheck quality assurance guidelines, along with this **paper insert** so that the laboratory can identify this patient's sample for priority processing.

Please highlight on the transport box that a priority sample is enclosed.

GP payment will be processed as normal.

Letter B2 – Issued January 31st 2019

31 January 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck screening test (smear test) which you had on the above date(s). The result of this test was that low-grade (minor) changes were found in the cells of your cervix. Low-grade changes are quite common and most will clear up on their own.

When these changes are found, the lab also tests the smear test sample for the human papillomavirus (HPV). HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life. HPV infections usually clear without treatment. Some types of HPV can cause changes to develop in the cells of the cervix. Your test showed that HPV was not detected. The result of your HPV test in addition to the detection of low grade changes recommended that you be invited for routine screening.

It is recommended that HPV testing is carried out within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe.

We would like to reassure you that your HPV test result is almost certainly accurate but as a precaution, we recommend that you have a repeat screening test.

What should you do next?

Please contact your GP or smear taker as soon as is convenient and make an appointment for a free screening test. We have written to your GP/smear taker to inform them that this has happened. We have provided them with information to assist with questions you may have. You can also find more information at www.hse.ie/cervicalcheck

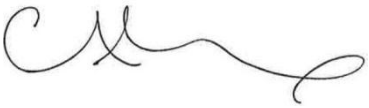
Please take this letter and the attached yellow insert with you to your appointment. This will help us to make sure that your test is processed as a priority. We expect to issue your results as a matter of priority after your GP or smear taker sends the sample.

Please note that a repeat smear test can only be carried out three months after your last smear test.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

We would like to offer you our sincere apologies for what has happened and for any inconvenience that this may cause for you. I assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely



Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Priority Sample

HPV only

Please include this insert with the cervical screening form and sample when dispatching to the laboratory to ensure priority processing

Re: **Name:** [Title] [Forename] [Surname] **CSP ID:** [CSPID] **Category:** [Category]
Address: [Address 1], [Address 2], [Address 3], [Address 4], [Address 5]

Dear Doctor

Quest Diagnostics has advised us of an issue in relation to a number of HPV reflex tests that were carried out outside of the manufacturer's recommended timeframe of 30 days.

It is important to highlight that there is no issue with the processing of the cytology slides. A number of HPV tests carried out on smear test samples, which reported low-grade abnormalities at cytology during the period 2015 to 2018, were done so outside of the manufacturer's guidelines.

Our clinical management team is assured that these HPV tests are likely to remain effective outside the manufacturer's recommended timeframe and that the risk of erroneous results is low. However, as a precaution and to ensure patients' management recommendations remain appropriate, we will be inviting some women to attend for a repeat smear test.

We have written to all women affected to inform them of this issue.

The above named patient has been offered an opportunity to attend for a repeat HPV test only. This test should be taken in the usual way and **dispatched within 5 days of test date**, as per CervicalCheck quality assurance guidelines, along with this **paper insert** so that the laboratory can identify this patient's sample for priority processing.

Please highlight on the transport box that a priority sample is enclosed.

GP payment will be processed as normal.

Letter C – Issued January 31st 2019

31 January 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck screening test (smear test) which you had on the above date(s). The result of this test was that low-grade (minor) changes were found in the cells of your cervix. Low-grade changes are quite common and most will clear up on their own.

When these changes are found, the lab also tests the smear test sample for the human papillomavirus (HPV). HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life. HPV infections usually clear without treatment. Some types of HPV can cause changes to develop in the cells of the cervix. Your test showed that HPV was not detected. The result of your HPV test in addition to the detection of low grade changes recommended that you be invited for routine screening.

It is recommended that HPV testing is carried out within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe.

Although, the test was carried out outside this timeframe, we would like to reassure you that your HPV test result is almost certainly accurate. We note you have had another smear test at a later date, which was done within 30 days and which we are not concerned about. Because of this second test you do not need another test now.

You do not need to take any further action.

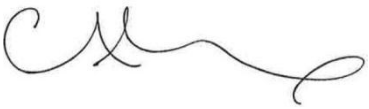
Keeping you informed

We are writing to you to ensure that you are fully aware of this issue which has come to our attention with one of the labs that we use.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

We would like to offer you our sincere apologies for what has happened and for any inconvenience that this may cause for you. We assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely



Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Letter D – Issued February 4th 2019

4 February 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck screening test (smear test) which you had on the above date(s). The results of your test were that low-grade (minor) changes were found in the cells of your cervix.

When these changes are found, the lab also tests the smear test sample for the Human Papillomavirus (HPV). HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life.

It is recommended that HPV testing is carried out within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe. We are confident that your original test is still accurate.

You do not need to do anything further in relation to this test.

The laboratory still has your sample and as a precaution, will now re-test this sample for HPV using a different type of HPV test which can be carried out for a longer period after the test is taken.

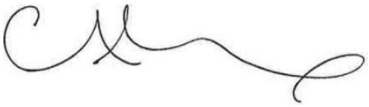
This test result, once available, will be issued to your doctor or nurse who took the original test and they will advise you of your next step. You will also receive a letter to notify you when the results are available.

Keeping you informed
We are writing to you to ensure that you are fully aware of this issue which has come to our attention with one of the labs that we use.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

We would like to offer you our sincere apologies for what has happened and for any concern this may cause you. We assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely



Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Letter E – Issued February 8th 2019

8 February 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck screening test (smear test) which you had on the above date(s) in the colposcopy clinic.

When this test was performed, the lab also tested the smear test sample for the human papillomavirus (HPV). HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life. HPV infections usually clear without treatment. Some types of HPV can cause changes to develop in the cells of the cervix. Your test showed that HPV was not detected.

It is recommended that HPV testing is carried out within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe.

We would like to reassure you that your HPV test result is almost certainly accurate but as a precaution, we recommend that you have a repeat smear test.

What should you do next?

Please contact your GP or smeartaker and make an appointment for a free repeat smear test. We have written to your consultant in the colposcopy clinic to inform them that this has happened and to let them know that you have been recommended to attend your GP for a repeat test. You can also find more information at www.hse.ie/cervicalcheck

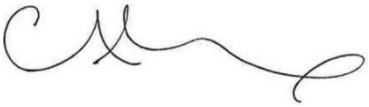
Please take the enclosed insert with you to your appointment. This will help us to make sure that your test is processed as a priority. We expect to issue your results as a matter of priority after your GP or smear taker sends the sample.

Please note that a repeat smear test can only be carried out three months after your last smear test.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

We would like to offer you our sincere apologies for what has happened and for any inconvenience that this may cause for you. I assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely



Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Priority Sample

Cytology & HPV

Please include this insert with the cervical screening form and sample when dispatching to the laboratory to ensure priority processing

Re: **Name:** [Title] [Forename] [Surname] **CSP ID:** [CSPID] **Category:** [Category]
Address: [Address 1], [Address 2], [Address 3], [Address 4], [Address 5]

Dear Doctor

Quest Diagnostics has advised us of an issue in relation to a number of HPV reflex tests that were carried out outside of the manufacturer's recommended timeframe of 30 days.

It is important to highlight that there is no issue with the processing of the cytology slides. A number of HPV tests carried out on smear test samples, which reported low-grade abnormalities at cytology during the period 2015 to 2018, were done so outside of the manufacturer's guidelines.

Our clinical management team is assured that these HPV tests are likely to remain effective outside the manufacturer's recommended timeframe and that the risk of erroneous results is low. However, as a precaution and to ensure patients' management recommendations remain appropriate, we will be inviting some women to attend for a repeat smear test.

We have written to all women affected to inform them of this issue.

The above named patient has been offered an opportunity to attend for a repeat cytology and HPV test. This test should be taken in the usual way and **dispatched within 5 days of test date**, as per CervicalCheck quality assurance guidelines, along with this **paper insert** so that the laboratory can identify this patient's sample for priority processing.

Please highlight on the transport box that a priority sample is enclosed.

GP payment will be processed as normal.

Letter F – Issued February 8th 2019

8 February 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

CSP ID: [CSPID]
Test dates: [Testdate1] [Testdate2]
[Category]

Dear [Forename]

We are writing to you about a CervicalCheck smear test and human papillomavirus (HPV) test which you had on the above date(s).

HPV is very common. Around 8 out of 10 people will have a HPV infection at some time in their life. HPV infections usually clear without treatment. However some types of HPV can cause changes to develop in the cells of the cervix and it is for this reason that HPV tests are carried out on smear tests.

It is recommended that HPV testing is undertaken within 30 days of the smear test being taken. One of our labs has told us that your HPV test was one of a number of samples that were tested after the recommended date i.e. after the recommended 30 day timeframe. This does not affect the results of the other tests you had done at the same time.

We would like to reassure you that your HPV test result is almost certainly accurate.

What should you do next?

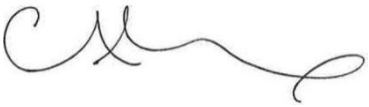
You don't have to do anything right now. As your smear test in question was taken in your colposcopy clinic, we have written to this clinic to inform them that this has happened. We have asked the colposcopy clinic to review your medical records and get in contact with you. We have asked then to do this as a matter of priority. You can also find more information at www.hse.ie/cervicalcheck

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. This was not our intention.

On behalf of CervicalCheck, we would like to offer you our sincere apologies for what has happened and for any inconvenience that this may cause for you. We assure you that we are working with the lab in question to ensure that this does not happen again.

Yours sincerely

Dr. Peter McKenna
Clinical Director
CervicalCheck



Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

Appendix 3

Explanation of Sample Categories

Explanation of Sample Categories

#	Letter Description	Insert	Current Count
A	HPV Detected: Letter advising of TIQ(s), recommendation of TIQ(s) and any subsequent tests unchanged	None	5223
B1	HPV Not Detected: Letter advising of TIQ(s), offer repeat test	Cytology + HPV test	1443
B2	HPV Not Detected: letter advising of TIQ(s), offer repeat test (as B-1, different insert)	HPV test only	2885
C	HPV Not Detected: Letter advising of TIQ(s), subsequent tests so no retest required	none	1037
D	HPV Detected or Not detected: Letter advising of TIQ(s), HPV test will be repeated by laboratory.	none	856
E	Last TIQ in Colposcopy, HPV Detected or Not Detected (excluding 11 'rescueable', included in D. above), woman no longer attending colposcopy, no subsequent tests.	Cytology + HPV test	161
F	Last TIQ in Colposcopy, HPS Detected or Not Detected (excluding 11 'rescueable', included in D. above) woman still attending colposcopy or just discharged.	None	145
G	Special Case.		22
H	Deceased.		13
I	Undetermined as yet- discrepancies, assessment as yet unresolved		8
	total		11763

Appendix 4

Letters sent by CervicalCheck to GPs

GP1 – Letter issued January 24th 2019

National Screening Service
King's Inns House
Parnell Street
Dublin 1
D01 A3Y8

24 January 2019

Dear Colleague

We are writing to inform you of an issue which has arisen in relation to a number of human papillomavirus (HPV) tests carried out on smear test samples by one of our laboratories between 2015 and 2018.

It is important to state that patients who are awaiting their smear test results are not affected by this issue. This issue concerns HPV tests carried out on a number of smear tests, following cytology, during the period 2015 to 2018 and where results were issued.

Quest Laboratories, one of CervicalCheck's three contracted laboratories, has advised us of an issue in relation to a number of standard HPV tests that were carried out outside of the manufacturer's recommended timeframe of 30 days.

These HPV tests were carried out on smear test samples which reported low-grade abnormalities, which is standard practice in the screening programme since 2015.

Our expert clinical team has reviewed the potential for any clinical impact. Evidence shows that these HPV tests are likely to remain effective outside the manufacturer's recommended timeframe. We are therefore assured that this issue poses little risk to women's health. However as a precaution and to ensure women's management recommendations remain appropriate, we will be writing to some women to ask them to attend their GP for a repeat smear test.

Based on our current assessment of the information provided by Quest Laboratories, we expect that up to 6,000 women will likely be called for a repeat smear test. These tests will be processed by the laboratory as a priority. We have been working to validate the details of patients affected, so that we can communicate with patients and their GPs. We expect these letters to be issued by the end of next week.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. We would like to state that this was not our intention and formal communication to patients and their GPs was planned to be issued in advance of other public communication.

We understand that patients may have queries or concerns and we appreciate your assistance during this time to provide support and reassurance to any concerned patients.

We will be keeping information on this issue, and all aspects of cervical screening, updated on our website – www.hse.ie/cervicalcheck.

Yours sincerely

_____
Dr Peter McKenna
Clinical Director
CervicalCheck – The National Cervical Screening Programme

GP2 - Letter issued January 31st 2019

31 January 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

Dear Colleague

We are writing to you following our enclosed letter issued to all GPs on 24 January 2019.

As explained in this prior correspondence, Quest Diagnostics, one of CervicalCheck's three contracted laboratories, has advised us of an issue in relation to a number of HPV tests that were carried out outside of the manufacturer's recommended timeframe of 30 days. These HPV tests were carried out on a subset of smear test samples which reported low-grade abnormalities, in line with reflex HPV testing which was introduced in CervicalCheck in 2015.
It is important to highlight that there is no issue with the processing of the cytology slides.

The HPV tests in question were carried out on smear test samples processed by Quest Diagnostics between 2015 and 2018. We are writing to you because your patient(s) have been identified as affected by this issue.

Our clinical management team is assured that these HPV tests are likely to remain effective outside the manufacturer's recommended timeframe and that the risk of erroneous results is low. However, as a precaution and to ensure patients' management recommendations remain appropriate, we will be inviting some women to attend for a repeat smear test.

Quest Diagnostics will be issuing amended results for those smear test samples affected over the coming weeks with a comment explaining the rationale for the amended result.

- For those tests originally reported as HPV positive, the result will be amended to indeterminate with an additional comment. No further action is required for these women and the colposcopy discharge recommendation will be followed. We have written to these women to advise them of this issue in relation to their test, for their information.

- For those tests originally reported as HPV negative, the result will be amended to indeterminate. As a precautionary measure and to provide reassurance, we are inviting these women to have a repeat smear test. Their recommendation may therefore

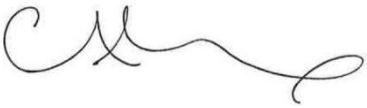
change. Some women have attended for further valid smear tests after this affected test. They have been advised that repeat testing is not necessary.

- We have written to women who are recommended to attend for a repeat smear test with their GP and have issued them with a **separate yellow insert**, which they have been advised to bring to their appointment. This test should be taken in the usual way and **dispatched within 5 days of test date** as per CervicalCheck quality assurance guidelines, along with the paper insert so that the lab can identify these samples for priority processing. GP payment will be processed as normal. We will also shortly write to women who are invited to return to colposcopy for a repeat smear test.

- It is important to note that some women may receive a HPV positive result on the repeat test when their previous HPV test was negative. This may be because the virus was dormant at the time the last test was taken; there has been new exposure to the virus; or due to the limitations of all screening tests.

We thank you in advance for your assistance with this process and in addressing concerns or queries that your patients may have. An FAQ for GPs and other smeartakers can be found in the Healthcare Professionals section of our website – www.hse.ie/cervicalcheck

Yours sincerely



Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

13 February 2019

[Title] [Forename] [Surname]
[Address 1]
[Address 2]
[Address 3]
[Address 4]
[Address 5]

Dear Colleague

We are writing to you following our previous letter issued to you 31 January 2019.

As explained in this prior correspondence, Quest Diagnostics, one of CervicalCheck's three contracted laboratories, has advised us of an issue in relation to a number of mRNA HPV tests that were carried out outside of the manufacturer's recommended timeframe of 30 days. For a small number of these tests, the sample vial was available and within date for HPV DNA testing. These samples were re tested for the presence of HPV DNA. In most instances the HPV DNA gave the same test result as the original HPV mRNA result.

For the tests listed on the attached sheet, the HPV DNA result is positive whereas the original HPV mRNA result was negative. This is because the HPV DNA test detects any HPV present in the cell whether the virus is active or latent. HPV mRNA tests detect only active infections.

Numerous clinical trials have demonstrated similar sensitivity among the various HPV DNA and mRNA assays. In most studies, sensitivity is well over 90 percent for both, indicating that false negatives are rare. mRNA testing is more specific than HPV DNA assays and so has a lower HPV positive rate because it is detecting active infections only[(1)]

We thank you in advance for your assistance with this process and in addressing concerns or queries that your patient(s) may have.

(1) Technology matters: The clinical utility of HPV mRNA testing compared to DNA testing Contemporary Ob/Gyn Aug 2018.

Yours sincerely

Dr. Peter McKenna
Clinical Director
CervicalCheck

Dr. Caroline Mason Mohan
Director of Public Health
National Screening Service

HPV DNA re-test result(s) with previous mRNA negative test result (single sample)

Name:	[Patient Name]		
CSP ID:	[CSPID]		
Date of test:	[Collected]		
Lab ID:	[Accession]		
mRNA E6/E7 result	[HPV mRNA E6/E7]	**DNA result:**	[HPV DNA}

Name:	[Patient Name]		
CSP ID:	[CSPID]		
Date of test:	[Collected]		
Lab ID:	[Accession]		
mRNA E6/E7 result	[HPV mRNA E6/E7]	**DNA result:**	[HPV DNA}

Name:	[Patient Name]		
CSP ID:	[CSPID]		
Date of test:	[Collected]		
Lab ID:	[Accession]		
mRNA E6/E7 result	[HPV mRNA E6/E7]	**DNA result:**	[HPV DNA}

Name:	[Patient Name]		
CSP ID:	[CSPID]		
Date of test:	[Collected]		
Lab ID:	[Accession]		
mRNA E6/E7 result	[HPV mRNA E6/E7]	**DNA result:**	[HPV DNA}

GP4 – Letter issued April 16th 2019

16 April 2019

Update on issues relating to the national cervical screening programme

Dear Colleague

I recently, on 4 February 2019, took up the post of Clinical Director of CercivalCheck. I am writing to provide you with an update in relation to CervicalCheck – the HSE National Cervical Screening Programme – and a number of issues the service is dealing with.

Overview

We are acutely aware of women's concerns regarding cervical screening over the past year and, in particular, women's anxiety due to the ongoing delays in reporting on their smear test results.

Our key focuses in particular are to:

1) Address the delays in getting smear results to women, caused by the backlog of smears

2) Plan for the introduction of HPV primary screening

3). Rebuild public and professional confidence in the programme.

1. **Result waiting times**

As you will be aware, in the past, screening test results would become available within four to six weeks of the test. **Currently, results for many of your patients are taking up to 13 weeks from the time the lab receives their smear test sample. In some cases, this is taking longer.**

We understand the anxiety this is causing for women and apologise for this delay. We are working tirelessly on solutions to reduce these waiting times.

2. **Actions taken to reduce current waiting times**

While we continue to pursue additional cytology capacity, this has proved very challenging due to the global shortage of resources in cytology. We have also found it particularly challenging to interest providers globally in the provision of cytology services in Ireland, given the increased insurance costs in Ireland compared to other markets.

Notwithstanding these challenges, we are actively trying to identify solutions that will help reduce result waiting times by working with existing contracted providers and we continue to work with others to try and find additional capacity.

While there is a medium term plan to develop a national cervical screening laboratory at the Coombe Women and Infants University Hospital, there is no possibility of sourcing additional capacity within the Republic of Ireland in the timeframe required to address the current backlog of smear tests.

3. Delayed smear test results - Risk to women

The natural history of cervical cancer would indicate that the disease would normally develop over a period of 10 to 15 years. In this context, the current period of up to 13 weeks for the return of cervical screening results in some cases, whilst undesirable, poses a very low risk to women. The same risk threshold also applies in cases where a woman would be required to undergo a repeat smear test three months after the previous test as a result of an unsatisfactory sample.

4. Private testing

While some women may choose to attend for a private screening test and /or private colposcopy, please note that CervicalCheck cannot incorporate these results or management recommendations to women's CervicalCheck record.

5. Increased colposcopy referrals

Colposcopy services have reported an increase in the referral rate based on 'suspicious cervix'. Inappropriate colposcopy referrals lead to overload of the colposcopy service, extended appointment waiting times and distress to those being referred. . A useful guidance note can be found at www.hse.ie/cervicalcheck/management-of-suspicious-cervix/

Smeartakers should be familiar with the appearance of normal anomalies, e.g. eversions and nabothian follicles. After clearly visualising the cervix, an assessment as to whether there is cause for concern can be made. It is important to note that screening is not diagnostic.

The cervix image library on www.nssresources.ie is a valuable reference point.

6. Accuracy/ completeness of screening forms

Please ensure that cervical screening forms are completed in full and have been checked for accuracy by your patient. When using pre printed labels please complete all additional fields on the form.

7. HPV expiration

In November 2018, Quest Diagnostics, one of CervicalCheck's three contracted laboratories, advised us that a number of mRNA HPV tests carried out on cervical screening samples during the period 2015 to 2018 were done so outside of the manufacturer's recommended timeframe of 30 days.

The clinical advice received is that these mRNA HPV tests are effective outside the manufacturer's recommended timeframe and the risk of incorrect results is low. However in order to provide complete reassurance, we have asked some women to attend for a repeat

smear test. These tests are being expedited by Quest Diagnostics, who aim to process samples within four to six weeks of the test being taken, to ensure a timely response for those women.

While we are aware that the establishment of the ICT system for dealing with these tests took longer than anticipated, Quest is confident that samples received to date will be reported within the next two weeks, while future repeat tests will be processed within the committed four to six week timeline.

We have now contacted all women affected and their healthcare professional in relation to this matter; this includes women who do not require any follow up.

In order to prevent recurrence, any sample approaching the 30 day storage limit is now sent for HPV DNA testing which can be performed up to 6 months post test date.

8. Difference between mRNA and DNA HPV testing

The HPV DNA test detects any HPV present in the cell whether the virus is active or latent. HPV mRNA tests detect active infections only. Sensitivity for both tests is well over 90%, indicating that false negatives are rare. mRNA testing is more specific than HPV DNA assays and so has a lower HPV positive rate because it is detecting active infections only.

9. ICT issues

In order to facilitate HPV DNA testing, another Quest Diagnostics facility in the USA is being used, however we are experiencing some ICT issues that has resulted in the lab being unable to send electronic results to the cervical screening register. As an interim measure, paper results are issued to healthcare professionals. Result letters are not being issued to women, nor is the facilitated referral form issuing for refer to colposcopy recommendation. A copy of this referral form is available on the CervicalCheck website: www.hse.ie/cervicalcheck/colposcopyreferralform/

Please print a copy from the website, complete and refer as usual to colposcopy without delay.

10. Increase in 'unsatisfactory smear' rate

An increase in this rate has been noted by many smeartakers and the programme. This increase is likely due to a number of factors including:

- A higher number of older women being screened
- Caution on behalf of screeners based on the current climate
- Use of lubrication by smeartakers

This unsatisfactory rate will be monitored and is currently within accepted standards.

11. HPV primary screening

A HSE Steering Group, Clinical Advisory Group and HPV Project Team are in place and are progressing the planning for the move to HPV primary screening and the implementation process. We remain committed to implementing HPV primary screening as soon as and as safely as possible; in order to achieve this we are focused on stabilising the cervical screening

programme and advancing the laboratory tender which will ultimately determine the implementation date.

12. Governance

In addition to my appointment as Clinical Director we have recently appointed a Director of Public Health for the National Screening Service, Dr Caroline Mason Mohan, and a CervicalCheck Laboratory Quality Assurance Lead, Dr Dave Nuttall. We will also be shortly seeking to fill additional key posts in colposcopy.

13. Information resources

We have recently updated the information resources relating to the CervicalCheck programme. These can be viewed on the CervicalCheck website at www.hse.ie/cervicalcheck

I would be grateful if you could share this update with all ancillary staff and locums in your practice.

Finally, I wish to acknowledge and thank you for your support and assistance during this difficult and challenging time for our national cervical screening programme.

Yours sincerely

Dr Lorraine Doherty
Clinical Director
CervicalCheck, National Screening Service