Review of the Implementation of Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme

Dr Gabriel Scally

Implementation Review Report
November 2022

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Foreword

Dear Minister,

This is the final report on progress in implementing the recommendations put forward by the Scoping Inquiry into CervicalCheck. It is my independent view of progress, and my assessment may therefore differ from the official opinion of some of the organisations responsible for implementing the recommendations.

As part of the terms of reference of my scoping inquiry, I was expected to engage directly with Vicky Phelan and the other women and families affected. I have continued to do so in producing reviews of the implementation of the recommendations. The recent death of Vicky has been a moment of national sadness, a sadness which I share. She was the first person I spoke with after my appointment to carry out the Scoping Inquiry. Vicky's enormous courage, dignity and determination changed cervical screening in Ireland for the better. In addition, she pushed forward the whole arena of women's health and highlighted the crucial issues of openness, truth and honesty in communication between health professionals and patients. I am, as are we all, in her debt.

In this report, I have included the expressed feelings of those most affected, as I did with my main Scoping Inquiry report in September 2018. The boxed quotes are taken from a powerful piece of work, *I DESERVE…*, produced from the words of those most affected by the CervicalCheck failures. Members of the 221+ organisation have collaborated with artists on a project exploring and responding to their experiences. The full text of *I DESERVE…,* and credits are included as an appendix in this report. I commend it to you.

I did not undertake this work alone. I am enormously grateful, yet again, for the support provided by Shane McQuillan, Catherine Rogers, Shannon Scott , Vanya Sargent, and their colleagues at Crowe. I owe a particular debt of gratitude to Dr Karin Denton, consultant cytopathologist, who contributed her invaluable expertise.

I hope this report will be helpful to you and your colleagues, both in recognising how much has been achieved and in assessing how further progress can be made in areas where there is still work to do.

Yours sincerely,

Gabriel Scally

Important Notice

When reading this report, it is important to bear the following in mind:

1. **The reports on the CervicalCheck Screening Programme were part of a Scoping Inquiry and not a Commission of Investigation.**
2. **This Implementation Review report should be read in conjunction with the following:**
   - First Report: Information Provided to Women Receiving Screening and Treatment through CervicalCheck;
   - Scoping Inquiry into the CervicalCheck Screening Programme Progress Report June 2018
   - Scoping Inquiry into the CervicalCheck Screening Programme: Final Report September 2018
   - Scoping Inquiry into the CervicalCheck Screening Programme: Supplementary Report June 2019
3. **Information on which any conclusions or views are based is confined of necessity to the information that was furnished to the Scoping Inquiry and this review.**
4. **The review team is grateful to the relevant bodies for responding to the team within the strict timeline adopted, of necessity, by the Scoping Inquiry and this review.**

Glossary

Organisations

CervicalCheck	The national cervical cancer screening programme
HSE	Health Service Executive
NCCP	National Cancer Control Programme
NCRI	National Cancer Registry Ireland
NHIU	National Health Intelligence Unit
NSS[1]	National Screening Service
RCOG	Royal College of Obstetricians and Gynaecologists
SCA	State Claims Agency

1 Introduction

1.1 Actions Arising from the April 2020 Review of the Implementation of the Recommendations

I have been requested by the Minister for Health to undertake a final review of the implementation of the recommendations made during the Scoping Inquiry into the CervicalCheck Screening Programme. This was in line with the statement at the conclusion of my last implementation report in April 2020, namely:

> *I would therefore suggest that I conduct one final progress review at a suitable point sometime after the coronavirus crisis has abated. I would hope and expect that the majority of outstanding actions would have been completed by then, and that there will be no further need for independent review and reporting.*

In total 58 recommendations were made across four reports, the breakdown of which is outlined below:

Report	No. of Recommendations
First Report: Information Provided to Women Receiving Screening and Treatment through CervicalCheck	4
Scoping Inquiry into the CervicalCheck Screening Programme Progress Report June 2018	2
Scoping Inquiry into the CervicalCheck Screening Programme: Final Report September 2018	50
Scoping Inquiry into the CervicalCheck Screening Programme: Supplementary Report June 2019	2
	58

In late November 2018, I submitted a preliminary assessment of the implementation plans of the relevant State bodies, in which I indicated that I was satisfied that all parties were taking seriously the findings and recommendations of the Scoping Inquiry report and that resources had been allocated to take this work forward at a high level of priority. A more detailed assessment followed in February 2019, which showed that good progress had been achieved by the end of 2018. Most recently, I conducted an implementation review of progress until the end of 2019, published in April 2020.

This review outlined the considerable amount of work done in the first 18 months since the publication of the Scoping Inquiry recommendations and highlighted the amount of work still to take place to deliver fully on these

recommendations. By carrying out this review we were able to identify, at an early stage, any significant blockages to progress.

This report focuses on the progress achieved up to the end of October 2022.

2 Overall Assessment of Progress

2.1 Ticking the Box Doesn't Make the Change!

This is my final report on implementing the recommendations of my Scoping Inquiry that submitted its reports to the Minister for Health in 2018 and 2019, respectively. As with my previous progress reports, I'm happy to confirm that substantial progress has been achieved and, in many ways, the CervicalCheck programme has improved substantially as a result of the coordinated efforts of the staff of the various organisations involved.

I want to start by making it clear that CervicalCheck is a substantially better screening programme today than it was in 2018. In my view, 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. But it isn't perfect. As with any other screening programme, research is continually being conducted to improve the accuracy of testing, improve the effectiveness of treatment, and reduce the anxiety involved in taking part.

What was revealed in the aftermath of Vicky Phelan's court case was that Ireland had a cervical screening programme that was deeply flawed. To touch only on three points: the cervical cytology slides of Irish women had been sent to far distant laboratories abroad that were entirely unknown to CervicalCheck; there was a quality assurance system within the Health Service Executive that was not fit for purpose; and some doctors working for CervicalCheck communicated to women and families the findings of an ill-designed audit in ways that were at times obstructive and callous. It is, in my view, entirely reprehensible to claim that, in the past, CervicalCheck was as good as any other cervical screening programme in the world. If you can't bring yourself to acknowledge past failings, why would anyone trust you today?

The COVID-19 pandemic, entirely understandably, interrupted progress on a variety of issues. To the enormous credit of all those involved with running and contributing to the cervical check programme, there continues to be a solid commitment to implementing the recommendations of the Scoping Inquiry and developing a screening service that meets the needs of the women of Ireland. I have been exceptionally pleased to see the growing level of commitment being given to the goal of eradicating cervical cancer in Ireland.

2.2 Women’s Health in Ireland

I noted in the Scoping Inquiry into the CervicalCheck Screening Programme: Final Report September 2018that, in recent decades, many of the major controversies in Irish healthcare have been related to women’s health. I concluded that the country needed to respond to this serious situation by giving

the whole area of women's health far higher prominence in health policy and practice.

I am greatly impressed by the commitment and effort to turn this recommendation into reality. The Ministers and all those responsible deserve to be congratulated on the work so far. If continued and amplified, these efforts will result in women's health issues receiving the attention and commitment they previously lacked and so manifestly deserve.

2.3 Gaining and Respecting the Contribution of Patient Advocates

I deserve peace of mind
To have proper professional care
To be able to trust my doctor
To be listened to by my medical team
To have my questions and concerns answered
To be supported
To feel supported

I DESERVE

Far too often, there remains a tendency for health service organisations and health care professionals to assume that everything they do is in the interest of patients and relatives. When this is reflected in paternalistic approaches to patient care, it can lead to patients being excluded from important decisions that profoundly affect the outcomes of their health problems. It is increasingly the case that health professionals do involve individual patients in these crucial decisions and take the time and care that is sometimes needed to ensure that the patient feels part of the process and is not merely a passive recipient of the outcome. This good practice concerning individual patients must also be extended more broadly to organisational decision-making and service planning.

I have stressed the importance of the engagement of 'patient advocates' in the processes surrounding cervical screening and, indeed, more widely in health service organisations. In particular, I recommended patient advocates' appointments to the HSE board. I am pleased to see that patient advocates are now included in some critical structures, such as the 'public voice' members of the National Screening Committee. It is disappointing that the 221+ organisation of women and relatives concerned with CervicalCheck is still not involved as fully as it might be in discussions, decisions, and committees around the CervicalCheck programme. Indeed, I am told that they are often made to feel like 'second-class citizens'. Worse than that, I have heard directly from women whose clinicians have questioned about any association with 221+ before the clinician will consider treating them. In the words of one woman, "I've been treated like a leper".

Respecting the role of patient advocates also involves treating them as equal partners in the system. It is simply impossible to achieve mutual respect when the patient advocates are the only people taking part in meetings in their own time, often neglecting work or family commitments, and receiving no remuneration for their attendance. I have pointed out this serious deficiency on previous occasions, and I am disappointed that there has been no agreed path forward to solving the problem.

2.4 Laboratory Services

The most complex issues concerning the structure and organisation of CervicalCheck have been in connection with laboratory services. In retrospect, it is practically unbelievable that the cytology slides of Irish women were being sent internationally to laboratories that were unknown to CervicalCheck and did not possess the specified accreditation status. Instead of the six laboratories known to CervicalCheck, 16 laboratories dealt with Irish cytology slides, and two of those laboratories had only one person reviewing slides.

A substantial change in the screening system has dramatically reduced the volume of cytology slides that require viewing by cytology screeners. The initial screening test, and for most women the only test they will need, is a test for the presence of the HPV virus. This HPV test is automated and has a very low false negative rate, i.e. the chance of a wrong result where the presence of HPV is missed is low. Only if the HPV virus is detected does the sample go on to be examined for the presence of abnormal cells. This new approach has dramatically reduced the number of cytology slides requiring examination and, thus, the need for the previous level of laboratory provision.

The concentration of cytology screening and the introduction of a properly structured quality assurance process by CervicalCheck are very welcome. Regarding future laboratory provision, there must be provision for back-up cytology laboratory services that can be called upon if an adverse event disables the primary laboratory provision.

2.5 Resolution

I deserve not to be treated as the aggressor
I deserve restoration
I deserve fair play
I deserve to speak with the decision makers
To not be dragged through the court procedure
when I placed my trust in the system

I DESERVE

In the Scoping Inquiry into the CervicalCheck Screening Programme: Final Report September 2018, I recommended that there should be effort put into achieving resolution, to whatever degree possible, of the damage done to individual patient/doctor relationships by the inadequacy of much of the communication of information about the outcome of the 'audit' carried out by CervicalCheck. I know this issue has been, and still is, vital to many women and families. This is not about redress; it is about grace and compassion and about recognising the profound importance of the patient-doctor relationship. Repairing some of the damage done, where it is possible to do so, will undoubtedly have benefits for all involved.

There has been some progress on this matter. Involving both the health service and the women and families in designing and implementing the process is crucial. There remains work to be done in this area.

From the outset, there was a desire expressed on all sides that women and families involved in the cervical check failure would not have to pursue their grievances through the court system. It was repeatedly stated that alternative mechanisms would be developed to avoid lengthy and traumatic legal proceedings and court appearances. It is very disappointing that little seems to have changed.

In my view, an approach based on the primacy of litigation is a sad indictment of any system for dealing with possible clinical errors. The litigation route only increases the strength of what I would term the 'Medico-Legal Complex'. By this, I mean the network of legal, judicial, insurance, medical expert and claims-management interests. Of course, citizens must have access to the judicial system to right grievous wrongs, but it should not be the first, or only, option.

Patients should be told the truth when things go wrong. If they are concerned that their treatment may have been deficient, patients should also have a clear and consistent route to bring forward their concerns and have them investigated. Such an approach will work best when the actions of health professionals and managers are based upon a commitment to candour on all relevant issues. Candour is the quality of being honest, open and truthful, especially about difficult and unwelcome situations or occurrences.

2.6 Duty of Candour

I deserve to know the truth
To be told the truth
I deserve answers
I deserve justice
I deserve for this never to have happened
I deserve closure
I deserve for it to be over

I DESERVE

The right of patients to know the truth about their health should be at the heart of all the interactions between health services, health professionals, and patients. And, as I have written elsewhere, for a health professional, telling the truth to patients should be as natural as breathing. There has undoubtedly been much good work carried out across the health service promoting the policy of 'open disclosure' to patients when something has gone wrong in the care process. The current policy within the HSE, in place since June 2019, is an 'interim revision' of the previous deeply unsatisfactory policy. It remains in 'interim' form awaiting further developments, notably the *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019,* which remains before the Oireachtas. It isn't easy to see how, as presently constituted, the Bill, if it becomes an Act, will move the system forward to the extent needed.

The slow pace of movement in creating a framework that fully supports telling patients the truth about possible errors in their care can be explained partially by the unprecedented collective burden of the pandemic. However, the underlying concern must be that there is no fully formed plan to fundamentally change how patients are dealt with and regarded within the health services. One of my recommendations in 2018 was that the Medical Council should put into effect its stated support for the concept of a duty and culture of candour (openness and honesty) by insisting that doctors 'must' be open and honest with patients rather than using the word 'should', which leaves it to the doctor's judgement as to what, if anything, happens. Unfortunately, the wording in the Medical Council guidelines remains unchanged. I reiterate my full support for the firm view, so well-expressed by the Houses of the Oireachtas Joint Committee on Health and Children in 2015 – "*A duty of candour should be regarded as absolute for Irish health professionals"*.[1]

In relation to a culture of openness and patient rights, I find it extraordinary that in the Health Act 2004, there is a legal prohibition on anybody making a complaint to the HSE about the clinical judgement of a doctor or other health

[1] Houses of the Oireachtas. Joint Committee on Health and Children. Report on the Cost of Medical Indemnity Insurance. 31HHCN20. June 2015. p16.

professional providing care funded by the HSE. The Act states, "*A person is not entitled to make a complaint about any of the following matters: …. (b) a matter relating solely to the exercise of clinical judgment by a person acting on behalf of either the Executive or a service provider"*.

An adequately constituted clinical complaints system is one thing that might help address the serious problem of patients being left with no choice but to take legal action if they are concerned that their clinical care may have been deficient.

I make no apology for again pointing out that patients usually want three things when they think something might have gone wrong in their care. First, they want a complete account of what has gone wrong and why it happened. In short, they want to know the truth. Their second explicit request is for a clinician involved to take some responsibility for the situation and, if appropriate, to say sorry. Thirdly, they want to know what is being done to ensure the error does not occur again and that damage to any more patients will be prevented. If these three things are done well and in a timely fashion, all the evidence from elsewhere shows that patients will usually be, if not fully satisfied, at least content that their concerns have been addressed.

The development of an effective complaints system, based on an individual and organisational duty of candour, would be popular with the public, provide patients with answers to their concerns, and remove most of the need for patients to have recourse to the legal system to meet their needs.

2.7 Public Health

One of the Scoping Inquiry recommendations was that public health expertise should be more readily available to the screening services. The announcement in April 2021 of the enhancement of the status of public health doctors within the Irish health system and the creation of a significant number of consultant posts was a substantial and welcome step forward. It is to be hoped that the activities of the screening services will continue to benefit from this increased public health provision.

2.8 National Screening Advisory Committee

One of the most important recommendations of the Scoping Inquiry was that Ireland should have a committee of experts and laypeople to advise the Minister for Health on all new screening proposals and revisions to existing screening programmes. The role of the National Screening Advisory Committee (NSAC) is both to protect the public from the adoption of poorly evaluated attempts at population screening and to ensure that the screening programmes that are in place follow the scientific evidence of what is effective. The committee's formation happened speedily, and its operation is transparent and a great credit to its chair, its members, and all the staff involved in supporting and informing

the committee. It is particularly commendable to see the publication of the minutes of the committee's meetings. The NSAC is well placed to make a significant contribution to the improvement of population health in Ireland.

2.9 Cancer Registration

A high-quality cancer registration function is a requisite part of any country's public health system. The Scoping Inquiry into cervical screening concluded that the disconnect between CervicalCheck and the National Cancer Registry Ireland (NCRI) was a severe deficiency. It was also unacceptable that the NCRI did not have data-sharing agreements, contracts, or memoranda of understanding in place to govern the data transfers in which it engaged.

These deficiencies have been addressed, for the most part – although improvement has been slower than might have been hoped. However, governance and staffing issues remain problematic. In the short term, the continued function of cancer registration depends on the NCRI's ability to recruit additional and replace departing staff in a timely fashion. In the intermediate term, the development of information systems across the field of health should lead to consideration of how information systems in the area of public health in Ireland should be structured and developed.

2.10 Conclusion

I deserve health
I deserve security
To be well
To be free
I deserve justice for the wrong done to me
I deserve happiness
Peace
Peace of mind
I deserve for this not to define me
I deserve to live
I deserve to be here
I deserve to be alive

I DESERVE

Much progress has been made, and those involved should be congratulated on what has been achieved. But, as will be apparent from this implementation review, areas remain where improvement has lagged behind what might reasonably be expected. The necessity of future oversight and leadership of the cervical screening programme should not be neglected. There are broader issues raised and highlighted by the CervicalCheck failures, such as the necessity of a duty of candour on health professionals, the absence of a clinical

complaints system, and the over-reliance on the judicial system as means of solving problems arising in clinical care. These are matters of great importance and will require a firm commitment to reform and modernisation.

3 Overarching Structures for Implementation

3.1 CervicalCheck Steering Committee

The CervicalCheck Steering Committee was established by the Minister for Health in June 2018 with responsibility for oversight of the implementation of the recommendations from the Scoping Inquiry. The committee is chaired by Professor Anne Scott, with representatives from the Department of Health, HSE, and clinical representative organisations. Patient advocates are also included in this group.

3.2 Master Implementation Plan

The Steering Committee provides oversight on the Implementation Plan covering all the State bodies involved in CervicalCheck. Three of the organisations concerned – the Department of Health, the HSE, and the National Cancer Registry Ireland – have specific actions allocated to them, whilst the fourth, the State Claims Agency, were involved in certain activities to be progressed by the Department of Health but were not be directly responsible for their implementation. Quarterly Reports on the Implementation of the Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme are produced, with the most recent publicly available report for quarter one 2022.

The detailed implementation plan contains 170 individual actions, and lead responsibility for taking them forward is broken down as follows:

Lead responsibility	Number of actions
Department of Health	30
Health Service Executive	116
National Cancer Registry Ireland	23
221+ Support Group	1
Total	**170**

Some of the 58 recommendations in the four reports are covered by a single action within the implementation plan, whilst others (typically the more complex issues which required time to resolve) have several actions associated with them. Some actions are reliant on external factors such as the approval of legislation by the Oireachtas.

4 Overall Progress – All Organisations

The table displayed overleaf shows the progress achieved to the end of October 2022 in respect of the recommendations made across the four reports. An overview of these reports and the number of recommendations in each is below:

Report	No. of Recommendations
First Report: Information Provided to Women Receiving Screening and Treatment through CervicalCheck	4
Scoping Inquiry into the CervicalCheck Screening Programme Progress Report June 2018	2
Scoping Inquiry into the CervicalCheck Screening Programme: Final Report September 2018	50
Scoping Inquiry into the CervicalCheck Screening Programme: Supplementary Report June 2019	2
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The table displayed overleaf includes which organisations are allocated implementation responsibility for each recommendation.

The following sections of this report contain further commentary and analysis relating to the Department of Health, HSE, Laboratory Services, and National Cancer Registry respectively.

The colour coding in the table is as follows:

Colour	Status
Green	On track and expected to conclude
Amber	Slippage identified
Red	Action has not started, stopped, or is seriously off target
Blue	Action completed

Note: Some recommendations which were marked complete during previous implementation reviews, would now be considered incomplete due to changes in circumstance. Where this occurs we will outline our reasoning.

Recommendations in the First Report: Information Provided to Women Receiving Screening and Treatment through CervicalCheck

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
1	A more comprehensive guide to the CervicalCheck screening programme should be provided online so that women who wish to learn more about the programme can obtain the information easily.	**HSE**	A comprehensive guide to the CervicalCheck screening programme is available on the web page hse.ie/cervicalcheck.	
2	The information statements provided to women about the tests should be more explicit about the possible reasons why screening might miss abnormalities that are present as there can result in the development of cervical cancer. This information should be included in the leaflet sent to all women with their screening information, and in the information sheet accompanying the consent form.	**HSE**	The leaflets clearly outline the possible reasons why screening might miss abnormalities that are present. These leaflets are provided to women when they receive their letter of notice that they are due for screening.	
3	The information for women accompanying the consent form should guarantee that they will have full and open access to their cervical screening record upon request.	**HSE**	The consent form states that “You will have full and open access to your personal information held by CervicalCheck upon request”.	
4	The information for women accompanying the consent form should guarantee that should there be a problem or error of any significance with the screening or reporting process, open disclosure of all the details will take place in a timely, considerate and accurate manner.	**HSE**	The consent form states that “We will communicate with you in an open, honest, timely and transparent manner if: • Something goes wrong with your care • You experience harm as a result of your care • We think that harm may have occurred”	

Recommendations in the Scoping Inquiry into the CervicalCheck Screening Programme Progress Report June 2018

Recommendation		**Owner**	**Independent Assessment** (at Oct 2022)	
			Commentary	***Status***
1	That the Minister for Health offer an immediate ex gratia payment to each woman affected and to the next of kin of the deceased.	**HSE**	A €2,000 payment was offered to the 221 affected women or next of kin.	
2	That a process be commenced as soon as reasonably possible, to hold structured conversations with every woman affected who wishes to have her experience documented, and with the relevant surviving family member/s of any affected woman who has died if they so wish.	**HSE and DOH**	This recommendation was not actioned as Mr. Justice Charles Meenan was asked by the Government to make recommendations on how claims arising out of CervicalCheck could be resolved outside the court process.	

Recommendations in the Scoping Inquiry into the CervicalCheck Screening Programme: Final Report September 2018

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
Method of Approach				
1	The Department of Health and the HSE should revise their policies in respect of document management. This should ensure that good quality records are created and maintained which are authentic, reliable, and complete in searchable format. They should be protected and preserved to support future actions and ensure current and future accountability.	**HSE and DOH**	A revised HSE Records Management policy has been developed and is being implemented. The Department of Health has also reviewed and where necessary updated policies in relation to document management.	
Listening to the Voices of the Women and Families Affected				
2	The Minister for Health should give consideration to how women's health issues can be given more consistent, expert and committed attention within the health system and the Department of Health.	**DOH**	A Women's Health Taskforce was established in 2019 and consists of 60 staff from different grades and a small number of external contributors. Taskforce has taken part in outreach, education, listening, and policy work. The Women's Health Action Plan was launched in March 2022.	
3	The Department of Health should examine the current arrangements for patients to have access to their hospital medical records so that such access can be achieved in a timely and respectful way.	**HSE**	This is a medium to long term process which should be an integral part of health sector reform.	
CervicalCheck – Organisation and Governance				
4	The Minister for Health should consider seriously the appointment of two patient advocates to the proposed new Board for the HSE.	**DOH**	Two patient advocates were appointed to the HSE board on its establishment.	
5	A National Screening Committee should be constituted to advise the Department of Health and the Minister on all new proposals for screening and revisions to current programmes.	**DOH**	A National Screening Advisory Committee has been established and meets 3-4 times a year, playing a strategic role in the development and consideration of population-based screening programmes in Ireland. One of their recent pieces of work has included a call for submissions from the public on new screening programmes, as well as changes to the current screening programmes.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
6	The NSS, whatever its location within the HSE, should be able to access senior levels of the organisation and be located close to strategically and logically linked services.	**HSE**	The NSS Chief Executive Officer (CEO) reports directly to the HSE Chief Clinical Officer (CCO) who reports to the HSE CEO, giving the NSS access to the HSE Senior Management Team.	
7	A far greater component of professional and public health expertise should be deployed across the screening services, not as external advisors but with significant roles within the screening programmes.	**HSE and DOH**	A major development of public health medicine has been initiated, including within the area of screening.	
8	The implementation of new governance arrangements for the HSE should include a substantial revision to the organisational approach to risk management and its reporting.	**HSE and DOH**	A risk management approach now exists in HSE across the four programmes, as developed by the Head of Quality, Safety, and Risk, A clear process is now in place for risks, and any serious risks are escalated to the HSE risk register and the DOH risk register. Risks are updated at every quarterly meeting to show progress and actions.	
CervicalCheck – Laboratory Services				
9	CervicalCheck should revise its programme standards to clarify what is mandatory, and to clarify the level of reliance on external accreditation processes. This is particularly important in respect of laboratory service providers in other jurisdictions.	**HSE**	The National Screening Service adopted a policy for accreditation for programme standards including mandatory standards in CervicalCheck (NSS QA Policy Framework). Quality Assurance in Cervical Screening was updated in March 2020 to include accreditation requirements for both screening and diagnostic laboratories.	
10	As a priority, all providers should fully implement a single agreed terminology for the reporting of results and ensure that criteria for defining the different grades of abnormality are consistently applied.	**HSE**	A single agreed terminology is now in place across all laboratory service providers.	
11	Based on revised programme standards, a specification for a new and more robust quality assurance procedure should be documented and form part of the contract for services with cytology providers.	**HSE**	Quality Assurance in Cervical Screening was reviewed as part of the move to HPV primary screening. There are regular and schedule CervicalCheck QA Visits/Audits, as well as bi-weekly operational meetings with labs and continuous review against KPIs and dashboard metrics for laboratories.	
12	CervicalCheck should adopt a formal risk management approach to parameters which do not reach acceptable standards despite full intervention and monitoring.	**HSE**	Formal risk management approach is in place for when parameters do not reach acceptable standards.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
13	CervicalCheck should document which organisation (e.g. CervicalCheck, HSE, Providers) has responsibility for pursuing issues of continued non-compliance and the consequences thereof. An advisory group of cytopathologists and other laboratory-based staff should be established to advise on this process, and this should include input from those who work for non-State providers.	**HSE**	Governance and oversight within the NSS and HSE has been clarified with clear accountability and responsibilities. Compliance with standards are reviewed through monthly review of metrics, meeting with relevant service providers, and regular QA audits and visits. There is a Clinical Advisory Group that comprises national and international experts advising the CervicalCheck senior management team on clinical pathways and protocols.	
14	CervicalCheck should collate and publish annual data on reporting rates for all categories broken down by provider.	**HSE**	The CervicalCheck Annual Programme Reports include comparatives in all categories broken down by provider, up to the start of the HPV programme.	
15	In order to obtain comparable data, CervicalCheck should amend data specifications to exclude samples taken from colposcopy, and analyse and publish all performance statistics on samples taken in primary care, or equivalent, only.	**HSE**	A report in place which defines the exclusion of coloscopy samples for KPI monitoring since February 2020, with a test report in place before this date. Oversight approval for this report is provided by the SMTs of CervicalCheck and the National Screening Service.	
16	When this change to comparable data is made, further epidemiological investigation is required to establish whether the differential rates of abnormality persist and, if so, to what extent they can be attributed to underlying population differences.	**HSE**	The CervicalCheck database and the databases from the other screening programmes currently do not have the capability to meet this action as the database is not geo-coded. Eircodes are only captured for a small number of clients and IHI has not been rolled out yet. In addition, the epidemiological metrics relevant to cervical cancer are not captured. At this time, it is not possible to meet this action. This action has, therefore, been replaced with a medium to long-term proposal to develop IT systems to support the collection of this data across all programmes. This forms part of the Equity Strategy and the CC QI Portfolio.	
17	The different rates of sensitivity for ASCUS+ identified by second screen at each provider require further investigation by CervicalCheck.	**HSE**	The 221+ audit results paper concluded that the value of looking at this data by lab may be limited as client demographics will affect the small numbers of samples encountered and sent to each lab. The Laboratory Clinical advisor, with the Lab advisory Committee, reviewed detection rates for ASCUS + identified by each provider. Differing detection rates of ASCUS-H vs HSIL were found and remedial training in these sub-classifications was carried out by the laboratories concerned.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
18	The different inadequate rates are not a cause for immediate concern. The Scoping Inquiry recommends that the English HTA study findings are implemented across all providers to try to obtain more consistency	**HSE**	The Public Health England Health Technology Assessment study findings have been incorporated into the CervicalCheck Quality Guidance document. This is monitored through regular operational meetings with the individual laboratories.	
Procurement of Laboratory Services				
19	Winning proposals should be appended to the relevant contract and not destroyed until at least one year following the termination of the contract (and any extension thereof).	**HSE**	Successful proposals are now appended to contracts and kept for the necessary period following the termination of the contract	
20	A system should be put in place for proactive contract governance in order to safeguard the future of the service and the relationship of the service with the market place.	**HSE**	Quarterly meetings were established at the senior management level to monitor contract performance. There is now a much closer oversight of operational performance on a bi-weekly basis.	
21	Procurement processes for external laboratory services should be designed to test the market at reasonable intervals (e.g. every four years), to ensure that CervicalCheck does not become overly reliant on a small number of incumbent suppliers, and to ensure that innovative approaches and added value can be formally captured within the procurement process.	**HSE**	Market testing has been undertaken to establish the market for laboratory services. Market testing has also been included in the procurement strategy for HPV testing. A procurement exercise is currently under way.	
22	CervicalCheck should ensure that its procurement approach maintains a balanced focus on qualitative factors, supplier experience, and innovation, alongside cost considerations.	**HSE**	Any future procurement of laboratory services will focus on qualitative factors with cost being a pass-fail criterion.	
23	CervicalCheck should ensure that future procurements incorporate measures to test performance in the current contract.	**HSE**	Current contracts have incorporated metrics to aid the assessment of contract performance.	
24	External professional assistance should be sought in the construction of any future 'Request for a Proposal' (RFP) and the evaluation of proposals in order to ensure that best practices developed across the public sector since 2012 are incorporated into key areas such as development of RFP documents, supplier briefings, construction of award criteria, construction of evaluation panels, establishment of governance and continuous improvement programmes, etc.	**HSE**	A process auditor has been appointed to oversee procurement competitions.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
25	Assurances should be sought with respect to the capability to deliver the service as specified and without material change. Where change is possible, robust change management procedures, which include approval by the procuring authority, should be defined.	**HSE**	A process has been developed for the approval of additional laboratories where the need arises. This process was tested in 2019 and it met the requirements of CervicalCheck regarding quality and other metrics.	
Auditing Cervical Screening				
26	Audits should continue to be an important component of cervical screening as this complies with all good clinical practice. Common, robust, and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.	**HSE**	An audit is not in place to the level envisaged in the recommendation.	
27	There should be a minimum of two patient advocates involved in the oversight of clinical audits for the screening services.	**HSE**	Patient advocates are involved in the CervicalCheck Interval Cancer Audit Implementation Group.	
Open Disclosure and the HSE				
28	The HSE's open disclosure policy and HSE/SCA guidelines should be revised as a matter of urgency. The revised policies must reflect the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and, in particular, their right to be informed about any failings in that care process, however, and whenever they may arise. The revision process should be overseen by a working party or committee with a minimum of two patient advocates amongst its members.	**HSE and DOH**	The HSE policy was revised and published in 2019. This was an interim revision and has not been revised since.	
29	The option of a decision not to disclose an error or mishap to a patient must only be available in a very limited number of well-defined and explicit circumstances, such as incapacity. Each and every proposed decision not to disclose must be subject to external scrutiny and this scrutiny process must involve a minimum of two independent patient advocates.	**DOH and HSE**	There has been very limited progress on this extremely important issue. The Patient Safety Bill has only reached the fourth stage of an eleven stage legislative process, The Bill only makes provision for mandatory open disclosure in a limited number of circumstances, nearly all of which are associated with the death of the patient.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
30	A detailed implementation programme must be developed that ensures the principles and practice of open disclosure are well understood across the health service. In particular, medical staff must be required, as a condition of employment, to complete training in open disclosure.	**HSE**	Any new contracts for medical staff now include the requirement to complete open disclosure training as part of their 'mandatory training'. Open disclosure training is mandatory for all staff under the HSE Open Disclosure Policy. At the end of 2021, it was estimated 60.7% of staff had received this training. There is an aspiration that this should reach 90% by the end of 2022.	
31	A governance framework for open disclosure must be put in place that includes evaluation and audit.	**DOH and HSE**	It is not possible to have a Governance Framework for open disclosure given the lack of definitive policies in place and the complication posed by the stalled and not yet properly formed Patient Safety Bill. A National Office for Open Disclosure has been established within the HSE.	
32	An annual report on the operation of open disclosure must be presented in public session to the full Board that is to be appointed to govern the HSE.	**HSE and DOH**	An annual report on Open Disclosure is published for 2019 and 2020. There is not yet a published annual report for 2021.	
Open Disclosure and the Medical Council				
33	The Department of Health should enter into discussions with the Medical Council with the aim of strengthening the guide for registered medical practitioners so that it is placed beyond doubt that doctors must promote and practice open disclosure.	**DOH**	The guidance for registered medical practitioners on open disclosure and duty of candour has not yet been strengthened by the Medical Council and open disclosure remains optional.	
Open Disclosure and CervicalCheck				
34	A statutory duty of candour must be placed both on individual healthcare professionals and on the organisations for which they work.	**DOH**	There has been no progress on this.	
35	This duty of candour should extend to the individual professional-patient relationship	**DOH**	There has been no progress on this.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	*Status*
Cancer Registration				
36	NCRI should urgently negotiate and implement data-sharing agreements with all major providers and users of registration data. This is necessary in order to meet the requirements of the new EU General Data Protection Regulation but also, and more importantly, represents good governance. Where such an agreement is with an overarching statutory body, such as the HSE, there should also be individual MOUs in place with distinct organisational users of data, such as the cancer screening programmes.	**NCRI**	NCRI has finalised Data Sharing Agreements with all its major providers of data (i.e. organisations providing at least 1% of the NCRI's data). An MOU has been developed and signed with the NCCP and the NHIU in the HSE to facilitate the appropriate, purposeful and compliant sharing of data in order to support cancer service design, planning, monitoring and evaluation as appropriate. The Data Sharing Agreement with the HSE has been reviewed.	
37	Timely data is important to assure the effectiveness of both cancer screening and treatment services. This is a patient safety issue. To fulfil its role properly as a cancer registry: a) NCRI must be given additional support to recruit cancer registration officers and strengthen its public health medicine capacity. b) The Department of Health and the HSE should commit to make progress on electronic data capture by NCRI from hospitals, and set clear targets for its achievement.	**NCRI**	a) Progress has been made but there remain staffing deficiencies within NCRI that should be addressed and NCRI should be supported further in their recruitment process. b) The task on improving electronic data capture is ongoing.	
38	NCRI should review data definitions related to cervical cancer and CIN (cervical intra-epithelial neoplasia) cases to ensure that the screening flags are meaningful for analysis of the effectiveness of the CervicalCheck programme	**NCRI**	Completed and published on Core Dataset (Section 5).	
39	The need to duplicate the collection of patient level details of cervical cancers by both NCRI and CervicalCheck should be reviewed. It is notable that both CervicalCheck and NCRI have identified patients that the other has not. If it is determined that both systems should continue then properly functioning data sharing agreements must be put in place.	**NCRI**	There is a Data Sharing Agreement, MOU and Data Protection. Progress on the integration of data systems has been impacted by the cyber-attack in May 2021.	
40	The Department of Health must review the composition of the Board of NCRI in order to ensure more robust governance, in particular in QA, data sharing and patient safety.	**DOH**	Recent changes to the Board have included members with a QA background and a data background.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
41	Any future consideration of the governance of the NSS needs to acknowledge, and contribute to the effective oversight of, the specific role played by NCRI in working in conjunction with the cancer screening programmes.	**NCRI**	There appears to be a significantly strengthened working relationship between the NSS and NCRI, with an improved understanding of the strengths of each.	
42	The Department of Health should work with the Board of NCRI to commission an annual peer review, for at least the next three years, by external cancer registration and cancer control experts. The report of each review and the response to it by NCRI should be forwarded to the Minister for Health.	**NCRI**	It is recommended that going forward there should be a peer review of NCRI every two years. It is recognised that due to the process cycle an annual review is ambitious.	
43	NCRI should establish stronger and more regular contacts with external clinical and public health experts to ensure scrutiny of, and advice on, outputs from NCRI so as to enhance the level of its clinical and public health interpretation, importance and impact.	**NCRI**	This recommendation has not been achieved but an increase in staffing within NCRI will enable it to be progressed. The recent recruitment of the Communications Officer is a positive step for the Registry and has enabled progress to be made in this area. Communication with stakeholders and the public should be a key part of the work of NCRI. At a recent patient engagement event, feedback was received that people didn't know of the Registry or how to access the data.	
44	One of the requirements for the establishment and good management of a screening programme is that health services should be of a good standard to manage those people detected with disease by the screening programme. NCRI, through links with the clinical community, should seek to engage actively in the assessment of the quality of cancer services, comparing these for screen and non-screen detected cases	**NCRI**	This is included within the NCRI NCCP NHIU MOU. The development of this work is dependent on the staffing of NCRI and particularly the recruitment of public health capacity. The data collected by NCRI should extend to what treatment patients receive and how long it takes people to get treatment.	
Other Screening Programmes				
45	Considering the clinical and technical differences that characterise the different screening programmes, NSS needs to advance its thinking on cross programme learning, external QA, and governance oversight of the QA programmes.	**HSE**	QA Committees have been established across the screening programmes. There is closer working across the various screening programmes. The committees have been reviewed and the membership updated. The committees are operating based on revised terms of reference.	

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	***Status***
46	The composition and duration of appointments for all QA Committees should be reviewed, in conjunction with emerging clinical advisory committee structures.	**HSE**	QA Committees have been established across the screening programmes. There is closer working across the various screening programmes. The committees have been reviewed and the membership updated. The committees are operating based on revised terms of reference.	
47	The QA Committees should review and confirm the adequacy of the arrangements within their respective screening programmes for introductory training and continuing staff development, as well as the arrangements at all levels in the quality system for identifying and appropriately responding to inadequate technical or clinical performance.	**HSE**	QA Committees have been established across the screening programmes. There is closer working across the various screening programmes. The committees have been reviewed and the membership updated. The committees are operating based on revised terms of reference.	
48	NSS should consider, with external assistance, the relevance of the HSE policy on 'Open Disclosure' as it develops in light of this Scoping Inquiry, for all of its screening programmes.	**HSE**	QA Committees have been established across the screening programmes. There is closer working across the various screening programmes. The committees have been reviewed and the membership updated. The committees are operating based on revised terms of reference.	
Resolution				
49	The Department of Health should consult with interested parties as to how women and families who wish to, can be facilitated in meeting with the clinician who was involved with their care and/or disclosure.	**DOH and HSE**	The process of rebuilding trust between some of the clinicians and the women involved has made very limited progress.	
50	The Department of Health should encourage and facilitate (but not necessarily participate in) a meeting involving the presidents of the Medical Council, the Royal Colleges and their faculties, leaders of other leading medical organisations and representatives of the women and families involved with the cervical screening problems.	**221+ Support Group**	Successful engagement has taken place with the relevant medical organisations and the 221+ support group.	

Recommendations in the Scoping Inquiry into the CervicalCheck Screening Programme: Supplementary Report June 2019

Recommendation		Owner	Independent Assessment (at Oct 2022)	
			Commentary	*Status*
51	Future CervicalCheck contracts for the provision of cytology and other laboratory services should contain even more explicit provisions to ensure that no contracted cytology or other laboratory activity should be carried out anywhere other than in the precise locations, and by the precise company, identified in the written contract, without prior written permission from CervicalCheck.	**HSE**	There are more stringent provisions to ensure that additional laboratory facilities are not brought into the system without explicit agreement with CervicalCheck. Only precise locations and precise companies identified in the written contract may be used without prior written permission from CervicalCheck.	
52	The quality assurance (QA) process developed and operated by CervicalCheck must be based on a consistent and thorough approach to the quality of the laboratory services being provided to the cervical screening programme. This QA system must be designed and operated irrespective of the physical location of laboratories and the possession of external accreditation by the laboratory should not be viewed as in any way replacing or diminishing the need for QA processes.	**HSE**	Laboratory Quality Assurance Standards and Quality Requirements for the CervicalCheck Programme are in place as a mandatory compliance requirement across current and future providers of laboratory services to the HSE. All laboratories are subject to compliance with these standards and requirements, in addition to providing evidence of relevant accreditation for each laboratory specified within the contract. Regular QA Visits take place with follow-up reports and recommendations provided. Fortnightly operational meetings between the National Screening Service and the labs to improve communication and ensure any issues which arise can be dealt with swiftly.	

5 Department of Health

5.1 Implementation Actions

The Department of Health had 30 actions across 15 recommendations within the Implementation Plan. The main focus of the Department is on the development and implementation of legislative and health policy recommendations. Of the Departmental actions, seven relate to open disclosure and the Patient Safety (Notifiable Patient Safety Incidents) Bill. Many of the Departmental actions impinge upon the achievement of progress on various recommendations associated with other bodies.

5.2 Patient Safety (Notifiable Patient Safety Incidents) Bill

The Patient Safety (Notifiable Patient Safety Incidents) Bill was originally introduced in 2019, but partially due to the COVID-19 pandemic and a general election, amendments were only discussed at the committee stage in March 2022. Since March 2022 there has been no further progress of the Bill through the Houses of the Oireachtas. At the time of the publication of this report, it has remained at the report stage, the penultimate stage in the Dáil (which is stage four of eleven, including Seanad and the President signing into law).

The limited scope of the Bill is problematic. The Bill only specifies the mandatory requirement for open disclosure in the case of 13 categories of incidents. 12 out of the 13 highly specific incidents where notification would be mandatory relate to the death of a patient. This, under any circumstances, represents a tiny proportion of harm caused to patients through clinical error.

The enactment of a statutory duty of candour on individual healthcare professionals and on the organisations for which they work remains unaddressed.

5.3 The Independent Patient Safety Council

The first meeting of the Independent Patient Safety Council happened on 27th January 2020, with meetings happening two to three times a year. Their first piece of work was to make recommendations to the Minister on a National Policy Framework for Open Disclosure in Healthcare in Ireland, which were provided to the Minister for Health in January 2021.

5.4 Women's Health

The Women's Health Taskforce was set up in 2019 and has recently been reviewing and updating its purpose. Their role includes outreach, education, policy work, and listening to the voices of women. The Women's Health Action Plan 2022-23 outlines clearly how they plan to improve health services for

women in Ireland and specific areas of focus. This action plan has been widely embraced across the HSE and externally. The change in culture to empower women clinical leaders and ensure they have a voice is essential in making strides in women's health in Ireland. Recommendation Two was a challenge for the system which involved significant amounts of bravery and innovation, as well as listening, before any action was taken. The work in this area deserves appropriate recognition and it is important that the approach taken is based on longevity and sustainability.

5.5 The National Screening Advisory Committee

The National Screening Advisory Committee was established in 2019 as an independent advisory committee, advising the Minister and the Department of Health about the population-based screening programmes in Ireland. The Committee meets three to four times a year, with their meeting minutes published on the Government website, alongside any of their publications, such as their annual report.

5.6 CervicalCheck Tribunal (Restoration of Trust Meetings)

The CervicalCheck Tribunal Act, which was signed into law on the 23rd of July 2019, allowed for the appointment of a Facilitator of the restoration of trust process. A qualified mediator was recruited in December 2020 following the establishment of the Tribunal in October 2020.

To date work in this area has included the creation of a website, hiring of moderators, and collaboration with them on the development of a process. An important aspect of this work has been considering how the process allows for women who may not be ready to become involved until a later date.

It has been brought to my attention that there has been a lack of sufficient engagement with the 221+, and with other relevant organisations, in the early development of an effective process in this area. Recent developments in co-designing a process and preparing an agreed briefing document for all stakeholders with the 221+ Group are acknowledged.

5.7 Guidance for Registered Medical Practitioners

While engagement has occurred with the Medical Council about their guidance for registered medical practitioners, this has still not been updated to say that doctors **must** promote and practice open disclosure. The current guidance states that doctors **should** promote and practice open disclosure. This piece of work is included in their Business Plan for 2022.

5.8 Overall Assessment

The recommendations falling to the Department of Health are, in several areas, demanding of major change in attitudes and approaches. There are major achievements to report in respect of progress on Women's Health and the creation of a national screening advisory body. However, some major issues arising from the CervicalCheck scoping inquiry have not seen significant progress.

6 Health Service Executive

6.1 Implementation Actions

The HSE has been allocated 116 of the 170 actions set out in the Master Implementation Plan.

6.2 Governance structures

The Chief Executive Officer of the National Screening Service reports to the Chief Clinical Officer, who is a direct report of the HSE Chief Executive Officer. The HSE Board is accountable to the Minister for Health for the performance of its functions. This structure provides a clear reporting line between the National Screening Service and the HSE.

New functions have been added within the National Screening Service, including:

- Public Health
- Quality, Safety and Risk
- Client Services
- Strategy, Business and Projects
- Communications, Engagement and Information Development

Reporting lines have been made clearer across the service, and responsibility for the CervicalCheck Screening Programme sits with a Clinical Director.

The National Screening Service governance structures now have several committees providing oversight in specific areas, including the Quality, Safety and Risk Committee, Information Governance Committee, and programme Quality Assurance Committees. Clinical and laboratory advisory groups for specific areas also exist.

6.3 Open Disclosure

The revised HSE Open Disclosure Policy was published in June 2019. This policy specifies that open disclosure should happen in the following circumstances:

- An event where there is harm
- An event where there is suspected harm
- An event where there is no harm
- A near miss event

For the final two points, whether or not open disclosure happens is dependent on answering a specific set of questions outlined in the policy.

The Open Disclosure Policy states that it was due for revision by 12 June 2021.

An updated policy is currently on hold due to the pending publication of the National Open Disclosure Framework, and the progress of the Patient Safety Bill.

The National Open Disclosure Training Report 2021 (End of Year) indicates that 60.7% of staff have received Open Disclosure training within the previous three years (2019 – 2021). The HSE predicts that by the end of 2022 this will have reached 90%. There is a requirement for staff to complete this mandatory training every three years.

While this shows significant progress, a number of staff have yet to receive training in this area. Open Disclosure training is a mandatory requirement set out in the HSE Open Disclosure Policy, and instruction has been issued at a national level on this. Coordination and monitoring of the implementation of this training has been delegated by the CEO of the HSE to National Directors, Assistant National Directors, Hospital Group CEOs, CHO Chief Officers, and equivalent.

6.4 Overall Assessment

There has been a vast improvement in the governance structures of the National Screening Service since the publication of my main report in 2018, with clear reporting lines and accountability throughout the structure.

While the level of training in Open Disclosure has seen significant improvement, it is disappointing, but understandable, that only 60.7% of the workforce had engaged in this mandatory training by the end of 2021. It is vital that all clinical staff working within the HSE have a full and proper understanding of Open Disclosure and how it should operate in practice.

7 Laboratory Services

7.1 Assessment of Current Position

Since the initial Scoping Inquiry reports, significant developments have taken place in delivering laboratory services to the Irish cervical screening programme.

The changes to cervical screening have taken place against a background of the enormous disruption caused by the Covid-19 pandemic and cyber-attacks on Ireland's health services. In common with all health service provision, the pandemic caused significant disruption to all aspects of cervical screening, including laboratory services.

After some of the previous laboratory providers withdrew, two laboratory providers remained in the programme: Quest Diagnostics (a US-based company) and the Coombe Women and Infants University Hospital in Dublin. During 2021, the Coombe hospital suffered two cyberattacks, which have had a significant impact on the ability to deliver the service.

The achievements in the laboratory area of the CervicalCheck programme include the following:

- The programme has successfully implemented HPV testing as the primary test. This automated test detects the presence of the virus that causes cervical cancer and, combined with cervical cytology as the secondary test, is better at identifying the need for further treatment. This important development brings Ireland into line with international best practice.
- The building and commissioning of a new laboratory at the Coombe Hospital has proceeded. Although not yet commissioned, it is close to being ready and has the potential to be an excellent facility.
- There is now an excellent system of Quality Assurance (QA) for laboratory service provision in place, with a robust operating procedure developed by a QA steering committee with international and national expertise - Standards for Quality Assurance in Cervical Screening: Quality Assurance in Laboratories Providing HPV Testing, Cytology and Histopathology Services[2]
- There is good evidence of robust implementation of the operating procedures, with meaningful QA visits and regular surveillance data being monitored for both laboratories, together with robust follow-up of any non-compliances.

[2] https://www.cervicalcheck.ie/_fileupload/QualityAssurance/Quality%20assurance%20in%20Laboratories%20providing%20HPV%20testing%20Cytology%20and%20Histopathology%20Services.pdf

- The appointment by CervicalCheck of an external expert as Laboratory Clinical Advisor has been an important element of the development and implementation of robust QA.

It is important to note that, at the current time, no cervical screening cytology or HPV testing is being carried out at the Coombe Hospital. The entire national laboratory workload is currently being reported at Quest Diagnostics in the US. The reasons for this are described below.

7.2 Engagement with Quest Diagnostics

Members of the team carrying out this implementation review visited the Quest Diagnostics facility at Clifton, New Jersey in May 2022. This is a newly built and technologically advanced facility. A high volume of contract work for other healthcare organisations across the whole range of pathology analysis is carried out here, but the specification for the Irish cervical screening contract specifically conforms to the requirements of the Irish screening service.

No cervical cytology or HPV testing is currently carried out on any other site. There is however a 'back-up' site for HPV testing identified for purposes of business continuity. This is a Quest laboratory in Chantilly, Virginia. Due to the specific requirements of the Irish contract, no back up location exists for cytology. The team at Quest were open and fully engaged with the review team, as they were with CervicalCheck's QA team. All documents requested were provided for review and illustrate an excellent service with excellent quality management. The review team did not identify any quality concerns about this service. Fortunately, the service is able to cope with the increased workload while the Coombe laboratory is not functioning, and turnaround times are acceptable.

No reviews of cervical cytology for the purpose of invasive cancer audit have taken place since the time of the original report. The review team was made aware of significant ongoing litigation activity which involves Quest Diagnostics.

7.3 Engagement with the Coombe

The review team visited the Coombe in August 2022. At this time, there was no cervical screening activity taking place and this remains the case.

The activity was initially paused because the laboratory was unable to function due to a cyber-attack, but since then they have faced other challenges, including a critical loss of cytopathologist staff, due to retirement and long-term sickness absence. We have been informed by the Coombe that; a) the current position is that the issues associated with sickness absence no longer apply,; b) they have engaged an additional cytopathologist from London who visits the Coombe monthly; c) a consultant has been 'signed-off' to report cytology; and, d) a further consultant is awaiting 'sign-off'.

The laboratory service remains strongly supported by the management of the Coombe hospital and significant progress (as noted above) has been reported on consultant staffing. However, several issues highlighted in the QA process as 'non-compliances' remain unresolved, and mandatory data returns have not been made.

CervicalCheck has made resolution of the 'non-compliances' a stipulation of recommencing the contract, but, to date, the criteria set have not been met.

An interim director for the service has recently been appointed, who is a very experienced laboratory director in virology and brings significant expertise. There is an expectation from the Coombe that the non-compliances will be resolved quickly, but the review team wishes to highlight that many months have already passed without successfully resolving these issues.

Any return to the processing of cervical screening samples would initially take place in the original facilities and testing platform, which hold INAB accreditation. The process of building and commissioning the new national laboratory is well advanced. INAB accreditation is not yet in place but there is a process agreed upon to achieve this, and accreditation will be required before it goes live.

There remain concerns about the level of staffing, retraining screeners after a long break, laboratory information systems, data provision, and formal quality management processes.

A particular concern is the role of the Lead Pathologist for cervical cytology triage. This essential role is fully described in the programme guidance (section 3.3.2). The requirements of this role are not currently met by any member of staff at the Coombe and it is imperative that a qualified individual is appointed as soon as possible.

This role is critically important to assuring the quality of the cytology element of the new pathway (HPV primary screening with Cytology Triage).

These issues will need to be addressed before the service resumes. The concerns highlighted above have been documented in the QA visits and subsequent correspondence between CervicalCheck and the Coombe.

There is a process for holding operational meetings but these have not been regular. Progress appears to have been stalled for many months. The latest information from the Coombe is that the operational meetings have resumed in early November 2022.

7.4 Findings

The laboratory service is currently being safely provided through Quest Diagnostics, and the quality assurance process led by CervicalCheck is now adequate. However, the key person in this, the CervicalCheck Clinical Laboratory Advisor, has left the organisation and no replacement is yet in place. There will be a need to ensure that CervicalCheck has sufficient clinical expertise in place to ensure that it can accurately assess progress against its requirements before service delivery resumes at the Coombe Hospital and, separately, in approving the commissioning of the new national laboratory.

The review team remains of the view that it will be essential to have at least two providers of laboratory services, because of the risk to the continuity of the programme if a single provider were unable, for whatever reason, to deliver the service. Finally, external clinical input will be required to properly and expertly assess the awarding of contracts for the ongoing delivery of the service.

8 National Cancer Registry Ireland

8.1 Implementation Actions

Of the 58 recommendations, nine (recommendations 36 through 44) relate to cancer registration, and responsibility for their implementation falls in the first instance to the National Cancer Registry Ireland (NCRI) for eight of these[3].

8.2 Data Sharing

A significant piece of work that has been completed by NCRI since the last review is that data-sharing agreements with all providers who provide at least 1% of NCRI's data have been finalised. This is a big step forward for NCRI in terms of its approach to data.

A Memorandum of Understanding between NCRI, the National Cancer Control Programme (NCCP), and the National Health Intelligence Unit (NHIU) was signed in May 2022.

8.3 Recruitment

It is evident that, while NCRI has been active in their attempts to recruit the staff necessary to fulfil their function, this has been difficult due to the current job market and availability of the necessary skills. The key areas of need are in the recruitment of public health capacity, research capacity, data capacity, and Cancer Data Registrars (CDRs). It is suggested that there is a need for a 10% further increase in staff across the service. The recruitment of these additional resources should be supported by the DOH and included in their targets.

8.4 Communication

During the initial Scoping Inquiry, it was evident that there was a lack of communication and collaboration between NCRI, HSE, and NSS. Our review has shown a significant improvement in these relationships and an improved understanding of roles and strengths across each organisation.

A patient engagement event took place in 2019 which highlighted the lack of knowledge around NCRI and accessing data. The NCRI Board, as part of its strategy, identified the need to resource a dedicated communications role and to develop a three-year communications strategy. One positive step for NCRI has been the recruitment of their new Communications Officer who has led on the Communications Strategy, including key account and stakeholder development systems as well as a social media strategy.

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3 Whilst the Board of the NCRI has the power to review its own composition, any decision on appointments to the Board rests with the Minister.

8.5 Peer Review

The first peer review of NCRI happened in early 2022 and was carried out by the International Agency for Research on Cancer (IARC). My initial recommendation was that these reviews be carried out annually for three years. This did not happen for several reasons, including Covid-19, and the complex process involved in setting up and carrying out a review. It may be more appropriate to hold a peer review every two years.

8.6 NCRI Board

The NCRI Board recognised a need to expand their skillset following a skills appraisal. Work is currently being done to fill any gaps identified. The NCRI has established an Advisory Council in addition to the Board so as to strengthen links with external clinical and public health experts.

8.7 Overall Assessment

Overall, many of the recommendations which were the primary responsibility of NCRI have now been completed. However, progress in getting to this stage has been slow. Data-sharing agreements are an area where progress should have been more rapid.

One of the key issues that still exist within NCRI is resourcing, with a lack of capacity in public health, research, and data. The recruitment of Cancer Data Registrars (CDRs) has also proven difficult.

The peer review which took place this year is an important step for NCRI and any findings from this review must be supported in their implementation.

Appendix 1 *I DESERVE…*

I deserve peace of mind
To have proper professional care
To be able to trust my doctor
To be listened to by my medical team
To have my questions and concerns answered
To be supported
To feel supported
I deserve to know where I can go
and to whom I can turn to for support
I deserve to live life without fear of cancer
I deserve good health
To be free from pain and hurt
To live without having to worry
what life will be after procedures
I deserve my body back
I deserve my life back

I deserve to be myself
My own unique self
I deserve to experience love
I deserve happy relationships
The love of family and friends
I deserve to have a regular married life
I deserve to have children
I deserve moments of laughter
and everything life has to offer
I deserve to feel normal

I deserve to cry
I deserve to be allowed to grieve
To not be manipulated by fear
I deserve the head space to heal my heart
To not be an unnecessary burden
To not feel guilty for being alive
I deserve quiet
Rest
Time for myself
A free and calm mind
I deserve healing
I deserve to make peace with my story
and to accept my ordeal
I deserve to reach acceptance
I deserve to sleep at night

I deserve to be seen
To be valued
To be treated with compassion
To be treated with humanity
I deserve dignity and respect
To be acknowledged
To be able to act without constant worry about
what others think
I deserve to feel that I matter
I deserve my say
I deserve my right to tell my story in my words if I choose
I deserve to be listened to
I deserve to get my story heard
I deserve to be heard

I deserve for those who caused this
to understand what it has done to my life
What surgeries I had to go through
What radiation I had to endure
What chemotherapy I had to endure
I deserve for them to know the damage done to my body
I deserve for them to understand how my life has changed
My bowel
My bladder
Incontinence
Hip pain
Back pain
Lymphoedema
Inability to have sex
I deserve for them to know how it destroyed
the life I had been living
I deserve to have the respect
of the laboratories who rushed our samples
and made mistakes
For the women who have lost their lives
and their families are in tatters

I deserve to be treated as a person who has been let down
by the HSE and the government
I deserve the government to act on our behalf
and not to oppose this group
I deserve not to be treated as the aggressor
I deserve restoration
I deserve fair play
I deserve to speak with the decision makers
To not be dragged through the court procedure
when I placed my trust in the system

I deserve an apology
A meaningful apology
I deserve to know the truth
To be told the truth
I deserve answers
I deserve justice
I deserve for this never to have happened
I deserve closure
I deserve for it to be over

I deserve to not have to worry about the future
To be able to plan for the future
To get on with my life
To get an even chance at life
I deserve a future
I deserve to hope
I deserve to be given new hope
I deserve to know that best efforts are being made
to reduce the likelihood of this happening again
I deserve to believe
I deserve to be able to show my children the correct values
to fight for
I deserve to make things better
without first having to make things worse

I deserve health
I deserve security
To be well
To be free
I deserve justice for the wrong done to me
I deserve happiness
Peace
Peace of mind
I deserve for this not to define me
I deserve to live
I deserve to be here
I deserve to be alive

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I Deserve credit:

I Deserve is compiled from the words of 221+ members by artists Fiona Whelan and John Conway, as part of a long-term collaborative arts project exploring and responding to the lived experiences of those failed by the CervicalCheck screening programme. *I Deserve* was first shared as a spoken word performance by a group of 221+ members at one of the project's regional gatherings of members with the artists in The Model, Sligo on 1 Oct 2022 at which Dr. Gabriel Scally was in attendance. The text forms part of an accumulating body of artistic research informing the development of a larger body of artworks in the coming years. The project was commissioned in 2021 by 221+ and is to date supported by the Arts Council, Create - the national development agency for collaborative arts, Waterford Healing Arts Trust, The Glucksman, The Model, Regional Cultural Centre and the National Museum of Ireland at Collins Barracks.

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Image credit:

Patient ID Wristband (Female). Anon 221+ member, 2022. An artefact from the 221+ collaborative arts project (2021 - ongoing).