

CervicalCheck Steering Committee
Weekly report to the Minister
31 August 2018

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

The HSE reports that Liaison Officers have held 284 face-to-face meetings with women and families to discuss their needs. This includes 176 initial meetings and 108 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 €160,000 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.
- In addition to financial assistance, it is understood that some women have sought guidance on adoption and the HSE has been engaging with Tusla to facilitate the women in establishing contact. Following discussion at the Steering Group of 23 August, the Department engaged with DCYA 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 203 payments have now been made. Remaining payments will be made as applications are received.

2. 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 reports that:

- 120 legal requests have been received to date, of which 2 were received within the past week; 101 have been processed, of which 3 were within the past week
- 279 FOI or data access requests have been made and 251 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. One solicitor has expressed some disagreement with the protocol and the HSE is examining the matter, seeking to understand and address any issues.

- 19 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:

- On Monday 13 August an introduction letter, a set of FAQs, a patient information sheet provided by RCOG and a 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. The Patient Support Services Liaison from the RCOG Support Team participated in the weekly teleconference with the Community Liaison Officers to update them on the process and receive feedback.
- The HSE has advised that the process of quality assurance and validation of data for the remaining women is ongoing, and plans to issue the next batch of letters w/b 3 September, with all letters to have issued by first week in October. The Department is engaging with HSE in relation to any opportunities that may exist to speed up this schedule.
- Of the letters already issued, 49 have consented and 10 have refused consent.
- 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. 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.

- Other issues raised included the benefit for women of the RCOG review, given that it is not a medico-legal review, and some confusion in relation to the protocol governing release of slides and whether that is separate to consent for the RCOG review. The HSE is continuing to make every effort to ensure clear information is provided that addresses any queries, issues or concerns raised by women about the review or the consent process.
- The 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. The Department and the HSE are scheduled to meet again Monday 3 September in this regard.

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, receiving research findings on 24 August and has been used to update draft materials, which are awaiting feedback. The next 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 and will be subject to a tendering process for any 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.

Recognising that this is a policy and operational priority, the project steering group is working to secure further specialist expertise including necessary clinical expertise. Participants have been nominated and terms of reference agreed for a Clinical Advisory Group and invitations are to issue imminently. Site visits to the UK and Netherlands are planned which will inform the procurement process; procurement of market analysis to inform specification and market model is to be completed by 3 September.

Interviews for a Clinical Director for CervicalCheck took place on 22 August.

6. 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 67,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 54 days.

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.

7. Alternative resolution mechanisms

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

31 August 2018

CervicalCheck Steering Committee
Weekly Report from HSE 30th 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	Yes																					
	Project Team Composition National Director, Chief Officer Liaison Officers in each of (Community Healthcare Organisations)																						
	Project Plan																						
		This week	To date																				
	Number of meetings held with affected women & families (Liaison Officers)	12	176 initial meetings and 108 additional meetings.																				
	Number of medical cards issued	0	668																				
	Number of ex gratia payments made	1	203																				
	Number of supports requested	10	476 Top ten supports requested to date; <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	11	352 Top ten supports provided to date; <table><tr><td>Counselling</td><td>102</td></tr></table>	Counselling	102																		
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	Current position, issues & challenges <ul style="list-style-type: none">• Clients have expressed concern with regard to the RCOG process.• Clients continue to advice of their infertility issues and their desire for support on these matters.																				

CervicalCheck Steering Committee
Weekly Report from HSE 30th August 2018

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. - 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)	2	120
	Number of legal requests responded to (reclassified)	3	101
	0 - 30 days	-	90
	*30 days +	-	11
	Number of requests on hold, awaiting clarification from solicitor	-	2
	Number of FOI / Data access Requests made	5	279
	Number of FOI / Data access Requests responded to	3	251
	0 - 30 days	-	234
	**30 days +	-	17
	Number of slide requests made (per protocol) Action 7/39	3	19
	Number of slide requests processed (per protocol)	0	11

CervicalCheck Steering Committee
Weekly Report from HSE 30th August 2018

	<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 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 30th 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 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 <ol style="list-style-type: none"> 1. Issues regarding searchability have been addressed. Closed. 2. Documentation has been provided to Dr Scally in line with his requirements and we are now supporting him in providing specific information as he moves to finalise his report. 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		

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1.d	Interface with RCOG Review	Yes	No
	Project Manager in Place The Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1 st of August. The Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1 st of August.	√	
	Project Team Composition <ul style="list-style-type: none"> • Meeting of RCOG Working Group held on the 23rd of August to progress RCOG Review Panel Support Programme Governance, Workstreams and Communications. • Project Initiative Document (PID) drafted. Work progressing on comprehensive project plan with detailed processes and timeframes. • Workstreams have been updated as follows: <ol style="list-style-type: none"> 1. Patient Support Services 2. Call Centre Coordination 3. Case Management System 4. Communications 5. HSE Services (Acute, Primary and Social Care Services) 6. Laboratory Services Coordination A lead coordinator has been nominated for each workstream in order to oversee actions and workflow, and to ensure agreed deliverables are achieved within timeframes.	√	
	Progress against Project Plan	√	

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Weekly Report from HSE 30th August 2018

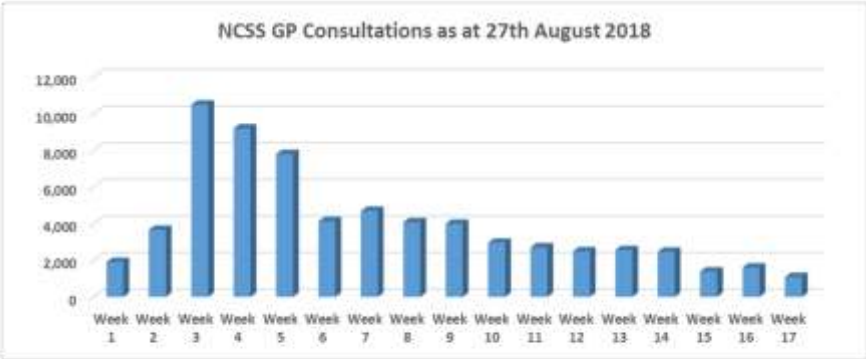
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<p>Current Position, Issues and Challenges</p> <ul style="list-style-type: none">Data management system being progressed.Letters for remaining cohort of women and next of kin in draft and will be updated to reflect information received from RCOG.Timeline for phased issue of letters of next cohort of letters agreed. <p>Next Steps</p> <ul style="list-style-type: none">RCOG Governance: Complete Project Initiative Document and Project Plan.Patient Support Services: When feedback received from RCOG re slides process, issue reminder letters to 1st cohort of women. When data is validated progress to issue remaining letters. Continue regular communication with Patient Liaison Officers.																	

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1.d	Interface with RCOG Review	Yes	No
	<ul style="list-style-type: none"> Call Centre: further training to call centre staff on slide tab in the CMS. Follow up on calls received through information line. HSE Services: Teleconference with Acute Hospital CEOs scheduled for Wed 29th Aug. Progress establishing process to supply relevant medical records from acute and primary care services to RCOG Review Panel, where requested CMS: Progress validation of data with CC and NCRI. Communications: Complete plan to respond to media queries. Meeting scheduled with Client Services to agree escalation process for legal queries Laboratory Services: Meeting 28th Aug to progress slide protocol process for the RCOG Support Programme. Call scheduled for 30th between RCOG, Support Office and DOH to ensure clarity around slide protocol. 		
	Update Action		

	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.		

CervicalCheck Steering Committee Weekly Report from HSE 30th August 2018

	Negotiations continue with existing labs and they are at a critical point in terms of financial and future service. This is the most significant risk to the programme. While contingency plans are being developed there are very limited alternatives to sustain the programme at current levels.																																																				
	<p>Uptake of smear tests: <i>Out of cycle smears</i></p> <p>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 delaying the reporting on 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.</p>																																																				
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	The average processing time is currently 54 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.		

1.f	Introduction of HPV Screening	Yes	No
	Project Manager in Place Yes. 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. Immediate activities <ul style="list-style-type: none"> Detailed capacity planning with the Coombe to be scheduled for the end of August to review their capability to deliver HPV primary testing (i.e. adequate resources, IT requirements and timelines to deliver any changes to their systems) Planned site visits to England & Holland to explore their approaches to HPV testing roll out. These visits & the workshops with Coombe & NVRL will inform the public procurement process for additional capacity through a third vendor. Procurement to lead out on a market analysis to inform specification and market model to be completed by 11th Sept. Date for Periodic Indicative Notice (PIN) release was discussed at the Steering Group for 	✓	

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Weekly Report from HSE 30th August 2018

1.f	Introduction of HPV Screening	Yes	No
	<p>mid-late Sept.</p> <ul style="list-style-type: none"> Interim clinical programme lead has nominated representation for a Clinical Advisory Group. TORs and letters of invite to be issued next week. <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) Appointment of a clinical lead for the HPV primary screening project or project team require access to clinical panel (to include colposcopist) ASAP as delaying the project- Clinical Input is required on: <ul style="list-style-type: none"> ❖ Decision required on the cervical screening pathway ❖ Decision required on the HPV test assay 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.</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.</p> <p>Update Action 04/29 A review meeting is being scheduled with DoH regarding the project plan.</p>		

CervicalCheck Steering Committee

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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 30th 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	Top line findings for the research was presented to working group on 24 th Aug. Letter, information sheet and leaflet updated with some of the findings from the research. Materials to be clinically and legally proofed as well as being reviewed by NALA for plain English before final sign-off by NSS. Future plans need to be scoped out based on the research findings including videos and visual materials. Public Patient Involvement (PPI) took place on 21 st – currently have 9 panel members and next meeting with take place on September 24 th . Feedback from the panel on the materials is due on 29 th of August.	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

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3.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	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		
	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			