

CervicalCheck Steering Committee
Weekly report to the Minister
14 September 2018

1. Update on support package and *ex gratia* payment

The HSE reports that Liaison Officers have held 310 face-to-face meetings with women and families to discuss their needs. This includes 177 initial meetings and 133 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

Delivery of supports

- The HSE has now issued 680 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.
- Alongside the provision of medical cards, supports, including counselling, physiotherapy, occupational therapy, dental, ophthalmic and nursing services have been made available to those requesting them. Guidance is also provided regarding grants and services available from local authorities. The HSE has advised that there has been a reduction over the past week of the number of supports requested and provided. This reflects the fact that some individuals have decided not to take up supports that they previously felt were required. These supports remain available, should an individual decide to access them at a later date.
- 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 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. The HSE has developed a simplified claim process for women and their families to minimise the burden involved while providing the required assurance from a public finance perspective. To date, almost €427,000 has been reimbursed in respect of various health and social care costs, some €311,000 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.
- 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.
- The Department has been engaging with DCYA to further progress contact between patients and Tusla. HSE advises that, following contact with Tusla, follow-up with those who have indicated an interest in adoption will take place with a view to arranging a joint briefing session by Tusla.

Ex gratia payment as recommended by Dr Scally

Liaison Officers have been coordinating the arrangements for the ex-gratia payment of €2,000 to each of the women affected or, where a woman has died, to their next-of-kin. The HSE reports that 208 payments have now been made. Any remaining payments will be made as applications are received.

2. Release of records

The HSE remains focused on responding to all requests for records as soon as possible. CervicalCheck has assigned an operational manager with a significant team to oversee access to records and smear results and the HSE reports that:

- 123 legal requests have been received to date, of which 3 were received within the past week; 103 have been processed, of which 1 was within the past week
- 285 FOI or data access requests have been made and 258 have received a response
- All requests responded to this week were within 30 days

It is intended to expand the team further to ensure the timely release of records continues.

The HSE's protocol for providing women with access to their physical smears aims to provide women with access while preserving the integrity of the slides. The protocol also provides a tracing mechanism for slides. Information in relation to the protocol continues to be issued to women with their records to facilitate them in accessing smears should they wish to do so. The HSE advises that solicitors are using this protocol to access smears when required.

- 22 slide requests have been made in accordance with the protocol; 11 have been processed.

3. Independent Expert Panel Review

A senior and experienced HSE Project Manager is in place, together with key project leads and support staff, to ensure all possible support is provided for the RCOG review. Progress to date is as follows:

- Information in relation to consent together with consent form issued to 216 women and families in mid-August. Five women of the initial 221 elected not to receive any further correspondence from the HSE and so did not receive this pack.
- There was some concern among women with pending legal cases or those considering taking legal action in relation to the length of time that their slides would be unavailable to them during the RCOG process. At a teleconference of 30 August between HSE, RCOG and DOH it was confirmed that women who choose to participate will be able to exit the review process at any time, and that the time period for return of their slides will be no longer than a month.
- The Department continues to engage with the HSE to ensure remaining letters issue as expeditiously as possible. 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. A dedicated information line is available to answer queries people may have when they receive their letter. Additional clinical and

administrative resources have been identified to support calltaking where women have queries, with opening hours extended to weekends

- The Department is committed to continuing to support and facilitate RCOG and the HSE in progressing this review as expeditiously as possible, and to do so in a way that ensures quality, comprehensiveness and integrity of the results.

4. 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 are in the process of proofing. A Patient and Public Involvement meeting is scheduled for 24 September.

5. Introduction of HPV as the primary method of testing

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. A project steering group comprising all key stakeholders is in place and a project manager has been appointed.

A key decision is the choice of HPV assay, required before finalisation of tender documentation. This requires clinical input and in the absence of a clinical lead, a Clinical Advisory Group has been identified and was due to meet 13 September last.

Negotiations on the extension of existing lab contracts are currently ongoing, to maintain the programme pending introduction of the new test and related procurement.

6. Clinical Director

Interviews for a Clinical Director for CervicalCheck took place on 22 August and the HSE advises that final negotiations are ongoing with the successful candidate.

7. 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 70,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 56 days. The National Screening Service and HSE Procurement are engaging with laboratory service providers to address capacity issues.

8. 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.

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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 CHO's (Community Healthcare Organisations)																																
	Project Plan	This week	To date																														
	Number of meetings held with affected women & families (Liaison Officers)	17	177 initial meetings 133 additional meetings.																														
	Number of medical cards issued	0	680																														
	Number of ex gratia payments made	1	208																														
	Number of supports requested		477 Top ten supports requested to date <table><tr><td>Counselling</td><td>122</td></tr><tr><td>Complimentary Therapy</td><td>52</td></tr><tr><td>Transport costs</td><td>39</td></tr><tr><td>Medical Notes</td><td>32</td></tr><tr><td>Medical appointment expenses</td><td>32</td></tr><tr><td>Childcare Costs</td><td>25</td></tr><tr><td>HCP</td><td>21</td></tr><tr><td>Medication</td><td>18</td></tr><tr><td>Diagnostic</td><td>21</td></tr><tr><td>OT</td><td>9</td></tr></table> Supports which saw a reduction in requests this week <table><tr><td>Counselling</td><td>-19</td></tr><tr><td>Dietetics</td><td>-5</td></tr><tr><td>Disabilities</td><td>-3</td></tr><tr><td>Diagnostic</td><td>-3</td></tr><tr><td>Dental</td><td>-3</td></tr></table>	Counselling	122	Complimentary Therapy	52	Transport costs	39	Medical Notes	32	Medical appointment expenses	32	Childcare Costs	25	HCP	21	Medication	18	Diagnostic	21	OT	9	Counselling	-19	Dietetics	-5	Disabilities	-3	Diagnostic	-3	Dental	-3
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	Number of supports provided		<div>327</div> <div>Top ten supports provided to date</div> <table><tr><td>Counselling</td><td>81</td></tr><tr><td>Complimentary Therapy</td><td>36</td></tr><tr><td>Transport costs</td><td>32</td></tr><tr><td>Medical Notes</td><td>27</td></tr><tr><td>Medical appointment expenses</td><td>26</td></tr><tr><td>Childcare Costs</td><td>19</td></tr><tr><td>HCP</td><td>15</td></tr><tr><td>Medication</td><td>15</td></tr><tr><td>Diagnostic</td><td>15</td></tr><tr><td>OT</td><td>8</td></tr></table> <div>Supports which saw a reduction in requests this week</div> <table><tr><td>Counselling</td><td>-24</td></tr><tr><td>HCP</td><td>-6</td></tr><tr><td>Diagnostic</td><td>-5</td></tr><tr><td>Dietetics</td><td>-5</td></tr><tr><td>Disabilities</td><td>-4</td></tr><tr><td>Dental</td><td>-3</td></tr><tr><td>Physio</td><td>-2</td></tr><tr><td>OT</td><td>-2</td></tr><tr><td>Transport costs</td><td>-1</td></tr><tr><td>Childcare Costs</td><td>-1</td></tr></table>	Counselling	81	Complimentary Therapy	36	Transport costs	32	Medical Notes	27	Medical appointment expenses	26	Childcare Costs	19	HCP	15	Medication	15	Diagnostic	15	OT	8	Counselling	-24	HCP	-6	Diagnostic	-5	Dietetics	-5	Disabilities	-4	Dental	-3	Physio	-2	OT	-2	Transport costs	-1	Childcare Costs	-1
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	<p>Current position, issues & challenges</p> <ul style="list-style-type: none">• Many clients are focusing on the meeting scheduled for 16.09.18 and Liaison Officers are assisting where appropriate.• There has been a reduction this week in supports requested and provided. During ongoing engagement with clients overtime the clients have now decided not to participate in supports they previously felt they required and which the LOs had put in place for them. All of these supports remain available should individuals later decide to access them.• Contact has been made with TUSLA in relation to adoption queries. This will be followed up with families who have indicated an interest with a view to TUSLA organising a joint briefing session on the process for them.• Contact was made by Liaison Officers to ensure that everyone has access to the published Scally Review.
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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. - Three legal personnel in Dublin. - Two 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 (reclassified)	0	123
	Number of legal requests responded to (reclassified)	1	103
	0 - 30 days	-	91
	*30 days +	-	12
	Number of requests on hold, awaiting clarification from solicitor	-	2
	Number of FOI / Data access Requests made	4	285
	Number of FOI / Data access Requests responded to	2	258
	0 - 30 days	-	238
	**30 days +	-	20
	Number of slide requests made (per protocol) Action 7/39	3	22
	Number of slide requests processed (per protocol)	0	11

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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 17 requests which extended over the 30 days. In addition there were a number of requests where verification of patient or next-of-kin details were required with the individuals solicitor, this is a necessary step in the process.</p>

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Oversight and engagement with the HSE on modules of their work as follows			
1.c	Interface with Scally Inquiry	Yes	No
	Project Manager in Place A senior manager is assigned to oversee the timely release of documents to facilitate Dr Scally's review.	√	
	Project Team Composition There is an external legal services partner with a team of solicitors to support the release of documents. In addition we have a HSE senior manager assigned to support the legal team in the provision of documents. HSE divisions have also assigned lead personnel to support the provision of documents to the central team.	√	
	Project Plan We are working to the timeframes as outlined by Dr Scally.	√	
	Current position, issues & challenges 1. All information has been provided to Dr Scally.		
	Update Action		

1.d	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 Daily meetings and teleconference calls with the Project Team to identify critical actions, timeframes, and areas for escalation, risks, issues, and dependencies are taking place.	√	
	Project Plan Communication to/from Women <ul style="list-style-type: none"> Detailed project plan for coordination and circulation of remaining letters outlining actions, timeframes, and dependencies. As of Fri 7th Sept: <ul style="list-style-type: none"> 471 additional letters have issued to women (687 letters have issued in total) 71 (33%) consent forms returned with 54 (25%) consenting to be part of the review. 	√	

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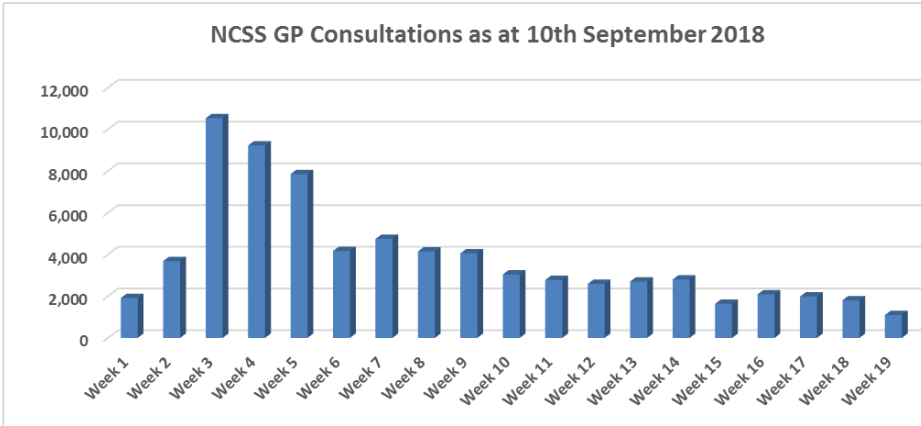
	<ul style="list-style-type: none"> Progressing to issue c. 1,200 remaining letters Acute hospitals supporting validation of NOK where PCRS has confirmed women deceased (1-2 week processing time). Weekly teleconferences with Patient Liaison Officers. <p>Call Centre: Additional resources have been identified (clinical and administrative) to support call centre. Opening hours extended to weekends 9am – 6pm to support anticipated volume of calls.</p> <p>Acute & Community Services: Actively linking with key stakeholders, acute hospitals representative identified and working with Team. Developing protocol to supply RCOG with relevant medical records from acute and community services where requested.</p> <p>Laboratory Logistics: Engagement with NSS, RCOG and the labs has commenced with the view to transferring slides as quickly as possible. Draft process map developed, requires technical input from NSS. Identifying timelines for immediate transfer of first batch of slides to RCOG.</p>		
	<p>Current Position, Issues and Challenges</p> <ul style="list-style-type: none"> RCOG Support team is preparing to process any queries from women/NOK, clinicians, media and public as remaining cohorts of women or next of kin receive letters. <p>Next Steps</p> <ul style="list-style-type: none"> Issue remaining letters as per schedule. Continue regular engagement with Patient Liaison Officers and other stakeholders. 		
	Update Action		

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	Oversight and engagement with the HSE on modules of their work as follows		
1.e	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 comprise 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 and the potential introduction of overtime for screeners from September. 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 70,000. The normal capacity for a lab 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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<p>Average time for processing results</p> <p>The average processing time is currently 56 days.</p>																																																								
<p>Update Action</p> <p>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 meeting are scheduled to take place 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.</p>																																																								

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1.f	Introduction of HPV Screening	Yes	No
	Project Manager in Place Yes. A Project Manager is in place and negotiations are continuing again this week with a possible clinical Lead for the HPV primary screening project.	√	
	Project Team Composition <ul style="list-style-type: none"> In the absence of a clinical lead for the project, a clinical advisory group will meet on Thurs 13th to be chaired by the interim Clinical Director of the programme. This group will make recommendations for clinical decisions required for project advancement. <p><u>Work on the key workstreams has progressed as follows:</u></p> <p>Clinical</p> <ul style="list-style-type: none"> Clinical Advisory Group established and meeting scheduled. <p>Procurement</p> <ul style="list-style-type: none"> Market analysis to inform specification and market model progressed. <p>ICT</p> <ul style="list-style-type: none"> Development and testing on changes to the Cervical Screening Register were progressed Resource planning analysis for testing capacity commenced. <p>Lab Configuration</p> <ul style="list-style-type: none"> Draft configuration options developed further. <p>Resources for Health care Professionals</p> <ul style="list-style-type: none"> E-learning resource commissioned. Resource Planning progressed <p>Immediate activities</p> <ul style="list-style-type: none"> Detailed capacity planning with the Coombe and NVRL to continue in September to review their capability to deliver HPV primary testing (i.e. adequate resources, IT requirements and timelines to deliver any changes to their systems) Potential site visit to England to explore their approach to HPV testing roll out. Together with workshops with Coombe & NVRL, will inform the laboratory configuration and procurement processes for sufficient and appropriate capacity. Procurement will further develop the market analysis work completed to date. Date for Periodic Indicative Notice (PIN) release was discussed at the Steering Group for mid-late 	√	

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1.f	Introduction of HPV Screening	Yes	No
	<p>Sept.</p> <ul style="list-style-type: none"> Interim Clinical Director has nominated representation for a Clinical Advisory Group. Meeting scheduled for September 13th. <p>Current position, issues & challenges</p> <ol style="list-style-type: none"> 1) Stabilisation of the current programme (increase in demand on the laboratories and colposcopy with repeat and additional workload) 2) Intense negotiations continue with existing labs. Key issue for the laboratories are reputational and financial concerns. 3) Absence of a fulltime Clinical Director for the programme is impacting a number of key activities. <ul style="list-style-type: none"> Decision required on the cervical screening pathway Decision required on the HPV test assay <p>A Clinical Advisory Group is being setup to mitigate the risk of no Clinical Director or lead for the programme.</p> <ol style="list-style-type: none"> 4) Requirement to conclude the HPV test assay in order to allow the tendering process for an external partner to progress. 5) Communications resources (external & internal) for implementation of the project to be defined. 		
	<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.</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.</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>		

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3	<p>Implementation assurance on Scally Inquiry and RCOG recommendations</p> <p><u>Members of the Scally Implementation working group</u></p> <p>CervicalCheck Team:</p> <ul style="list-style-type: none"> • Smear taker Co-ordinator • Senior Health Promotion Officer <p>National Screening Service team:</p> <ul style="list-style-type: none"> • Communications Information Manager • Information and Communications Officer <p>Advocacy Team:</p> <ul style="list-style-type: none"> • Head of Open Disclosure • Members of the Advocacy team on a needs basis <p>Communications Team:</p> <ul style="list-style-type: none"> • Client Services Director • Senior Comms Manager • Content Manager • Content writer • Communications Manager <p>Based on the phase of development different skill sets such as user testing, web development and social media management will be used.</p> <p>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.</p> <p>Reference Group Membership</p> <p>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.</p>
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CervicalCheck Steering Committee
Weekly Report from HSE 12th September 2018

3.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	Legal proofing and clinical proofing of communications and information materials are in the process of being implemented. An additional 2 members will be briefed on Friday 14 th with respect to the work of the PPI. Video content for the new website is being developed. Testing of the old website is due to take place on 24 th September in order to provide a baseline for the new website and to provide data and evidence for future online development	01.10.18	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.	01.10.18	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.	01.10.18	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.	01.10.18	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 not encounter	N/A		

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3.a	Scallly Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	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.b	RCOG recommendation	Current position, issues & challenges	Deadline	Status
	TBC			