An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Implementation of Prof MacCraith Report:

Review by the National Screening Service

22 February 2023

Contents

Executive Summary

Cervical screening in Ireland came under sustained public focus in 2018. Record numbers of samples were taken during the period 2018-2019, when over 100,000 women took up the government offer of an out-of-cycle (non-scheduled) screening test. During this time two incidents were identified:

(i) a number of backlog samples in Quest Diagnostics that were close to expiry (the "expiry issue")

(ii) IT issues with one laboratory facility arranged to help with backlog (the "IT issue").

Prof MacCraith[1] was asked to review both incidents and his subsequent report contained nine recommendations. This paper confirms that:

- All 4,083 women affected (4,088 samples) by these issues received their results by the end of August 2019
- All women were offered an apology from the HSE
- All women were referred to the appropriate next stage in their screening pathway i.e., either referred to colposcopy or returned to routine recall, by end September 2019.

The recommendations made by Prof MacCraith were accepted in full by CervicalCheck, the National Screening Service and the HSE and implemented in conjunction with the recommendations made by Dr Scally in his CervicalCheck Scoping Inquiry reports[2, 3]. This paper outlines the recommendations from the MacCraith Report[1] not covered by Implementation of Dr Scally Reports: A review by National Screening Service[4].

1. Background

In 2018, the then Minister for Health offered an additional cervical screening (smear) test to all eligible women in Ireland. This led to an additional 100,000 samples being sent to the programme laboratories for processing. This 30% increase created unprecedented pressure on the CervicalCheck systems, most notably on capacity at the laboratory providers. There was an urgent need to increase capacity to deal with this increased demand for screening, which was threatening the viability of the entire screening programme.

Quest Diagnostics, which at the time processed 45% of CervicalCheck samples, agreed to increase their service to take on this additional workload. They also increased their capacity to take on a further 45% of CervicalCheck samples when the main other Irish provider (Medlab) was unable to continue operations.

In November 2018, Quest Diagnostics advised CervicalCheck that due to the high volume of samples being taken, a number of samples due for human papillomavirus (HPV) - Ribonucleic acid (RNA) - testing had expired at its Teterboro facility where CervicalCheck samples were processed. Samples for HPV-RNA testing expire after 30 days.

Quest Diagnostics' Chantilly laboratory uses a HPV-DNA test which has a longer expiry date and can be performed on samples up to 6 months after the sample collection.

An internal assessment by CervicalCheck determined that the expired samples should be analysed using DNA-based HPV testing in Chantilly laboratory, for which they were still eligible.

This meant that the Quest Diagnostics Chantilly laboratory would retest samples from the Teterboro laboratory (thereby 'rescuing' expired samples) and test 'backlog' samples that were close to expiry for RNA testing. This decision was made to minimise the number of women who would face the delay, anxiety and inconvenience of having a repeat test. Between December 2018 and July 2019, a total of 4,088 samples were sent to the Chantilly Laboratory for HPV DNA tests. This was known as the 'expiry issue'.

At the time, CervicalCheck understood that all such DNA-based HPV tests were carried out as per usual protocols and that the relevant test results were being communicated in the usual way (i.e. electronically, through existing automated systems). On 31 Jan 2019, however, it was found that Quest Diagnostic's IT systems were not configured to transmit DNA-based test results to CervicalCheck or to referring doctors. An interim solution was developed by Quest Diagnostics to ensure that hard copy reports containing the relevant test results would be issued in all such cases to patients' referring clinicians. Subsequently, however, the NSS learned (on 29 June 2019) that the Quest interim solution had not been sufficiently implemented. This resulted in a delay in getting the results to women and their doctors, which took some time to resolve. This was termed the 'IT Issue'.

Both incidents were managed with the National Screening Service (NSS) in line with the HSE Incident Management Framework by two separate Serious Incident Management Teams (SIMT). These SIMTs included relevant senior management and experts who were responsible for the management and oversight of the incidents.

By August 2019, all women and their doctors had received their results. As their results were communicated to patients and their doctors, the women were appropriately referred onward if further tests or treatments were required.

The management of the incident focused on ensuring that all women received the appropriate management based on their results letter. The SIMT reviewed the 4,088 samples sent to Chantilly for HPV DNA testing. By the end of Sept 2019, CervicalCheck also sent additional individual letters to the 4,083 women involved. The letters included the individual's results again, an explanation of what happened and an apology. A breakdown of the different groups is available in Appendix 7.3 and is summarised as follows:

- 3,215 backlog samples sent to Chantilly for HPV DNA testing due to backlog in Teterboro and risk of expiry before HPV RNA testing could be performed
- 871 HPV rescue samples - Chantilly laboratory retested samples (DNA test) previously tested in Teterboro laboratory (RNA test) as the sample had expired
  - 816 HPV results with no change from original result
  - 55 samples initially identified with result change from negative to positive*; this was subsequently revised to 48 samples.

*A discrepancy between HPV DNA testing and HPV mRNA testing is not unexpected and does not mean that either result is incorrect. The DNA and mRNA test processes are different and the likelihood of both giving the same result is 87%. Therefore, there is a 13% chance that the two tests will give different results for the same person. Each test is recognised internationally as being suitable for use in screening processes.

2. Implementation of Recommendations

Prof Brian MacCraith was commissioned by the HSE to review both incidents and his subsequent report[1] was published on 02 August 2019, with nine recommendations as outlined in *Appendix 7.1*. As advised by Prof MacCraith in recommendation 5, the implementation of the recommendations from the MacCraith report was integrated into the remit of the existing Oversight Group for Scally Report Implementation as illustrated in *Appendix 7.2.* This oversight group co-chaired by the HSE Chief Operations Officer and HSE Chief Clinical Officer, managed the implementation of recommendations and included representation from CervicalCheck, the National Screening Service, Acute and Community Operations, Public Health, service users in relation to the Prof MacCraith Report.

While both the Dr Scally reports[2],[3] and the Prof MacCraith Report[1] were commissioned following two different issues in CervicalCheck, both found similar themes and made some similar recommendations. These common recommendations involving governance and accountability in the NSS and CervicalCheck were addressed in the recently published Implementation of Dr Scally Reports: A review by National Screening Service[4] and therefore the following recommendations from the Prof MacCraith Report[1] are not covered again in this paper:

- Governance
  - Recommendation 1 & 9
- CervicalCheck Screening Programme
  - Recommendation 1, 3, 4, 7 & 9

3. Communication and Public Engagement: Recommendation 2 & 8

Providing health and care services that people can trust and have confidence in is part of the HSE's core purpose. Through an integrated approach, the NSS Communications, Engagement, and Information Development (CEID) function is focused on placing the patient at the heart of NSS communication processes; improving visibility of work; building staff and public trust; and inviting and responding to feedback. CEID works in partnership with the Public Health Department to deliver evidence-based, easily accessible, and understandable communications that promote informed participation in screening. CEID and Public Health are working to embed patient and public involvement across the NSS. The NSS is listening to and learning from the experiences of public representatives engaging with us as we improve information channels and materials. CEID seeks at all times to enhance understanding of screening among the wider population, with the aim of creating better outcomes for the people involved in screening.

One of the key lessons arising from the MacCraith report was the importance of communicating directly with women as well as with their doctors. At the start of the incident the communication focused on informing doctors and sample takers. As the incident progressed, the focused changed, and in addition to the result letters, individual letters (which included an explanation of what had happened and an apology) were also sent to the women concerned between July and October 2019. When an issue is identified we now have a woman-first approach to communications.

The Patient and Public Partnership Strategy 2019-2023 sets out the NSS commitment to a partnership approach between patient and public representatives and staff in the NSS. The Patient and Public Partnership Progress Report 2022 highlights what has been achieved under the strategy so far to strengthen the Patient and Public Partnership (PPP) and identifies the strategy's priorities for the remainder of its timeframe. The report finds that a systematic change towards a 'person-centred' culture is demonstrated in the numerous projects across the NSS that have engaged in the PPP process.

4. Review of women identified as low risk: Recommendation 6

Recommendation 6 (available in Appendix 7.1) refers to a small group of women who at the time were under the care of colposcopy units. These women received a discordant HPV test result when tested with HPV DNA compared to their original HPV RNA test*. The HPV results were communicated to the clinical team, as well as the women concerned, in 2019. This was accompanied by an explanation regarding the discordant HPV result.

All women who were within the group were offered an evaluation of their care. Before commencing an evaluation of their referral pathway, these 48 women were asked to consent to share their clinical records for the evaluation. Of these women, 32 consented (highlighted in Appendix 7.3) and the evaluations were completed by a Consultant Obstetrician and Gynaecologist. The evaluation found that the different HPV test results did not have a clinical impact on the care provided to each woman. The clinical risk to each woman was deemed low, and the women were contacted in 2020 with an update on the evaluation process. These evaluations have been completed with each woman who consented sent individual communication from the Consultant.

5. Learning from the two incidents involved in Prof MacCraith report

Incidents occur in all healthcare services; however, learning from these incidents and their management brings an opportunity to improve our service. The NSS has a standard and consistent approach to managing incidents in line with the HSE Incident Management Framework and HSE Open Disclosure Policy, and promotes shared learning across the NSS.

CervicalCheck now has regular operational meetings with the laboratories and this close relationship facilitated the effective and timely transfer of the laboratory service from the Coombe Hospital to Quest Diagnostics after the cyber-attack on the Coombe in December 2021, which ensured that there was no impact on the services provided to women. Quest Diagnostics has a dedicated Irish laboratory team who meets with the CervicalCheck operations team on a fortnightly basis.

Continuous review of CervicalCheck monthly key performance indicators (KPI) and dashboard metrics for the programme, colposcopy, primary care, and laboratory ensures that they are aligned with national KPIs and quality assurance standards. They facilitate timely and effective identification and management of potential issues.

CervicalCheck has a Quality Initiative portfolio where key projects are proactively identified through workshops and managed within project management settings. The following two key projects have begun, reflecting the MacCraith recommendations; (i) electronic ordering where a sampletaker electronically orders a cervical screening test which alerts the laboratory that a test has been taken and (ii) a new Information Management System i.e. Cervical Check register as the existing register is over 20 years old.

A significant learning from the incidents was in regard to any change made to a process or system, end-to-end testing and validation must be completed before the changes are authorised for use. This did not happen with the expiry & IT incidents from the MacCraith Report[1] but is now a part of any change process in the screening programmes.

6. Conclusion

The MacCraith report highlighted necessary improvements; in particular, the need for a transparent and improved governance structure in the NSS/CervicalCheck, which have now been addressed. The resultant organisational and reporting structure from CervicalCheck up to the Minister for Health has strengthened good practices in place and made a positive impact on the services provided by the NSS and within the HSE as a whole. This is outlined in Implementation of Dr Scally Reports: A review by National Screening Service[4].

The NSS interim strategic goals of Trust, Involvement and Governance highlight a commitment to clear governance and stakeholder involvement to build trust and confidence in the service. A key part of this is to promote learning and education for all in society regarding what screening can and cannot do, and to enable people to make informed choices about participation in screening. The NSS is including the voice of the public in ongoing work to reform the way screening services are delivered. The recently published Patient and Public Partnership Progress Report 2022 finds that a systematic change towards a 'person-centred' culture is demonstrated in the numerous projects across the NSS that have engaged in the PPP process.

CervicalCheck puts women at the heart of cervical screening by focusing on quality measures for the programme that impact on the experience of women, including public and patient

representatives in committees and by being open with what is happening in the programme with regular stakeholder engagement and updates.

The NSS has accepted and implemented all recommendations from both the Dr Scally and Prof MacCraith reports, cementing clear governance, meaningful patient and stakeholder involvement, improved quality assurance and transparent reporting structures, which was reflected in Dr Scally report 2022[5]. Independent reports[6,7] identified that CervicalCheck operates to best international standards in patient outcomes and the noted 'excellent' Quality Assurance from Dr Scally Report, 2022[5] report should give reassurance to the HSE Board, Department of Health, and the people of Ireland.

While the NSS and Cervical Check acknowledge work is always ongoing, great strides have been made in recent years with strong governance foundations in place and continued partnership with the people we care for, and our professional screening teams around the country. This was recently supported by Dr Scally Report 2022[5] which states that: "women can have confidence in and should take full advantage of the cervical screening programme. It has saved many women's lives and will continue to do so".

7. Appendices

7.1 Professor MacCraith 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.

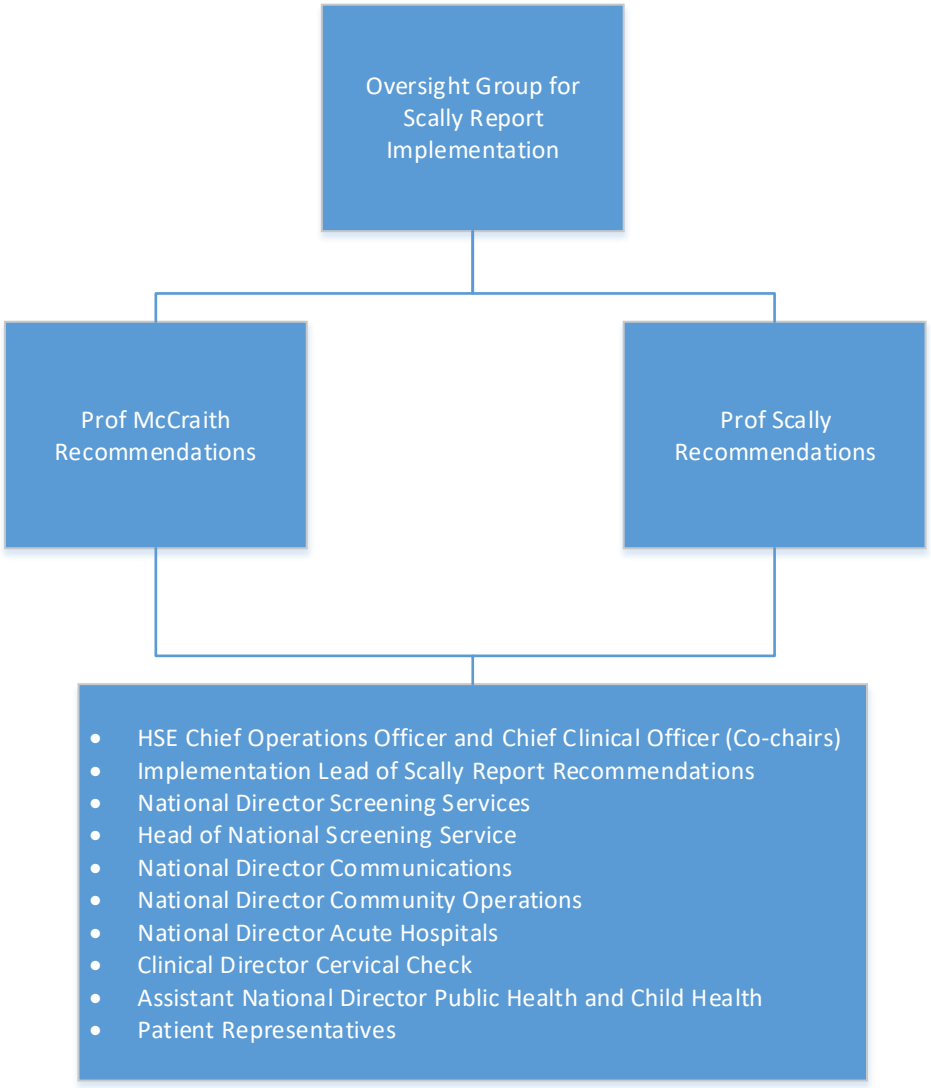
6. Although the clinical risk is deemed to be low for the patients in the cohort covered by this review (see section 6.4), for complete assurance more detailed evaluation of the referred history and subsequent findings should be carried out for this cohort.

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.

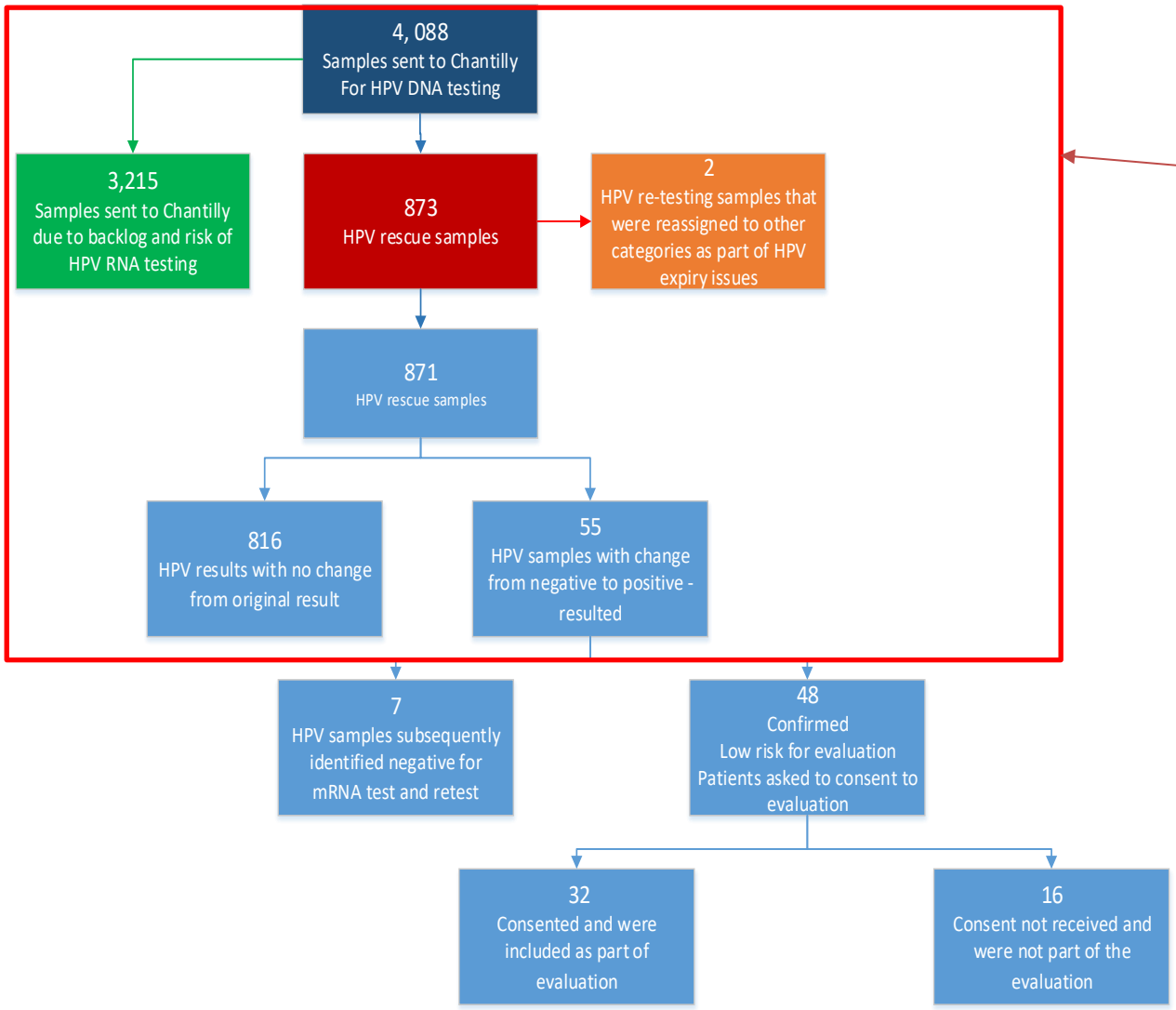
8. The issue of recognising the important role of patient representatives should be addressed with a view to placing it on a more stable footing and enhancing relationships with all relevant elements of the healthcare system.

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

7.2 Implementation of Prof MacCraith Report Recommendations



7.3 Quest Diagnostic Chantilly IT Samples



7.4 References

[1]Independent Rapid Review of Specific Issues in the CervicalCheck Screening Programme, Professor MacCraith, 2019

[2]Scoping Inquiry into the CervicalCheck Screening Programme, Dr Scally, 2018

[3]Scoping Inquiry into the CervicalCheck Screening Programme Supplementary Report, Dr Scally, 2019

[4]Implementation of Dr Scally Reports: A review by National Screening Service, 2023

[5]Scoping Inquiry into the CervicalCheck Screening Programme, Review of the Implementation of Recommendations, Dr Scally, 2022

[6]Cervical screening in cases of cervical cancer in Ireland between 2008 – 201, Royal College of Obstetricians and Gynaecologists (RCOG) Independent Expert Panel Review, 2019

[7]IntervalCancer Report CervicalCheck, Expert Reference Group, 2020