

**CervicalCheck Steering Committee**  
**Weekly report to the Minister**  
**16 August 2018**

## **1. Overview**

The CervicalCheck Steering Committee did not meet this week. The next meeting will be on Thursday, 23 August 2018.

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

The HSE report that Liaison Officers have held 264 face-to-face meetings with women and families to discuss their needs. This includes 176 initial meetings and 88 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

### ***Delivery of supports***

- The HSE has issued 650 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 G.P 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.
- Most recently, guidance is being 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, almost €80,000 has been reimbursed in respect of various health and social care costs.
- The process of reimbursing retrospective costs is underway. Guidance will be given to the Liaison Officers to ensure nationwide consistency and ease of payment for all. 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 reports that clients continue to advise of their dissatisfaction with the omission of loss of earnings and fertility assistance from the support packages.

### ***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 201 payments have now been made. Remaining payments will be made as applications are received.

#### **4. 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.

CervicalCheck has assigned an operational manager with a significant team to oversee access to records and smear results and ensure that women and their legal representatives receive their records in the most timely manner possible. The team recently reviewed all requests and reclassified them as necessary:

- 115 legal requests have been received to date, of which 5 were received within the past week; 98 have been processed, of which 5 were within the past week
- 254 FOI or data access requests have been made and 226 have received a response

The HSE has advised that a protocol for providing women with access to their physical smears is now in place, aimed at preserving the integrity of the smears for women who may wish to take legal action. The protocol also provides a tracing mechanism for slides. Information in relation to the protocol is now 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.

- 13 slide requests have been made in accordance with the protocol; 9 have been processed.

#### **5. 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. The project team continues to work on the development of the systems and supports required to manage the process as, recognising the very sensitive nature of this issue, the approach for obtaining consent will be tailored to the different cohorts of women and families involved.

The initial focus is on validation of the details of the 1,850 women within the review cohort (other than the details of the 221 women and families already known) in advance of sending out consent documentation for the review.

An introduction letter, a patient information sheet provided by RCOG, the consent form and FAQs issued to the 221 women and families on Monday 13 August. A dedicated information line is available to answer queries people may have when they receive their letter. Letters also issued to Hospital Group CEOs, colposcopy clinics and GPs to advise them the process had commenced.

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.

In recent days, RCOG have decided that they will make the protocol they are using for their review public. They will provide the protocol to the Department for publication on the DOH and HSE websites. Communications teams from RCOG, the Department and the HSE are in close contact to insure a consistent message to any queries arising from the publication.

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.

## **6. Implementation of recommendations of the Scally Inquiry**

A working group has been established and will be supported in their work by a research process and a reference group to provide expert advice at key points of the project. Invitations to participate in the reference group are with a number of national and international experts. The HSE report that work is progressing on each of the four recommendations from the First Report.

## **7. 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 has been carried out. 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. The Steering Committee continues to engage with the HSE to ensure the switch to HPV testing progresses as quickly as possible.

## **8. Smear-taking activity**

The HSE has reported that lab activity remains approximately 20% above normal levels. The total number of additional consultations to date is over 62,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 46 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 (estimated to be in the 100's). 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.

## **9. Communications**

Work by the HSE on the organisation of workshops for the 221 women and families is underway, with support from the Irish Cancer Society.

## **10. Alternative resolution mechanisms**

In addition to his work on the Expert Group<sup>1</sup>, Mr. Justice Charles Meenan will undertake a specific review and

(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.

*16 August 2018*

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<sup>1</sup> Judge Meenan is currently the Chairperson of an Expert Group established to consider an alternative mechanism to the court process for resolving clinical negligence claims.

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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	
	<b>Project Team Composition</b> David Walsh ND, Mary Walshe Chief Officer Maria Kavanagh <b>Liaison Officers in each of ( Community Healthcare Organisations)</b> <div style="display: flex; justify-content: space-between;"> <span>CHO 1 C Walsh</span> <span>CHO 6 D Healy</span> </div> <div style="display: flex; justify-content: space-between;"> <span>CHO 2 B Austin</span> <span>CHO 7 C Hanley</span> </div> <div style="display: flex; justify-content: space-between;"> <span>CHO 3 B Carroll</span> <span>CHO 8 J Bourke</span> </div> <div style="display: flex; justify-content: space-between;"> <span>CHO 4 H Sweeney</span> <span>CHO 9 B Horgan</span> </div> <div style="display: flex; justify-content: space-between;"> <span>CHO 5 S Murphy</span> <span></span> </div>		
	<b>Project Plan</b>		
		<b>This week</b>	<b>To date</b>
	<b>Number of meetings held with affected women &amp; families (Liaison Officers)</b>	16	176 initial meetings and 88 additional meetings.
	<b>Number of medical cards issued</b>	13	650
	<b>Number of ex gratia payments made</b>	1	201
	<b>Number of supports requested</b>	7	464 <b>Top ten supports requested to date</b> <div style="display: flex; justify-content: space-between;"> <span>Counselling</span> <span>139</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Complimentary</span> <span></span> </div> <div style="display: flex; justify-content: space-between;"> <span>Therapy</span> <span>40</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Transport costs</span> <span>39</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Medical app exp</span> <span>29</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Medical Notes</span> <span>25</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Childcare Costs</span> <span>22</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Diagnostic</span> <span>22</span> </div> <div style="display: flex; justify-content: space-between;"> <span>HCP</span> <span>21</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Physio</span> <span>18</span> </div> <div style="display: flex; justify-content: space-between;"> <span>Medication</span> <span>17</span> </div>

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		<b>This week</b>	<b>To date</b>
	<b>Number of supports provided</b>	10	335 <b>Top ten supports provided to date</b> Counselling 101 Transport costs 31 Medical appointment expenses 25 Complimentary Therapy 24 Childcare Costs 20 HCP 19 Diagnostic 19 Medical Notes 18 Medication 12 Disabilities 11
	<b>Current position, issues &amp; challenges</b> <ul style="list-style-type: none"> <li>• LOs are working toward providing clarity and assistance to clients with regard to the various communications which they have received over the past two weeks.</li> <li>• Clients continue to advise of their dissatisfaction with the omission of loss of earnings and fertility assistance from the support packages</li> </ul>		
	<b>Update Action</b>  Update Action 2/1207 Information pack issued to the 221 women on the 27 <sup>th</sup> July 2018. Communication was developed with multiple stakeholders and the communication was issued by the HSE Advocacy Unit  Update Action 3/1207 Preliminary work to begin within the HSE in relation to the holding of workshops for the 221 women. An update on this is to be provided at next week's meeting  Update Action 4/1207 Simplification of the claims process is now in place.		

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1.b	<b>Provision of documents to patients</b>	<b>Yes</b>	<b>No</b>
	<b>Project Manager in Place</b> There is an operational manager assigned to oversee access to records and smear results.	√	
	<b>Operational Team Composition</b> 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"> <li>- PM (Kevin Murphy) for overall coordination.</li> <li>- Three legal personnel in Dublin.</li> <li>- Two Administrative support personnel.</li> <li>- Additional two admin resource's required.</li> </ul>	√	
	<b>Project Plan</b> There is a defined operational process for the release of records.	√	
		<b>This week</b>	<b>To date</b>
	Number of legal requests made (reclassified)	5	115
	Number of legal requests responded to (reclassified)	5	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	17	270
	Number of FOI / Data access Requests responded to	13	243
	0 - 30 days	-	224
	**30 days +	-	19
	Number of slide requests made (per protocol) <b>Action 7/39</b>	4	13
	Number of slide requests processed (per protocol)	0	9
	<b>Current position, issues &amp; challenges</b> 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		

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	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.
	<b>Update Action</b> *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.  **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. 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.



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1.c	Interface with Scally Inquiry	Yes	No
	<b>Project Manager in Place</b> A senior manager is assigned to oversee the timely release of documents to facilitate Dr Scallys review.	√	
	<b>Project Team Composition</b> 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.	√	
	<b>Project Plan</b> We are working to the timeframes as outlined by Dr Scally.	√	
	<b>Current position, issues &amp; challenges</b> <ol style="list-style-type: none"> <li>1. Dr Scally has indicated that he has received the majority of documents.</li> <li>2. CervicalCheck are now addressing specific requests on documents pertaining to certain aspects of the review.</li> <li>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.</li> </ol>		
	<b>Update Action</b>		

## CervicalCheck Steering Committee

### Weekly Report from HSE 16<sup>th</sup> August 2018

1.d	Interface with RCOG Review	Yes	No
	<b>Project Manager in Place</b> Maria Lordan Dunphy (Assistant National Director, HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1 <sup>st</sup> of August. Roisin Egenton (Project Manager, HSE) commenced working as the Project Manager on Wednesday the 1 <sup>st</sup> of August.	√	
	<b>Project Team Composition</b> Work streams have been identified as follows, with lead coordinators nominated for each: <ol style="list-style-type: none"> <li>1. Patient Service Liaison</li> <li>2. ICT (Call centre and Case Management System)</li> <li>3. Communications</li> <li>4. HSE Services Liaison/ (Acute Services, Primary/Social Care Services, and Labs)</li> <li>5. Others being considered as needs emerging i.e. Logistics process re labs</li> </ol>	√	
	<b>Project Plan</b> <ul style="list-style-type: none"> <li>• Work has advanced devising a comprehensive project plan to support the RCOG Review Panel, with detailed processes and timeframes.</li> <li>• Meeting held with 2 lead Review Clinicians and Project Manager from RCOG and representatives of RCOG Support Panel Programme Team on Tues 7<sup>th</sup> Aug to discuss data required for the review and provide a walk-through of the current CervicalCheck data management system. Further to this meeting, RCOG will identify their specific data requirements and revert to the HSE.</li> <li>• Case management system (CMS) in development. Demo presented on the 9<sup>th</sup> of August and further requirements identified.</li> <li>• An information line has been established for the women should they have any queries relating to the RCOG Review Panel Support Process, once the letters have been issued.</li> <li>• Information line manual developed for the information line team.</li> <li>• It has been agreed that the NSS PO Box will be used as the return point for all consent forms, for the specific attention of “RCOG Review Support Panel”. Processes for scanning returns and data management to be discussed with ICT and Xpertivity.</li> <li>• Briefing provided for Patient Liaison Officers from Programme Lead. Pack in</li> </ul>	√	

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1.d	<b>Interface with RCOG Review</b>	<b>Yes</b>	<b>No</b>
	development to provide PLOs with related information. <ul style="list-style-type: none"> <li>Internal comms (HSE and NSS) briefed by Denise Ryan, Communications Manager.</li> </ul>		
	<b>Current Position, Issues and Challenges</b> <ul style="list-style-type: none"> <li>The first cohort of letters is ready and will be issued on the 13<sup>th</sup> August 2018.</li> <li>Administration capacity issue on-going with actions underway to address.</li> <li>Validation of legal representative vs. next of kin will require to be addressed prior to issue of the next cohort of letters.</li> </ul>		
	<b>Update Action</b>		

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1.e	Management of laboratory capacity issues	Yes	No
	<b>Project Manager in Place</b> Yes.	√	
	<b>Project Team Composition</b> 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.	√	
	<b>Project Plan</b> 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.		
	<b>Uptake of smear tests:</b> <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. This is presenting serious patient safety issues for the HSE and the laboratories. 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.		
	<b>Average time for processing results</b> The average processing time is currently 46 days.		
	<b>Update Action</b> 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 next week.		

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1.f	Introduction of HPV Screening	Yes	No
	<b>Project Manager in Place</b> Yes. A Project Manager is in place and negotiations are continuing with a possible clinical Lead for the HPV primary screening project.	√	
	<b>Project Team Composition</b> <ul style="list-style-type: none"> <li>• Project lead and PMO support is in place.</li> <li>• 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 22<sup>nd</sup>.</li> </ul>	√	
	<b>Update Action 04/28</b> An update on the possibility of appointing a clinical lead for the move to HPV testing will be provided next week.  <b>Update on 14/08/18:</b> 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.  <b>Update Action 04/29</b> A more detailed project plan is to be provided for next week's meeting		

## CervicalCheck Steering Committee

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3	<p><b>Implementation assurance on Scally Inquiry and RCOG recommendations</b></p> <p><b><u>Members of the Scally Implementation working group</u></b></p> <p>CervicalCheck Team:</p> <ul style="list-style-type: none"> <li>• Smear taker Co-ordinator</li> <li>• Senior Health Promotion Officer</li> </ul> <p>National Screening Service team:</p> <ul style="list-style-type: none"> <li>• Communications Information Manager</li> <li>• Information and Communications Officer</li> </ul> <p>Advocacy Team:</p> <ul style="list-style-type: none"> <li>• Head of Open Disclosure</li> <li>• Members of the Advocacy team on a needs basis</li> </ul> <p>Communications Team:</p> <ul style="list-style-type: none"> <li>• Client Services Director</li> <li>• Senior Comms Manager</li> <li>• Content Manager</li> <li>• Content writer</li> <li>• Communications Manager</li> </ul> <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><b>Reference Group Membership</b></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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3.a	<b>Scally Inquiry recommendations</b>	<b>Current position, issues &amp; challenges</b>	<b>Deadline</b>	<b>Status</b>
	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 has commenced on the invitation letter, information sheet, leaflet and certain aspects of the digital content. Work has progressed on planning for the PPI. A number of members of the reference group have been met and notes from the meeting have been shared with the working group.	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 any financial obstacles to participating and making their voices heard in relation to both the Scoping Inquiry and any resulting Commission of Inquiry	N/A		

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3.a	<b>Scally Inquiry recommendations</b>	<b>Current position, issues &amp; challenges</b>	<b>Deadline</b>	<b>Status</b>
	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		
	<b>Update Action</b>			

3.b	<b>RCOG recommendation</b>	<b>Current position, issues &amp; challenges</b>	<b>Deadline</b>	<b>Status</b>
	TBC			