## CervicalCheck Steering Committee Weekly report to the Minister 21 September 2018

## 1. Update on support package

The HSE reports that Liaison Officers have held 311 face-to-face meetings with women and families to discuss their needs. This includes 177 initial meetings and 134 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

An event for the 221 women and families involved in the CervicalCheck audit was held on Sunday 16<sup>th</sup> of September. Approximately 140 women and family members attended. The event was very well received.

Workshops were held on a variety of subjects, including bereavement, psychosexual issues, fertility and dealing with symptoms post treatment. Many of those in attendance at the event had requested to meet with Dr Scally to discuss his report. It was agreed that the Department would liaise with Dr Scally to make arrangements for such meetings to take place, in a similar format as the previous meetings held in Dublin, Cork and Galway.

## Delivery of supports

- The HSE has now issued 685 medical cards to women and family members or next-of-kin where the woman has, sadly, died. This includes the amendments that have been made to the terms of existing medical cards or GP visit cards in 94 cases to recategorise these as medical cards under the terms of the CervicalCheck support package. Numbers of medical cards issued in total now appears stable.
- Alongside the provision of medical cards, supports, including counselling, physiotherapy, occupational therapy, dental, ophthalmic and nursing services have been made available to those requesting them. Guidance is also provided regarding grants and services available from local authorities. The HSE has advised that there has been a reduction over the past week of the number of supports requested and provided. This reflects the fact that some individuals have decided not to take up supports that they previously felt were required. These supports remain available, should an individual decide to access them at a later date.
- Women have been contacted by their Liaison Officers to ensure that everyone is aware
  of and has access to the report of the Scoping Inquiry, following its publication on
  Wednesday 12<sup>th</sup> September.
- The Government decision of 11 May provided that where women had been prescribed a medicine by their treating clinician, any out-of-pocket costs would be met. Arrangements are in place to reimburse, on receipt of claims, a range of costs that the women and their families incur from 11 May including travel costs, childcare costs and medical appointment costs among others. The HSE has developed a simplified claim process for women and their families to minimise the burden involved while providing the required assurance from a public finance perspective. To date, almost €513,000 has been reimbursed in respect of various health and social care costs, some €397,000 of which relates to retrospective payments. There will also be additional costs associated with the medical cards that have been issued and the meeting of certain drug costs.

- Reimbursement of retrospective costs is taking place, and an automatic review system is
  in place to simplify and streamline the process to ensure prompt payment of all items
  covered by the Government decision.
- The Department has been engaging with DCYA to further progress contact between patients and Tusla. HSE advises that, following contact with Tusla, follow-up with those who have indicated an interest in adoption will take place with a view to arranging a joint briefing session by Tusla.

#### 2. Release of records

The HSE remains focused on responding to all requests for records as soon as possible. The HSE reports that:

- 123 legal requests have been received to date, of which 103 have been processed
- 285 FOI or data access requests have been made and 258 have received a response

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.

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

## 3. Independent Expert Panel Review

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

- Information in relation to consent together with consent form issued to 216 women and families in mid-August. Five women of the initial 221 elected not to receive any further correspondence from the HSE and so did not receive this pack.
- As of 19 Sept, approximately 1200 letters have issued. Approximately 300 consent forms have been returned to date, with 92% of women who have responded agreeing to take part in the review.
- The Department continues to engage with the HSE to ensure remaining letters issue as expeditiously as possible. The HSE is continuing to make every effort to ensure clear information is provided that addresses any queries, issues or concerns raised by women about the review or the consent process. A dedicated information line is available to answer queries people may have when they receive their letter. Additional clinical and administrative resources have been identified to support calltaking where women have queries, with opening hours extended to weekends
- The Department is committed to continuing to support and facilitate RCOG and the HSE
  in progressing this review as expeditiously as possible, and to do so in a way that
  ensures quality, comprehensiveness and integrity of the results.

## 4. Implementation of recommendations of the Scally Inquiry

The HSE working group which is addressing the recommendations of the First Report on information about screening for women has continued its work. Communications and information materials have been shared with the Committee for comment. A Patient and Public Involvement meeting is scheduled for 24 September.

Planning for the implementation of the 50 recommendations contained in the final report of the Scoping Inquiry has begun. The CervicalCheck Steering Committee will oversee the implementation of these recommendations.

## 5. Introduction of HPV as the primary method of testing

The introduction of HPV testing as the primary screening mechanism for CervicalCheck, with cytology as a reflex test, will involve a reconfiguration of the laboratory work involved. Detailed capacity planning is ongoing and introduction will be subject to a tendering process for work carried out outside the public sector. A project steering group comprising all key stakeholders is in place and a project manager has been appointed.

A key decision is the choice of HPV assay, required before finalisation of tender documentation. This requires clinical input and a Clinical Advisory Group has been identified. The first meeting of this group was held on the 13<sup>th</sup> of September, with the next scheduled for the 26<sup>th</sup> of September.

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

### 6. Clinical Director

Interviews for a Clinical Director for CervicalCheck took place on 22 August and the HSE advises that the contract is currently being finalised.

### 7. Smeartaking activity

The HSE has reported that lab activity remains above normal levels up to last week. The total number of additional consultations to date is over 75,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 59 days. The National Screening Service and HSE Procurement are engaging with laboratory service providers to address capacity issues.

## 8. Alternative resolution mechanisms

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

1	Oversight and engagement with the HSE on modules of their work as follows		
1.a	Management of supports to patients/families	Yes	No
	Project Manager in Place David Walsh/Mary Walshe	Yes	
	Project Team Composition David Walsh ND, Mary Walshe Chief Officer Maria Kavanagh Liaison Officers in each of the Community Healthcare Organisations		
	Project Plan	This week	To date
	Number of meetings held with affected women & families (Liaison Officers)	1	177 initial meetings 134 and additional meetings.
	Number of medical cards issued	5	685
	Number of ex gratia payments made	0	208
	Number of supports requested	8	Top ten supports requested to date;  Counselling 123 Complimentary Therapy 55 Transport costs 39 Medical Notes 34.00 Medical appointment expenses 33 Childcare Costs 26 HCP 21 Diagnostic 21

		Physio	19
		Fertility	19
Number of supports provided	11	338	
		Top ten supports provide	d to date;
		Counselling	82
		Complimentary Therapy	40
		Transport costs	32
		Medical Notes	29
		Medical appointment	
		expenses	27
		Childcare Costs	20
		HCP	15
		Medication	15
		Diagnostic	15
		Nursing	9

Current position, issues & challenges

Contact was made by Liaison Officers to ensure that everyone has access to the published Scally Review.

- Many clients shifted focus to the meeting scheduled for 16.09.18 and reengagement with LOs has commenced during this week with clients who attended the meeting reporting positively.
- Many clients have outlined queries regarding the Scally report which they wish to address; especially in relation to the laboratories.
- Some Clients would like a summary document of the Scally Review.
- Structured feedback from the Athlone meeting is awaited which will guide how supports will be targeted going forward.

Ove	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	٧				
	results.					
	Operational Team Composition	٧				
	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:			
- PM for overall coordination.			
- Three legal personnel in Dublin.			
<ul> <li>Two Administrative support personnel.</li> </ul>			
Project Plan	V		
There is a defined operational process for the release of records.			
	This week	To date	
Number of legal requests made (reclassified)	0	123	
Number of legal requests responded to (reclassified)	0	103	
0 - 30 days	-	91	
*30 days +	-	12	
Number of requests on hold, awaiting clarification from solicitor	-	2	
Number of FOI / Data access Requests made	9	294	
Number of FOI / Data access Requests responded to	19	277	
0 - 30 days	-	248	
**30 days +	-	29	
Number of slide requests made (per protocol)	1	23	
Number of slide requests processed (per protocol)	0	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 process with the labs but these are being addressed.

## **Update Action**

\*During the setup of the client services team in April/May in the early part of the crisis there were 10 requests which extended over the 30 days. 6 of the 10

were pre-GDPR requirement for 40 days but resourcing was a constraint at the start of this process.

\*\*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.

Over	sight and engagement with the HSE on modules of their work as follows		
1.c	Interface with Scally Inquiry	Yes	No
	Project Manager in Place	٧	
	A senior manager is assigned to oversee the timely release of documents to facilitate Dr Scally's review.		
	Project Team Composition	٧	
	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	٧	
	N/A		
	Current position, issues & challenges		
	<ol> <li>All information has been provided to Dr Scally.</li> </ol>		
	Update Action		·

1.d	Interface with RCOG Review	Yes	No
	Project Manager in Place		
	Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on		
	Wednesday the 1 <sup>st</sup> of August.		
	Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1st of August.		
	Programme Governance	٧	
	Daily meetings and teleconference calls with the Project Team to identify critical actions, timeframes, and		
	areas for escalation, risks, issues, and dependencies are taking place.		
	Project Plan Communication to/from Women (updated Wed 19th Sept)		
	The datasets that are coming from the National Cancer Registry Ireland (NCRI) have required extensive		
	validation reflecting the fact that the cancer registry was never designed as an operational database.		
	1,224 letters have issued to date to women or their next of kin. Remaining letters are ready to issue		
	within 24 hours upon receipt of the final cohort of validated data from NCRI. Acute hospitals are		
	supporting the validation of Next-of-Kin contacts where PCRS has confirmed that the women are		
	deceased (est. 1-2 week processing time).		
	• 297 consent forms have been returned, with 274 consenting to be part of the review (92% of returns are		
	consents)		

- Weekly teleconferences with Patient Liaison Officers are taking place.
- Reminder letters are to be issued to women who have not returned consent forms to date.

#### **Call Centre:**

- Additional resources have been identified (clinical and administrative) to support call centre.
- Opening hours extended to weekends 9am 6pm to support anticipated volume of calls.

## **Laboratory Logistics:**

- The transfer of slides process has been mapped, the protocol is to be finalised this week. RCOG has iconfirmed that their labs can begin to accept slides from w/c 24<sup>th</sup> Sept.
- The transfer of the first batch of slides to RCOG is planned w/c 24<sup>th</sup> Sept, subject to final negotiations with the laboratories.

#### **Current Position, Issues and Challenges**

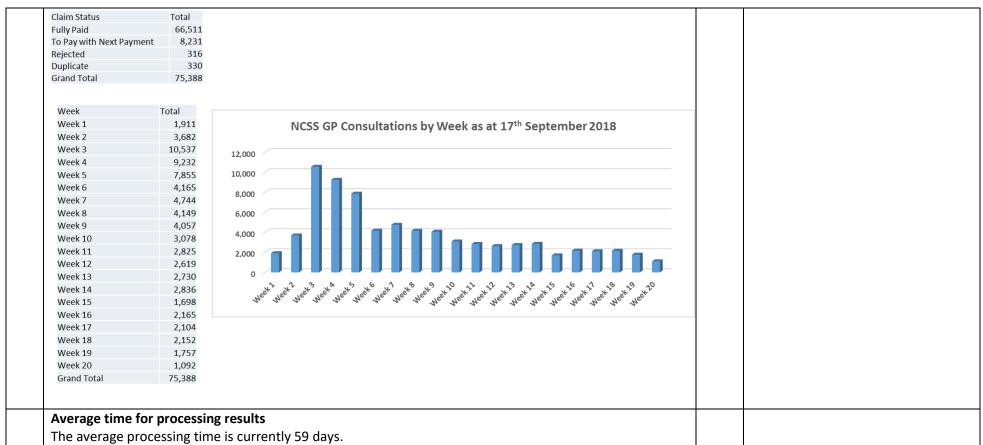
- The RCOG Support Programme has not received a final valid assured dataset as validation of the national cancer data registry is on-going. The RCOG Programme is committed to issuing the remaining letters within 24 hours of this information being finalised.
- Managing feedback and queries from women/Next-of-kin, clinicians, the media and the public as the remaining cohorts of women or next-of-kin receive letters.
- Following the receipt of the RCOG letters the helpline has received a number of calls from women seeking clarification on the nature of their cancer and the reason for their inclusion in the review. A procedure has been agreed to route these queries back to their treating consultant so they can be dealt with appropriately.

## **Next Steps**

- Complete the validation of the National Cancer Registry data.
- Issue final cohort of letters. Issue reminder letters where identified. Continue regular engagement with Patient Liaison Officers and other stakeholders.
- As consents return, continue to update the Case management System (CMS. Expand the CMS to include supply chain management of the slides transfer. Training on CMS to continue for relevant staff.
- Finalise agreement of slide protocol process with NSS, laboratories, and RCOG. Workshop scheduled for Tues 18<sup>th</sup> Sept with key stakeholders in CervicalCheck, client services, legal, and RCOG. Identifying timelines to commence transfer of first batch of slides to RCOG w/c 24<sup>th</sup> Sept.
- As remaining letters issue, identify and assign further additional clinical & administrative resources to the call centre in line with the project plan timelines.

## **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	٧			
	Yes.				
	Project Team Composition	٧			
	Given the nature of the issues presenting a working group was put in place to support the project				
	manager. This group comprise HSE procurement, HSE Legal and the CervicalCheck Operations team. This				
	will ensure a coordinated response to the operational issues presenting as a result of the demand arising				
	from the out of cycle smear tests.				
	Project Plan				
	Since April any woman who is concerned can attend her GP for a free smear and this has resulted in a				
	testing backlog in all three labs. These delays remain a priority concern for the HSE.				
	Actions taken to address backlog include additional recruitment to assist on clerical support to free up				
	screening staff, the streamlining of processes around release of reports and QA checks of same and the				
	potential introduction of overtime for screeners from September.				
	Negotiations continue with existing labs and they are at a critical point. This is the most significant risk to				
	the programme. Contingency plans are being developed and it should be noted that there are limited				
	alternatives to sustain the programme at current levels.				
	Uptake of smear tests:				
	Out of cycle smears				
	Total number of additional consultations to date is more than 75,000. The normal capacity for the labs is				
	approximately 5,000 per week so we are still seeing a 20% increase in uptake as a result on the free smear				
	test. This is delaying the reporting of smears to women. All the labs have expressed concern at the				
	continuing extension of the free smears due to the serious impact on the normal reporting cycle. The				
	table below sets out the increased number of GP consultations.				



## **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 meetings are scheduled to take place again 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.

Introduction of HPV Screening	Yes	No
Project Manager in Place	٧	
Yes. A Project Manager is in place and the expression of interest is still open for the appointment of a		
Clinical Lead for the HPV primary screening project. Also, an expression of interest is currently open for a		
lead cytopathologist and lead colposcopist to join the project team.		
Project Team Composition	٧	
<ul> <li>In the absence of a clinical lead for the project, a clinical advisory group have met on Thurs 13<sup>th</sup> and</li> </ul>		
was chaired by the interim Clinical Director of the programme.		
This group will determine the clinical decisions required to advance the project.		
Project Plan		
Update on the key workstreams		
Clinical		
Clinical Advisory Group met on 13 <sup>th</sup> Sept.		
• Proposals on key clinical decisions were drafted & discussed on the 13 <sup>th</sup> with further work needed, eg		
consensus on the HPV test assay, screening pathways and eligibility framework.		
As part of the project research a conference call was held with New Zealand on the rollout of their		
project. A lessons learned report has been provided to the HPV Steering Group.		
Procurement		
Market analysis to inform specification and market model is still in progress and is awaiting the clinical		
decisions to move forward.		
ICT		
Development and testing on changes to the Cervical Screening Register were progressed		
Still addressing the availability of testers in terms of resourcing		
Lab Configuration		
Draft configuration options prepared, work is ongoing on detailing this further.		
Resources for Health care Professionals		
Resource Planning is still in progress		

f	Introduction of HPV Screening	Yes	No
	Immediate activities		
	<ul> <li>The Clinical Advisory Group (CAG) will meet again on Thursday 27<sup>th</sup> Sept to discuss and examine the clinical decisions necessary. Efforts are continuing to expand the membership of the CAG team to include a colposcopist and a public health representative.</li> </ul>		
	<ul> <li>Detailed capacity planning with the Coombe and NVRL to continue into September &amp; October to</li> </ul>		
	review their capability to deliver HPV primary testing (i.e. adequate resources, IT requirements and timelines to deliver any changes to their systems).		
	<ul> <li>A market information session is planned to allow services required to be explored with a view to determine the level of interest of potential contractual challenges.</li> </ul>		
	<ul> <li>Work on the development and testing of changes to the Cervical screening register is continuing.</li> </ul>		
	Current position, issues & challenges		
	<ol> <li>Stabilisation of the current programme (increase in demand on the laboratories and colposcopy with repeat and additional workload)</li> </ol>		
	<ol> <li>Intense negotiations continue with existing labs. Key issue for the laboratories are reputational and financial concerns.</li> </ol>		
	<ol> <li>The Clinical Advisory Group was setup to mitigate the risk of the Clinical Director or lead for the programme. However, no final decisions have yet been made on the;</li> </ol>		
	<ul> <li>Cervical screening pathway</li> <li>The HPV test assay</li> </ul>		
	<ul> <li>Also, no colposcopist or public representative currently exist on the CAG at the moment</li> <li>There is a dependency to conclude the HPV test assay to allow the market information session to take place.</li> </ul>		
	Update Action 04/28 Update on the possibility of appointing a clinical lead for the move to HPV testing will be	provi	ded next week.
	<b>Update on 14/08/18:</b> The negotiations with the possible candidate to take on the clinical lead role were unsure expression of interest to the clinical community. <b>Update on 05/09/18</b> A further expression of interest was issued		
	this expression of interest has been extended for an additional fortnight.		-
	<b>Update on 28/08/18</b> Interviews for a clinical director took place last week and an offer will be made to the ide		
	05/09/18 The offer was made and final negotiations are concluding with the successful candidate. Update 19	/09/18	R NRS are finalising the contract.

ion 04/29 A review meeting is being scheduled with DoH regarding the project plan. Update on 12/09/18 This meeting took place on 06/0 ation assurance on Scally Inquiry and RCOG recommendations  of the Scally Implementation working group with NSS text Team: tear taker Co-ordinator tior Health Promotion Officer treening Service team: the munications Information Manager tormation and Communications Officer team: the dof Open Disclosure the Advocacy team on a needs basis
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clinical, non-clinical input and patient representation alongside experience in screening programmes, communication, health literacy and behavioural

economics.

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	<ul> <li>In light of the publication of Dr Gabriel Scally's scoping report and recommendations, the current versions of the communications and information materials were reviewed and updated.</li> <li>2 additional members of the PPI were met with and briefed on the work of the PPI.</li> <li>Testing of the old website is due to take place on 24<sup>th</sup> September. This user testing will provide us with a baseline for the new website and to provide data and evidence for future online development.</li> <li>Video content and infographics are being developed to support the new communications and information materials.</li> <li>Work is progressing on a communications plan to support the introduction of the new materials.</li> <li>The enhanced communications and information materials based on the Scally Recommendations are going to be approved by the DoH Steering committee and by the Public Patient Involvement Panel at the end of September. It may take some time to fully disseminate and implement the materials for all the different systems involved in the CervicalCheck Screening Programme – including the 4,500 centres contracted by CervicalCheck.</li> </ul>	31.01.18	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.	31.01.18	In progress

3.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	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.	31.01.18	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.	31.01.18	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		
	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			