

**CervicalCheck Steering Committee**  
**Weekly report to the Minister**  
**12 July 2018**

**1. Overview**

The Steering Committee met on Thursday 12 July. The meeting was co-chaired by the CMO, Dr Tony Holohan, and Ms Tracey Conroy, Assistant Secretary, Acute Hospitals Policy Division.

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

With Liaison Officers engagement with women now well established, it is not expected that numbers of meetings held will change significantly from week to week. The HSE reported that Liaison Officers have to date held 210 face-to-face meetings with women and families to discuss their needs. This includes 158 initial meetings and 42 follow-up meetings.

It is important to note that every individual's circumstances will be unique to them and thus the HSE has taken care to respect the wishes of the women and their families regarding the timing of contacts and subsequent meetings. Where meetings have not yet been held, this reflects the wishes of the individuals concerned either to meet at a future date that suits them or, in some instances not to take up the offer of support.

***Ex gratia* payment as recommended by Dr Scally**

Arrangements to make the ex-gratia payment of €2,000 to each of the women affected or, where a woman has died, to their next-of-kin are being coordinated through the Liaison Officers. The HSE reported that by the end of this week (13 July) it was expected that 182 payments would have been made. Remaining payments will be completed once individuals' banking details have been received.

***Delivery of supports***

- As of 11 July, the HSE had issued 557 new 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 87 cases to recategorise these as medical cards under the terms of the CervicalCheck support package.
- Alongside the provision of medical cards, primary care supports, including counselling, have been made available to those requesting them. This is very much a client-driven process and requests for supports will differ from individual to individual. A range of other health supports is being provided including in response to requests for physiotherapy, occupational therapy, dental, ophthalmic and nursing services among others.
- 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. This includes medicines not officially approved for reimbursement and any other non-standard therapies, once prescribed for the patient by their doctor. Arrangements are in place to reimburse 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. These will be reimbursed upon receipt of claims from individuals. The HSE is working to develop a simplified claim process for women and their families to minimise the burden involved while providing required assurance from a public finance perspective.

#### **4. Release of records**

A team is in place in CervicalCheck to deal with requests for records. The HSE has confirmed that all legal requests were delivered inside the timeframe up to week commencing 2 July. Due to the requirement for clarification on some requests and resourcing issues in that week, there were 29 sets of records not issued within the 30-day target; this has now been addressed. 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.

- 126 legal requests have been received to date, of which 6 were received within the past week; 71 have been processed, of which 13 were within the past week
- 189 FOI or data access requests have been made and 168 of these have been responded to.

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. 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.

#### **5. International Clinical Expert Panel Review**

The International Clinical Expert Panel Review is being carried out under the auspices of the Royal College of Obstetricians and Gynaecologists (RCOG) with expertise also sourced through the British Society for Colposcopy and Cervical Pathology. The scope of the review includes all cases of invasive cervical cancer in Ireland since CervicalCheck was established, to include the 1,482 cases notified to CervicalCheck since then and a further 1,630 cases registered by the National Cancer Registry of Ireland which had not been notified to CervicalCheck. Women who developed cancer and who were screened by CervicalCheck will be identified and their screening histories will be examined. Within this overall cohort, the number who were screened prior to diagnosis is 1,850, hence this is the number to be included in the Independent Review.

The terms of reference and scope of the review have been agreed and the preparatory phase of the review is underway in line with the terms of reference. The consent process is being examined as part of these preparations, including requirements and any time implications. The Department of Health is committed to continuing to support and facilitate RCOG and the HSE in progressing this review as expediently 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**

An implementation plan outlining the key actions to be undertaken by the HSE to address the four recommendations contained in the First Report from Dr Scally, on information for women, has been drafted.

The HSE has reported that initial arrangements for implementing the plan are already in place, including the establishment of working groups to coordinate the various streams of work and the appointment of a project manager to lead the development and implementation of the plan. The implementation team will throughout its work consult both with subject matter experts and with women who use the CervicalCheck screening services to ensure that all information is of high quality and user friendly.

## **7. Disclosure of newly received clinical audit results**

Disclosure is now underway for the 12 women for whom clinical audit results have been newly received by CervicalCheck, and 10 women have now been contacted. These women are among the 1,482 whose diagnoses of cervical cancer were notified to CervicalCheck since 2008 and for whom CervicalCheck initiated the process of clinical audit. Contact for these 12 women with a Liaison Officer, in relation to the package of primary care supports, is being provided immediately following disclosure.

## **8. 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 advised that a Project Steering Group is in place for this work, recognising that this is a policy and operational priority. The Department is continuing to engage with the HSE, within the Steering Committee, to ensure the switch to HPV testing progresses as quickly as possible.

## **9. Smeartaking activity**

The HSE has reported that lab activity, which had risen as a consequence both of out-of-cycle smears and increased uptake generally, has begun to diminish to more normal levels. The HSE is monitoring this through weekly calls and meetings with the labs to manage the situation. With regard to GP consultations and smeartaking activity, the HSE has advised that claims for 43,690 GP consultations have been submitted in the past ten weeks.

## **10. Communications**

The importance of communication with affected women and families and the need to ensure that clear and consistent information is available to them was raised and the Steering Committee discussed various approaches to achieving this. More broadly, there is a need for clear communications with the public and stakeholders in relation to immediate and longer-term issues and planning is underway in this regard.

*13 July 2018*

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

1	<b>Oversight and engagement with the HSE on modules of their work as follows</b>			<b>Deadline</b>	<b>Status</b>
1.a	Management of supports to patients/families	Yes	No		
	Project Manager in Place: David Walsh, National Director, Mary Walsh Chief Officer CHO 9				
	Project Team Composition Liaison Officers in place in each of the 9 Community Healthcare Organisations nationally				
	Project Plan				
		This week	To date		
	Number of meetings held with affected women & families (Liaison Officers)		210		
	Number of medical cards issued	25	557		
	Number of ex gratia payments made	16	166		
	Number of supports requested	138	388		
	Number of supports provided	51	120		
	<p>Current position, issues &amp; challenges</p> <p>Clients are engaging well with the community support package and appear to be taking a more structured approach to tailor their package to meet their needs.</p> <p>Clients are frustrated with the absence of clarity regarding retrospective payments.</p>				
1	<b>Oversight and engagement with the HSE on modules of their work as follows</b>			<b>Deadline</b>	<b>Status</b>
1.a cont.	Update Action 050718/1.a/1 - Feedback from women & families to be sought to inform meetings of Liaison Officers			<b>12/07/18</b>	

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**Weekly Report from HSE 12th July 2018**

1	<b>Oversight and engagement with the HSE on modules of their work as follows</b>			<b>Deadline</b>	<b>Status</b>
1.b	<b>Provision of documents to patients</b>	Yes	No		
	Operational Manager in Place; Interim NSS Operations Mgr and Lead Legal Advisor in place	Yes			
	Operational Team Composition; Legal team of four now in place to support legal requests and additional administrative support provided.	Yes			
	Project Plan; N/A as this is an operational process	N/A			
		This week	To date		
	Number of legal requests made	6	126		
	Number of legal requests responded to	13	71		
	0 - 30 days		26		
	30 days +		29		
	Number of FOI / Data access Requests made	25	189		
	Number of FOI / Data access Requests responded to	39	168		
	0 - 30 days				
1	<b>Oversight and engagement with the HSE on modules of their work as follows</b>	This week	To date	<b>Deadline</b>	<b>Status</b>
1.b cont.					
	<p>Current position, issues &amp; challenges</p> <p>All legal requests were delivered inside the timeframe up to week commencing 2nd July. Due to the requirement for clarifications on some requests and resourcing issues in that week there were 29 record packs outside the 30 days target. These have been addressed and are being sent in the current week or the clarifications are being addressed with the solicitor concerned.</p> <p>Access for women to their physical smears is through an agreed protocol that was developed with legal team, State Claims and the hospitals. This was developed to protect the integrity of the smears for women who may wish to take legal action. This is now issued with all record packs providing women with the option to receive their smears should they or their legal team wish to do so. Solicitors are now using the protocol to access smears where required.</p>				
	<p>Update Action 050718/1.b/1: HSE to examine implementation of a single-point data access system and to report on the timeline for implementing this at the next meeting</p> <p>Historically medical records are accessed from each specific service by a patient or their representative where required. The request is to see can we have a single point of access for all records related to the CervicalCheck cases in the HSE who can coordinate a response, without causing undue delay for women. A meeting is arranged for next week with the different divisions involved to define how feasible this may be. Further updates will be provided as this work progresses.</p>			<b>12/07/18</b>	Ongoing

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.c	<b>Interface with Scally Inquiry</b>	Yes	No		
	Project Manager in Place; Dara Purcell	Yes			
	Project Team Composition; Internal HSE mgmt assigned and legal team contracted to support supply of documentation to Dr Scally review.	Yes			
	Project Plan	Yes			
	Current position, issues & challenges The issue regarding reliability of documents has been resolved. Dr Scally has confirmed the progress in recent weeks to ensure he can proceed with his enquiry in a time efficient manner.				

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.d	<b>Interface with RCOG Review</b>	Yes	No		
	Project Manager in Place; HSE seeking to assign a senior manger to oversee this project				TBC
	Project Team Composition; This will be agreed with the RCOG at forthcoming meetings.				TBC
	Project Plan; This is being developed by RCOG.	N/A			
	Current position, issues & challenges				
	The terms of reference have now been agreed with RCOG. Two workshops were held in the HSE to prepare for the RCOG review. A separate meeting was held with the DoH & RCOG to start to scope out the process by which RCOG will work. The process document will be key to the project and resource plans for this project.				
	Update Action 050718/1.d/1: Consideration to be given to best approach in regard to clinical audit for those outside the RCOG review, in this transitional phase. Clearly the original CervicalCheck audit has issues in its design and execution. The RCOG review has to have a baseline date which is agreed as all women with cervical cancer notified to the HSE NSS or the National Cancer Registry by 31st Dec 2017. Those people who are not in the RCOG review will form part of the future CervicalCheck audit process that will be developed as a result of the Scoping Inquiry.			12/07/18	Closed
	Update Action 050718/1.d/2: Update on plans for RCOG review to be provided at next meeting: The process document to support the scope is required to enable a detailed plan to be developed. This detailed plan is being developed by RCOG.			12/07/18	Ongoing
1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.e	Management of laboratory capacity issues	Yes	No		
	Project Manager in Place; Managed by NSS Cervical Check Programme Manager	Yes			
	Project Team Composition; NSS Cervical Check Operations Team	Yes			
	Project Plan	N/A			
	Uptake of smear tests:				
	The number of the new samples received in the last week is as follows;				
	Coombe = 760				
	MedLab = 2,705				
	Quest = 3,786				
	GP submissions to PCRS indicate a reduction in recent weeks on the demand, bearing in mind these submissions are processed in arrears.				

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

<p>Average time for processing results</p> <p>The target cycle time is 17 days and the average time currently is 39 days. The major concern is to ensure that (a) all smears are transcribed onto a slide within the requires six weeks and (b) that the backlog from the additional demand is addressed. All labs are currently ensuring that the smears are transferred to a slide within the six weeks. The NSS CervicalCheck operations team continue to work with the labs each week on plans to address the increased demand.</p>			
<p>Current position, issues &amp; challenges</p> <p>Weekly calls and meetings with the labs to manage the situation. Extra resources and additional shifts have been included, where possible, to help address the backlog in the laboratories.</p>			
<p>Update Action 050718/1.e/1: Detail on lab activity to be provided, including result response times; provided above</p> <p>Update Action 050718/1.e/2: Detail on GP activity to be provided</p>		<p><b>12/07/18</b></p> <p><b>12/07/18</b></p>	<p>Complete</p> <p>TBC</p>



**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.f	<b>Introduction of HPV Screening</b>	Yes	No		
	Project Manager in Place; Restructuring of Cervical Check to ensure a dedicated HPV Project PM in place	Yes			
	Project Team Composition				
	Formal HPV screening project team has been established and is supported by the newly established NSS Programme Management Office who will oversee a programmatic approach to the planning and implementation of the project through standardised reporting, methodology, governance etc.	Ongoing			
	Project Plan	Ongoing			
	<p>Current position, Issues &amp; challenges; No work has been possible in recent months on the HPV project due to the cervical check crisis. A HPV Project Steering Group and Working Group have been put in place. The first meeting of the HPV steering group was held at the end of June and the next meeting is scheduled for 24th July. Project team members attended the RCPI Information day on HPV this week. Work continues on the project and resource plan with the priorities being:</p> <ul style="list-style-type: none"> <li>- Appointment of a clinical lead for the HPV screening project</li> <li>- Recruitment of a clinical director for CervicalCheck Programme</li> <li>- Decision required on the HPV screening methodology- clinical input required</li> <li>- Public laboratory reconfiguration option (Coombe/NVRL)</li> <li>- Tendering process for a new lab contract through EU tendering process</li> <li>- Stabilisation of the current programme (increase in demand on the labs and colposcopy with repeat and additional workload)</li> <li>- Demand on CervicalCheck resources due to RCOG and Scally review</li> </ul>				
	Update Action 050718/1.f/1: Project plan to be provided to Committee for next week's meeting			12/07/18	Ongoing

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

3	Implementation assurance on Scally Inquiry and RCOG recommendations		Deadline	Status
3.a	<b>Scally Inquiry recommendations</b>	Current position, issues & challenges		
	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>Review of all CervicalCheck information provided to the public in both hard copy and online to be undertaken.</p> <p>Identify critical information gaps (including commissioning research) and develop proposals for the best model and formats for explaining the screening programme. This will include the information requirements set out in the 4 recommendations contained in Interim Report.</p> <p>Produce draft Guide and consult with subject matter experts and women using CervicalCheck screening services to ensure that all information provided is validated and user friendly.</p> <p>Complete final design of Guide</p> <p>Communications Plan to be developed to promote the Guide to the women availing of the screening service</p> <p>Comprehensive Guide to be available for use and dissemination</p>	<p><b>31.7.2018</b></p> <p><b>31.7.2018</b></p> <p><b>31.8.2018</b></p> <p><b>15.9.2018</b></p> <p><b>15.9.2018</b></p> <p><b>From 1.10.2018</b></p>	Ongoing

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

<p>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</p>	<p>Identify information in all CervicalCheck materials that is provided to women about the limitations of screening and any additional materials in which this information needs to be provided.</p> <p>Create a simple and easy to understand explanation of screening, its benefits and limitations and consult with subject matter experts and women using CervicalCheck screening services to ensure that all information provided is validated and user friendly.</p> <p>Revised information to be available for use and dissemination.</p>			<p><b>31.7.2018</b></p> <p><b>31.8.2018</b></p> <p><b>From 1.10.2018</b></p>	<p>Ongoing</p>
<p>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</p>	<p>Agree and put in place the arrangements for women to receive full and open access to their cervical screening record on request. This will include defining roles and responsibilities, monitoring arrangements and control mechanisms to ensure compliance.</p> <p>Describe the process developed under Action 3.1 for inclusion in all relevant materials accompanying the consent form and for the website and consult with subject matter experts and women using CervicalCheck screening services to ensure that all information provided is validated and user friendly.</p> <p>Revised process to be operational and information in relation to the process made available for use and dissemination.</p>			<p><b>16.09.18</b></p> <p><b>16.09.18</b></p> <p><b>From 01.10.18</b></p>	<p>Ongoing</p>
<p>3</p>	<p><b>Implementation assurance on Scally Inquiry and RCOG recommendations</b></p>			<p><b>Deadline</b></p>	<p><b>Status</b></p>

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

3.a cont.	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	<p>Agree and put in place the arrangements for women to receive full and open access to their cervical screening record on request. This will include defining roles and responsibilities, monitoring arrangements and control mechanisms to ensure compliance.</p> <p>Create a simple and easy to understand explanation of that in the event of a problem or error of any significance with the screening or reporting process, open disclosure of all details will take place in a timely, considerate and accurate manner and with subject matter experts and women using CervicalCheck screening services to ensure that all information provided is validated and user friendly.</p> <p>Identify every element of CervicalCheck communications where this information needs to be provided.</p> <p>Revised information to be available for use and dissemination.</p>			16.09.18	Ongoing
					16.09.18	
					31.08.18	
					From 01.10.18	
	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					
	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					
3	Implementation assurance on Scally Inquiry and RCOG recommendations				Deadline	Status

**CervicalCheck Steering Committee**  
**Weekly Report from HSE 12th July 2018**

3.a cont.	Update Action 050718/3.a/1: Requirements for reference group to be considered and set out	12/07/18	
3.b	<b>RCOG recommendations</b>		
	tbc		