

CervicalCheck Steering Committee
Weekly report to the Minister
23 August 2018

1. Overview

A meeting of the CervicalCheck Steering Committee was held on Thursday the 23rd of August, chaired by Tracey Conroy. It has been agreed that meetings of the CervicalCheck Steering Committee will continue to be held fortnightly. The next meeting will be held on the 6th of September. Reports will continue to be weekly.

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

The HSE report that Liaison Officers have held 272 face-to-face meetings with women and families to discuss their needs. This includes 176 initial meetings and 96 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

Delivery of supports

- The HSE has now issued 668 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.
- 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 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, over €100,000 has been reimbursed in respect of various health and social care costs.
- The process of reimbursing retrospective costs is underway. 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 HSE and patient representatives present at the Steering Committee emphasised the need for clarity in relation to assistance for fertility treatments as part of the support packages. The HSE has been asked to provide the Department with necessary information about what has been requested, and a note is being prepared for the Minister on this matter.
- In addition to financial assistance, it is understood that some women have sought guidance on adoption. The HSE is engaging with Tusla to facilitate the women in establishing contact and following on from the discussion at the Steering Group the Department undertook to engage with DCYA so as to provide assistance in this regard.

Ex gratia payment as recommended by Dr Scally

Liaison Officers are 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 202 payments have now been made. Remaining payments will be made as applications are received.

3. Release of records

The HSE is fully committed to providing any requested documents in line with the Minister's expressed expectation that all patient information, including documents, files and audits related to patients, will be made available to patients or their representatives without delay, and that the provision of information will be streamlined to the fullest extent possible to avoid unnecessary bureaucracy. This is now being achieved and:

- 118 legal requests have been received to date, of which 3 were received within the past week; 98 have been processed, of which 0 were within the past week
- 274 FOI or data access requests have been made and 248 have received a response
- All requests responded to this week were within 30 days

CervicalCheck has assigned an operational manager with a significant team to oversee access to records and smear results. 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 now in place is aimed at preserving the integrity of the slides. The protocol also provides a tracing mechanism for slides. Information in relation to the protocol is being issued to women with their records to facilitate them in receiving smears should they wish to do so. The HSE advises that solicitors are now using this protocol to access smears when required. One solicitor has expressed some disagreement with the protocol and the HSE is examining the matter, seeking to understand and address any issues.

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

4. 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:

- On Monday 13 August an introduction letter, a set of FAQs, a patient information sheet provided by RCOG and consent form for participation in the review issued to 216 women and families. 5 women of the initial 221 elected not to receive any further correspondence from the HSE and so did not receive this pack.
- A dedicated information line is available to answer queries people may have when they receive their letter. So far the number of queries has been relatively low.
- Community Liaison Officers have been briefed. Letters also issued to Hospital Group CEOs, colposcopy clinics and GPs to advise them the process had commenced.
- The HSE has advised that the process of validating the data for the remaining ~1,600 women is well underway. There are two stages to this process. The first involves

validation of the basic personal details of each woman, and this is nearly complete. The second phase involves engagement with treating hospitals to complete the validation process. It is anticipated that a further batch of consent letters will be ready to issue by end of next week, after which consent letters will continue to issue in batches as the second phase of validation is completed. It is anticipated that all letters will have been issued by the first week of October.

- Of the letters already issued, approximately 30 consent forms have been returned, with the majority of these women consenting to take part in the review.
- It is understood that some women who are currently undertaking legal actions have been advised by their solicitor not to take part in the RCOG review. The reasons given for this advice include the length of time for which slides may be unavailable to women for review by experts engaged for their legal cases; the benefit for women of the RCOG review, given that it is not a medico-legal review; some confusion in relation to the protocol governing release of slides and whether that is separate to consent for the RCOG review. The issues were discussed in detail at the Steering Committee meeting which agreed a number of actions including:
 - consideration of how women who are taking legal actions can be facilitated (a teleconference with RCOG is arranged for 30th August)
 - a review of the information issued to women to date, to address the issues being raised, including the purpose of the review and its value;
 - an amendment to the protocol for the release of slides to remove any confusion.

The HSE is continuing to make every effort to address any queries, issues or concerns raised by women about the review or the consent process, and to ensure clear information is provided.

RCOG's review protocol will be provided shortly to the Department of Health for publication on the DOH and HSE websites. The RCOG Project Manager, Lead Assessor and Deputy Lead Assessor continue to liaise with the HSE and the Department to discuss and examine data and information systems that will be used to support the review.

The Department of Health 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.

5. Implementation of recommendations of the Scally Inquiry

A working group has been established in the HSE to address the recommendations of the First Report on information about screening for women. The group is being supported in its work by a research process and a reference group to provide expert advice at key points of the project. The HSE reports that work is progressing on each of the four recommendations from the First Report.

A Patient and Public Involvement session took place on the 21st of August, led by a senior Health Promotion Officer. In addition, a literature review on how members of the public perceive and understand risk and probability has been commissioned from the ESRI and it is expected that this will be complete by end-August.

6. 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 and will be subject to a tendering process for any work carried out outside the public sector. The HSE has confirmed that substantial implementation planning is ongoing. A project steering group comprising all key stakeholders is in place and a project manager has been appointed.

Recognising that this is a policy and operational priority, the group is working to secure further specialist expertise to support the project and efforts are ongoing to secure a clinical lead. Interviews for the position of clinical director were held on the 22nd of August.

7. Smeartaking activity

The HSE has reported that lab activity remains approximately 20% above normal levels. The total number of additional consultations to date is over 64,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 52 days.

Due to the skilled nature of cytology screening and the difficulty in recruiting trained staff, lab turnaround time issues can be slow to resolve as they require the use of overtime for existing staff and there are workload limits set for quality assurance purposes. Every effort is being made to ensure that tests are processed as quickly as possible, having regard to the high standards required for testing. To aid resolution, laboratories have recruited additional clerical support to free up screening staff. They have also streamlined processes around release of reports and QA checks of same as well as overtime for screeners.

The lab working group continues to work closely with the three labs to understand and manage capacity issues. The labs are reporting to the HSE CervicalCheck team on a weekly basis providing status updates on the number of samples received, processing times etc. Lab action plans are being monitored to ensure that they address the problem in the shortest possible timeframe.

While it is too early to discuss any particular pattern the HSE has indicated that in a small number of cases, certain smears may have to be retaken. This can occur where the smear is not sufficient for reading, the smear has expired for various reasons or the slide is damaged. Laboratories have to ensure the smear is on a slide no later than 6 weeks in order to ensure it does not expire. The HSE is aware of only a small number of these situations. All efforts are being taken to avoid such circumstances as the HSE is conscious that this requires the woman to have a further smear taken and they are continuing to monitor this closely with the laboratories.

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. As part of this work he will:

(1) Engage with the women, their families and their representatives to assess what, in their opinion, could be done to provide an alternative to court;

(2) Assess the management of cases, liability and quantum that arise, in conjunction with the State Claims Agency and other relevant bodies (State parties, laboratories, insurers, indemnifiers and affected parties);

(3) Have regard to the work of the Scally Inquiry and the RCOG Review;

(4) Report to the Minister for Health within two months, and the report is to recommend a way through which these cases can be resolved, in a sensitive and timely manner, that is appropriate to these cases involving complex liability issues and multiple parties, outside of adversarial court processes.

23 August 2018

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

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 National Director, Mary Walshe Chief Officer Liaison Officers in each Community Healthcare Organisation																						
	Project Plan																						
		This week	To date																				
	Number of meetings held with affected women & families (Liaison Officers)	7	176 initial meetings and 96 additional meetings.																				
	Number of medical cards issued	18	668																				
	Number of ex gratia payments made	1	202																				
	Number of supports requested	2	466 <table><tr><td>Counselling</td><td>139</td></tr><tr><td>Complimentary Therapy</td><td>40</td></tr><tr><td>Transport costs</td><td>39</td></tr><tr><td>Medical appointment expenses</td><td>29</td></tr><tr><td>Medical Notes</td><td>25</td></tr><tr><td>HCP</td><td>23</td></tr><tr><td>Childcare Costs</td><td>22</td></tr><tr><td>Diagnostic</td><td>22</td></tr><tr><td>Physio</td><td>18</td></tr><tr><td>Medication</td><td>17</td></tr></table>	Counselling	139	Complimentary Therapy	40	Transport costs	39	Medical appointment expenses	29	Medical Notes	25	HCP	23	Childcare Costs	22	Diagnostic	22	Physio	18	Medication	17
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		This week	To date																				
	Number of supports provided	6	341 <table><tr><td>Counselling</td><td>102</td></tr></table>	Counselling	102																		
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CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

			<table><tr><td>Transport costs</td><td>31</td></tr><tr><td>Complimentary Therapy</td><td>27</td></tr><tr><td>Medical appointment expenses</td><td>25</td></tr><tr><td>HCP</td><td>21</td></tr><tr><td>Childcare Costs</td><td>20</td></tr><tr><td>Diagnostic</td><td>19</td></tr><tr><td>Medical Notes</td><td>18</td></tr><tr><td>Medication</td><td>12</td></tr><tr><td>Disabilities</td><td>11</td></tr></table>	Transport costs	31	Complimentary Therapy	27	Medical appointment expenses	25	HCP	21	Childcare Costs	20	Diagnostic	19	Medical Notes	18	Medication	12	Disabilities	11
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	Current position, issues & challenges <ul style="list-style-type: none">• LOs are providing clients with ongoing support regarding RCOG request and retrospection claims.• Clients continue to advise of their infertility issues and their desire for support on these matters																				
	Update Action																				

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.	√	

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

	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. - Additional two admin resource's required. 	√	
	Project Plan There is a defined operational process for the release of records.	√	
		This week	To date
	Number of legal requests made (reclassified)	3	118
	Number of legal requests responded to (reclassified)	0	98
	0 - 30 days	-	88
	*30 days +	-	10
	Number of requests on hold, awaiting clarification from solicitor	-	2
	Number of FOI / Data access Requests made	4	274
	Number of FOI / Data access Requests responded to	5	248
	0 - 30 days	-	231
	**30 days +	-	17
	Number of slide requests made (per protocol) Action 7/39	3	16
	Number of slide requests processed (per protocol)	2	11
	Current position, issues & challenges 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		

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

	process with the labs but these are being addressed.
	<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 40days 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>

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

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 Scallys 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 <ol style="list-style-type: none"> 1. Dr Scally has indicated that he has received the majority of documents. 2. CervicalCheck are now addressing requests on documents pertaining to specific questions to enable Dr Scally to complete his work 3. The HSE DG has continued to link with Dr Scally on a regular basis to ensure that the review is supported by HSE leadership. 		
	Update Action		

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

1.d	Interface with RCOG Review	Yes	No
	Project Manager in Place Programme Lead Project Manager	√	
	Project Team Composition Work streams have been identified as follows, with lead coordinators nominated for each: <ol style="list-style-type: none"> 1. Patient Service Liaison 2. ICT (Call centre and Case Management System) 3. Communications 4. HSE Services Liaison/ (Acute Services, Primary/Social Care Services, and Labs) 5. Others being considered as needs emerging i.e. Logistics process re labs 	√	
	Progress against Project Plan <ul style="list-style-type: none"> • Letters to the first cohort of women and next of Kin were issued on Monday 13th August. • Information line went live on Tuesday 14th August for the women and next of kin should they have any queries relating to the RCOG Review Panel Support Process. • An overview of the Expert Panel Review of Cervical Screening, the Terms of Reference and the RCOG Patient Information Sheet was published on the Department of Health website on 14th August. • Case management system (CMS) has gone live and training has been provided to call centre staff on 17th August. • Pack in development to provide PLOs with related information. • Process agreed for managing return of consent forms. • Letters to the Group CEOs, Colposcopy Units and Healthcare Service Providers are under review. • Letters for remaining cohort of women and next of kin are in draft. • Reminder letters for first cohort of women and next of kin are in draft. • Work is progressing on devising a comprehensive project plan to support the RCOG Review Panel, with detailed processes and timeframes. 	√	
	Current Position, Issues and Challenges		

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

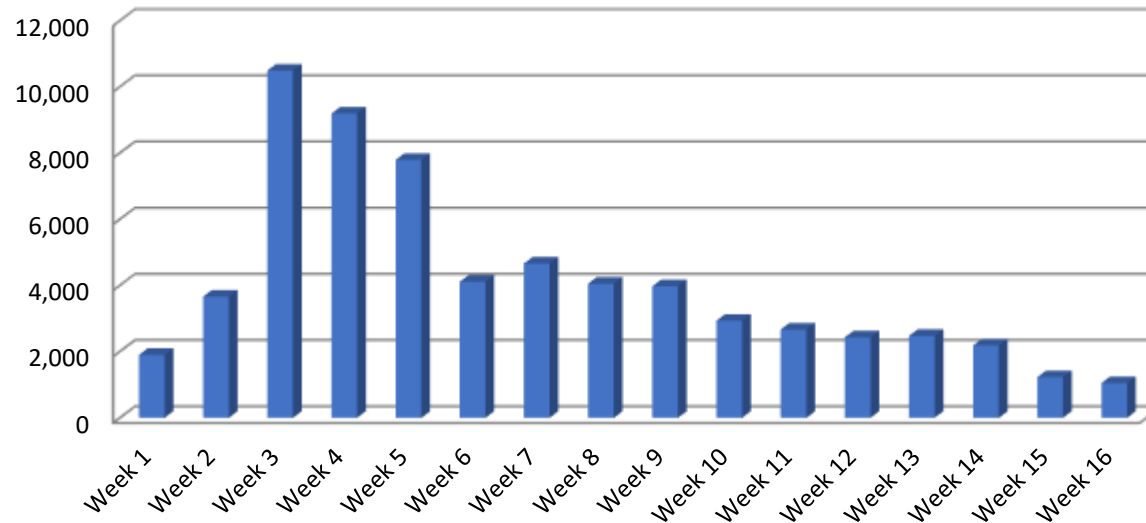
1.d	Interface with RCOG Review	Yes	No
	<ul style="list-style-type: none"> • The first cohort of letters were issued on the 13th August 2018. • Dublin based support office will be based in Kings Inn House until further arrangements can be made. • Data Validation for the remainder of women must be carried out prior to the issue of the next cohort of letters. This must include identifying deceased women and their next of kin etc. <p>Next Steps</p> <ul style="list-style-type: none"> • Commence process to validate the data for the next group of women to be communicated with. • Progress to issue remaining letters to next group of women once the data is validated. • Agree whether calls will be made to all women and the deceased next of kin that are eligible to be included in the RCOG Panel Review. • Follow up on call backs with the women who were told they would be part of the RCOG review via the call centre. • Complete Project Initiative Document and Project Plan. 		
	Update Action		

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

	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. Because of the skilled nature of cytology screening and the difficulty in recruiting trained staff, lab turnaround time issues can be slow to resolve as they require the use of overtime for existing staff and there are workload limits set for quality assurance purposes. 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.		
	Uptake of smear tests: <i>Out of cycle smears</i> Total number of additional consultations to date is more than 60,000. 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. 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.		

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

NCSS GP Consultations as at 20th August 2018



Week	Total
Week 1	1,903
Week 2	3,660
Week 3	10,491
Week 4	9,196
Week 5	7,793
Week 6	4,113
Week 7	4,663
Week 8	4,053
Week 9	3,976
Week 10	2,932
Week 11	2,665
Week 12	2,434
Week 13	2,476
Week 14	2,187
Week 15	1,230
Week 16	1,049
Grand Total	64,821

Average time for processing results

The average processing time is currently 52 days.

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 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.

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

1.f	Introduction of HPV Screening	Yes	No
	Project Manager in Place A Project Manager is in place and negotiations are continuing with a possible clinical Lead for the HPV primary screening project.	√	
	Project Team Composition <ul style="list-style-type: none"> Project lead and PMO support is in place. Efforts are ongoing to secure a clinical lead for the project (Issue). In lieu of a clinical lead, a clinical panel has been discussed to govern the clinical decisions. To be discussed at the Steering Group meeting on August 29th. 	√	
	<p>Update Action 04/28 An 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.</p> <p>Update Action 04/29 A review meeting is being scheduled with DoH regarding the project plan</p>		

CervicalCheck Steering Committee

Weekly Report from HSE 23rd August 2018

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 23rd August 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	Research is ongoing and due to be finalised this week. Top line findings will be presented to working group on 24 th Aug. Workshop planned for afternoon of the 24 th to implement findings. Public Patient Involvement (PPI) session is taking place on 21 st August. The ESRI Behavioural Research Unit has been commissioned to conduct a literature review on how members of the public perceive and understand risk and probability. The findings have implications for establishing best practice for the effective communication of risk.	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		

CervicalCheck Steering Committee
Weekly Report from HSE 23rd August 2018

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			