

# **Scoping Inquiry into the CervicalCheck Screening Programme**

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**Implementation Progress Report  
February 2019**

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## Foreword

Dear Minister,

When I wrote to you at the end of November 2018 I indicated that a further, more detailed summary of progress would be provided to you in due course.

I am now pleased to provide you with a detailed assessment of progress in the implementation of the Scoping Inquiry's 50 recommendations from the main report published in September 2018 and also progress on the implementation of the six recommendations from my earlier interim report.

I am very encouraged by progress to date and, in particular, how the HSE has committed resources and efforts to make a reality of a major goal of the report, which is to help build a stronger and more effective cervical screening service for the women of Ireland.

You have suggested that I should continue to monitor progress and I am happy to do so. I suggest a timeframe for this future monitoring in the final section of this report.

Yours sincerely,

**Gabriel Scally**

## 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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<sup>1</sup> 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.

My team and I have since continued to engage with the State bodies concerned, and this report provides a more detailed analysis of their individual implementation plans and proposed actions.

## 2 Overarching Structures for Implementation

### 2.1 Establishment of Working Group

To progress the implementation work, the Department of Health has established a Working Group, chaired by the Head of the CervicalCheck Project Team; the remit of the Working Group is to progress the implementation activities arising from the Scoping Inquiry report. This Working Group is operating under the auspices of the CervicalCheck Steering Committee which had previously been established by the Minister in order to provide oversight and assurance on the implementation of key decisions taken by Government.

### 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 131 individual actions, and lead responsibility for taking them forward is broken down as follows:

Lead responsibility	Number of actions
Department of Health	20
Health Service Executive	93
National Cancer Registry of Ireland	17
221+ Support Group	1
<b>Total</b>	<b>131</b>

Some of the 56 recommendations within my September 2018 report and the earlier interim 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.

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

<sup>2</sup> The plan went through a number of iterations; the analysis presented in this report relates to the version which was supplied to the CervicalCheck Scoping Inquiry team by the HSE on 4 December 2018 (and was dated 29 November 2018). The Inquiry team has seen other, earlier versions which in most cases differ only marginally from that analysed herein.

detailed plans. For example, an Implementation Steering Group for CervicalCheck was established within the HSE, co-chaired by the Deputy Director General (Operations) and the Chief Clinical Officer, and a project manager was appointed. Similarly, the National Cancer Registry has devoted significant effort to its implementation of the recommendations contained within the Scoping Inquiry report.

### 2.3 Involvement of Patients and Families

The importance of openness and engagement with the women and relatives of those most affected by the CervicalCheck problems was central to the September 2018 report. I remain firmly of the view that continued engagement with those most affected is crucial for the successful implementation on many of the recommendations.

For example, the involvement of two representatives of the 221+ CervicalCheck Patient Support Group in the CervicalCheck Steering Committee is an important contribution to the progress currently being achieved and a good indicator of the desire to include patient advocates in future activity. It is welcome that it is recognised that having one patient advocate is not enough. Having two patient advocates allows for mutual support, and acts to inhibit isolation and marginalisation.

The implementation of one very important recommendation, number 50 in the main report, was taken on by the 221+ CervicalCheck Patient Support Group and this dialogue with some of the major medical bodies is now ongoing and will, I believe, be very productive.

One outstanding issue that has still to be resolved is the inequity that results from patient advocates engaging in crucial regular and demanding work on implementation but having to do so on a voluntary, unpaid basis.

### 3 Overall Progress – All Organisations

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

The table also illustrates progress with the six recommendations contained within the June 2018 Scoping Inquiry first report, which are also addressed within the master implementation plan. (Most of this work had, in fact, been concluded by the end of 2018.)

Sections 4, 5 and 6 of this report contain further commentary and analysis relating to the Department of Health, HSE 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



## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>Method of Approach</b>					
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	Q4 2019	5 subtasks are scheduled against this recommendation, with 4 falling to the HSE and one to the Department of Health. The subtasks involve a variety of activities involving policy review, staff training, accountability setting and compliance evaluation, and represent a reasonable approach to resolving the issues identified.	On track
<b>Listening to the Voices of the Women and Families Affected</b>					
2	The Minister of 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	Q2 2019	2 subtasks are identified, involving development of a scoping exercise for a Women's Health Action Plan, and a review to identify optimum solutions and changes to policy analysis, processes and decision-making. The approach is reasonable, to be concluded by the end of Q2 in 2019.	On track
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	Q4 2019	As data controller for patient records, responsibility for this recommendation has been allocated to the HSE. 4 subtasks have been identified (one of which has already been completed), culminating in the development and implementation of improvement plans for service users to access their medical records in publicly funded hospitals. As the detail is still to be worked out, the subtasks and the end date of Q4 2019 are reasonable.	On track

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b><i>CervicalCheck – Organisation and Governance</i></b>					
4	The Minister for Health should consider seriously the appointment of two patient advocates to the proposed new Board for the HSE.	DOH	Q4 2018	2 subtasks are identified; involving a campaign undertaken by the Public Appointments Service looking for applications to the Board of the HSE and the completion of the legislative process. The new Board was announced in January 2019. The new board includes two patient advocates. The Health Service Executive (Governance) Bill is still passing through the legislative process.	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	Q2 2019	3 subtasks identified; to review the draft specification for the committee included as an appendix to the Scoping Inquiry report, to consider elements not included in the specification and to establish the committee. This approach is reasonable and should be completed by the end of Q2 2019.	On track
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	4 subtasks are identified – two (status of the Head of the NSS and reporting lines to the DG) are complete, and the other two (development and implementation of a governance improvement plan) are under way. Progress appears to be good.	On track
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	Q1 2019	5 subtasks are identified. The Department was to prepare a response to the Crowe Horwath review of public health medicine, which was scheduled for end of Q4 2018 but had not been made available to the Scoping Inquiry by that stage. Three subtasks relating to public health staff appointments and public health involvement in the Clinical Advisory Group for CervicalCheck have been completed. One subtask relating to public health involvement in QA Committees is under way and due for completion in Q1 2019.	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	Q2 2019	8 subtasks are identified. Four (under the HSE) are noted as complete – these relate to risk management resources and governance. One (under DOH) was noted as under way and due for completion in Q4 2018 – this related to legislation for new HSE governance arrangements. The other three subtasks (under the HSE) relate to longer-term change initiatives in risk management within the NSS. All subtasks appear reasonable and progress is good.	On track

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Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>CervicalCheck – Laboratory Services</b>					
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	3 subtasks are listed, all under the HSE and for completion in Q1 and Q2 2019. These relate to policies for accreditation, enhanced QA arrangements, and the formal inclusion of better standards in any future contracts for HPV primary screening. This work programme is reasonable as are associated timescales.	On track
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	3 subtasks, for completion in Q2 and Q3 2019, relate to terminology for service specifications, laboratory performance monitoring and QA guidelines and standards. This work appears to be reasonable and making effective progress.	On track
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	4 subtasks, all for completion in Q2 2019. These relate to enhanced QA standards and documentation, service specifications for HPV primary screening, and the recruitment of clinical leads for cytopathology and colposcopy. All activities and timescales appear reasonable.	On track
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	One subtask, relating to the updating of QA standards, with a delivery date by end of Q2 2019, appears to be reasonable and capable of being achieved.	On track
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	3 subtasks, all under the HSE, include one which is noted as complete (re-establishment of the Clinical Advisory Group for CervicalCheck), and two under way – a review of membership of the lab sub-committee (due to have been complete by Dec 2018) and a new performance management approach, due by end of Q2 2019. All appear to be reasonable and on track.	On track
14	CervicalCheck should collate and publish annual data on reporting rates for all categories broken down by provider.	HSE	Q1 2019	2 subtasks for completion by the HSE in Q1 2019, relating to data collation and reporting. All appear reasonable and capable of successful completion on time.	On track

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Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
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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	3 subtasks for completion by the HSE in Q2 2019, relating to reporting specifications, testing and approval. All of these activities appear to be reasonable and capable of being achieved.	On track
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	Q2 2019	2 subtasks for the HSE to complete by Q2 2019, relating to data investigation and QA oversight. Both appear reasonable and capable of successful completion within the stated timescales.	On track
17	The different rates of sensitivity for ASCUS+ identified by second screen at each provider require further investigation by CervicalCheck.	HSE	TBC	No specific subtasks identified – plan states that actions will be developed when a cytopathology lead is appointed.	Actions not yet planned
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	TBC	No specific subtasks identified – plan states that actions will be developed when a cytopathology lead is appointed.	Actions not yet planned

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>Procurement of Laboratory Services</b>					
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	2 subtasks for HSE Procurement are listed – one relating to an update of financial records policy (for completion by end 2018), and the other relating to revised procedures (by Q2 2019). These actions appear to be reasonable and on schedule.	On track
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	3 subtasks are listed, the most significant of which is for NSS Procurement to become part of HSE (Health Business Services) Procurement; the other two subtasks relate to development of service delivery metrics and procedures for contract extensions. These subtasks, all due for completion by end of Q2 2019, appear to be appropriate responses to the issues raised in the Scoping Inquiry report, and to be scheduled within a reasonable delivery timeframe.	On track
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	2 subtasks are listed, and both are marked as complete: a sourcing strategy for laboratory services, and a market sounding exercise.	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	3 subtasks are listed, including NSS Procurement becoming part of HSE (Health Business Services) Procurement [also listed under #20 above]; the other two subtasks refer to a review of contract award criteria, and ensuring a balance in the scoring system for the HPV screening contract. These subtasks, all due for completion by end of Q2 2019, appear to be reasonable and taking place according to schedule..	On track
23	CervicalCheck should ensure that future procurements incorporate measures to test performance in the current contract.	HSE	Q3 2019	2 subtasks are listed: development of service delivery metrics by Q3 2019, and development of performance testing measures by Q2 2019. These actions are reasonable and appear to be taking place within the expected timescales.	On track

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
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	2 subtasks are listed, including NSS Procurement becoming part of HSE Procurement [also listed under #20 above]; the other subtask refers to the incorporation of recommendations from the Scoping Inquiry report into future RFT documentation. These subtasks are due for completion by end of Q2 2019. No specific mention is made in the implementation plan of the securing of external professional assistance, but the Scoping Inquiry is aware that such assistance has been engaged by the HSE. These subtasks therefore appear to be reasonable and taking place according to schedule..	On track
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	3 subtasks are listed for the HSE to complete by end Q2 2019, covering contract management, document control and staff training. All of these activities appear to be reasonable and capable of being achieved.	On track
<b>Auditing Cervical Screening</b>					
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	TBC	2 subtasks are listed for the HSE: one relates to setting up an Expert Group to review clinical audit processes across cancer screening programmes and is listed as complete; the other refers to the implementation of recommendations following a review of clinical audit processes across cancer screening programmes, and has no identified end date. This is reasonable, given that the HSE is not yet in a position to confirm the nature of any such recommendations before the review is complete. It would be expected that a definitive end date, and specific actions, should be identified in a future iteration of the implementation plan.	On track
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

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
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<b>Open Disclosure and the HSE</b>					
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	4 subtasks are listed for completion at various stages in 2019. One is allocated to the Department of Health and relates to the establishment of an Independent Patient Safety Council. The other three are allocated to the HSE and relate to revision of the open disclosure policy, the launch of an interim revision of the policy, and the implementation of the policy, including staff training. This work appears to be a reasonable response to the recommendations in the Scoping Inquiry report of Sept 2018. However, it is notable that the previous policy, which has been judged to be deeply flawed, remains in place.	On track
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	Q2 2019	2 subtasks identified; for the Department to oversee the introduction of the patient safety bill and for the HSE to revise its open disclosure policy. The Department will be responsible for ensuring that the Patient Safety Bill reflects this recommendation. The HSE will ensure that the open disclosure policy reflects appropriate developments. This approach is reasonable and should be completed by the end of Q2 2019.	On track
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	3 subtasks are listed for the HSE, all for completion by end of Q2 2019: the establishment of a forum of experts to scope the open disclosure implementation programme; incorporation of the programme into the training curriculum; and the continued running and development of the training programme on open disclosure. These activities appear to be reasonable and capable of being achieved.	On track
31	A governance framework for open disclosure must be put in place that includes evaluation and audit.	DOH and HSE	Q2 2019	2 subtasks identified; one for the Department of Health and one for the HSE. The Department will consider how this recommendation is reflected in the draft legislation. The HSE will develop key performance indicators to manage open disclosure. This approach is reasonable and should be completed by the end of Q2 2019.	On track

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>32</b>	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.	<b>HSE and DOH</b>	<b>Q2 2020</b>	1 subtask is listed for the Department of Health, which will progress recommendation #32 in the context of the work to be done by the Independent Patient Safety Council, by Q3 2019. In addition, 2 subtasks for the HSE, for completion by Q2 in 2020, relate to the HSE annual report and to internal HSE management reporting processes. These activities appear to be appropriate and capable of being achieved.	<b>On track</b>
<b>Open Disclosure and the Medical Council</b>					
<b>33</b>	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.	<b>DOH</b>	<b>Q2 2019</b>	The Department of Health is engaging with the Medical Council and Post-Graduate training bodies regarding the practice of open disclosure. A review of the guide for registered practitioners is under way. This approach is reasonable and should be completed by the end of Q2 2019.	<b>On track</b>
<b>Open Disclosure and CervicalCheck</b>					
<b>34</b>	A statutory duty of candour must be placed both on individual healthcare professionals and on the organisations for which they work.	<b>DOH</b>	<b>Q1 2019</b>	This will be addressed through the Patient Safety Bill which is currently being drafted following pre-legislative scrutiny. The approach and time frame for completion appear reasonable.	<b>On track</b>
<b>35</b>	This duty of candour should extend to the individual professional-patient relationship	<b>DOH</b>	<b>Q1 2019</b>	This will be addressed through the Patient Safety Bill which is currently being drafted following pre-legislative scrutiny. The approach and time frame for completion appear reasonable.	<b>On track</b>



## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>Cancer Registration</b>					
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	Q1 2019	There is a single subtask identified for the NCRI for the implementation of this recommendation. The NCRI has drafted a template MOU and is actively engaged with data providers regarding the establishment of data sharing agreements. The approach appears reasonable and sufficient to address the recommendation. As it continues to proceed with the support of stakeholders (such as the HSE and non-HSE data providers), it is expected to complete before the end of Q1 2019.	On track
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: <ul style="list-style-type: none"> <li>a) NCRI must be given additional support to recruit cancer registration officers and strengthen its public health medicine capacity.</li> <li>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.</li> </ul>	NCRI	Q1 2022	5 subtasks are identified against this recommendation, all of which are the responsibility of the NCRI, but contingent upon the sanction of DOH. The overall approach is for the planned, phased increase in capacity in terms of key qualified staff and the development of ICT infrastructure. Assuming the timely allocation of required resources, the recommendation will likely be satisfactorily addressed by end of Q1 2022.	On track
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 2019	The actions associated with this recommendation include 4 distinct subtasks related to the review and redevelopment of the NCRI approach to and procedures for recording cancer data. The first of these is to review and re-release its standard operating procedure by the end of Q4 2018, which appears incomplete. The approach for the 4 subtasks is reasonable, and necessary to ensure a robust and useful dataset for the future, but corrective action is required to place implementation back on track.	Behind schedule

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Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				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	Q3 2019	There are 2 subtasks scheduled against this recommendation. The tasks involve drawing stakeholders together to collaborate in the establishment of a <i>National Cancer Screening Registry</i> . This appears reasonable and is an action associated with this recommendation and the implementation of recommendation 41 as well.	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	A recruitment process is to be run by the Department to identify prospective board members. The key skills for the new board members will be in the areas of governance and quality assurance. The approach appears reasonable and completion by the end of Q1 2019 should be achievable.	On track
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	Q3 2019	The approach to addressing this recommendation is, as with recommendation 39, to work toward the establishment of a <i>National Cancer Screening Registry</i> . As above, this recommendation is considered reasonable and is on track for implementation by Q3 2019.	On track
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 2019	The single NCRI action identified is the establishment by the NCRI (for agreement by DOH) of a framework and protocol for a series of three peer reviews commencing in 2019. This represents a sound approach to addressing this recommendation and there is no obvious reason why it will not commence in Q1 and complete by Q4 2019.	On track
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	Q2 2019	There are two subtasks associated with this recommendation which relate to the inclusion of external expert and stakeholder perspectives within the governance system. The appointment of clinical and patient advisory groups is considered a reasonable proposal and is due to complete by end Q2 2019, but is somewhat dependent on the review of the NCRI Board by the Department. The conduct of a stakeholder survey appears to be behind schedule.	Behind schedule

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Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
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 2019	The single subtask identified with this recommendation is for the NCRI to conduct a data quality and audit programme. The approach is considered reasonable and there are no concerns regarding the timely completion of this action by NCRI.	On track
<b>Other Screening Programmes</b>					
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	2 subtasks fall to the HSE: the development of a project implementation plan for all QA programmes, based on international best practice, by end Q1 2019; and the implementation of recommendations from that plan, by the end of 2019. Both actions appear to be reasonable and capable of being achieved.	On track
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	1 subtask for the HSE to achieve by the end of Q1 2019 is to agree and implement operating principles for all QA committees. The approach and time frame for completion appear reasonable.	On track
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	3 subtasks allocated to the HSE relate to a review of all staff job descriptions involved in the screening programmes, and ensuring that all new roles have a proper job description (by Q1 2019); ensuring that all new NSS staff receive formal induction training (also Q1 2019); and ensuring that the HSE performance management process operates across the NSS (by end 2019). These actions appear proportionate and the time schedule is reasonable.	On track
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	1 subtask is listed, committing the HSE to ensuring that the implementation of the Open Disclosure policy applies across all screening programmes, by the end of 2019. The action and timescale appear to be reasonable.	On track

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>Resolution</b>					
<b>49</b>	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.	<b>DOH and HSE</b>	<b>Q1 2019</b>	2 actions identified, one for the Department and one for the HSE. The Department action relates to the development of the structures that will underpin any engagement. The HSE will be responsible for facilitating the meetings. This approach is reasonable and should be completed by the end of Q1 2019.	<b>On track</b>
<b>50</b>	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.	<b>221+ Support Group</b>	<b>Q4 2018</b>	1 subtask was allocated to the 221+ Support Group, and entailed the Group arranging a meeting between the medical organisations and the representatives of the women and families. The first of these meetings has taken place.	<b>On track</b>
<b>Recommendations of First Report (11 June 2018)</b>					
<b>A</b>	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.	<b>HSE</b>	<b>Q4 2018</b>	1 subtask is allocated to the HSE, involving the establishment of a working group to implement the recommendations of the Scoping Inquiry report, and to provide more comprehensive information, including a newly developed web page. This work appears to be taking place according to schedule.	<b>On track</b>
<b>B</b>	The information statements provided to women about the limitations of the tests should be more explicit about the possible reasons why screening might miss abnormalities that are present, as these can result in the development of cervical cancer. This information should be included in the leaflet sent to all women with their screening invitation, and in the information sheet accompanying the consent form.	<b>HSE</b>	<b>Q4 2018</b>	1 subtask is allocated to the HSE, and is part of the development of a new leaflet and information sheet included in the response to item A above. This work appears to be taking place according to schedule.	<b>On track</b>
<b>C</b>	The information for women accompanying the consent form should guarantee that they will have full and open access to their cervical screening record on request.	<b>HSE</b>	<b>Q4 2018</b>	1 subtask is allocated to the HSE, and is part of the development of a new leaflet and information sheet included in the response to item A above. This work appears to be taking place according to schedule.	<b>On track</b>

## Scoping Inquiry into the CervicalCheck Screening Programme

Recommendation		Owner	Completion by	Independent Assessment (at Dec 2018)	
				Commentary	Status
<b>D</b>	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	Q4 2018	1 subtask is allocated to the HSE, and is part of the development of a new leaflet and information sheet included in the response to item A above. This work appears to be taking place according to schedule.	On track
<b>E</b>	That the Minister of Health offer an immediate <i>ex gratia</i> payment to each woman affected and to the next of kin of the deceased.	HSE	Q4 2018	1 subtask was allocated to the HSE, and following Government approval, the payment of €2000 was offered to the 221 affected women or next of kin. Action completed.	Complete
<b>F</b>	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	Q4 2018	2 subtasks were allocated. The HSE was tasked with facilitating women and families to engage with Dr Scally and his team, and an <i>ex gratia</i> payment was issued to assist them to do this. The Department of Health was to engage with other Government departments regarding the report of Mr Justice Meenan with a view to the Minister returning to Government with proposals in November 2018. These matters have been concluded.	Complete

# 4 Department of Health

## 4.1 Implementation Actions

The Department of Health have 20 actions across 16 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.

The key internal action is to revise policy in relation to document management. Many of the Departmental actions form one element of the implementation of various recommendations.

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. At the end of December 2018, the Health Service Executive (Governance) Bill had passed through the Seanad, and completed the first and second stage in the Dáil. The general scheme of the Patient Safety Bill was published in July 2018 and drafting was underway at the end of 2018. These two bills are subject to legislative scrutiny and the timing of their enactment is outside the control of the Department.

Work is ongoing to develop the specification for the National Screening Committee. The Department is reviewing the suggested service specification for a National Screening Committee included as an appendix to the September 2018 Report of the Scoping Inquiry. Additional elements are being considered to develop a proposal for the Minister which aligns with other areas of public health. It is expected that the committee will be established in the first half of 2019.

The Crowe Horwath report on the Role, Training and Career Structures of Public Health Physicians in Ireland was published by the Department in December 2018 and a Departmental response was being prepared at year end.

## 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.

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, including the establishment of a National Screening Committee.

### 4.4 Overall Assessment

Having reviewed the actions being taken by the Department to implement the recommendations of the Scoping Inquiry report, I believe that the approach appears to be reasonable. There is a number of actions that are dependent on completion of the legislative process and these should be kept under regular review. Any actions that are not dependent on legislation should continue to be progressed. A significant number of the actions are due for completion in Q2 2019 and should be managed closely to ensure that timeframes do not begin to slip.

There is no indication that the Department lacks resources to complete the actions, but there are few if any staff for whom the implementation of the recommendations is their sole job. The impact of the actions will vary across divisions and units and there should be careful monitoring to ensure that all of the actions continue to be appropriately resourced.

# 5 Health Service Executive

## 5.1 Implementation Actions

86 of the 124 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 2018.

To support the implementation of the recommendations within the Scoping Inquiry report, the HSE has established a Programme Management Office (PMO) structure with dedicated and full-time resources assigned. A series of charters to help guide the implementation process was prepared by the PMO team and was shared with the Scoping Inquiry in December 2018 – these covered the following areas:

- **Contracting Charter** (to implement a Memorandum of Understanding and data sharing agreement with the NCRI);
- **Data Charter** (to ensure availability of data and information and to conduct analysis of the same – required to measure performance against key quality standards and metrics);
- **PMO Portfolio** (structure to implement the recommendations of the Sept 2018 Scoping Inquiry report);
- **Organisation Design Model and Governance Charter** (to plan and implement an improved operating and governance structure between the HSE and NSS and within the NSS; to embed greater clinical and external oversight);
- **Patient and Public Involvement Charter** (to develop a Patient and Public Involvement strategy to partner with patients in designing, planning, implementing and evaluating NSS services);
- **Performance Management Charter** (to implement a formal, structured, monitored approach to performance manage service providers);
- **Quality Assurance Operating Model Charter** (to develop a shared methodology, common language and culture for Quality Assurance across NSS screening programmes).

It is worth noting that 71% of the actions within the implementation plan fall to the HSE. Of these, the following features may be observed:



Deadline	HSE Actions	Cumulative
Already complete	15%	15%
Q2 2018	1%	16%
Q4 2018	10%	26%
Q1 2019	14%	40%
Q2 2019	41%	82%
Q3 2019	4%	86%
Q4 2019	9%	95%
2020	2%	97%
2021	0%	97%
2022	0%	97%
To be confirmed	3%	100%
<b>Total</b>	<b>100%</b>	

(It may be noted that one action for the HSE is allocated the timescale of Q2 2018, which may be an error as it long predates the preparation of the implementation plan.)

Overall, it is very striking that the implementation plan specifically in respect of HSE subtasks appears to be very front-loaded, with 40% of all implementation actions expected to be completed by the end of March 2019, and 82% completed by the end of June 2019.

Whilst it is creditworthy that the HSE wishes to make swift progress and to conclude much of the work within a relatively short timescale, I would be concerned that the implementation plan appears to be over-ambitious, with too many activities concentrated within a single time period, and that future progress reviews may find that some of this activity has been subject to delay or has been unable to be concluded as speedily as desired.

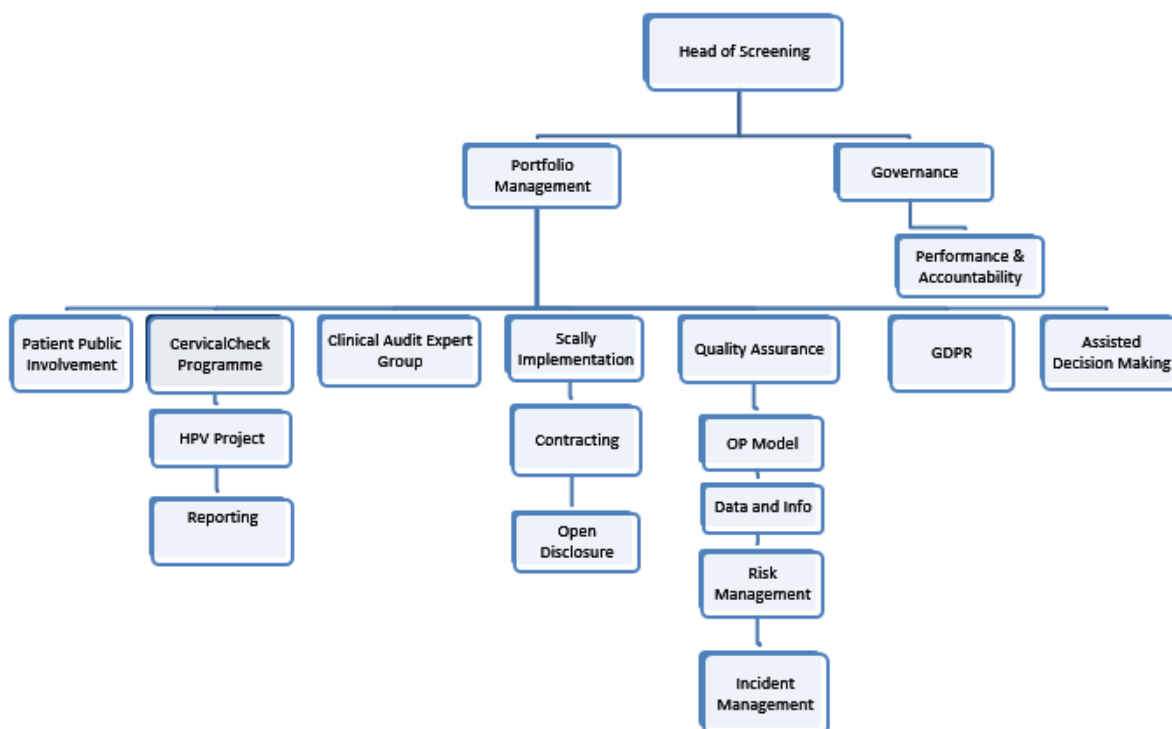
### 5.2 Allocation of Responsibilities

The subtasks within the implementation plan have been 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 Head of Procurement, the National Director responsible for Communications, the National Director of Community Operations, and the Director-General.

### 5.3 Resources Assigned

The organisational structure adopted by the HSE for implementation of the recommendations set out within the Scoping Inquiry report entails a range of

dedicated responsibilities being allocated within the National Screening Service, as shown in the chart displayed below:



The team assembled by the HSE to undertake this work appears to be well constructed and to involve experienced personnel with the appropriate level of seniority. Overall, the HSE resourcing of this work is a proportionate response to the scale of the issues and challenges set out in the Scoping Inquiry report. Furthermore, the creation of a PMO structure to manage the implementation process represents an effective means of progressing this work under proper executive oversight and governance.

### 5.4 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 am somewhat concerned that elements of the plan may be overly ambitious and that too many activities may have been scheduled for the first six months of 2019; this position will be reassessed at the time of the next progress review.

## 6 National Cancer Registry Ireland

### 6.1 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 reflects a credible and phased plan to both 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<sup>st</sup> December 2018 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.

### 6.2 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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<sup>3</sup> 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.

### 6.3 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.

### 6.4 Overall Assessment

I find the approach outlined by the NCRI to be a credible and reasonable proposal. There are a number of actions which are contingent upon the sanction of the Department for action, and some that depend upon collaboration with other stakeholders in the healthcare sector, but this presents minimal risk to successful implementation, and indeed is likely to foster a more collaborative and integrated approach to cancer registration in Ireland.

While overall implementation appears to be on track, some specific actions appear to have fallen behind schedule, specifically:

- The review and re-release of the NCRI standard operating procedure as an action against recommendation 38; and
- The conduct of a stakeholder survey as an action against recommendation 43.

Progress against these actions will be assessed at the time of the next independent review.

## 7 Overall Assessment of Progress to Date

With an implementation plan covering 131 actions against 56 original recommendations, this implementation process represents a very substantial body of work for the various statutory bodies involved, particularly as many of the tasks involved are complex, interlinked and likely to take many months to bring to a successful conclusion.

In my September 2018 report, I referred to the problems associated with CervicalCheck as being 'redolent of a whole-system failure'. I note that all of the statutory bodies involved have accepted my findings and have committed significant effort and resources to rectifying the problems which were identified.

The implementation plan is a comprehensive response to the Scoping Inquiry report, and its resourcing and project management structures reflect the seriousness with which the plan has been developed.

Whilst a small number of the 131 actions / subtasks are slightly behind the expected timescales or were (in late 2018) yet to commence, an opportunity exists for either the plan to be recast to reflect more achievable deadlines, or for the project leaders to get these actions back on track in the coming months.

As noted earlier, 71% of the implementation actions fall to the HSE, and very many of these are front-loaded, with 82% of all implementation actions expected to be completed by the end of June 2019. I have indicated my concern at the capacity of the HSE to deliver so many actions within such a short time period, and it may be prudent for the HSE to review the deadlines of some of these actions prior to the next independent progress review.

## 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, will focus the attention of all parties and will also provide objective assurance that the problems associated with the CervicalCheck programme are being resolved as planned.

I would therefore propose future progress reviews along the following timeframe:

- **April 2019:** re-engagement with the relevant statutory organisations to assess progress over the period December 2018 to April 2019, with a view to providing an independent report to the Minister in May 2019;
- **August-September 2019:** re-engagement with the relevant statutory organisations to assess progress over the period April to September 2019, with a view to providing an independent report to the Minister in September 2019 (i.e. one year on from publication of the Scoping Inquiry report);
- Thereafter, progress reporting **every six months** until all actions are satisfactorily concluded, or until otherwise agreed.