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

**Dr Gabriel Scally** 

Implementation Review Report April 2020

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## **Foreword**

Dear Minister,

In keeping with the proposal in my main report in September 2018 on the problems surrounding cervical screening in Ireland, I reported to the Minister for Health in 2019 on the progress being achieved in creating an effective and safe screening system.

I am pleased to submit this further report on progress in the implementation of my recommendations for the improvement of cervical screening in Ireland. Comments on the progress are included in respect of each of the recommendations and reflect the position as I was aware of it at the time of writing. The current coronavirus crisis has had an inevitable effect of the work of my team in recent months.

In general, the progress has been good, and in some cases exemplary. Inevitably in the case of a programme of change and development, there will be some areas that have progressed faster than others. In my earlier assessment of progress, I noted that the timescales were challenging in some areas and this is taken into account in the assessments in this report. There are five particular areas on which I wish to comment in this foreword. But I would like to start by commending all those who have worked so hard to ensure that the cervical screening programme can be delivered effectively and safely for the women of Ireland and that it is a programme in which they and their families can have confidence.

I have been very impressed by the commitment and competence of the staff of the Health Service Executive (HSE) who have been working to implement the recommendations. They have achieved enormous progress in a relatively short period of time and have managed this despite the difficult task of planning for the major change in the system whereby Human Papilloma Virus (HPV) testing will become the primary screening method. Similarly, some of the progress achieved by the Department of Health, for example in respect of the creation of a national screening committee to oversee and advise on policy issues in all screening programs, and the establishment of a Women's Health Taskforce, is highly commendable. Changing the way in which women's health needs are identified and responded to will require substantial and energetic work programmes. I hope that the Women's Health Taskforce and its work will be accorded the importance and prominence it deserves.

The first issue on which I wish to comment specifically is in respect of the role and engagement of patient advocates. My recommendations about the important, indeed vital, contribution that can and should be made by patient advocates in many aspects of health service provision were accepted and are being implemented alongside my other recommendations. However, recent resignations of patient advocates from the board of the HSE and the Department of Health's steering committee for cervical screening are a sign that all is not well. I believe further effort is needed to ensure that the role of patient advocates is understood and supported by the civil servants and public servants with whom they are expected to work. The further issue of a scheme to ensure that those undertaking

these roles in the future do not do so at their own, sometimes considerable, expense still remains to be resolved.

One area where very limited progress has been made and where it is extremely important to secure progress, is in the important task of cancer registration. In my comments contained within this implementation report I make it clear where progress is still lacking. On the other hand, I am pleased that substantial progress is being made in developing the public health system in Ireland, and the existence of a global infectious disease epidemic reinforces the need for rapid progress. However, within the context of this broader development of public health, the vital role of cancer registration must not be ignored. The recent or pending loss of key staff is, I believe, a reflection of an organisation that has been neglected and is in crisis. It may be worthwhile taking the opportunity to consider how cancer registration could fit within a wider public health intelligence function, perhaps within a national Public Health Observatory. But, whatever about future opportunities for development, the need for speedy action to resolve the problems currently affecting cancer registration is very apparent and should not be ignored.

My third comment is in respect of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019. I am pleased to see that the Bill places an obligation on both a healthcare organisation and an individual health practitioner to engage in open disclosure to patients when it is needed. But it is not clear to me that if the Bill, as currently written, had been in force at the time of the CervicalCheck non-disclosures it would have been of any assistance to the patients and families. I hope that the 33rd Dáil will give careful consideration to the content and implications of the Bill and that the final legislation will provide the basis for the substantial and ongoing work that is required to ensure that when things go wrong in healthcare, patients can, and will, be told the truth, receive an appropriate apology, and where possible receive assurance that action will be taken to minimise the chances of such an error happening again.

The fourth area on which specific comment from me is very necessary is the issue of clinical audit. In the main report of the Scoping Inquiry I emphasised the importance of developing clinical audit. Carrying out lookback exercises whereby cytology examinations are repeated some years, often many years, after they were first carried out undoubtedly has a value under some circumstances, although there are many countries where this does not occur. But the most valuable type of clinical audit is that which happens in real time, and where the carrying out of clinical care is examined in the context of the standards that have been preset. These standards can then be modified in the light of the audit findings so that care is improved. This 'audit cycle' approach should be a standard in the practice of doctors, other health professionals, and in the teams within which they work. The importance of contemporary and ongoing clinical audit is reinforced by the findings of the Royal College of Obstetricians and Gynaecologists (RCOG) review published in December 2019. The review noted that in 27 out of 1034 patients with cervical cancer, the colposcopy examination and process was suboptimal. Although this represents only 2.8% of patients, it highlights the need for continuous clinical audit programmes to be in place.

Finally, in my work on CervicalCheck I have repeatedly stressed the need to introduce the concepts of grace and compassion into the way in which people are dealt with when

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something goes wrong in their health care. At the present time there are substantial legal barriers deliberately and highly effectively obstructing the proper investigation and resolution of patient complaints about clinical care. I am aware that the Department of Health is working on this issue, and has been doing so for some time, but making effective progress on the fundamental right of a patient to have justifiable concerns about their clinical care taken seriously is an absolute necessity. It is a vital first step in addressing patients' three concerns when things go wrong. I would urge that in the interests of patients and of the health service, rapid progress is now set in train to establish a proper mechanism for dealing with clinical complaints.

Eighteen months after my main report was published I am pleased to be able to report substantial progress. My many meetings and discussions with all those involved have, I believe, been valuable. It is important that the momentum is continued, not only because of the crucial importance of the cervical screening programme, but also because many of the issues raised and solutions proposed will result in widespread benefits to the health system as a whole.

Yours sincerely,

**Gabriel Scally** 

# **Important Notice**

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

- 1. This is a Scoping Inquiry and not a Commission of Investigation.
- 2. This Implementation Review report should be read in conjunction with the Final Report of the Scoping Inquiry, which was published in September 2018, and with the Supplementary Report published in 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. It has not been possible to offer each person or body who is named or referred to in the report an opportunity to comment on the report, or to canvass and represent views of all parties on every issue therein or on opinions expressed by other parties who met with the Scoping Inquiry. Those who were given a preview of the preliminary analysis and permitted to make submissions on the conclusions reached in this report, insofar as it might affect them directly, include the following bodies: Quest Diagnostics Incorporated, the Health Service Executive, and the National Cancer Registry of Ireland.
  - The Inquiry team is grateful to each such body for responding to the team within the strict timeline adopted, of necessity, by the Scoping Inquiry.
- 4. All views expressed within the report are subject to the caveat that persons or bodies affected have not been given the opportunity to cross-examine or test the sources of information made available to the Scoping Inquiry, and the information, and hence the conclusions and views expressed as a result of the information, must therefore be treated with a certain degree of caution.

# **Glossary**

#### **Organisations**

CervicalCheck	The national cervical cancer screening programme
HSE	Health Service Executive
NCRI	National Cancer Registry Ireland
NCSS <sup>1</sup>	National Cancer Screening Service
NCSSB <sup>1</sup>	National Cancer Screening Services Board
NSS <sup>1</sup>	National Screening Service
RCOG	Royal College of Obstetricians and Gynaecologists
SCA	State Claims Agency

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The organisation now known as the National Screening Service (NSS) has previously been called the National Cancer Screening Services Board (NCSSB) and the National Cancer Screening Service (NCSS) at different times since its establishment, as set out in more detail in Section 5. Throughout this document, references may variously be made to the different names of this entity depending on the period of time being referred to within the text in question.

## 1 Introduction

#### 1.1 Actions Arising from the September 2018 Scoping Inquiry Report

Following the publication of the CervicalCheck Scoping Inquiry report on 12th September 2018, I was requested by the Minister for Health to undertake a review of the implementation plans of each of the statutory organisations named in the report. This was in line with the statement in the Foreword to my report, namely:

Within three months of the publication of the Scoping Inquiry report, there should be an independent review of implementation plans to be produced by each State body named in this report, in respect of the recommendations contained herein. The findings of this independent review of implementation plans should be submitted to the Minister and published.

The Scoping Inquiry report listed 50 recommendations, and a further six recommendations appeared in my first report / progress report of June 2018. 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 56 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, although I noted some concerns regarding the fact that many of the actions allocated to the HSE were "front-loaded" and were potentially subject to delay.

This report focuses on the progress achieved up to the end of 2019.

# 2 Overarching Structures for Implementation

#### 2.1 Working Group

A working group was established at the beginning of the process to oversee the implementation process. This group has continued to meet to review progress, and as the number of actions complete has increased, the frequency of the working group meetings has changed.

#### 2.2 Development of Master Implementation Plan

The Working Group has developed a detailed implementation plan covering all of the State bodies involved in CervicalCheck. Three of the organisations concerned – the Department of Health, the HSE, and the National Cancer Registry of Ireland – have specific actions allocated to them, whilst the fourth, the State Claims Agency, will be involved in certain activities to be progressed by the Department of Health but will not be directly responsible for their implementation.

The detailed implementation plan <sup>2</sup> contains 163 individual actions, and lead responsibility for taking them forward is broken down as follows:

Lead responsibility	Number of actions
Department of Health	28
Health Service Executive	111
National Cancer Registry of Ireland	23
221+ Support Group	1
Total	163

Some of the recommendations within my September 2018 report and Supplementary Report, are covered by a single action within the implementation plan, whilst others (typically the more complex issues which will require time to resolve) may have several actions associated with them. Some actions are reliant on external factors such as the approval of legislation by the Oireachtas.

It is also worth noting that whilst all of the organisations involved in CervicalCheck are committed to working from the implementation plan established by the Working Group, there has also been considerable activity within these bodies to develop more detailed plans. For example, an Implementation Steering Group for CervicalCheck was established within the HSE, co-chaired by the Chief Operations Officer and the Chief Clinical Officer, and a project manager was appointed. Over the period in

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The plan went through a number of iterations; the analysis presented in this report relates to Quarterly Progress Report on Implementation of Scoping Inquiry Recommendations, Quarter 4 2019.

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question, some of these plans have been reviewed to ensure they reflect other changes within the health sector and to ensure other issues that have arisen have been addressed.

# 3 Overall Progress – All Organisations

The table displayed overleaf shows the progress achieved to the end of December 2019 in respect of the 50 recommendations within the September 2018 Scoping Inquiry report and the two additional recommendations within the Supplementary Report, covering all organisations allocated implementation responsibility.

Sections 4, 5, 6 and 7 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 within stated deadline		
Amber Slippage identified or work not yet started			
Red	Action has stopped or is seriously off target		
Blue	Action completed		

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
Meth	od of Approach				
1	The Department of Health and the HSE should revise their	HSE and	Q1 2020	Both the Department and HSE have reviewed their policies on	Behind
	policies in respect of document management. This should	DOH		document management and have set action in train to ensure	schedule
	ensure that good quality records are created and maintained			that they will in the future will comply with the goal set out in the	
	which are authentic, reliable, and complete in searchable			recommendation. This work is on-going across both	
	format. They should be protected and preserved to support			organisations and progress will need to be reviewed in due	
	future actions and ensure current and future accountability.			course.	
Liste	ning to the Voices of the Women and Families Affected				
2	The Minister of Health should give consideration to how	DOH	Q3 2019	A Women's Health Taskforce has been established for an initial	Complete
	women's health issues can be given more consistent, expert			two-year period to look at women's health issues. It will merit	
	and committed attention within the health system and the			further consideration at the end of the two-year period as to how	
	Department of Health.			women's health matters will be reviewed into the future.	
3	The Department of Health should examine the current	HSE	Q4 2019	An audit of access to patient records has been undertaken, this	Behind
	arrangements for patients to have access to their hospital			included engagement with a panel of patients. According to HSE,	schedule
	medical records so that such access can be achieved in a			Improvement plans are being developed and will be implemented	
	timely and respectful way.			in 2020.	

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)		
			by	Commentary	Status	
Cer	vicalCheck – 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	Q2 2019	Two patient advocates appointed to the HSE board on its establishment.	Complete	
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	Q4 2019	National Screening Advisory Committee has been established and held its first meeting on the 18 <sup>th</sup> November 2019. Support staff for the committee are being recruited. The membership of the committee was announced on the 29 <sup>th</sup> of October 2019. The Committee has been given its first task by the Minister, that is to review infant screening. The committee includes two lay members to provide a public voice in its deliberations.	Complete	
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	Q4 2019	The NSS has appointed an interim CEO who reports directly to a senior member of the HSE management team. The future reporting lines have been agreed internally and will be implemented during 2020.	Complete	
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	Q3 2020	Senior Public Health input now in place across the screening service. New structures for public health across the HSE is in development and will be rolled out in 2020.	On track	
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	Q4 2019	New HSE Board has been reviewing how the organisation approaches risk and is developing a standard approach to the measurement and recording of risk.	On track	

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
Cer	vicalCheck – 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	Q2 2019	Two quality assurance visits have taken place during 2019 to ensure that all current laboratory service providers are adhering to the programme standards.	Complete
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	Q3 2019	A single agreed terminology is now in place across all laboratory service providers.	Complete
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	Q2 2019	In general, there has been significant progress in reviewing and amending structures of quality assurance. There remains scope for better engagement with the colposcopy community and gaining their involvement with the programme organisation and functioning. It is to be noted that significant investment has been provided to enhance colposcopy provision in advance of the roll out of HPV testing.	Complete
12	CervicalCheck should adopt a formal risk management approach to parameters which do not reach acceptable standards despite full intervention and monitoring.	HSE	Q2 2019	Governance structures have been updated to reflect the new structures. QA risks have been standardised by the director of Public Health	Complete
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	Q2 2019	Memorandums of Understanding reflecting enhanced quality assurance, risk management and performance management. A steering group to review the wider performance framework for all screening programmes was convened in mid-2019. The terms of reference for the CervicalCheck clinical advisory group have been agreed. A laboratory subgroup has been established and the arrangements for monitoring quality have been agreed.	Complete

Reco	ommendation	Owner C	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
14	CervicalCheck should collate and publish annual data on reporting rates for all categories broken down by provider.	HSE	Q1 2019	A report containing the breakdown as per the recommendation was published in Nov 2019. However, given the reconstruction of screening services over the recent period it is unsurprising that the timeliness of reporting has slipped but, every effort should be made to bring the report up to date so that the valuable information they contain is available publically in a timely fashion.	Complete, but with further updates required
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	Q2 2019	Data as per the recommendation included in the CervicalCheck Annual report for 2016/2017.	Complete
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	Q4 2019	QA Committee will oversee the approval of reports generated by CervicalCheck. The Director of Public Health will be responsible for ensuring that the available data is used to support epidemiological analysis.	Complete
17	The different rates of sensitivity for ASCUS+ identified by second screen at each provider require further investigation by CervicalCheck.	HSE	Q3 2019	CervicalCheck continues to monitor cytology reporting and quality through the Cyto1 laboratory returns and other quality metrics including site visits. Evidence required that differing rates no longer occur or are being investigated.	On Track
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	Q2 2019	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.	Complete

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
Prod	curement 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	Q2 2019	Winning proposals are now appended to contracts and kept for the necessary period following termination of the contract	Complete
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	Q2 2019	Quarterly meetings established at senior management level to monitor contract performance. There is now a much closer oversight of operational performance on a bi-weekly basis.	Complete
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	Q2 2019	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.	Complete
22	CervicalCheck should ensure that its procurement approach maintains a balanced focus on qualitative factors, supplier experience, and innovation, alongside cost considerations.	HSE	Q2 2019	Any future procurement of laboratory services will focus on qualitative factors with cost being a pass fail criterion.	Complete
23	CervicalCheck should ensure that future procurements incorporate measures to test performance in the current contract.	HSE	Q3 2019	Current contracts have incorporated metrics to aid assessment of contract performance.	Complete
24	External professional assistance should be sought in the construction of any future 'Request for a Proposal' 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	Q2 2019	A process auditor has been appointed to oversee procurement competitions.	Complete
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	Q2 2019	A process has been developed for the approval of additional laboratories where the need arises. This process has been tested during 2019 to ensure it meets the requirements of CervicalCheck regarding quality and other metrics.	Complete

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)		
			by	Commentary	Status	
Aud	iting 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	Q1 2020	Work continues to develop the audit framework for each of the screening programmes.	Behind schedule	
27	There should be a minimum of two patient advocates involved in the oversight of clinical audits for the screening services.	HSE	Completed	The inclusion of two patient advocates has been completed.	Complete	

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
Ope	n 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	Q4 2019	The HSE policy has been revised and issued, subject to any changes that may be required following the enactment of the patient safety legislation. Patient advocates were consulted as part of the process. HSE should undertake an assessment of the effectiveness of the training programme and the revised guidance.  An Independent Patient Safety Council has been established; its first task is to review existing open disclosure policy.	Complete
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	Q3 2019	This recommendation has only been partially implemented as, according to the policy, the requirement to scrutinise non disclosures only applies to category one incidents i.e. those that are rated as 'major or extreme'.  This recommendation has only been partially implemented, due to it being dependent upon the Patient Safety Bill; the movement of this Bill into an Act being dependent on timing outside the control of the Department or the HSE.  The current Open Disclosure policy includes provision for the inclusion of patient safety advocates in a decision not to disclose.	Complete
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	Q2 2019	Any new contracts for medical staff now include the requirement to complete open disclosure training. However, this still leaves an issue in respect of doctors who are currently employed by the HSE.  The creation and implementation of a training programme is still in development.	Overdue to Finish
31	A governance framework for open disclosure must be put in place that includes evaluation and audit.	DOH and HSE	Q3 2019	This recommendation is being looked at as part of the Patient Safety Bill (noted in Recommendation 29). Recruitment of a National Open Disclosure Office within the HSE has been completed and a work plan has been developed.	Complete
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	Q2 2020	Produced a 2018 report on Open Disclosure. The 2019 report will be submitted to the Board in the first half of 2020.	On track

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
Ope	n 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	Q4 2019	The guidance for registered medical practitioners on open disclosure and duty of candour has not yet been strengthened.	Overdue to finish
Ope	n 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	Q3 2019	The Government has introduced the Patient Safety Bill which will deal with the issue of duty of candour, which should be placed on both healthcare organisations and individual healthcare professionals. The provisions of the Bill should also allow for appropriate sanctions in the case of breech of these statutory duties.	Complete
35	This duty of candour should extend to the individual professional-patient relationship	DOH	Q3 2019	The Government has introduced the Patient Safety Bill which will deal with the issue of duty of candour, which should be placed on both healthcare organisations and individual healthcare professionals. The provisions of the bill should also allow for appropriate sanctions in the case of breech of these statutory duties.	Complete

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	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	Q4 2020	A short-term data sharing agreement has been put in place between NCRI and HSE, and this is now due for review and renewal. A MOU is now in place between NCRI and NSS. A MOU is being negotiated between NCRI, NCCP and the HSE's Health Intelligence Unit. Data sharing agreements have been concluded with some private hospitals and others are in progress of agreement. The original recommendation noticed the urgency of this work. Whilst there has been progress, the pace of action has not been satisfactory.	Behind schedule
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	Q4 2021	A) Whilst some additional resource has been made available to NCRI further action is needed to enable recruitment of the technically skilled staff required for a registration function that, in the future, will be based upon electronic data flows. A skills analysis of future staffing requirements should be carried out as this would support appropriate recruitment. The need for additional public-health medicine capacity for NCRI should be considered in overall context of the development of public health intelligence functions across the health service. However, the overall functioning of the NCRI is now in jeopardy due to resignations of key personnel.  B) The opportunity exists to make a reality of automated electronic data flows to the cancer registry from hospital laboratory IT systems. However, this cannot happen until the	Behind schedule
				information function within HSE accords the issue a higher level of priority.	
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	Q4 2020	NCRI has only recently completed definition of its own core datasets. The rate of progress is slower than will be expected and should be prioritised for earlier achievement.	On track

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
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	Q4 2020	Data sharing between NCRI and cervical check has been operational since late 2018. Progress however has been slower than would have been expected, but is moving in the right direction. It is important that progress continues and, where possible, the pace of that progress is accelerated.	On track
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	Q1 2019	The composition of the Board of NCRI is specified in legislation and the level of change required in the Board will likely require amendment of that legislation. Two new members were appointed to the Board April 2019 as part of a routine change, but further refreshment of the Board is still needed. In order to provide the Board with additional skills prior to any change in its statutory composition, the Department of Health should consider appointing non-statutory advisors to the Board, notwithstanding the fact that such Board participants would not be full voting members at this point.	
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	Q4 2020	Work is underway to ensure that the governance of the relevant organisations interlinks sufficiently to ensure cohesive working arrangements. This recommendation has therefore been partly achieved and its continuance will be dependent on the strengthening and development of coordination of public health systems more widely. NCRI needs to be firmly embedded in the broader and increasingly coherent approach to public health in the country.	
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	Q4 2021	It is commendable that the International Agency for Research on Cancer (IARC) has been approached by the Department of Health can to conduct a peer review of NCRI. The original recommendation of the Scoping Inquiry, in September 2018, was that reviews should be annual and take place for at least the following three years. Given that a review has regrettably not taken place in 2019, annual reviews should take place at least for the years 2020, 2021 and 2022.	On track

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2019)	
				Commentary	Status
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	Q3 2019	NCRI has completed a stakeholder survey and has held public engagement events. They have, in particular, worked with The Patient Voice in Cancer Research initiative. The feedback received is regarded as invaluable and has influenced and been incorporated into the NCRI work programme.	Overdue to finish
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	Q4 2020	In the memorandum of understanding between NCRI, NCCP the HSE Health Intelligence Unit, which is due to be finalised in the near future, it is envisaged that systems will be put in place to enable NCRI to engage with the structures determining cancer care programmes.	On track
Othe	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	Q4 2019	QA Committees have been established across the screening programmes. There is closer working across the various screening programmes	Complete
46	The composition and duration of appointments for all QA Committees should be reviewed, in conjunction with emerging clinical advisory committee structures.	HSE	Q1 2019	The committees have been reviewed and 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	Q4 2019	The QA committees will provide documentation in respect of training and development of staff in the various screening services.	
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	Q4 2019	Open disclosure training has been provided for senior staff in the NSS. A training programme for colleges and training bodies is still in progress. However, work should continue to ensure that the principals of open disclosure are applied within policies and activities of all screening programmes.	Overdue to finish

Recommendation		Owner	Completion	Independent Assessment (at Dec 2019)	
			by	Commentary	Status
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	Q4 2019	The CervicalCheck Tribunal Act which became law on the 23 <sup>rd</sup> July 2019 allows for the appointment of a Facilitator of meetings to restore trust. The practical arrangements for the establishment of this process are still in train.	On track
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	Q4 2018	Successful engagement has taken place with the relevant medical organisations and the 221+ support group.	Complete
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	Q3 2019	There are more stringent provisions to ensure that additional laboratory facilities are not brought into the system without explicit agreement with CervicalCheck.	Complete
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	Q4 2019	Improved QA process are in place and would appear to be operating very satisfactorily with a programme of scheduled QA visits having been completed.  A laboratory QA specification manual for CervicalCheck is being implemented.	Complete

# 4 Department of Health

#### 4.1 Implementation Actions

The Department of Health had 28 actions across 13 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 Bill. Many of the Departmental actions form one element of the implementation of various recommendations

The key internal action is to revise policy in relation to document management. A suitable document management system has been identified; this system is already in use in other Departments and feedback has been positive. The implementation of the document management system across the Department is still to be completed. The Document and Records Management Protocol has been developed, but other relevant policies are yet to be developed, such as a Retention Policy and guidance documents for staff.

A number of the Departmental recommendations are subject to the Patient Safety Bill and the Health Service Executive (Governance) Bill passing through the Houses of the Oireachtas. On 5 June 2019, the Health Service Executive (Governance) Act 2019 was signed into law by the President. This Act established a Board for the HSE, which held its first meeting on 28 June 2019.

The general scheme of the Patient Safety Bill was published in July 2018, has undergone pre-legislative scrutiny, and has currently passed the second stage of the Dáil. This bill is subject to legislative scrutiny and the timing of its enactment is outside the control of the Department.

The Independent Patient Safety Council held its first meeting on 27 January 2020. Members are appointed for three to five years. The current members include three patient/public representatives and an international patient safety expert. The first task of the Council will be to complete a detailed review of existing policy on open disclosure.

A Women's Health Taskforce has been established and met for the first time on 26 September 2019. It has been established for a two-year period and many of the members are from the Department of Health, alongside external members from organisations such as the National Women's Council of Ireland, the HSE, and the Institute of Public Health in Ireland.

The National Screening Advisory Committee has been established and members have been selected, including two public representatives. The first meeting of this Committee took place on 18 November 2019.

The CervicalCheck Tribunal Act 2019 was signed into law on 23 July 2019. It does not appear that any cases have been brought to the tribunal yet; the requisite number of judges do not appear to have been appointed.

The meetings to restore trust – meant to occur between the women and/or family members affected and the clinicians involved – have also not yet occurred. A process for the meetings to restore trust has been developed; the 'facilitator' and mediator positions for these meetings need to be recruited.

With regard to the payment of patient representatives, there is still work to be done. International policies of a similar nature have been reviewed. Analysis regarding a rate of remuneration has begun, with engagement with the Department of Public Expenditure and Reform. A stakeholder consultation process has also commenced. It is anticipated that remuneration for patient representatives will be in place shortly.

Engagement with the Medical Council is awaiting the renewal of membership of the Medical Council's Ethics Committee. Once the new Committee has been appointed and has met, it will begin a review of the current Ethical Guide. The Department aims to input into this process.

#### 4.2 Allocation of Responsibilities

For the 20 actions, lead responsibility has been allocated to four senior officials. The Chief Medical Officer has overall responsibility for 13 of these actions, with the remaining seven split between the Deputy Secretary – Governance and Performance Division, the Deputy Secretary – Policy and Strategy Division, and the Assistant Secretary – Acute Hospitals Policy Division. These senior officials are supported by Principal Officers who have the day-to-day responsibility for ensuring the actions progress in a timely manner. As part the review, meetings were held with each team responsible for the implementation of actions.

This allocation of responsibilities ensures that each of the actions has the appropriate level of oversight at the highest level within the Department.

#### 4.3 Resources Assigned

Each of the actions has a least one Principal Officer or equivalent assigned to manage it on a day-to-day basis. The responsibilities for each action and the dependencies across the actions are clear from the implementation plan. While some of the recommendations impact on the work of one unit or division, others impact on all staff.

There is also support from the internal CervicalCheck Project Team and the Department of Health CervicalCheck Steering Committee. The Steering Committee comprises senior Departmental Officials, patient representatives and the HSE. The

terms of reference for the Committee include implementation assurance on the Scoping Inquiry and policy responses.

#### 4.4 Overall Assessment

Having reviewed the actions taken by the Department to implement the recommendations of the Scoping Inquiry report, I believe that the approach taken has implemented the recommendations as set out in the Final Report. There are a number of actions which remain to be completed as they rely on the legislative process. The outstanding legislative matters should be addressed as soon as possible following the establishment of the 33<sup>rd</sup> Dáil. Any remaining actions that are not dependent on legislation should continue to be progressed.

I welcome the progress to date, including the establishment of the Independent Patient Safety Council, the Women's Health Taskforce, and the National Screening Advisory Committee. These groups should continue to meet regularly and receive resources required to adequately advise the Minister and to assess proposed health policy.

## 5 Health Service Executive

#### 5.1 Implementation Actions

111 of the 163 actions / subtasks within the implementation master plan are allocated to the HSE; as the table in Section 3 shows, the vast majority of these actions were on track at the end of December 2019. A number of the actions associated with the implementation plan had also been incorporated into the HPV project plan. These were all expected to be completed during the first quarter of 2020 when HPV primary was planned to go live.

Deadline	<b>HSE Actions</b>	Completed	To be completed
Q4 2018	10%	100%	0%
Q1 2019	16%	94%	6%
Q2 2019	46%	98%	2%
Q3 2019	9%	80%	20%
Q4 2019	16%	72%	28%
Q1 2020	2%	0%	100%
Q2 2020	1%	0%	100%
Q3 2020	0%	0%	0%
Q4 2020	0%	0%	100%
Total	100%		

Overall, it is very striking that while the implementation plan specifically in respect of HSE subtasks appears was very front-loaded, with 97% to be completed by the end of 2019, a significant number of these actions have been completed.

Significant work has been undertaken by the HSE to improve the governance structures within screening and in particular within CervicalCheck. This includes increasing the public health resources available to support the screening programmes, as well as other professionals to specifically support the CervicalCheck programme.

The HSE has also put in place new governance procedures with each of the labs involved in the CervicalCheck programme. This has included a number of laboratory visits during 2019. Systems have also been put in place to ensure that only laboratories which have been approved are used by providers. The system for approving additional laboratories has been agreed and tested. For any new facilities approved in 2019, an approval process was conducted in advance of CervicalCheck work being undertaken in new locations.

CervicalCheck has recommenced quality assurance visits as part of the laboratory governance and oversight. These visits have highlighted some issues that require addressing but none that raised significant concerns about quality.

Work has also been undertaken to update the open disclosure policy. This update provides an interim position while the Patient Safety Bill is discussed and voted on by the Oireachtas. The HSE has also been involved in the development of an online communications course to support open disclosure as it is classified as a more complex part of patient communication.

Progress has also been made regarding the management of healthcare records. An audit of healthcare record access has been undertaken and this included engagement with a panel of patients who have accessed medical records to get their insights and views on the process.

#### 5.2 Allocation of Responsibilities

The subtasks within the implementation plan were allocated to a range of senior managers within the HSE, including the Chief Clinical Officer, Chief Information Officer, the National Director responsible for the National Screening Service, the National Director of Procurement, the National Director responsible for Communications, the National Director of Community Operations, and the HSE CEO. The Interim CEO of the Screening Service and a number of other individuals within both the Screening Service and CervicalCheck have been involved in the implementation of various actions.

The project management approach taken by the HSE appears to have provided an effective and efficient way of ensuring that the individual actions were progressed in a timely fashion.

#### 5.3 Overall Assessment

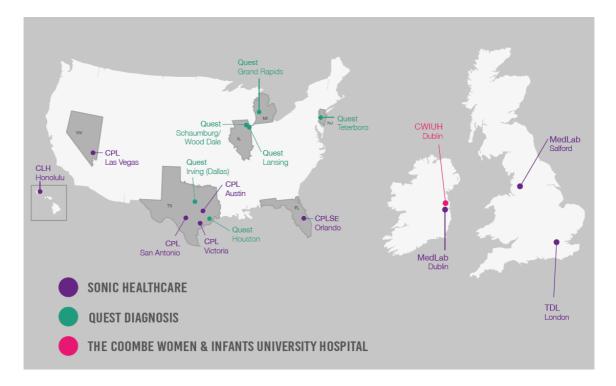
The structures developed by the HSE to implement the Scoping Inquiry recommendations are in line with good practice and appear to be well resourced. From my engagement with the HSE, I am satisfied that this work is being taken forward very seriously and that an effective project management process is in place. As noted above, I was somewhat concerned that elements of the plan may be overly ambitious and that too many activities may have been scheduled for completion during 2019. However, progress by the end of 2019 has been satisfactory.

## 6 Laboratory Services

#### 6.1 Findings within June 2019 Supplementary Report

In my Supplementary Report published in June 2019, I reported that the total number of laboratories involved in Irish cervical screening was 16, compared with the six laboratories which were originally believed to have been used since the CervicalCheck programme commenced in 2008.

The locations of these 16 laboratories, which are widely distributed geographically, are illustrated below.



My concerns regarding the use of these laboratories centred around a number of aspects:

- The HSE appears to have been unaware of the involvement of most of the US laboratories, dating back to the early days of the CervicalCheck programme the fact that Irish cytology work was routed through certain laboratories operated by both CPL / Sonic Healthcare and Quest Diagnostics was first revealed by the Scoping Inquiry in my reports dated September 2018 and June 2019. There was very limited evidence made available to the Scoping Inquiry to show that the HSE / CervicalCheck was ever consulted actively and in writing about the potential or actual use of 10 of the 16 laboratories.
- The 16 laboratories included a facility in Salford, Greater Manchester, which was owned and operated by the Dublin-based MedLab Pathology Ltd, a subsidiary of Sonic Healthcare. The Scoping Inquiry was unable to find any evidence that the HSE had been advised that the Manchester facility was in use for CervicalCheck

screening, nor did the HSE's permission to use the Manchester laboratory for CervicalCheck work appear to have been sought or granted. This arrangement was in operation from February 2016, and the HSE appears only to have been formally advised by MedLab in October 2018 that CervicalCheck slides were being sent to Manchester for cytology screening.

- Whilst 15 of the 16 laboratories were covered by appropriate accreditation and external quality assurance arrangements in their respective countries, the accreditation arrangements for the Manchester laboratory operated by MedLab presented some difficulties for the Scoping Inquiry. The Irish National Accreditation Board (INAB) considered that the cytology screening carried out in the Manchester ancillary laboratory was automatically included in MedLab's Irish accreditation. I found this to be both surprising and disturbing, particularly given that INAB did not appear to have been conscious that this facility was operational, and I concluded in my June 2019 report that it was stretching credibility that a laboratory facility can reasonably be accredited retrospectively for periods of time during which its existence was unknown to the accrediting body.
- Quality assurance (QA) arrangements in place within the HSE for much of the
  existence of the CervicalCheck programme were deficient. Early QA visits to the
  US laboratories failed to identify the fact that a significant amount of
  CervicalCheck was being routed through a wide network of laboratories whose
  existence was unknown to the HSE, and whose involvement had not been
  approved by the HSE.
- Overall, it was disappointing that the Scoping Inquiry only learnt about the
  additional 10 laboratories as a result of our extensive and intensive probing. With
  regard to both CPL / Sonic Healthcare and Quest Diagnostics, full disclosure
  was only made after a series of meetings and site visits to the US, which took
  place between mid-2018 and early 2019. Full transparency and disclosure from
  the outset would have significantly shortened the time taken to conduct the
  Scoping Inquiry, and would have reduced its costs accordingly.

#### 6.2 Assessment of Current Position

Against that backdrop, the Scoping Inquiry sought to address the following critical questions during this phase of the implementation progress review:

- What laboratories are now used for the screening of Irish cytology slides as part of the CervicalCheck programme?
- What level of engagement exists between the HSE and the laboratory service providers in respect of ongoing oversight of cytology services?
- How robust are the governance, oversight and quality assurance arrangements which are currently in place?

Since the publication of my last report in June 2019, Sonic Healthcare has ended its involvement with the CervicalCheck programme, with MedLab Pathology completing

its final tests in early August 2019. CPL, another subsidiary of Sonic Healthcare, completed its work on the CervicalCheck programme when its contract came to an end in 2013.

Accordingly, the service providers which currently deliver laboratory-based cytology services to CervicalCheck are Quest Diagnostics in the US, which is responsible for approximately 90% of the total volume, and The Coombe Women and Infants University Hospital in Dublin, which handles the balance of 10%.

This assessment has therefore been confined to Quest Diagnostics, given the nature of the issues set out in my June 2019 report. We have not re-engaged on this occasion with The Coombe, but we have analysed the activity data from its laboratory and we are satisfied from our discussions with the HSE that it continues to perform effectively.

(It should be noted that under current plans, CervicalCheck will transition this year to a model of primary HPV screening, which will reduce significantly the volume of cytology based testing. The HSE's current contract with Quest Diagnostics for cytology screening is of a short-term nature and is based on the planned transition to primary HPV screening.)

#### 6.3 Engagement with Quest Diagnostics

In order to answer the questions posed above, the Scoping Inquiry team held a series of meetings with the HSE and with Quest Diagnostics in order to understand the current arrangements, including a detailed engagement with a senior team from Quest in late 2019 at the company's headquarters in Secaucus, NJ. The key purpose of this engagement was to determine whether the issues identified in my June 2019 report were addressed, and whether effective governance processes are in place with respect to CervicalCheck work.

At the time of our visit, Quest was processing CervicalCheck slides in the following locations:

- Teterboro, NJ (this site, which was visited by the Scoping Inquiry team in July 2018, has been involved in CervicalCheck work from the outset, and is a "hub" location through which Irish slides are routed);
- Marlborough, MA;
- Horsham, PA;
- Baltimore, MD;
- Chantilly, VA.

The majority of CervicalCheck work was being conducted at the Teterboro and Marlborough laboratories, both of which are very substantial in scale. We were advised by Quest that all five of these laboratories conduct large volumes of Pap

testing, and cytopathologists are based at all sites. This arrangement provides close monitoring and supervision for the cytotechnologists involved in the CervicalCheck screening work, and standard operating procedures were reported to exist across all sites in order to provide a consistent approach.

All five laboratories listed above have current accreditation certificates in place, which are viewable and downloadable from the Quest Diagnostics corporate website.

From our discussions with the HSE, we can confirm that all five laboratories have been approved for handling CervicalCheck work. Robust protocols and documented approval processes appear to be in place regarding any changes to the delivery model, for example if it were necessary to involve an additional laboratory due to a significant increase in demand.

Overall, the liaison mechanisms between the HSE and Quest appear to be strong. These include bi-weekly quality operations meetings (generally conducted by video or audio conference), weekly discussions on the HPV primary conversion process, and quarterly business meetings in Dublin between senior Quest executives and senior HSE management.

All of the Quest laboratories currently involved in CervicalCheck work have been visited by inspection teams appointed by the HSE. These visits appear to have been thorough and detailed, and Quest advised the Scoping Inquiry team that they regard the HSE inspection visits as being comparable to regulatory or accreditation inspections.

#### 6.4 Findings

From the analysis undertaken by the Scoping Inquiry team, I am satisfied that the liaison and oversight mechanisms which are now in place between the HSE and Quest Diagnostics are both effective and robust.

There is clarity regarding the laboratories conducting CervicalCheck work, and all have been approved in advance by the HSE. Quest has an internal management and governance structure specifically relating to CervicalCheck which is designed to be transparent, both to senior executives within the company and to the HSE.

The process of ongoing engagement between the HSE and Quest appears to be working well, and both sides report that the various meetings and conferencing discussions are providing an effective forum for oversight of the service, resolution of issues arising, and future planning.

The inspection regime introduced by the HSE also appears to be effective.

These are welcome developments and all should be continued.

# 7 National Cancer Registry Ireland

#### 7.1 Implementation Actions

Of the fifty recommendations, nine (recommendations 36 through 44) relate to cancer registration, and responsibility for their implementation falls in the first instance to the NCRI for eight of these<sup>3</sup>.

The approach set out by the NCRI for implementing these actions would, under normal circumstances, reflect a credible and phased plan both to address the NCRI's role in improving the system of cancer registration and to improve capacity for carrying out its statutory functions.

The actions cover a variety of types of activities including:

- Building capacity in terms of personnel and technical infrastructure;
- Review and revision of internal policies and procedures; and
- Working with healthcare sector and public stakeholders to establish improved sectoral conventions for cancer registration.

The implementation status of each action established by the NCRI against these eight recommendations as at 31 December 2019 is set out in the table in Section 3 above.

Progress against the proposed actions against the recommendations has been reasonably positive (such as progress towards the establishment of data sharing agreements) as is the overall approach. Two actions appear to be behind schedule, and there are some critical dependencies within the implementation of the NCRI's recommendations to be noted.

#### 7.2 Allocation of Responsibilities

Alongside the specific 18 actions identified, the NCRI has established a project management structure to oversee implementation planning and execution. A small subset of the executive management group maintains oversight for implementation and reporting externally on progress. Subtasks are assigned to specific positions or groups within NCRI.

I note that responsibility for critical tasks and actions is appropriately situated with senior responsible individuals reflecting the seriousness and priority attached to successful implementation of the recommendations. Equally, there is delegation of component and support tasks to individuals throughout the NCRI's existing available operational structures.

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The NCRI does not have the vires to implement **Recommendation 40**, to review the composition of its own Board, which is the responsibility of the Department.

#### 7.3 Resources Assigned

Several NCRI actions may necessitate the deployment of new staff and technical resources as direction actions (such as the appointment of new cancer data registrars) or as enabling resources for specific activities (such as procurement of a data architecture system). As a body under the aegis of the Department of Health, the NCRI requires sanction for appointments and significant expenditure. This requirement is a critical dependency for the implementation of elements of the recommendations.

I understand that discussions are ongoing between NCRI and the Department regarding the allocation of staff resources to assist in the implementation of the recommendations from the CervicalCheck Scoping Inquiry report, and I would strongly encourage early resolution of this matter so that NCRI may proceed with implementation along the expected timescales. However, the recent resignations of a number of senior staff would appear to be putting the operation of the NCRI in jeopardy and call into question its continued effective operation.

#### 7.4 Overall Assessment

There has undoubtedly been some progress in respect of cancer registration. That progress, however, has been slow and achievement in implementation of the recommendations can only be regarded as partial. Recent and impending staff changes may put progress and effective operational management in question. The Department of Health should ensure urgent support to NCRI, as indeed should the HSE, in achieving progress in what should be regarded as a major programme of change designed to ensure the embedding and sustainability of the progress achieved. In order to improve coordination and integration of cancer registration with other closely linked parts of the system it would be valuable to consider, amongst other measures, the establishment of a Dublin office for NCRI.

# 8 Further Independent Review and Reporting of Progress

Keeping progress of the implementation process under regular review, and providing an independent assessment of progress to the Minister by means of a formal report, has helped to focus the attention of all parties and has provided objective assurance that the problems associated with the CervicalCheck programme are being resolved as planned.

As this report has demonstrated, significant progress has been achieved in the last 18 months, and there is still work to be concluded. The coronavirus crisis has had an inevitable effect on the screening services in general. It will be important that pauses and delays in the cervical screening programme should not have a long term effect on the programme, the implementation of the recommendations or on the health of women.

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.