

CervicalCheck Steering Committee
Weekly report to the Minister
5 October 2018

1. Update on support package

The HSE reports that Liaison Officers have held 333 face-to-face meetings with women and families to discuss their needs. This includes 179 initial meetings and 154 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

The HSE advise that there is work ongoing in relation to supporting individuals who are having difficulty navigating the health system to facilitate ease of access to supports.

Delivery of supports

- The HSE has now issued 685 medical cards to women and family members or next-of-kin where the woman has, sadly, died. This includes the amendments that have been made to the terms of existing medical cards or GP visit cards in 94 cases to recategorise these as medical cards under the terms of the CervicalCheck support package. Numbers of medical cards issued in total now appears stable.
- Women have been contacted by their Liaison Officers to ensure that everyone is aware of and has access to the report of the Scoping Inquiry, following its publication on Wednesday 12th September. The Department understands that Dr Scally intends to hold meetings in Dublin, Cork and Galway, in line with the meetings which he has held already, to inform women of his findings, with the first of these to be held on 9 October.
- The Government decision of 11 May provided that where women had been prescribed a medicine by their treating clinician, any out-of-pocket costs would be met. Arrangements are in place to reimburse, on receipt of claims, a range of costs that the women and their families incur from 11 May including travel costs, childcare costs and medical appointment costs among others. Reimbursement of retrospective costs is taking place, and an automatic review system is in place to simplify and streamline the process to ensure prompt payment of all items covered by the Government decision.
- To date, almost €720,000 has been reimbursed in respect of various health and social care costs, more than €452,000 of which relates to retrospective payments. There will also be additional costs associated with the medical cards that have been issued and the meeting of certain drug costs.

2. Release of records

The HSE remains focused on responding to all requests for records as soon as possible. The HSE reports that:

- 117 legal requests have been received to date, of which 112 have been processed (several legal data access requests were processed as data access request, which explains the drop in numbers since last week)
- 322 FOI or data access requests have been made, of which 305 have received a response
- 24 slide requests have been made in accordance with the protocol; 11 have been processed.

3. Independent Expert Panel Review

- Almost 1,600 letters have now issued providing information in relation to consent and consent form. The HSE has reported that validation of the dataset for women who have sadly died is on-going, with next-of-kin details being provided by the relevant acute hospital. The Department will continue to engage with HSE to ensure remaining letters issue as expeditiously as possible.
- Approximately 515 consent forms are reported to have been returned up to end of last week, with 95% of women who have responded agreeing to take part in the review.
- The HSE is continuing to make every effort to ensure clear information is provided that addresses any queries, issues or concerns raised by women about the review or the consent process. The HSE established a dedicated phone line at the outset of the consent process, to answer any questions women may have arising from the process.
- Following the issuing of consent letters to the wider group of women diagnosed since the inception of the programme in 2008, including those not previously notified to CervicalCheck, a number of women who had been diagnosed with micro-invasive cancer¹ contacted the helpline reporting they were unclear as to the categorisation of their diagnosis. Additional clinical and administrative resources have been identified to enable swift response to these and other clinical queries, with opening hours extended to weekends, ensuring that women's questions are being fully and appropriately addressed.

4. Introduction of HPV as the primary method of testing

Negotiations on the extension of existing lab contracts are currently ongoing, to maintain the programme pending introduction of the new HPV test and related procurement. The introduction of HPV testing as the primary screening mechanism for CervicalCheck, with cytology as a reflex test, will involve a reconfiguration of the laboratory work involved. Detailed capacity planning is ongoing and introduction will be subject to a tendering process for work carried out outside the public sector.

The Clinical Advisory Group established to advise on the project has now made a decision in relation to the choice of HPV assay, required before tender documents can be finalised, as well as the final age range and intervals and genotyping. Further discussion is required in relation to finalising screening pathways and the eligibility framework. A further site visit, to NHS England, is planned for w/b 8 October.

5. Clinical Director

Interviews for a Clinical Director for CervicalCheck took place on 22 August and the HSE advises that the contract is currently being finalised.

6. Smeartaking activity

The HSE has reported that lab activity remains above normal levels up to last week. The total number of additional consultations to date is over 81,000. The issue of the backlog of

¹ The review includes a cohort of women who had been diagnosed as having micro-invasive cancer. Microinvasive cancer is defined as a cancer that has not yet spread locally and which does not usually appear in lymph glands or in distant tissues. While microinvasive cancer rarely develops into invasive cancer it still classified, for the purposes of the National Cancer Registry, as a cancer.

smear tests is a priority concern for the HSE. The National Screening Service and HSE Procurement are engaging with laboratory service providers to address capacity issues.

7. Alternative resolution mechanisms

Mr. Justice Charles Meenan is currently the Chairperson of an Expert Group established to consider an alternative mechanism to the court process for resolving clinical negligence claims. In addition to this work, Justice Meenan is undertaking a specific review regarding the claims arising out of the issues surrounding CervicalCheck. He has confirmed that this work is underway and will be completed in October.

8. Implementation of recommendations of the Scally Inquiry

The HSE working group which is addressing the recommendations of the First Report on information about screening for women has continued its work. Communications and information materials have been shared with the Committee for comment.

Planning for the implementation of the 50 recommendations contained in the final report of the Scoping Inquiry has begun. The CervicalCheck Steering Committee will oversee the implementation of these recommendations. A draft implementation plan was discussed at this week's Steering Committee meeting. It is intended that a further draft will be circulated to the Committee ahead of its next meeting on Thursday 1 November.

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1	Oversight and engagement with the HSE on modules of their work as follows		
1.a	Management of supports to patients/families	Yes	No
	Project Manager in Place David Walsh/Mary Walshe	Yes	
	Project Team Composition David Walsh ND, Mary Walshe Chief Officer Maria Kavanagh Liaison Officers in each of (Community Healthcare Organisations)		
	Project Plan	This week	To date
	Number of meetings held with affected women & families (Liaison Officers)	8	179 initial meetings 154 and additional meetings.
	Number of medical cards issued	0	685
	Number of ex gratia payments made	2	209
	Number of supports requested	4	512 Top ten supports requested to date;

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	<div>Current position, issues & challenges</div> <ul style="list-style-type: none">• Clients are focussing on retrospection and those who attended the 221 support meeting are beginning to process the discussions and information from the day.• Liaison Officers are compiling details of locations and types of supports so as to facilitate additional targeted supports to women and their families.• Work continues to support individuals in navigating the health system to facilitate ease of access to required services in conjunction with colleagues within the Acute Hospital system.																						

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Oversight and engagement with the HSE on modules of their work as follows			
1.b	Provision of documents to patients	Yes	No
	Project Manager in Place There is an operational manager assigned to oversee access to records and smear results.	√	
	Operational Team Composition While this process was not in place prior to the cervical check crisis a team has been created and work is progressing to expand the team to ensure that women and their legal representatives receive their records in the most timely manner possible. The team comprises of: <ul style="list-style-type: none"> - PM for overall coordination. - Two legal personnel in Dublin. - Four Administrative support personnel. 	√	
	Project Plan There is a defined operational process for the release of records.	√	
		This week	To date
	Number of legal requests made	0	117*
	Number of legal requests responded to	6	112
	0 - 30 days	-	94
	*30 days +	-	18
	Number of requests on hold, awaiting clarification from solicitor	-	1
	Number of FOI / Data access Requests made	5	322
	Number of FOI / Data access Requests responded to	17	305
	0 - 30 days	-	260
	**30 days +	-	45
	Number of slide requests made (per protocol)	1	24
	Number of slide requests processed (per protocol)	0	11
	*Several legal data access requests were processed under data access, figures updated to reflect this.		

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	<p>Current position, issues & challenges</p> <p>The team remains focused on responding to all requests as soon as possible. External legal advisors are liaising with women and their solicitors on the release of slides. Solicitors are required to provide specific information about their chosen laboratory before slides can be released. This ensures the integrity of the slide is protected and all slides can be traced when they leave their current location. There have been some teething problems in this process with the labs but these are being addressed.</p>
	<p>Update Action</p> <p>*During the setup of the client services team in April/May in the early part of the crisis there were 10 requests which extended over the 30 days. 6 of the 10 were pre-GDPR requirement for 40 days but resourcing was a constraint at the start of this process.</p> <p>**During the setup of the client services team in April/May in the early part of the crisis there were requests which extended over the 30 days, many of these were during the setup period and others have occurred due to waiting for hospital medical records, verification of patient or next-of-kin details and screening queries.</p>

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1.c	Interface with RCOG Review		Yes	No											
	Project Manager in Place Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1 st of August. Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1 st of August.														
	Programme Governance <ul style="list-style-type: none">Project Team holds daily meetings and teleconferences to progress deliverables, to identify critical actions / timeframes, areas for escalation, risks, issues, and dependencies.Workshop scheduled to enhance stakeholder engagement and communication plan (Oct 2nd).		✓												
	Project Plan		✓												
	Workstream	Actions Progressed (w/e 28 Sept)													
	Patient Support Services	As of Friday 28 th Sept: <ul style="list-style-type: none">1,591 letters have issued to individuals requesting consent to participate in RCOG ReviewConsent forms returned by 514 individuals (32%), of which 492 have consented to participateParticipate in weekly teleconference with Patient Liaison Officers (latest held 24th Sept).													
	Information Services	<ul style="list-style-type: none">Additional resources have been identified (clinical and administrative) to support call centre.Opening hours 7 days a week 9am – 6pmSOP established with the NSS, NCRI and Acute Operations to manage queries to the information line which require escalation for follow-up.As of Fri 28th Sept, there have been 66 calls to the information line. <table><tr><td>Total Calls to Information Line</td><td>66</td></tr><tr><td>Total Calls (general)</td><td>11</td></tr><tr><td>Total Calls (clinical)</td><td>55</td></tr><tr><td>Calls (clinical) resolved at initial contact</td><td>34</td></tr><tr><td>Calls (clinical) escalated to acute hospitals, following SOP</td><td>21</td></tr><tr><td> • Closed</td><td>8</td></tr><tr><td> • Open</td><td>13</td></tr></table>			Total Calls to Information Line	66	Total Calls (general)	11	Total Calls (clinical)	55	Calls (clinical) resolved at initial contact	34	Calls (clinical) escalated to acute hospitals, following SOP	21	• Closed
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	Case Management System (CMS)	<ul style="list-style-type: none">CMS updated to identify laboratory locations for relevant slides, and to manage the supply chain management processes for slide transfers.		
	Laboratory Logistics	<ul style="list-style-type: none">Protocol for Audit received from RCOG.27th Sept: Letters issued to the CervicalCheck laboratories, disseminating the RCOG Audit Protocol. Laboratories were also provided with slide details pertaining to 415 women who have consented to be part of the RCOG Review.SOP drafted to facilitate safe and secure transport of slides between the CervicalCheck laboratories and RCOG lab in Bristol. Currently under clinical review.Engaging with CervicalCheck ICT and RCOG to facilitate RCOG with access to electronic records where required.		
	Communications	<ul style="list-style-type: none">To support distribution of letters to women: Liaising with HSE Comms / HSE Digital to coordinate approach; issuing proactive communications as appropriate/agreed; and developing a draft press statement and media FAQ.		
	Acute & Community Services	<ul style="list-style-type: none">27th Sept: Letter issued from Interim ND NSS to ND Acute Services with suite of documents relating to the RCOG Support Programme.Protocol agreed with Acute services to expedite validation of next-of-kin where women were identified as deceased in the database provided by NSS.Weekly teleconference established with key stakeholders, including Acute Operations and CervicalCheck Interim Programme Manager.		
	Current Position, Issues and Challenges <ul style="list-style-type: none">The RCOG office is still validating the dataset for women who have passed away, whereby Next-Of-Kin details must be provided by acute hospitals (following agreed Standard Operating Procedure).Managing feedback and queries from women/next-of-kin, clinicians, media and public as remaining cohorts of women or next-of-kin receive letters.			

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	Next Steps	
	Workstream	Actions Planned
	Patient Support Services	<ul style="list-style-type: none">w/c 1st Oct: Reminder letters to issue to women where target date for consent form return has now passed.Continue plan to issue remaining letters to Next of Kin, as details are received from acute services.Continue scanning and logging consent returns on the Case Management System, as they are received.Continue regular engagement with Patient Liaison Officers and other stakeholders.
	Information Services	<ul style="list-style-type: none">Follow-up on calls to information line and to dedicated email address for health professionalsEmploy regular quality checks to ensure capacity meets demand. Where required, identify and assign further additional clinical & administrative resources to the call centre in line with the project plan timelines.
	Case Management System (CMS)	<ul style="list-style-type: none">As letters issue, continue to update CMS validated data received from NSS.Training on CMS to continue for relevant staff.Design of CMS to be updated further in line with agreement on the lab transport process.
	Laboratory Logistics	<ul style="list-style-type: none">w/c 1st Oct: Draft SOP to support slide transfers to go to CervicalCheck labs and RCOG for further technical input, consultation and agreementEngage with laboratories to facilitate transport of slides to RCOG lab in Bristol.
	Communications	<ul style="list-style-type: none">Managing feedback and queries from women/next of kin, clinicians, media and public as remaining cohorts of women or next of kin receive letters.
	Acute & Community Services	<ul style="list-style-type: none">Weekly teleconference regarding acute services engagement with RCOG Support ProgrammeContinue developing protocol to support RCOG with relevant medical records from acute and community services where requested.
	Update Action	

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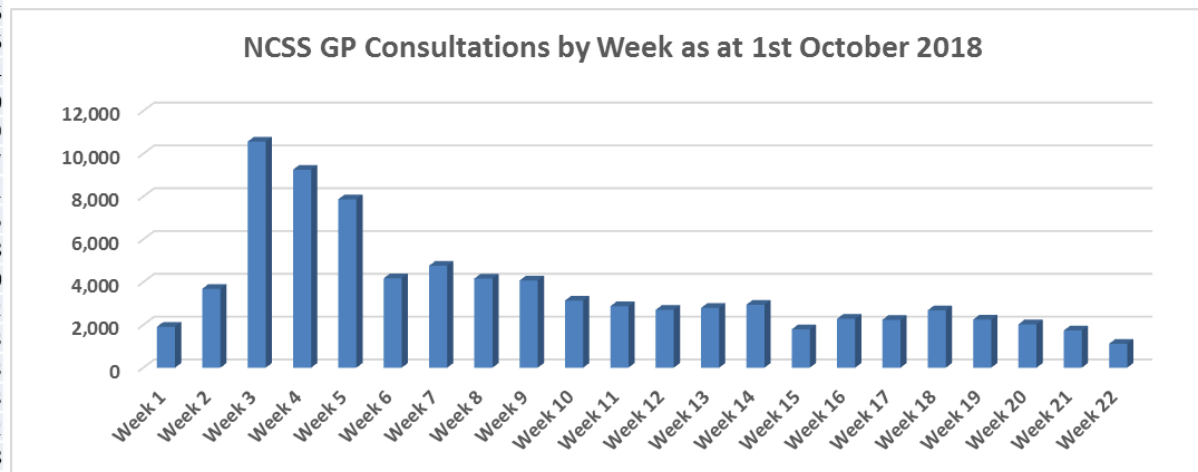
	Oversight and engagement with the HSE on modules of their work as follows		
1.d	Management of laboratory capacity issues	Yes	No
	Project Manager in Place Yes.	√	
	Project Team Composition Given the nature of the issues presenting a working group was put in place to support the project manager. This group comprises HSE procurement, HSE Legal and the CervicalCheck Operations team. This will ensure a coordinated response to the operational issues presenting as a result of the demand arising from the out of cycle smear tests.	√	
	Project Plan Since April any woman who is concerned can attend her GP for a free smear and this has resulted in a testing backlog in all three labs. These delays remain a priority concern for the HSE. Actions taken to address backlog include additional recruitment to assist on clerical support to free up screening staff, the streamlining of processes around release of reports and QA checks of same. One of the main contracted lab service providers has requested to use one of their other accredited sites that meet all the aspects of the contract. NSS have agreed and confirmed this as appropriate. This process has been initiated. The lab contractors continue to provide overtime, manage annual leave and schedules with their best efforts to address the backlog. Negotiations continue with existing labs and they are at a critical point. This is the most significant risk to the programme. Contingency plans are being developed and it should be noted that there are limited alternatives to sustain the programme at current levels.		
	Uptake of smear tests: <i>Out of cycle smears</i> Total number of additional consultations to date is more than 81,000. The normal capacity for the labs is approximately 5,000 per week so we are still seeing a 20% increase in uptake as a result on the free smear test. This is delaying the reporting of smears to women. All the labs have expressed concern at the continuing extension of the free smears due to the serious impact on the normal reporting cycle. The table below sets out the increased number of GP consultations.		

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Claim Status	Total
Fully Paid	66,511
To Pay with Next Payment	13,857
Rejected	348
Duplicate	330
Grand Total	81,046

Week	Total
Week 1	1,916
Week 2	3,686
Week 3	10,564
Week 4	9,250
Week 5	7,869
Week 6	4,177
Week 7	4,761
Week 8	4,165
Week 9	4,078
Week 10	3,140
Week 11	2,872
Week 12	2,703
Week 13	2,793
Week 14	2,943
Week 15	1,792
Week 16	2,288
Week 17	2,238
Week 18	2,681
Week 19	2,248
Week 20	2,027
Week 21	1,737
Week 22	1,118
Grand Total	81,046



Update Action

The National Screening Service and HSE Procurement along with Legal Representation are engaging directly with the Laboratory Service Providers in order to address capacity issues i.e. contingency labs, performance, and other contract related issues. More intensive contract meetings are scheduled to take place again this week. We are now at a critical point on extending the laboratory contracts and it is clear that to address the backlogs in some labs will require clarity on future extensions.

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1.e	Introduction of HPV Screening	Yes	No														
	Project Manager in Place Yes. A Project Manager is in place and the expression of interest is still open for the appointment of a Clinical Lead for the HPV primary screening project. Also, an expression of interest is currently open for a lead cytopathologist and lead colposcopist to join the project team.	✓															
	Project Team Composition <ul style="list-style-type: none">Clinical Advisory Group: international expert Dr. Marc Arbyn is supporting this group. Dr Arbyn was a member of the HIQA HTA panel and is a leading expert on HPV primary screening in EuropeThere has been no expression of interest for either the Clinical lead or the Cytopathology lead posts Project Plan <table><tr><th>Workstream</th><th>Actions Progressed (w/e Sept 28th)</th></tr><tr><td>Clinical</td><td><ul style="list-style-type: none">Decisions taken at CAG meeting on 27th Sept re final age range & intervals, test assays and genotypingFurther discussion required in relation to finalising screening pathways and eligibility framework.</td></tr><tr><td>Procurement</td><td><ul style="list-style-type: none">Procurement market analysis to inform specification and market model can progress now that some clinical decisions have been taken.</td></tr><tr><td>ICT</td><td><ul style="list-style-type: none">Work on development and testing of changes to Cervical Screening Register was progressed for Scally recommendations.Addressing issue of testing capacity (resources).Laboratory IT development awaiting decisions on laboratory configuration and procurement.</td></tr><tr><td>Lab Configuration</td><td><ul style="list-style-type: none">Draft configuration options prepared and presented to Steering Group. Work on further detailing in progress to detail the capacity required through public vs private</td></tr><tr><td>Communications</td><td><ul style="list-style-type: none">Next steps scheduled by Communications team from October - April.</td></tr><tr><td>Resources for HPs</td><td><ul style="list-style-type: none">Resource development – e-learning - commissioned. Resources cannot be finalised without clinical pathways (above) resolution.</td></tr></table>	Workstream	Actions Progressed (w/e Sept 28th)	Clinical	<ul style="list-style-type: none">Decisions taken at CAG meeting on 27th Sept re final age range & intervals, test assays and genotypingFurther discussion required in relation to finalising screening pathways and eligibility framework.	Procurement	<ul style="list-style-type: none">Procurement market analysis to inform specification and market model can progress now that some clinical decisions have been taken.	ICT	<ul style="list-style-type: none">Work on development and testing of changes to Cervical Screening Register was progressed for Scally recommendations.Addressing issue of testing capacity (resources).Laboratory IT development awaiting decisions on laboratory configuration and procurement.	Lab Configuration	<ul style="list-style-type: none">Draft configuration options prepared and presented to Steering Group. Work on further detailing in progress to detail the capacity required through public vs private	Communications	<ul style="list-style-type: none">Next steps scheduled by Communications team from October - April.	Resources for HPs	<ul style="list-style-type: none">Resource development – e-learning - commissioned. Resources cannot be finalised without clinical pathways (above) resolution.	✓	
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1.e	Introduction of HPV Screening	Yes	No
	<p>additional workload)</p> <p>3) Absence of a fulltime Clinical Director for the programme is impacting a number of key activities.</p> <p style="padding-left: 40px;">❖ Decision required on the cervical screening pathway</p> <p style="padding-left: 40px;">A Clinical Advisory Group has been set up to address these decisions.</p> <p>4) Failure to recruit colposcopy or cytopathology leads for the program and project. There were no applicants. A letter of invite for a colposcopy lead has been issued to Dr. Peter Boylan, Chair of the Institute for Gynaecologist and Obstetricians.</p> <p>5) Laboratory configuration strategy being constrained by requirements to stabilise current programme.</p> <p>6) Assay has been decided on. Market analysis to be completed in October to assess private lab interest in tendering for HPV primary screening once current contracts are extended.</p> <p>7) Communications resources (external & internal) for implementation of the project to be defined.</p>		
	<p>Update Action 04/28 Update on the possibility of appointing a clinical lead for the move to HPV testing will be provided next week.</p> <p>Update on 14/08/18: The negotiations with the possible candidate to take on the clinical lead role were unsuccessful. We are going to issue another expression of interest to the clinical community. Update on 05/09/18 A further expression of interest was issued again last week. Update on 12/09/18 this expression of interest has been extended for an additional fortnight. Update on 02/10/18-The expression of interest has been extended to the 10th Oct.</p> <p>Update on 28/08/18 Interviews for a clinical director took place last week and an offer will be made to the identified candidate this week. Update on 05/09/18 The offer was made and final negotiations are concluding with the successful candidate. Update 19/09/18 NRS are finalising the contract.</p> <p>Update Action 04/29 A review meeting is being scheduled with DoH regarding the project plan. Update on 12/09/18 This meeting took place on 06/09/18</p>		
2	Implementation assurance on Scally Inquiry and RCOG recommendations		

CervicalCheck Steering Committee Weekly Report from HSE 3rd October 2018

Members of the Scally Implementation working group with NSS

CervicalCheck Team:

- Smear taker Co-ordinator
- Senior Health Promotion Officer

National Screening Service team:

- Communications Information Manager
- Information and Communications Officer

Advocacy Team:

- Head of Open Disclosure
- Members of the Advocacy team on a needs basis

Communications Team:

- Client Services Director
- Senior Comms Manager
- Content Manager
- Content writer
- Communications Manager

Based on the phase of development different skill sets such as user testing, web development and social media management will be used.

The working group will be supported in their work by a research process and a reference group, which will provide expert advice at key points of the project.

Reference Group Membership

Invitations to join the Reference Group are currently with a number of national and international experts, drawn from the relevant fields and ensuring clinical, non-clinical input and patient representation alongside experience in screening programmes, communication, health literacy and behavioural economics.

CervicalCheck Steering Committee
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2.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	1. A more comprehensive guide to the CervicalCheck screening programme should be provided online so that women who wish to learn more about the programme can obtain information easily	<p>Work is progressing on the migration of some of the content from the old website to the newly developed hse.ie/cervicalcheck.</p> <p>The updated materials are being uploaded onto the website.</p> <p>It will take several weeks and months to fully disseminate and implement the materials for all the different systems involved in the CervicalCheck Screening Programme – including the 4,500 centres contracted by CervicalCheck</p>	31.10.18	In progress
	2. 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 their consent form	See above.	31.10.18	In progress
	3. 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	See above.	31.10.18	In progress
	4. The information for women accompanying the consent form should guarantee that should there be a problem or error of any significance with the screening or reporting process, open disclosure of all the details will take place in a timely, considerate and accurate manner	See above.	31.10.18	In progress
	5. The provision of an immediate ex gratia payment of €2,000 to each woman involved and to the next of kin of the deceased, recognising that it is important that women do	N/A		

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2.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	not encounter any financial obstacles to participating and making their voices heard in relation to both the Scoping Inquiry and any resulting Commission of Inquiry			
	6. That a process be commenced to hold structured conversations with each of the women affected by the CervicalCheck issues who wish to have their experience documented, and with the relevant surviving family members of any affected woman who has died, if they so wish	N/A		
	Update Action			

3.a	RCOG recommendation	Current position, issues & challenges	Deadline	Status
	TBC			